THE U.S. CONTRIBUTION TO THE FIGHT AGAINST MALARIA

HEARING AND MEETING

BEFORE THE

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

OF THE

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THE U.S. CONTRIBUTION TO THE FIGHT AGAINST MALARIA

FRIDAY, MAY 17, 2013

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 10 o'clock a.m., in room 2172, Rayburn House Office Building, Hon. Christopher H. Smith (chairman of the subcommittee) presiding.

Mr. SMITH. The committee will come to order, and good morning to everyone, and thank you for being here this morning, especially at this hearing to examine the United States' contribution to the global fight against malaria.

Leadership matters. In 2005, President George W. Bush established the President's Malaria Initiative, or PMI, and then targeted several African malaria endemic countries to receive over $1 billion to mitigate and, some day, eradicate this killer disease. The positive consequences of that bold and compassionate initiative now include over 1 million lives saved over the last decade. The program and its expansion and sustainability of the funding have been all important in that battle.

Although we will hear statistics about malaria cited several times during the course of this hearing, the global impact of this disease is so severe that they are worth repeating, and I say that, even though we are making progress.

The World Health Organization estimates that in 2010, there were 219 million malaria cases and 660,000 deaths. While still unconscionably high, and every life is absolutely precious and of extraordinary importance, the loss of life has declined from approximately 985,000 deaths in 2000.

Not surprisingly, malaria has a particularly devastating impact on the most vulnerable. Nearly 86 percent of those who died are children under 5 years of age, living in sub-Saharan Africa. Dr. Mark Dybul, executive director of the Global Fund and George W. Bush's extraordinarily effective Global AIDS coordinator, says that, in Africa alone, malaria takes a life of a child every minute. He also notes, as do our other panelists, that pregnant women are also disproportionately affected with the disease.

WHO emphasizes in its 2012 World Malaria Report that malaria is strongly associated with poverty. Countries in which a larger percentage of the population lives in poverty also have a higher

mortality rate from malaria. Children living in poorer populations, and in rural areas, have the highest parasite prevalence rates. And it is also important to note, to the extent to which the prevalence of malaria is concentrated, 80 percent of malaria deaths occur in just 14 countries, and almost 80 percent of cases occur in 17 countries.

Over 40 percent of malaria deaths occur in just two countries. The Democratic Republic of the Congo and Nigeria, and 40 percent of the malaria cases are in the Democratic Republic of the Congo, Nigeria, and in India. These high morbidity and mortality rates are not necessary. Malaria is both preventable and treatable. We will hear today from our distinguished witnesses who are leaders in the field about the cost-effective measures that are currently available and already having a profound impact or are in the development process.

And the United States, despite the current financial constraint, is making a significant contribution to the global fight against malaria. In addition to our contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria, the United States provided $871 million in anti-malaria assistance in Fiscal Year 2012 alone, and the request for Fiscal Year 2014 is $893 million.

But these levels, even when combined with contributions from other donors, do fall short of the global need. So our question today will be, "What are the major challenges going forward and how can we best use our resources to meet those challenges to save the most lives and have the greatest impact in controlling, if not eradicating, this dreaded disease?"

We will also be taking a close look at several immediate threats to global efforts to combat malaria. On April 23, this subcommittee held a hearing on "Meeting the Challenges of Drug-Resistant Diseases in Developing Countries." In his testimony at our hearing, Dr. Thomas Friedman, director of the Centers for Disease Control and Prevention, warned that in recent years, malaria infections in parts of Southeast Asia have been showing resistance to artemisinin drugs. These drugs are the last remaining class of antimalarial drugs and form the basis of malaria treatment globally. If these resistant parasites manage to spread to sub-Saharan Africa, he stated that the results could be "devastating," an assessment that will likely be repeated by our witnesses today.

Insecticide-treated nets, bednets, which have an average useful life of 2 to 3 years are also an extremely important malaria prevention tool. According to WHO, 150 million nets are needed each and every year to provide protection to the vulnerable populations in sub-Saharan Africa. For the past 2 years, however, the supply has been considerably lower than this level, resulting in an estimated current shortfall of 77 million nets. The consequences, if not urgently addressed, could place entire populations, especially children, at risk of a dramatic malaria resurgence, and of course that means more death and more morbidity.

We are fortunate again to have three distinguished experts who will provide us with valuable insights. These are truly leaders in this field. C–SPAN is here and we are grateful they are here. I would hope that Americans would sit up and take note of the extraordinary work you three individuals are doing.

You know, people sometimes are very dismissive of foreign aid and initiatives that taxpayer funds are used for. This is one of the greatest success stories. It is not the only one, there are many, but this is one of the greatest success stories, but it is a work that remains unfinished. I thank our witnesses for being here and for being such leaders.

I would like to now yield to Mr. Bera.

Mr. BERA. Thank you, Chairman Smith, and thank you for holding today's hearing and the series of hearings on global health, incredibly important topics, and I look at this from the perspective of being a doctor who has worked internationally, and the work that you guys are doing is incredibly important, and I look forward to hearing your testimony.

You know, as has already been mentioned, there are over 219 million cases of malaria worldwide. The Democratic Republic of the Congo, India, and Nigeria account for 40 percent of all malaria cases. Those cases account for over 600,000 deaths in 2010. Very preventable. So this is an incredibly important issue.

Like so many other diseases, you know, with the right policy, with the right partnerships, we can save hundreds of thousands of lives. Unfortunately, far too often, these tools are not reaching those in need, and I am looking forward to hearing the testimony of best practices and how we get the therapies and the prevention and the nets out to those where we can make the biggest difference.

You know, while malaria continues to take the lives of children and adults, you know, we also have seen the international community coming together and some great demonstrations of remarkable success. The Global Fund, the President's Malaria Initiative, the Gates Foundation, the World Health Organization, just to name a few, have helped reduce unnecessary deaths in Africa by an estimated 33 percent in less than a decade. We can still do better.

The fund has 779 active grants, 217 of which are for malaria. It has approved almost $7 billion or 27 percent of its funds in the fight against malaria. Since 2000, malaria mortality rates from fallen by more than 25 percent and 50 countries are on course to reduce malaria incidence by 75 percent by the end of 2015. These are efforts to be applauded.

Again, I look forward to supporting and doing more. Chairman Smith has done an excellent job laying out the profound challenges that we face in fighting malaria. I would like to share with the committee just a couple of success stories over the course of testimony, and I certainly look forward to hearing the success stories and the best practices.

In addition, you know, today we don't have a vaccine that prevents someone from being infected with malaria, but I am here to say as a research scientist, as a physician, there is nothing that we can't do in this country and in our academic community if we set our minds to it, and ultimately, that is where we need to go if we want to truly prevent disease and save lives.

So thank you for being here, thank you for the testimony. You know, I look forward to hearing from each of you and, you know, again, Chairman Smith, thank you for calling this important hearing.

Mr. SMITH. Thank you very much. I would like to now yield to Mr. Weber.

Mr. WEBER. Thank you, Mr. Chairman. Very important topic. I appreciate the opportunity to be here and have this hearing. My dad, one of the last of the greatest generation, 88 years old, served in the Philippines, contracted malaria. To this day, he cannot give blood. He has the rarest blood type there is. Half a percent of America has AB negative, which is what I have, and now you know what is wrong with me. But just a great guy. I try to give blood as often as I can, and so it is very, very important, because that keeps those who contract the disease from giving blood. I think it is very vital, so I appreciate being here and looking forward to the testimony. Thank you.

Mr. SMITH. Thank you very much, Mr. Weber. Just parenthetically, my father, too, served in World War II in New Guinea. He was a combat infantryman, and he got malaria, and my family was very well aware of the impact it had on him as well, so thank you.

I would like to now yield to Mr. Cicilline.

Mr. CICILLINE. Thank you, Chairman Smith, and thank you to you and Ranking Member Bass for holding today's hearing on the role of the United States in the fight against malaria, and I want to thank my colleague and friend, Congressman Bera—Dr. Bera for his leadership on this issue and on issues of global health in general. This remains a serious worldwide public health emergency. The World Health Organization estimates that 219 million cases of malaria worldwide with 660,000 malaria deaths, so this is still an urgent, urgent issue.

I want to begin by offering my gratitude to the witnesses not only for being here today and for your testimony, but for your incredible leadership in the work that you have led that is making a real difference all across the world as we combat this scourge of this disease.

Our country, the United States, has a vested interest in addressing health conditions around the world in order to improve lives, to strengthen the economies of our trading partners, and to maintain our moral leadership position in the world. I think it is concerning to all of us that malaria remains a leading cause of death in many countries, especially when we have made such astonishing gains in health care here at home, and I hope that the United States will continue to support the funding of global health development as we transition to country ownership and eventually eradication of this disease and that we continue to value the work of the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Gates Foundation, the President's Malaria Initiative, and to just note that these are, as Chairman Smith said, great success stories of what our role around the world has been when we make the right kinds of investments, and these have been bipartisan efforts, and I know they will continue to be, and I thank the chairman again and yield back.

Mr. SMITH. Thank you very much. I would like to yield to Mr. Meadows.

Mr. MEADOWS. Thank you, Mr. Chairman, and thank you to each one of you for your service to our country. We appreciate it. We are here today to address a disease that has been a scourge on human-

ity for almost our entire history. And as we have been fighting malaria for a very long time, it is encouraging to see how far we have come, but also what is left to be done, and so I look forward to your testimony today.

We have seen malaria generally eradicated in the developed world and, but yet there is still a lot of work to do. As you know, some 80 percent of malaria deaths occur in just 14 countries, and as we see that, you know, 80 percent of the cases and 90 percent of the deaths occur in Africa, and we have learned over the past 60 years that eradicating this disease is an ongoing challenge requiring multiple efforts working in concert and there is no magic bullet to do that.

We heard testimony even in this very room in a hearing that the chairman conducted from the CDC offering some of the challenges that we face with different strains that are resistant to even the drugs that we have today, and so I am encouraged by Dr. Bera. We have teamed up on a number of bipartisan initiatives to try to work on finding some of those solutions, and so I look forward to hearing your testimony.

I am proud of the role that the U.S. has played in this ongoing struggle. It has really been our leadership that has really worked very well, and I am mindful that that does not mean that we can advocate our duties to be good stewards of the taxpayers' money either. And corruption cannot be tolerated in any manner.

I have traveled a number of times to Africa, and when you start to see the lack of accountability in certain areas, it gives you great concern, and so part of the reason for holding this hearing is so that we remain vigilant in that we work against the bad actors that we have to deal with, but also that we encourage others and those that are suffering, certainly, that we come to their aid.

This would include pressuring local governments and making sure that we have the encouragement there, not just from an oversight standpoint, but to make sure that what we do is that the American taxpayers' dollars are invested wisely. When we do that, there is always a drawback. You know, when I go back home, there is a consistent call, "Why are we giving aid? We have people that are hungry and out of work here. Why are we doing that?" I would look for some of the testimony and really what it might do in terms of our men and women that serve in some of the things that we have in terms of challenges, not just from a global perspective, but as we bring that back home, and so I would look for each one of you to hopefully address that.

You know, Fiscal Year 2014, we look at both in USAID and the CDC have both requested increases in their funding as we see that, and what I would love to see from you is how I can make sure that we put forth and share with the voters back home that not only are we being wise stewards, but that we are being accountable and we are doing the very best that we can to make our money go as far as we can.

The growth of public/private partnerships, the encouragement there, some of the work that we have already seen there, I applaud that. You know, in recent years, we have seen, you know, the President's Malaria Initiative, you know, working with the World

Health Organization and other institutes using the Federal dollars to be leveraged in that private/public partnership in a real way.

And so I just applaud you on the work you have done. I would love to hear and so we can share with those in these tight fiscal times how we are managing that properly and perhaps what we can do from an oversight standpoint to make sure that not only are we investing wisely but that those funds meet the real needs that are there.

But I thank you, and with that I yield back, Mr. Chairman.

Mr. SMITH. Thank you very much, Mr. Meadows.

Mr. Stockman.

Mr. STOCKMAN. In the course of building a Panama Canal, as you probably recall from your history, they had to address first the health problems there, and when I was over at the Democratic Republic of the Congo, DRC, I think they have assumed the circumstances, some of the health issues are holding back their productivity and their production and GDP, but I believe that even the great expense they have made, they still need help in that area.

When I was over there, I noticed they were selling some of their mosquito nets, so I am looking forward to your testimony to find out if there is alternatives ways besides just mosquito netting, and I appreciate all the efforts that you have done and continue to do on behalf of the United States, and I think this sends a large signal to the rest of the world, the compassion of the Americans, and I yield back my time, chairman. Thank you.

Mr. SMITH. Thank you very much, Mr. Stockman.

I would like to now introduce to the panel our two first witnesses. Rear Admiral Tim Ziemer was appointed in June 2006 to lead the President's Malaria Initiative, a $1.2 billion, 5-year initiative to control malaria in Africa, which was expanded through an authorization in the 2008 Lantos-Hyde Act.

Admiral Ziemer was born in Iowa but raised in Asia, the son of missionary parents serving in Vietnam. After graduating from college, he joined the Navy, completed flight school and returned to Vietnam during the war. During his naval career, Admiral Ziemer commanded several squadrants and Naval stations in an air wing supporting the first Gulf War.

Prior to his appointment at PMI, he served as executive director of World Relief, a humanitarian organization, and has had a distinguished stint as leader of the President's Malaria Initiative. Those of us on this committee are very well aware of the great contributions you have made and the leadership you have provided.

We will then hear from Colonel Peter Weina, who is assigned to the Walter Reed Army Institute of Research, where he serves as deputy commander. He leads many medical initiatives in the Army and his work has been published extensively in journals and books.

Colonel Weina is a recognized expert on numerous diseases. He was the lead behind the availability and licensure of a life-saving drug for the treatment of severe malaria throughout the United States and Canada from 2002 to 2009, an effort that was recognized by CDC's Silo Busters Collaborative Award of Excellence in 2008. Among his many other impressive awards, he is the recipient of the Bronze Star for service in Iraq during Operation Iraqi Freedom.

I would like to yield to Admiral Ziemer.

STATEMENT OF REAR ADMIRAL TIM ZIEMER, U.S. GLOBAL MALARIA COORDINATOR, PRESIDENT'S MALARIA INITIATIVE

Admiral ZIEMER. Chairman Smith, members of the committee, it is a pleasure to be back before you today. Before I begin my testimony, I would like to take a moment to acknowledge and express my appreciation for Congress' ongoing and steadfast support for malaria control. The global fight is succeeding. Deaths have decreased by one-third with bipartisan support in Congress for both bilateral and multi-lateral efforts. Through the Malaria Initiative and the Global Fund, malaria is being rolled back. It is a triumph of partnership, all of us working together, the U.S. Government, our partners, host countries and the communities we are trying to serve. We simply would not be seeing the impact we are seeing today without your support and commitment. Thank you very much.

The United States malaria program through the PMI continues to be a game changer. In the 7th year of the Initiative, the financial and technical contributions made by the United States Government are the major catalyst in the remarkable progress that has been achieved in many countries to reduce the devastating burden of malaria on child mortality. At the same time, with the U.S. Government support, countries are also strengthening their own capacity to fight this disease.

PMI, at its very core, is an example of success and real impact that the United States Government can achieve through a solid interagency partnership. Through PMI, the core strength of both USAID and the Centers for Disease Control and indeed across the entire U.S. Government spectrum, Walter Reed, DOD and NIH, as well as the Peace Corps, it is a tremendous success story, yet it is still incomplete.

I just returned from Uganda, and despite the recent progress, malaria remains the largest killer of children. In the midst of these tragic statistics, we have some good news. This year, with 21 million insecticide-treated bednets provided by the Global Fund, the U.S. Government, DFID, World Vision, and other partners, the Government of Uganda is poised to make real and substantial gains against malaria.

Seeing children suffering from malaria, I am reminded of my childhood days in Vietnam. My parents, as was indicated in the opening statement, were missionaries there. I was fortunate to sleep under a bednet and yet I caught malaria. I was fortunate to have anti-malaria medicine to cure the disease. Every child in a malarious part of the world should be protected as I was. In the last 7 years, substantial reductions in mortality among children under 5 has dropped 16 to 50 percent in 12 of our original PMI countries. Although multiple factors may be influencing the decline in under 5 mortality rates, strong and growing evidence suggests that malaria prevention and treatment are playing a major role in these unprecedented reductions in mortality.

PMI is participating in in-depth evaluations to ascertain the contribution of malaria control efforts to these reductions in mortality, with Tanzania being first country to complete this evaluation.

63,000 lives have been saved over a 10-year period because of the scale-up of malaria interventions.

In 2011, PMI commissioned an external evaluation team to review its performance. The evaluation affirmed that PMI's planning, implementation, partnerships and funding have been key to the global efforts to combat malaria. The evaluation team made five policy and five technical recommendations that will guide programmatic improvements over the next years. PMI views these recommendations as relevant and useful for program improvement. We have come a very long way since the inception of the Global Fund in 2002 and the creation of PMI 3 years later when President Bush committed $1.2 billion for malaria control.

The Initiative started with Tanzania, Uganda and Angola. Since then, 16 additional focus countries have been added with three non-focused countries. In addition to the bipartisan support of Congress, PMI benefited from the full support of President Bush and First Lady Laura Bush, and now the Obama administration.

In 2010, President Obama launched his vision for how the United States would approach global development, which seized development assistance as a pillar for foreign policy, and is crucial to America's national security and economic interests.

In his 2013 State of the Union address, President Obama framed two goals, that the United States would join with our allies to eradicate extreme poverty in the next two decades, and saving the world's children from preventable deaths. Malaria is a major cause of child mortality in Africa, and consequently, preventing and controlling malaria are a key focus of the U.S. Government foreign assistance program. PMI is playing a lead role in implementing the President's vision.

Partnership is the hallmark of how PMI does business. Partnership with host countries, other donors, the private sector, non-profits, and faith-based groups underpin our success. PMI has supported malaria activities through more than 200 non-profit organizations. Approximately one-third of those are faith-based. These groups often have strong and effective bases of operations in underserved rural areas where the burden of malaria is the greatest.

The Global Fund and PMI's commitment to effective coordination is maximizing our impact on the global malaria burden. Each program has its own unique strengths lending to the complementarity of the partnership and significant successes on the ground. Currently, all 19 PMI focused countries in Africa and the greater Mekong subregion receive substantial funding from the Global Fund.

Because of the strength of our in-country technical staff, we support the effective implementation of Global Fund programs. While the risk of malaria is declining and more children are surviving, the gains are fragile and could be reversed without continued support. We recognize and appreciate the continued commitment of Congress and the American people to fighting malaria through PMI and the Global Fund in this time of budget austerity. The goal is to continue to shrink the malaria map and to ensure successes are not rolled back, even as the dual threats of artemisinin and drug resistance and insecticide resistance is growing. A strain of malaria, of the malaria parasite has appeared in parts of Southeast

Asia with resistance to the most effective medicines to fight the parasite, and some fear that the parasite might ultimately become resistant to all drugs we currently have to treat malaria.

The emergence of this resistant parasite to Africa would be devastating. We must also be diligent in identifying and monitoring mosquito resistance to insecticides so that our most effective prevention measures, insecticide-treated mosquito nets and indoor residual spraying aren't undermined. If mosquitos become resistant to those insecticides, the efficacy of the interventions will be compromised.

Tackling these new strategic challenges is a priority, and we are working with the private sector to develop new anti-malaria drugs as well as insecticide-based tools. At the same time, we must continue to expand our toolbox by developing a highly effective inexpensive vaccine that could result in hundreds of thousands of lives saved.

So in closing, I would like to thank the U.S. Congress for its continued support and reiterate that together with our partners, we remain deeply committed to the global fight against malaria. Thank you, and I look forward to your questions.

Mr. SMITH. Admiral Ziemer, thank you very much for your testimony and again for your leadership.

[The prepared statement of Admiral Ziemer follows:]

Rear Adm. Tim Ziemer
U.S. Global Malaria Coordinator

Congressional Testimony Before
House Committee on Foreign Affairs
Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations
Malaria Progress & Challenges
May 17, 2013

Introduction

Chairman Smith, Ranking Member Bass, Members of the Committee, thank you for having me here today. Before I begin with my testimony, I would like to take a moment to express my appreciation for Congress' ongoing and steadfast support for malaria control. Thank you. The global malaria fight is succeeding. Deaths have decreased by a third over the past decade, from a million per year to an estimated 660,000 per year. With bipartisan support in Congress, for both bilateral and multilateral efforts, through the President's Malaria Initiative (PMI) and the Global Fund to Fight AIDS, Tuberculosis, & Malaria, malaria is being rolled back. It's a triumph of partnership — all of us working together – the U.S. Government and our partners; partner countries, the private sector, nonprofit organizations, faith groups, and the communities we are trying to serve.

PMI, at its very core, is also an example of the success and real impact that the U.S. Government can achieve through a solid interagency partnership. Through PMI, the strengths and talents of both USAID and the Centers for Disease Control and Prevention, are being brought to bear on malaria and we are working in synergy and with determination to tackle this devastating disease. The United States malaria program through the President's Malaria Initiative (PMI) continues to be a "game changer" in the global fight against malaria. In the seventh year of the initiative, the financial and technical contributions made by the U.S. Government are a major catalyst in the remarkable progress that has been achieved in many countries to reduce the devastating burden of malaria on child mortality. At the same time, with the U.S. Government's support, countries are also strengthening their own capacity to fight the disease.

Investments in malaria prevention and control are making a significant impact on the lives of millions of children, pregnant women and families in Africa. It is a tremendous success story, yet it is still incomplete.

Toll of Malaria

The World Health Organization (WHO) estimates that malaria caused 219 million cases of disease in 2010 and 660,000 deaths. But in the almost 10-year accelerated campaign against malaria, it is estimated that 1.1 million lives have been saved. In spite of this, malaria remains one of the major public health problems on the African continent, with about 80 percent of worldwide malaria deaths occurring in African children under five years of age.

Malaria also places a heavy burden on individual families and national health systems. In many African countries, at least 30 percent or more of outpatient visits and hospital admissions in children under five are reported to be caused by malaria. Because most malaria transmission occurs in rural areas, the greatest burden of the disease usually falls on families who have lower incomes and whose access to health care is most limited.

On a sun-drenched morning in Ghana's Ashanti region, I joined village chiefs and their wives for the launch of an insecticide-treated mosquito net distribution and hang-up campaign. As I watched volunteers perform a drama about sleeping under mosquito nets, I was reminded of my childhood in Vietnam, where I was fortunate to have slept under the protection of a mosquito net. And I was grateful that I had access to an effective antimalarial medicine when I fell ill with malaria.

Malaria no longer threatens boys and girls in the United States, but across Africa, it remains a reality for many children. The lives of potential future presidents, scientists and nurses are lost prematurely, and their hope for making an impact on the world is greatly diminished.

History of the Program

By 1990, much of the world had successfully controlled or eliminated malaria as a public health threat. But in Africa, and certain other areas, it persisted. Malaria – largely preventable, treatable and curable – was an insidious disease of poverty and a cause of poverty, killing more than 1 million people each year on the continent.

In June 2005, before the Gleneagles summit in Scotland of the Group of Eight major industrialized nations, President Bush created the President's Malaria Initiative, and committed $1.2 billion for malaria control. The initiative started with Tanzania, Uganda, and Angola, and, since then, 16 additional African countries have been added. PMI is an interagency program led by USAID and implemented together with the Centers for Disease Control and Prevention. Its goals were ambitious: cutting in half the death toll of a disease that ravaged Africans, hitting children and pregnant women the hardest.

This bold initiative was buoyed by new tools to prevent and treat the disease including new diagnostic tools and antimalarial medicines as well as insecticide-treated nets to hang over sleeping spaces. For the first time, the tools, the political will, and the funding were in place at sufficient levels to really have an impact on malaria in Africa.

With the passage of the 2008 Lantos-Hyde United States Leadership against HIV/AIDS, Tuberculosis, and Malaria Act and the launch of the GHI, PMI's goal has expanded to achieve Africa-wide impact by halving the burden of malaria in 70 percent of at-risk populations in sub-Saharan Africa, i.e., approximately 450 million residents.

In the last seven years, substantial reductions in mortality among children under five have been recorded together with improvements in coverage with malaria interventions. Of the twelve PMI focus countries (Angola, Ethiopia, Ghana, Kenya, Madagascar, Malawi, Mozambique, Rwanda, Senegal, Tanzania, Uganda and Zambia), where baseline and follow up health surveys with data on childhood mortality have been conducted, all-cause mortality rates among children under five have dropped by 16 percent (in Malawi) to 50 percent (in Rwanda). Although multiple factors may be influencing the decline in under-five mortality rates, strong and growing evidence suggests that malaria prevention and treatment are playing a major role in these unprecedented reductions in mortality. PMI is participating in in-depth impact evaluations to ascertain the contribution of malaria control efforts to these reductions in mortality, with Tanzania being the first country to complete this impact evaluation. Conducted in collaboration with the Government of Tanzania, the Roll Back Malaria Partnership, WHO, and the Ifakara Health Institute, the impact evaluation concluded that malaria mortality in children under five in Tanzania has fallen and that nearly 63,000 lives have been saved in that country over the 10-year period between 2000 and 2010 due to the scale up of malaria interventions.

In fiscal year 2012 alone, PMI protected over 50 million people with prevention measures, such as insecticide-treated mosquito nets to hang over sleeping spaces and/or indoor residual spraying of homes with insecticides. PMI also procured more than 72 million treatments of life-saving antimalarial medicines for distribution to targeted populations.

External Evaluation

Across Africa, PMI advisors from USAID and CDC, in-country USAID health teams, national malaria control programs, and partners, are working together to roll back malaria. In 2011, PMI commissioned an external Evaluation Team to review its performance. The External Evaluation Report affirmed that PMI's planning, implementation, partnerships, and funding have been key to global efforts to combat malaria.

A rigorous external evaluation not only concluded that PMI is "by-and-large a very successful, well-led component of the U.S. Government Global Health Initiative," but challenged us to re-

examine critically what we have been doing and how we could improve programming in the face of falling malaria transmission in most PMI countries.

The Evaluation Team made five policy and five technical overarching recommendations that will guide programmatic improvements in the coming years. PMI views these recommendations as relevant and useful for program improvement. In fact, several of the recommendations are directly in line with management and technical improvements that are already underway. PMI leadership and technical teams have carefully reviewed all comments in the report and, with input from PMI's Interagency Advisory Group, have developed a detailed management response including a plan and timeline for implementation of each recommendation.

Bold Vision

Malaria prevention and control are major national security and foreign assistance objectives of the U.S. Government. In 2010, President Barack Obama launched his vision for how the United States would approach global development, which sees development assistance as a pillar of foreign policy and crucial to America's national security and economic interests. In his 2013 State of the Union Address, the President stated that "... the United States will join with our allies to eradicate such extreme poverty in the next two decades ... by saving the world's children from preventable deaths ..." Malaria is a major cause of childhood mortality in Africa. Consequently, preventing and controlling malaria are a key focus of U.S. Government foreign assistance. PMI is playing a lead role in implementing the President's vision.

PMI's efforts to reduce malaria mortality also directly contribute to the goal to end preventable child deaths as articulated by the USAID 2012 Call to Action and reaffirmed by A Promise Renewed, a joint global effort led by UNICEF and endorsed by the U.S. Government. Reducing the level of malaria transmission has the dual effect of preventing mild cases of malaria from progressing to severe disease and death while unburdening the health system, so health workers can focus their time and energy on other important childhood illnesses, such as pneumonia, diarrhea and malnutrition.

The human and economic toll of malaria in Africa has been reduced but remains devastating. The mortality and health impact that malaria has in sub-Saharan Africa, predominantly on pregnant women and children under the age of five, is well known. Our support to national malaria programs in Africa are focused on reaching these two most vulnerable groups and we focus on delivering equitable care by targeting rural areas where the greatest burden of the disease usually falls on families who have lower incomes and whose access to health care is most limited.

In addition to its human toll, malaria imposes a high cost on macroeconomic growth, household income (through absenteeism and expenditures on treatments); and negatively impacts

childhood cognitive development. These factors pose serious impediments to poverty alleviation and overall development in Sub-Saharan Africa.

- **Malaria hurts macroeconomic growth in Africa**: Economists estimate countries with high burden of malaria grew 1.3 percent less (gross domestic product) due to malaria. This is further estimated to equal up to $12 billion in lost productivity due to malaria in Africa annually.
- **Malaria is impoverishing to families in Africa, 50% live on less than $1.25 a day**: Economic studies have shown that the total cost (direct and indirect) imposed by malaria can cost families from 9-18% of household income in Kenya and up to 32% of household income in Malawi.
- **Malaria negatively impacts childhood cognitive development, which can lead to reduced educational attainment and earning potential in adulthood**. A recent study among children in Uganda concluded that an episode of cerebral malaria was associated with a 3.7 fold risk of cognitive impairment compared to children in the control group not exposed to cerebral malaria. Cognitive impairment has been associated with poor reading and arithmetic achievement in children. Lower grades in school among children exposed to non severe malaria infections have been demonstrated in studies in Brazil and Sri Lanka.

Global Fund and PMI Collaboration

The Global Fund is a multilateral public-private partnership created in 2002 to provide financial support through grants for large-scale prevention and treatment services for HIV/AIDS, tuberculosis and malaria.

The Global Fund and PMI are committed to coordinating their efforts in-country in an effort to maximize their impact on the global malaria burden. Each program has its own unique strengths, lending to the complementarity of the partnership and significant success on the ground. Currently, all 19 PMI focus countries in Africa, and one regional program in the Greater Mekong Subregion of Southeast Asia, receive substantial funding from the Global Fund, which, alongside PMI, is the leading donor for malaria. And because the Global Fund does not have in-country technical staff, it often relies on PMI Resident Advisors to help coordinate malaria activities and share information about potential bottlenecks with the Global Fund.

PMI also sits on the U.S. delegation of the Global Fund Board; therefore, it helps shape policy issues at the highest level of Global Fund governance. Moreover, PMI staff have also participated on the Technical Review Panel, which is responsible for reviewing the Global Fund's grant applications prior to Board consideration, and on the Global Fund's Country

Coordinating Mechanisms, which are country-level multi-stakeholder partnerships that develop and submit grant proposals. Country examples of collaboration include:

- Liberia: Almost half of the population in Liberia seeks medical treatment from the private sector; therefore, PMI and the Global Fund supply subsidized first-line anti-malaria drugs to the private sector, thereby expanding access to affordable malaria treatment to Liberians.
- Nigeria: PMI has helped to distribute over 15 million insecticide-treated nets procured by the Global Fund (among other donors) across Nigeria, and managed logistics and donor coordination.
- Democratic Republic of the Congo (DRC): PMI helped the DRC government develop its Round 10 grant proposal to the Global Fund, and together, PMI and the Global Fund are helping to ensure that all of the country's health zones receive a minimum package of antimalarial interventions.

Leveraging Partnerships

Partnership is a hallmark of how PMI does business. We coordinate our activities with a broad set of partners ranging from national malaria control programs of PMI focus countries to multilateral and bilateral institutions, such as WHO, the United Nations Children's Fund (UNICEF), the World Bank, The Global Fund, DFID, and AusAID as well as private foundations, such as the Bill & Melinda Gates Foundation, William J. Clinton Foundation and UN Foundation; and numerous nonprofit and faith-based organizations. Examples of these partnerships include:

- PMI supported the Roll Back Malaria Harmonization Working Group to help six African countries (Benin, Burkina Faso, Chad, Ethiopia, Niger and Zambia) prepare their malaria proposals for the Global Fund's Transitional Funding Mechanism – all of which were successfully funded.

- In Zambia, DFID has channeled funds through PMI for the procurement of commodities. And, in four additional PMI focus countries (Kenya, Malawi, Rwanda and Uganda), PMI and DFID have initiated discussions to develop partnerships.

- In the 2012 fiscal year, Peace Corps volunteers in 14 PMI focus countries assisted with malaria control activities.

- To date, PMI has supported malaria activities through more than 200 nonprofit organizations, approximately one-third of which are faith based. These groups often have strong and highly effective bases of operations in underserved rural areas, where

the burden of malaria is greatest. And, recently, I witnessed how the voice of the faith community can help raise awareness around malaria. For example, the United Methodist Church recently helped rally interest around malaria during the screening of the HBO film, "Mary and Martha" – which tells the story of two mothers who are joined together by the loss of their children to malaria.

PMI also works with private sector partners to help leverage their capabilities and resources and ensure that their efforts are well coordinated with government strategies and plans. For example, PMI has partnered with mining and sugar cane companies to implement IRS activities in Ghana, Liberia, Malawi and Zambia. In FY 2012, the ExxonMobil Foundation provided $500,000 to PMI to support PMI objectives in Angola, bringing its total contributions to PMI to $4.5 million since 2006. The foundation's support is for the scale-up of ACTs and IPTp through subgrants to nongovernmental and faith-based organizations in eight provinces where government health infrastructure is weak.

Budget

Thanks to strong bipartisan support we are on track to provide continued life-saving health assistance to more people than ever before although the needs remain great. The FY 2014 Global Health request supports our goals of creating an AIDS-free generation, ending preventable child and maternal deaths.

Because of continued bipartisan support, PMI was able to expand its efforts in Africa by:

- ✓ Designing PMI programs and beginning implementation of malaria control activities in two new PMI focus countries – Guinea and Zimbabwe; and
- ✓ Expanding PMI programs in Nigeria to eight of 36 states (total population of 27 million) and the Democratic Republic of the Congo to four of 11 provinces (total population of 19 million).

PMI now includes 19 focus countries in Africa and one regional program in the Greater Mekong Subregion of Southeast Asia. PMI's efforts in the Greater Mekong are primarily focused on combating antimalarial drug resistance and finding new methods to reduce outdoor transmission among migrant populations and forest workers. In addition, USAID malaria funding also supports control efforts in three other African countries as well as one regional program in Latin America: the Amazon Malaria Initiative.

The United States continues to provide global leadership in the fight against malaria and in global health. We continue to challenge endemic countries to increase their domestic contribution to malaria control and use their malaria funding wisely and strategically.

The announcement of a substantial increase in malaria support from the British Government through DFID will help meet some of the global need for malaria funding, but malaria control is a long-term challenge, and sustained external donor support will be critical to the continued progress of national malaria control programs in focus countries. The fact that DFID is choosing to channel its own funding through USAID's in-country bilateral programs and mechanisms is a vote of confidence in the efficiency of our systems. We are pleased to see that we have a strong and trusted partner in DFID that has shown this level of commitment to malaria control.

Challenges

Tremendous progress has been made over the past decade, including a 25% reduction in estimated malaria deaths at the global level and a 33% reduction in Africa alone.

The risk of malaria is declining and more children are surviving, but the gains are fragile and could be reversed without continued support. We recognize and appreciate the continued commitment of Congress and the American people to fighting malaria through PMI and Global Fund in this time of budget austerity.

Despite the significant gains the Global Fund, PMI, national governments, and others have made in the fight against malaria, the disease remains a serious global public health problem. The goal moving forward is to maintain and build on previous efforts and ensure the successes to date are not rolled back, even as the dual threats of artemisinin drug resistance and insecticide resistance grow.

A strain of the malaria parasite has appeared in parts of Southeast Asia with resistance to what have been the most effective medicines to fight the parasite. And some fear that the parasite may ultimately become resistant to all drugs we currently have to treat malaria. Migration of this resistant parasite to Africa would be devastating.

We must also be diligent in identifying and monitoring mosquito resistance to insecticides so that our most effective prevention measures, insecticide-treated mosquito nets and indoor residual spraying, aren't undermined. This is especially important because both insecticide-treated mosquito nets and indoor residual spraying rely on the use of insecticides. If mosquitoes become resistant to those insecticides, the efficacy of these interventions will be compromised. We must also find new ways to interrupt outdoor transmission, where LLINs and IRS are less effective. In some areas of the Greater Mekong Subregion, estimates are that more than 50 percent of transmission takes place outside of homes. Insecticide-treated clothing and spatial or area repellents or insecticides are promising interventions we are evaluating.

We recognize that tackling these new strategic challenges is a priority and we are working with the private sector to develop new antimalarial drugs as well as new insecticide-based tools. At

the same time, we need to continue to expand our tool box to combat malaria by developing a highly effective, but inexpensive, vaccine that could result in hundreds of thousands of lives saved.

Leveraging Innovation and Technology

Research to support malaria control efforts and reduce the burden of malaria has been a high priority of the U.S. Government for many years. USAID investments in science and global health research and development cut across a broad range of topics, including the development of malaria vaccines, antimalarial drugs, and diagnostic tools for malaria; implementation research to improve programs; and behavioral/social science research to improve service utilization and health-seeking behavior.

The U.S. Government malaria research effort involves the U.S. Centers for Disease Control and Prevention and the National Institutes of Health of the Department of Health and Human Services, the Naval Medical Research Center and the Walter Reed Army Institute of Research of the U.S. Department of Defense and the U.S. Agency for International Development. Each of these agencies has its own direct funding for malaria research. PMI funds operational research in addition to these other research efforts.

USAID support of drug development through product development partnerships such as the Malaria Medicines Venture has led to the approval and use of new treatments for malaria.

PMI support of malaria operational research focuses on topics, such as mosquito net durability; the effectiveness of combining interventions such as IRS and ITNs; and looking forward, the impact of insecticide resistance on mosquito net effectiveness, the use of spatial repellents to interrupt outdoor biting, better use of diagnostics to guide malaria treatment and new vector surveillance and control technologies. PMI uses study results to help guide its program investments, make policy recommendations to national malaria control programs and target interventions to increase their cost-effectiveness. Some examples of PMI-funded operational research studies include:

- Eight PMI focus countries (Angola, Benin, Kenya, Malawi, Mozambique, Rwanda, Senegal and Zambia) are conducting studies on the physical and insecticidal longevity of ITNs. Overall study results have shown that many mosquito nets do not last the expected three years due to loss of physical integrity. Thus, ITNs may need to be replaced more frequently than anticipated in order to maintain high coverage. These findings are being used to inform research on ITN care and repair behaviors, as well as to aid design changes to ITNs to improve physical durability.

- In Nigeria, preliminary results from a study looking at mosquito net care and repair behaviors indicate that few residents repair their mosquito nets when they are damaged. Encouraging mosquito net repair could help prolong the useful lifetime of a mosquito net and thus reduce the cost of mosquito net procurements over time.
- In Kenya, where mosquitoes have developed resistance to pyrethroid insecticides used in IRS campaigns, PMI supported a study to assess the effect of nine different insecticides or insecticide formulations on mosquito populations. Results were presented to the national vector control technical working group, which then made recommendations to the NMCP to use a carbamate insecticide in future IRS campaigns.

And we are also looking at ways to apply new technology to solve malaria problems. In Zanzibar, PMI created a mobile application that builds on an early epidemic detection system for malaria. This innovative mHealth system allows health facilities to report new malaria cases using a cell phone, which ensures that outbreaks of malaria are identified within two weeks of their onset. These mHealth applications are helping Zanzibar to sustain the remarkable gains it has made against this dangerous and debilitating disease. Opportunities exist to expand on the lessons learned from these technology-based activities in malaria programs and introduce them as solutions to other global health projects that are facing similar challenges.

The goal over the next 5 to 10 years will be to sustain and build on these efforts in the face of such challenges as antimalarial drug resistance, insecticide resistance, and uncertainties around donor and national funding for malaria control.

Research and development are critical components of the fight against malaria, and we will need to continue to expand our tool box to combat malaria. The sustained bipartisan support for global health in the U.S. Congress over two administrations is a testament to the fact that we have been able to demonstrate an incredible return on investment for every dollar spent on saving lives and improving opportunity. The health of a nation is the foundation upon which economies are able to grow and new markets for U.S. products are established.

In closing, I would like to thank the U.S. Congress for its continued support and reiterate that, together with our partners, we remain deeply committed to the global fight against malaria.

Mr. SMITH. We do have a vote, two votes on the floor, and I apologize for the inconvenience to our witnesses. We thought we would take a very brief recess, come back, and Colonel, then we will receive your testimony. We really do want to hear what you have to say. So the subcommittee stands in recess.

[Recess.]

Mr. SMITH. The subcommittee will resume its sitting, and Colonel Weina, if you could proceed with your testimony.

STATEMENT OF COLONEL PETER J. WEINA, PH.D., M.D., DEPUTY COMMANDER, WALTER REED ARMY INSTITUTE OF RESEARCH, U.S. DEPARTMENT OF DEFENSE

Colonel WEINA. Thank you, sir. Chairman Smith and distinguished members of the subcommittee, thank you for the opportunity to appear before you to discuss the Army's medical research initiatives to improve soldier readiness and global health and highlight the incredible work of the military medical research community.

I extend our appreciation to Congress for their support to military medicine faithfully given, which provides the resources we need to deliver leading edge health services and diligently continue innovative research. Malaria is a global agent scourge that has haunted mankind for much of our history, and yet it still impacts our lives in our society today. I know it has been said many times, but it bears repeating: Over 3.3 billion people remain at risk for the disease. Over 200 million cases of the disease appear every year along with over 650,000 deaths.

Among the most vulnerable are the young children who account for over 85 percent of the malaria-related mortality globally. A preventable disease, malaria is a leading cause of death in children under 5 years old in sub-Saharan Africa.

The U.S. military has also felt the threat of malaria as far back as 1775 when George Washington expended limited resources to purchase quinine for the treatment of malaria. Malaria has been diagnosed during the Civil War, World War II, Vietnam and even recently in Afghanistan.

Historically, the incidents depends primarily on deployment location, but during the last 10 years, we have seen approximately 100 cases every year, despite the resources we have to protect our troops. While the days of massive debilitating impact on malaria operations are behind us, we only have to look back to 2003 in order to appreciate the potential impact when a military peacekeeping operation in Liberia failed after only a few weeks due to 80 cases of malaria in 225 Marines, 44 of those requiring medical evacuation.

The destabilizing effects that diseases such as HIV/AIDS and malaria have on the critical infrastructure of developing nations is compelling evidence that global health is a means to global security. These diseases undermine the education and health systems, economic growth, micro-enterprises, policing and military capabilities, political legitimacy, family structures, and overall social cohesion. They undermine the stability of already weakened states and add to their vulnerability to extremists and terrorists who seek to corrupt or coerce. Our response, through medical engagement,

needs to be comprehensive, fought at many levels, and on many fronts to provide for global stability and our own nation's security.

The Walter Reed Army Institute of Research has a trusted partnership in several countries that has been established for decades. Long-term relationships have been built with host countries as well as health organizations allowing both personnel and logistical support to establish larger work.

We have been in partnership with the Royal Thai Army for over 50 years, and with the Kenyan Medical Research Institute for over 40 years. We have established robust relationships that have allowed the important work of military medicine's research as well as the important work of PEPFAR and PMI.

The U.S. military's exceptional science, logistic and regulatory expertise allows for the testing of new products to the best standards of care for the local population as well as the delivery of critical life-saving HIV/AIDS and malaria interventions.

Military medicine also serves as a partner in the critical platform of disease surveillance. Both the Army and Navy conduct oversees disease surveillance operations that not only keep a watchful eye on malaria patterns and malaria resistance throughout the world, but also survey for other infectious disease threats. These overseas operations are part of a complex ecosystem that provides not only surveillance, but also a platform for testing new products, medical engagement with many countries worldwide and outreach for the execution of PEPFAR and PMI missions and programs.

Vigilance in combating malaria is an enduring mission. The U.S. military is engaged in malaria research for several key reasons, to preserve the fighting strength of our men and women in uniform who go into harm's way, to protect our Nation's citizens who encounter these threats worldwide, and to positively impact the global health and stability of our allies.

In closing, I am proud of the global impact that military medicine research has done throughout history and the continued diligence being done to combat one of the oldest infectious disease threats man has known. In partnership with the Department of Defense, my colleagues here today, our global partnerships and the Congress, we will be prepared for tomorrow's challenges. Thank you for your time.

Mr. SMITH. Colonel, thank you very much for your leadership and for your testimony today.

[The prepared statement of Colonel Weina follows:]

RECORD VERSION

STATEMENT BY
COLONEL PETER WEINA
THE WALTER REED ARMY INSTITIUTE OF RESEARCH
UNITED STATES ARMY

BEFORE THE

HOUSE COMMITTEE ON FOREIGN AFFAIRS
SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS

FIRST SESSION, 113TH CONGRESS

ON THE US CONTRIBUTION TO THE FIGHT AGAINST MALARIA

MAY 17, 2013

NOT FOR PUBLICATION UNTIL RELEASED BY THE
HOUSE COMMITTEE ON FOREIGN AFFAIRS

Chairman Smith, Ranking Member Bass, and distinguished members of the subcommittee, thank you for the opportunity to appear before you to discuss the Army's medical research initiatives to improve Soldier readiness and global health, and highlight the incredible work of the military medical research community, the Walter Reed Army Institute of Research, and the US Army Medical Research and Materiel Command. On behalf of the over 150,000 dedicated Soldiers and civilians that make up Army Medicine, I extend our appreciation to Congress for the support to military medicine faithfully given, which provides the resources we need to deliver leading edge health services, and diligently continue innovative research.

The Global Threat of Malaria

Malaria is a global ancient scourge that has haunted mankind for much of our history, and yet it still impacts our lives and our society today. Conservative estimates suggest that over 3.3 billion people remain at risk for the disease worldwide; over 200 million cases of the disease appear every year along with over 650,000 deaths. Among the most vulnerable are young children, who account for over 85 percent of the malaria-related mortality globally. A preventable disease transmitted by the *Anopheles* mosquito, malaria is a leading cause of death in children under five years old in Sub-Saharan Africa.

Despite plans in the 1950s to eradicate malaria worldwide with powerful tools like chloroquine (a powerful drug for treatment) and DDT (dichlorodiphenyltrichloroethane, a remarkably effective mosquito control compound), the emergence of widespread chloroquine-resistant malaria parasites, along with concern regarding the environmental effects of DDT, resulted in the declaration of the eradication effort's failure and eventual demise in 1972.

Not to be defeated, Roll Back Malaria (RBM) was launched in 1998 with a goal to halve the number of malaria cases by 2010, and eliminate malaria in 8 to 10 countries by the year 2015. As progress continues around the globe, in Africa, where the majority of the malaria mortality burden is borne, we have seen malaria death cut by one-third in the last decade alone. Outside of Africa, of the over 50 countries affected by malaria, total numbers of cases have been reduced by fifty percent in the last decade. This progress, due in part to large distributions of insecticide-treated mosquito bed nets, vector control interventions, and to the wide-spread use of artemisinin-combination therapies, has been so dramatic that in 2008, malaria eradication, which was not thought possible thirty-five years earlier, was considered an attainable goal once again.

Malaria has existed for centuries as four recognized species of parasite, all with minor variations on the cycle, hosts, vectors, and sensitivity to treatments available. Some of the species are harder to treat or need longer periods of time to eliminate the disease burden from a population, taking as long as twenty years in some instances. Maintaining vigilance for that length of time, and the public health efforts needed for actual elimination are challenges that require extraordinary dedication and political will. Even if elimination on a global scale is achieved, medicine cannot overlook the possibility that there will be identification of additional malaria species and vectors entering into the human population, as science advances. The

identification of a fifth human malaria species in 2008, originally identified from a monkey source, brings to light the possibility of identifying an additional threat from an old adversary.

Military Relevance of Malaria

The U.S. military has felt the threat of malarial disease as far back as 1775, when George Washington had to expend his very limited monetary resources to purchase quinine for the treatment of malaria in the Revolutionary Army. In the 1860s, the Civil War saw 50 percent of Caucasian troops and a staggering 80 percent of Black troops contracting malaria annually. The military impact continued during World War II, Vietnam, and even recently in Afghanistan, where we still see approximately 100 cases annually, despite the resources we have to protect our troops. While the days of massive debilitating impact on military operations are behind us, we only have to look back to 2003, when a military peacekeeping operation in Liberia failed after only a few weeks due to 80 cases of malaria in 225 Marines, 44 requiring medical evacuation, in order to appreciate the potential impact on military readiness.

This is an enduring mission. The U.S. military is engaged in malaria research for several key reasons: to preserve the fighting strength of our men and women in uniform; to protect our Nation's citizens who encounter these threats world-wide; to impact the global health and stability of our Allies. It was less than a generation ago that malaria was present in the United States. Just as we have seen the spread of other vector-borne diseases such as West Nile Virus, there is a real potential, given the global nature of our population and the simple nature of the disease host, for malaria to be reintroduced into the U.S.

Global Health Impact

The destabilizing effects that diseases such as HIV and malaria have on the critical infrastructure of developing nations is compelling evidence that global health is a means to global security. These diseases undermine education and health systems, economic growth, micro enterprises, policing and military capabilities, political legitimacy, family structures, and overall social cohesion. They undermine the stability of already weakened states and add to their vulnerability to extremists/terrorists who will seek to corrupt or coerce. Our response through medical engagement needs to be comprehensive, fought at many levels, and on many fronts, to provide for global stability and our own Nation's security.

Partnerships and Progress

Assigned to the newly opened Army Medical School in 1893, Army Major Walter Reed was instrumental in defining the concept of mosquitoes transmitting disease. In the case of Yellow Fever, it was Major Reed's hypothesis on disease transmission that opened the door for

William C. Gorgas to abate the spread of Yellow Fever and malaria in the construction of the Panama Canal.

The first synthetic anti-malarial medication, Atabrine, was developed through the coordinated activities of the Allied medical forces, setting the stage for the involvement of the Walter Reed Army Institute of Research (WRAIR) in anti-malarial drug development. The Experimental Therapeutics branch of the WRAIR remains the only sustained drug development program in the Department of Defense, holding the distinction of initiating or being involved in virtually every anti-malarial drug development available for fighting malaria since WWII.

Developing a vaccine against malaria is a complex science, requiring an immune response differs from what is seen with natural infection. The best potential for a way forward is through several strategies at immune stimulation. The Malaria Vaccine Branch of WRAIR and the Malaria Department of the Naval Medical Research Center (NMRC) work cooperatively as the US Military Malaria Vaccine Program (USMMVP) on a joint mission to develop vaccines against the two types of malaria that cause the most serious disease in humans.

The WRAIR Malaria Vaccine Program, along with a pharmaceutical company, has developed what is currently the world's leading malaria vaccine candidate. Known as RTS,S/AS01, it is the first candidate malaria vaccine able to demonstrate reduction in the number of episodes (by 50 percent) or clinical severity of malaria infections, particularly in infants age five to seventeen months old. This product is currently in phase 3 clinical trials in Africa at our overseas operations, demonstrating a key step towards prevention.

The NMRC Malaria Department currently has two main vaccine research efforts, one in partnership with a commercial biotech company on a DNA prime/adenovirus boost vaccine, NMRC-M3V-D/Ad-PfCA, which has shown low level protection (27 %) in early stage clinical trials. Additionally, NMRC is partnering with a commercial pharmaceutical company and the National Institute of Allergy and Infectious Diseases Vaccine Research Center, of the National Institutes of Health, on a novel purified, radiation-attenuated, cryopreserved, whole sporozoite vaccine that is in an early stage clinical trial.

The Entomology branch of WRAIR has worked diligently on personal protective measures such as treated bed nets, new insecticides, and permethrin-treated clothing to prevent not only malaria, but several other insect-borne diseases.

The WRAIR has a trusted partnership in several countries that has been established for decades. Long term relationships have been built with host countries as well as health organizations, allowing both personnel and logistical support to establish larger work. We have been in partnership with the Royal Thai Army for over 50 years, where we use Thailand as a base of operations to work with malaria and other infectious diseases throughout the region. Our relationship with the Kenya Medical Research Institute is over 40 years old and serves as our touchstone in the African continent. There, as in Thailand, we have established robust relationships that have allowed the important work of Army medicine's research, as well as the important work of the President's Emergency Plan for AIDS Relief (PEPFAR) and the President's Malaria Initiative (PMI). The US military's exceptional science, logistic, and

regulatory expertise allows for testing of new products to the best standards of care for the local population as well as the delivery of critical life-saving HIV and malaria interventions.

Military medicine also serves as a partner in the critical platform of disease surveillance. Both the Army and Navy conduct overseas disease surveillance operations that not only keep a watchful eye on malaria patterns and malaria resistance throughout the world, but also survey for other infectious disease threats. Much of this work is accomplished through funding from the Global Emerging Infections Surveillance and Response System (GEIS) at the Armed Forces Health Surveillance Center (AFHSC). These overseas operations are a part of a complex ecosystem that provides not only surveillance, but also a platform for testing new products, medical engagement with many countries worldwide, and outreach for the execution of the PEPFAR and PMI missions and programs.

Military Medical Research Funding

Funding for malaria research and development in the military has been suffering since Vietnam. The US military is able to best utilize governmental funding for malaria research through research partnerships around the globe for malaria programs and projects, sustaining us to date despite the diminishing budget. The FY12 budget for all malaria effects in the DoD (approximately $20 million) was increased to $60 to $100 million through matched funds achieved by leveraging partnerships with other governmental agencies, private industry, and academic partners.

The military malaria research budget is approximately equal between drug and vaccine research and development (drug budget approximately $8.9 million and vaccine budget approximately $10.2 million in FY13 and FY14). The malaria drug effort feeds the entire range of pharmaceutical research, from looking at new chemical entities all the way through clinical trials for anti-malarial drugs getting licensed. The vaccine research effort of the joint Army/Navy program is exploring multiple different candidate vaccines and looking at what strategy will work the best.

Despite all of this exceptional work, which not only benefits the military but also those impacted by malaria worldwide, there is still much to be done. While we optimistically consider eradication, new threats emerge through resistance to current therapy and current insecticides. Despite being effective today, current medications for prophylaxis and treatment are being used to treat organisms that have consistently found a way to defeat most every one of our older drugs; these organisms will likely find a way to defeat any new medications discovered for malaria treatment. Resistance is a fact of drug development and even with the most cautious use of drugs, the organisms we are fighting will always find a way to defeat our treatments. The best we can do is through prudent use of these agents to extend the life of these drugs until new ones are found. While our vaccines show promise, it will likely be years, if not decades, before we have anything that can really make a global difference.

Like most tropical parasitic diseases, malaria is a disease that is tied to poverty and social disruption. Global medicine has reached a critical tipping point in terms of the technology used in medical research. Advances in genetics (such as with pyrosequencing) have helped us better understand the pathogens and organisms we are dealing with, providing the tools to make significant progress as we stay on course and effectively utilize what these new platforms have taught us.

Closing

In closing, I am proud of global impact that military medical research has had throughout history, and the continued diligence being done to combat one of the oldest infectious threats man has known. In partnership with the Department of Defense, my colleagues here at the panel today, our global partnerships, and the Congress, we will be prepared for tomorrow's challenges. The Army Medicine team is serving to heal -- and honored to serve.

Mr. SMITH. Just to lead off the questioning, let me start off with a question to Admiral Ziemer. You mentioned about one-third of the NGOs that are getting assistance happen to be faith-based. One of the concerns that I have expressed from the very beginning, both with PEPFAR and malaria and every other U.S. foreign aid program, especially as it relates to Africa, has been the early exclusion of faith-based organizations, primarily because of ideological reasons, but there appears to be, and I think there has been good strong support for them. I actually wrote the conscience clause for the PEPFAR program because of that exclusion.

If you could just elaborate a bit on how essential indigenous faith-based groups are being included. If we want to end the pandemic of HIV/AIDS, it seems to me, and TB, the problems associated there, and the malaria problem, we need to have as partners those faith-based groups. If you could touch on that.

Admiral ZIEMER. Thanks for the questions. When PMI was launched, one of the first things we did was to look at the best practices of PEPFAR and model some of our programmatics after the PEPFAR model. So, to the extent there were clear guidances coming from here and from the administration, we looked at them and embraced them. But I can tell you from the beginning of PMI, we intentionally looked at a deliberate engagement of the NGOs in the field, specifically looked at the merits of the faith-based organizations because we acknowledged, and from personal experience, accepted the fact that they were there before we got there, and they will be there after we go. And when we start embracing capacity building and sustainability of programs, the local NGOs, specifically the faith based, are a huge component of building for the future.

Mr. SMITH. I appreciate that. You know, the impact on childhood cognitive development, we know that obviously our goal is to eradicate malaria and to prevent deaths, but also to mitigate morbidity and other consequences like impact on cognitive development. Is the timeliness of the intervention key? I chair the Lyme Disease Caucus here in the House and have a bill pending that I hope will get brought up on establishing a blue ribbon commission on lyme disease, particularly chronic lyme. The longer the parasite grows inside an individual, the worse its deleterious effects. I am wondering, you know, the issue of how this mal-affects children as they become adolescents, adults and right on through the rest of their life.

Admiral ZIEMER. You are asking a rather technical question, and I would defer that to some of our scientists and colleagues when it comes to the impact or the delayed impact of delayed parasite clearance from a system. I do know that we have a very rigorous prenatal program, so that when pregnant women go into the clinics, we are providing preventative treatment. So in terms of the health of the newborn child, it is being addressed through that prevention measure, but when a child presents with a fever, we are committed to appropriate diagnosis and then treatment. So at an early age, if the child presents and is diagnosed with a fever, we do everything we can to provide treatment.

Mr. SMITH. In his testimony, Ambassador Dybul, the executive director of the Global Fund, points out that between 2004 and 2010

the need, the coverage need, the level of need was essentially met, but only 92 million nets were delivered by manufacturers in 2011, largely due to funding constraints, and in 2012, only 66 million nets were produced. He points out that in February of this year, the Global Fund and WHO and other partners, I am sure that includes you and us, the United States, estimated that 77 million nets were needed to maintain coverage for communities that the Global Fund has previously protected.

He also talks about the big push to replace insecticide-treated nets and its new, interim funding grant stream, along with fostering diagnostic and treatment needs, and bottom line, that between 2013 and 2015 there is a $3.5 billion gap. Now, I know the United States has been generous. It has been the leader. Is there more that we could be doing? I mean, can we, Congress, be partners in ensuring that that gap is closed?

Admiral ZIEMER. The fact that we know what the gap is and we can have these numbers, represents information that we didn't have 5 years ago.

Mr. SMITH. Right.

Admiral ZIEMER. So as we look at supporting the country's requirements, we are able to refine the net requirements, and then collectively discuss at the funding level, the partner level, and at the national level how best to direct those resources. I think it is important to acknowledge that since 2008 and 2009, our partners, along with the United States, have distributed over 300 million bednets to sub-Saharan Africa, which represents coverage to close to 600 million people. I think the figure is 578 million. So we are making tremendous progress.

As we look at those at risk, I think it is important to look at the full toolkit that we have. Four of the interventions that we use are focused on prevention. Bednets, of course, is one, along with indoor residual spraying. We are looking at country requirements, the most at risk population groups, and moving forward with the funding that we have. So, are there gaps? You bet. Are we dealing with them better? Yes. We just have to keep at it.

Mr. SMITH. And if you could help us—I mean, we want to be advocates. I certainly personally want to make sure that all that can be done is done. I thought that again Ambassador Dybul makes an excellent point. Either progress is made or we lose momentum. The reality is invest now or pay forever, which is a very strong and I think a very declarative statement that we could make a difference, but funding is key, and obviously deploying those resources prudently is key.

Colonel, if I could just ask you, your written testimony goes into some great length, thank you for your oral testimony as well. You point out that the Walter Reed Army Institute of Research, along with a pharmaceutical company, has developed what is currently the world's leading malaria vaccine candidate. You point out that the product is currently in Phase III clinical trials in Africa, if you maybe would touch on where in Africa. Is it Kenya where we have the lab? And the medical research collaboration, and how close are we to, you know, actually developing a vaccine that is deployable?

Colonel WEINA. Yes, Chairman Smith, the question of partnering with a drug company, we do partner all of the time with some sort

of commercial entity to make sure that our products go forward. None of the products that we actually produced are things that are necessarily borne strictly by the United States to move forward.

The question of where this work is being done, it is the Phase III trial is principally being done in Kenya right now where we have our laboratory. This work has moved forward significantly, but of course, the question of when are we going to have a vaccine is really tied up in some very significant details.

First of all, the vaccine that we have right now is not a vaccine that absolutely protects an individual from getting malaria. The great thing about this vaccine, and this is why it is being pursued principally in Africa, is the fact that it reduces the mortality associated with the disease. This vaccine, just like a lot of other vaccines that we are having difficulties with, such as HIV, are things in which they don't naturally occur in nature. We don't have a situation like we have, for example, with chickenpox in which maybe somebody gets chickenpox and then they aren't going to get chickenpox again. Those vaccines are the easy ones. Those are the ones that have already been developed.

What we are trying to do is actually develop a vaccine for a condition that doesn't occur in nature, so it is a lot tougher to do. What we have been able to mimic is the fact that children that have repeatedly gotten malaria are at lower risk of dying from malaria than individuals that may get it the first time. And this is a real success. It helps reduce the mortality, and it produces some information for us and possibly moving forward into a vaccine that does have significantly more efficacy and something that may actually prevent somebody from getting infected.

Mr. SMITH. Let me ask you, Colonel, if I could. You point out that funding for malaria research and development in the military has been suffering since Vietnam. You talk about how you have worked very creatively, partnering with others, to try to lessen the impact of that diminished funding, and I think $10 million is what you have in use for research.

You also point out that resistance is a fact of drug development in even the most cautious of drugs. Organisms we are fighting will always find a way to defeat our treatments, which is a very ominous statement and a very disconcerting statement. And we know in some four countries in Southeast Asia, Dr. Friedman was very emphatic on that when he appeared before our committee just a few weeks ago, there is concerns about drug resistance to artemisinin. Could you speak to that issue of drug resistance and also that budget for research? What would more money enable you to do, if it were to be available above the $10 million?

Colonel WEINA. Yes, sir. The issue of resistance is something that we deal with not just with for malaria but for a lot of diseases. The malarial parasite is a very ingenious organism that is actually, I guess, just trying to survive, and we are constantly trying to beat it down. It has found a way of practically defeating every single drug that we have produced all the way back to something that we have been using like quinine for over 300 years. All of the new drugs that are out there, Mefloquine, Fansidar, all of these types of drugs, Malarone even, there is resistance. And our biggest tool

in our arsenal right now are the artemisinins, artemisinin-based drugs.

We are seeing an increase in the potential for resistance in Southeast Asia, particularly along the Thai-Cambodian border where we have seen a lot of resistance arise, and we are going to—every single time we produce a new drug, these organisms are going to find a way around it, and that is why we need to have continued vigilance. That is why every single anti-malarial that has basically come out since World War II has had the involvement of the Walter Reed Army Institute of Research because of the fact that we have continually worked on it virtually our entire existence looking at a new drug. So every time we have a new one that is out there, we don't stop and celebrate that we have the new one. We are actually looking for yet the next one that is out there, and we have a full pipeline of drugs that are being developed and looking for yet that next generation because we know we are going to have resistance, and there is no way of actually stopping that from moving forward.

As far as the budget, I think everybody would just love to have more money. There are limited resources that are going to be available. I think what we would like to have more so than anything else is just to continue to get the money that we have been POM'd and that allows us to do the planning that is really necessary to move forward with our partnerships because our people are very entrepreneurial. And whatever investment that the U.S. taxpayer puts into developing these drugs, we are able to partner with private organizations, with academia, with other governmental organizations and really move the goal forward by bringing those types of partnerships together in this ecosystem that increases every single dollar three, four, five times and increase our budget to move things forward.

Mr. SMITH. I think Americans should be concerned just because we are our brothers' and sisters' keeper, and that is what this program is built on, but there is the possibility, as you pointed out, of malaria being reintroduced into the United States. It is something I never read in the history books, and we talked about the Civil War. You point out, in the 1860s, the Civil War saw 50 percent of the Caucasian troops and a staggering 80 percent of the Black troops contracting malaria annually. That is extraordinary. And that is information that I think just underscores—we had it here. It is gone. Now we have to hope and pray and work hard to see that it will soon be eradicated in Africa and everywhere else that it is.

Mr. Bera.

Mr. BERA. Thank you, Chairman Smith.

I think the American public, if you are out there watching, you can be very proud of what we have been able to accomplish and the reflection of our values as a Nation, you know the compassion, the humanitarian commitment to eradicating malaria; to the wonderful work that, Admiral Ziemer and Colonel Weina, you guys have been doing; and the fact that this is a real bipartisan effort. The President's Malaria Initiative started under a Republican President and it has continued under a Democratic President. The leadership demonstrated on this committee and the commitment to compas-

sionate and humanitarian need in eradicating some of the toughest diseases in the world, this is something that we can be proud of as an institution and as a country and Nation.

I look at this from the perspective of being a doctor. And the first course of medicine is always to try to focus on prevention of disease. If you can prevent it, then you don't have to treat it. And we are making strides. And when we think about prevention of malaria, we think about, obviously, nets and preventing the mosquito bites. We also look at the public health measures that we can do—you know, pools of water, et cetera—and educating the population where malaria's endemic.

Chairman Smith touched on the cornerstone of prevention in fighting infectious disease, which is vaccination. And if our goal is eradication, we really do have to focus on finding a vaccine.

Colonel, as you pointed out, malaria is a very smart challenge, and it is a smart parasite that has continually adapted. And yes, we are going to have to continue investing in the next generation of therapy. But until we can come up with an effective vaccine, it will be very difficult to eradicate.

I think you talked about where we are on the vaccination side. And I would just reiterate our commitment and my commitment, as a physician and a Member of Congress, to continue to fight for that research funding until we do get that vaccine.

You touched on the importance of partnership, and we do live in tight fiscal times. We do have a debt challenge here in this Nation, and we are forever grateful for individuals like Bill and Melinda Gates, who have stepped up philanthropically and have poured literally millions of dollars—billions of dollars into the fight to eradicate malaria.

To either one of you, I would love to hear what you think are best practices in partnership, the role of the philanthropic and NGO community in helping us eradicate malaria or at least hold it down and continue to make progress. And then the role in terms of capacity building in Africa, India, you know, countries that are affected by malaria. So whoever wants to take that question.

Admiral ZIEMER. Thanks for that question.

Let me just address a couple of points. The USAID has been investing in vaccine research for over 40 years. So it is a high priority, and we will continue to focus in on that for the reasons you have stated. On the prevention side, I am pleased to say, of the four interventions that we used, WHO approved, three are prevention. And then we are scaling up case management, diagnosis, and then proper treatment. So as we continue to work with the countries, our focus is truly on the prevention side.

Our partnership in this austere time is actually very critical. And I am really pleased to report that we are seeing significant progress made at every level. On the partnership advocacy piece, the work with the U.N. Special Envoy, Malaria No More, the U.N. Foundation, Nothing But Nets, the celebrities, as well as the athletes are informing the American public about this disease. And there has been a wonderful response collectively, as American citizens, to do something about that. So that is on the advocacy side.

On the technical side, the fact that the Gates Foundation is totally invested on the high tech end and the governments and the

multilaterals are invested on the country side, we have a global malaria vision and plan to bring those two together. And so, again, over the last 4 years, we have something that we never have had before, and that is a vision, a strategy and places for countries, donors, research folks to plug in to move us toward control, elimination and eradication.

One of the most important partners we have is the private sector. And we can showcase and give you more details. But let me just give you three examples: In Western Ghana, we are partnering with Ashanti gold through IRS. They are also funded by the Global Fund, the national government, as well as the U.S. Government in looking at best practices and scaling up IRS.

In Zambia, we are working with the copper mine companies to do the same thing. So let me just stop there. Oh, ExxonMobil is working with us in Angola and their contributions directly into the program have been $4.5 million just for nets and the scale-up of events. So we can give you multiple examples of how we are seeing the partnership not only on the advocacy side but in the planning and visioning as well as in the implementation side. I hope that is helpful.

Mr. BERA. Very helpful.

Colonel WEINA. Yes.

Dr. Bera, the idea of partnerships is absolutely critical when it comes to combating any disease and especially something that is as broad and as widespread as malaria is.

I describe it as an ecosystem. And when one part of an ecosystem suffers, then the entire part of the system suffers. But there is also strength in that ecosystem so that when one part suffers, the other parts can help them out. The partnerships are critical and the partnerships come at many different levels. There are the public-private partnerships. But there are also our partnerships with the overseas laboratories in which we have in Thailand and in Kenya, Egypt, and Peru. Some of them have been in existence for over 50 years. These partnerships are not just to provide us a platform for surveillance and for testing new products, but it is also a way of capacity building so that we can also pass on what we have learned and also learn from our partners. In most of these overseas laboratories, a majority of the people that are working there are local nationals. And there really is a trust relationship that is built up. Some of the people having been associated with that partnership for over 50 years. And there are strengths and weaknesses that each of the partners bring. And the more we talk to each other, the more we interact with each other, the more we learn where we can make a real difference. I know that we execute quite a bit of PMI funds. We execute quite a bit of PEPFAR funds at some of our overseas laboratories. And it is not just the laboratories. Those laboratories actually are a jump-off point for work in other countries as well. And it is not just a logistic aspect like that, but it is also a scientific aspect. We have learned a tremendous amount from the work that is being done with the HIV vaccine as well as the HIV vaccine finding, learning a tremendous amount from the work that is being done with malaria. So there are scientific interactions and partnerships that are done across diseases as well as all of the logistic work that I have just talked about.

Mr. BERA. It sounds like this is a remarkable partnership, public-private advocacy. Is there anything that this institution, that we can do here as men and women in Congress to help continue to facilitate this partnership? Or is there anything—obviously the law of unintended consequences sometimes hinders partnership. Is there anything that you would want us to do outside of increasing research funding?

Admiral ZIEMER. The fact that you are calling for an update and having this hearing to support this U.S. Government foreign assistance program is evident to our global partners and the countries that we are working with. There isn't an opportunity that goes by where I don't pay tribute to the leadership, the bipartisan support of this Congress. It is critical. We need to political leadership and we need the funding. Everybody understands the constraints that we are currently under.

So our pledge is that the funding that is appropriated to this program and our other health programs we are going to do everything we can to be transparent, accountable, and deliver impact that will convince the American people that their tax dollars are being wisely invested. When we show results, it is really kind of a no-brainer. They are going to say, I wish more money was going into programs like this. I hear it all the time.

Mr. BERA. Great. Thank you. We will bring some of that commonsense approach here to Congress as well.

Mr. SMITH. Thank you very much.

The vice chairman. Mr. Weber.

Mr. WEBER. Well thank you, Mr. Chairman.

A couple of questions for you: Of course you guys started with the valiant men and women overseas. What is the incidence of cases of malaria in our own armed forces? Is that up, down? Can you give me kind of a breakdown?

Colonel WEINA. Well, sir, we still suffer from malaria even though we have these interventions, principally because we do have troops that are going to be operating in areas in which they may not have expected to run into malaria. So they may not be on prophylaxis or it may be in the fog of war, if you will, in which they don't have opportunities to protect themselves with the bednets. We have done interventions though that may help drive the numbers down. As I said in my testimony, we have maybe 100 cases per year, yet that are still bothering us in the military. And we would sure like that to be down as close to zero as possible.

So some of the things that we could do are to intervene where we don't necessarily have to have the soldier involvement in it. A vaccine would be absolutely wonderful. But, in the meantime, we have situations in which, for example, the Army and the Marines now all of our battle dress uniforms are permethrin-treated from the factory. And that is a true improvement because now the individuals don't have to think about an intervention themselves. It is already there. Those types of efforts are going to help drive them down. It sure would be nice to have zero cases and not have to worry about malaria intervening like it did in 2003 in Liberia. But that is something we need to continually plan for and think about in the back of our minds.

Mr. WEBER. Well, thank you for that, Colonel. I wasn't here during the testimony. It turns out I don't walk as fast as the chairman does. So I apologize if this is redundant.

Malaria was pretty much eliminated in India, as I understand it, but now it is starting to come back. Speak to that if you would. Why is that?

Colonel WEINA. Yes. In India, in the 1960s, it was virtually eliminated from the entire subcontinent. Today they have actually increased the number of cases potentially up to 200,000 deaths per year. And it is fairly widespread. I have recently, over the last number of years, traveled in India to about 20 different cities. And from the rain forest all the way to the deserts, you can see patients lined up with malaria, and it is having a true impact.

The reasons for that are pretty much the same reasons that we should remain vigilant and do remain vigilant here in the United States. We have a susceptible population. We have the vector present—the mosquito that can carry malaria—present throughout the United States just like they did in India. And all it takes is the reintroduction of the infection into the population and into the mosquito population without an adequate response. We have been very fortunate that the CDC keeps a very, very close eye on this and has prevented any small outbreaks from becoming big ones like it has in India. But we remain vulnerable as long as there is malaria anywhere in the world. Certainly all it takes is somebody getting on a plane and 8, 10 hours later to be at one of our borders and potentially bring the disease back home.

Mr. WEBER. Okay. Thank you, Mr. Chairman.

I yield back.

Mr. SMITH. Thank you very much. Mr. Meadows.

Mr. MEADOWS. Thank you, Mr. Chairman.

And thank you both.

Admiral, thank you so much for being so candid with regards to your fiscal oversight and understanding the demands of where we are today. But also knowing that as a wise steward of that money, I take you at your word but also see it in your passion in your eyes that you are willing to invest that wisely. And I just want to say thank you, not on behalf of Congress but on behalf of the American people for doing that.

I want to go on a little bit further and let's talk about the dangers to our men and women in service.

Colonel, if you could speak to that because really, when it gets down to funding, most people are only concerned about providing funding if it affects them. And that is a sad commentary, but that is the truth, the truth of the matter.

So what I would like for you to do is help the folks back home understand, one, why do we need to be investing these dollars? What are the dangers to family members that may be serving overseas? And perhaps talk a little bit about the reintroduction into some of these areas that we felt like were malaria-free, but now we are seeing that it has come back. Because, as you say, we are in a global, transient world now. So one disease in Vietnam showing up in America is just a few hours away. So if you could comment on that, please, Colonel.

Colonel WEINA. Yes, sir. So the threat to our military, to our men and women that are serving in the uniform of our country is very much dependent upon where they happen to be doing it, where they happen to be serving at the time. If they are in an area, say in Iraq, we found that there was very little malaria, if any at all. And we really didn't have much of a problem with malaria there. Certainly we do have a problem with it though in places like Afghanistan and in other areas in which we may be providing peacekeeping missions, for example, in Africa, in which there is a tremendous amount of transmission. As I have said, the disease, the parasite is very smart. No matter what we produce, no matter what we come up with, be it an insecticide or a drug, it is going to figure out a way to work around this and actually——

Mr. MEADOWS. So what you are saying is it mutates and changes enough where it can go against the technology that we have.

Colonel WEINA. Yes, sir. So we need to continually take a look at this. The reason it is important though and the reason we talk about global health is because—one reason is that as we work on these solutions for our soldiers, it has got a much broader impact and it has got a much broader unintended consequence of being able to help other individuals that have malaria. But on the other hand, if we reduce the amount of malaria and other infectious disease threats worldwide, our soldiers serving in these areas are going to be at reduced risk as well and also the issue of making sure that we invest in decreasing the destabilizing effects of these particular diseases so that maybe we don't have to have soldiers there in the first place because they are not unstable areas because of the fact that their health is better.

Mr. MEADOWS. And so what you are saying is, part of the unrest is not just economic. It is health-generated, is that right?

Colonel WEINA. Well, health has an impact on the economy. If you are sick with malaria, you can't work. If you can't work, you can't provide for your family. And there is this vicious cycle that happens. While we may not think about health as the very first thing in an unstable country, health certainly has some impact in the background. We just have to trace back to where that is. If you are able to work, I think most people want to work no matter where they are in the world.

Mr. MEADOWS. Right. Let's go back to this partnership that has been alluded to with both the pharmaceutical companies, with CDC, with NIH. Who takes the lead? How do we make sure that we are charging—you know in our military we have rank. So we know who we follow. In these partnerships, it becomes much more problematic to see who is taking the lead and who is making decisions. What are some of the successes there? And perhaps if you care to comment, what are some of the barriers to that?

Admiral ZIEMER. Speaking from the PMI perspective, I appreciate the question a lot. But if you go back to the Lantos-Hyde bill, you will see that there were specific authorities and responsibilities given to how the program was to be established and run and managed and report back to you.

Mr. MEADOWS. And are we following that?

Admiral ZIEMER. Yes, sir, we are. And I would venture to say that that is one of the key reasons for the successes and the

progress that we are making. There are clear lines of authority and responsibility. And it also encourages and enables us to have an effective interagency, collaborative, functioning program. So I would commend a review of that simple governance concept as we ask the question about partnership.

Mr. MEADOWS. So you are saying it is a success?

Admiral ZIEMER. In my view yes, sir.

Mr. MEADOWS. So we need to repeat it throughout all other areas of Congress is what you are saying?

Admiral ZIEMER. I would say it is a good reference depending on what outcome is desired.

But on the global level, it is much more difficult. And there are collaborative bodies at WHO, partnerships, Stop TB, the Roll Back Malaria Partnership. At the Roll Back Malaria Partnership—which is meeting right now and I am skipping it because I am here—the Gates Foundation, the U.N. Foundation, Malaria No More, multiple private sectors, the pharmaceuticals are there, the countries, the endemic countries, Asia, Latin America, and Africa are there along with the major funders, the Global Fund, the UK, and the U.S. Government. We are looking at the global challenge, looking at the plan, and having discussions about how we work together on a global partnership to move toward control, elimination, and one day eradication. So there are different mechanisms depending on where we are to enhance and to develop these partnerships.

I would like to say that over the 6 years that I have been in this job, that program, those mechanisms have continued to mature and become more professional. And I spend my time by going to them because I think it is worth it, and we are able to influence and provide technical as well as programmatic leadership to achieve common ends.

Mr. MEADOWS. And you would agree with that, Colonel?

Colonel WEINA. I would. From the standpoint of being in the military, of course, we do what we are told. I would like to think we are very good at doing what we are told and making the best with what we have. So the partnerships have been very good.

Mr. MEADOWS. Do I have time for just two more questions, Mr. Chairman?

Mr. SMITH. Yes, sir.

Mr. MEADOWS. I wanted to follow up with that then.

From a legislative standpoint, you outlined some of the things that were good. And I am not asking you—unless you had something on the forefront of your mind, to speak to this. But I would love to see if there is anything legislatively—tweaks, reporting, accountability—that we could provide to, you know, follow under the chairman's leadership to address by Congress. Is there anything that comes to mind? And if not, if you could have your staff work on that and report back to the committee.

Admiral ZIEMER. Sir, I think that is a great question. I would like to come back to you with the specifics, depending on what you would find helpful as you look forward to fulfilling your responsibilities. But I think it is worth time to continue looking at that. And we will get back to you, sir.

Mr. MEADOWS. And then my last question. It really gets back—I think we are in clinical trials, in the third clinical trials in terms

of a vaccine. And having seen that, that is a hopeful sign if we are getting to stage three clinical trials. My question is, how do we look at the severity? Because I think you mentioned in your testimony the severity of those. They are 5 months to 17 months old. How do we measure quantifiably the success of that? I mean it is very difficult when we have children to figure out, you know, if pain is on a scale of 1 to 10 because they won't rate it out. How are we doing that?

Colonel WEINA. One of the ways of assessing severity when it comes to malaria is actually pretty simple because severe malaria is a disease—although we have very uniform and very stringent criteria that we need to follow, I think it is real simple. If you can't take water, if you can't swallow things, if you can't take a pill to treat the malaria and you need an IV treatment, that is pretty severe malaria. And the outcome measure is unfortunately very easy to measure, and that is death because once they start down that circle of having severe malaria, it takes some extraordinary measures——

Mr. MEADOWS. So primarily through dehydration or——

Colonel WEINA. There are a number of different mechanisms. Sometimes through pulmonary malaria, sometimes through cerebral malaria, there are a variety of different ways. But typically with children, it is because of anemia.

Mr. MEADOWS. I thank the chair's indulgence. I would also ask if you could for the record address if there are any nanotechnologies that we are using in terms of clothing, netting, and so forth that might be out there or at least hopes in terms of future research, in terms of nanotechnology.

And with that, I yield back, Mr. Chairman. Thank you.

Mr. SMITH. I thank the gentleman.

Mr. Stockman.

Mr. STOCKMAN. Thank you.

I don't know who could answer this question. But I think I was watching Frontline or one of those shows. And they talked about the Chinese counterfeiting malaria medication and how that impacts and creates resistance to malaria. And that is kind of a big elephant in the room. As we are spending millions, in some cases hundreds of millions of dollars developing a new drug, they are out there emulating and making fake copies of it. And as you take the pill and you stop taking it, of course, that is how the resistance builds. I guess I am asking, have you guys addressed that issue on how to stop the counterfeit?

Admiral ZIEMER. Sir, it is a global issue. It has a lot of visibility and attention. I know it is a priority for the State Department right now. It is a matter that we are very concerned about because people that are sick with malaria taking counterfeit, fake, or unsafe drugs are going to continue to get sick and die. So it is not only a health issue, but it does beat resistance, and it really is a concern to us in terms of how it manifests itself in the resistance of the parasite.

But on the criminal side, it is a high priority, and we are working with our governments and criminal agencies to take appropriate action. But we have got to stay at it at multiple levels, diplo-

matic, technical, and at the country level, where these drugs are being regulated, are not regulated, purchased, and distributed.

Colonel WEINA. There are actually two issues with that particular question, sir. One of them has to do with actually counterfeit ones in which they are trying to sell them for other manufactured ones so that they look the same. Typically they don't just put sugar pills in. Typically what they do is they add just enough of the drug there, so if somebody were to test it, they would detect a level of drug.

Mr. STOCKMAN. That is even worse, too.

Colonel WEINA. And that is even worse because what it does is it feeds into providing a low level exposure of that drug to the parasite so it kind of helps them learn how to become resistant. So that is a problem. But there is also a problem of poor quality drugs. And one of the hallmarks and one of the reasons why people love the U.S. medical machine, if you will, is because of the fact that we have good quality products that are available, manufactured under good manufacturing practices and tested under good clinical practices. And quite often, we compete with other countries that may produce a drug under different standards. They can sell it for a cheaper amount and, therefore, it becomes used. So quite often what happens is that we need to make sure that we look at, for example, the technical ways and the legislative ways and the diplomatic ways of making sure that we are using not just good quality drugs and that everybody is kind of following the same standards when it comes to that but also trying to make sure that we ferret out and get rid of these counterfeit drugs.

Mr. STOCKMAN. The implication in the program was is that there is a staggering amount of fake drugs out there. Do you have any way of quantifying how much is fake and how much—I mean do you guys ever sample it? Because they showed a package and you couldn't tell the difference. It was stunning. And it looked like an American-produced product. But they are implying that there was a lot of it out there. Is that quantifiable? Do you guys trace that?

Colonel WEINA. We aren't ourselves particularly following that. But there are a number of different organizations that take this on and really do a wonderful job of finding out exactly how much is out there. It is worthwhile for them because instead of the $60 that they could reap for it, it may only cost them pennies to make it. So they get quite a bit of profit as opposed to ours.

Mr. STOCKMAN. Do you know who those folks are so we can have them before our committee? I feel like what we are doing is we are competing against ourselves. We are throwing millions of dollars, which is what we want to do because we want to save lives, but at the same time if somebody is in the boat drilling holes, it would be nice to stop that person from drilling holes. So if you have some experts and if you could get with the chairman and let us know, I would love to hear their testimony on exactly how big this problem is because if we constantly are competing against ourselves trying to produce new stuff, and then they emulate it and then, like you said, the organ gets a little bit of it and adjusts again, then we will be in a never-ending—we are chasing our tail. But do you know the individuals that would have that information?

Colonel WEINA. I don't have that information right in front of me at this moment. But I do know that there are several—again, several organizations that are following that quite closely and there are congresses that meet, international congresses because this is an international problem. It is not just here in the United States. And they follow this very closely. They try and track down where these are. But finding the actual individuals or the actual country that is producing it has proven quite illusive.

Admiral ZIEMER. We do have some information. But I think what I would like to do is go back, look at our files and then get back to you specifically to make sure we can answer the questions that you have and share what we have. Okay.

Mr. STOCKMAN. I am trying to remember. I think the show was "Malaria." It was really fascinating. I can't remember.

The other question I have, if I may, we eliminated malaria here and a lot of us see the film clips of it, how we eliminate it. And no one ever wants to talk about it. But it was very effective. It was how it was eliminated in India and a lot of places around the world.

And now with atomizing our DDT, you cannot have the impact on the environment that we had in the 1950s. And I remember you see the film clips of kids just covered with DDT. My brother was one of them, and he turned out, I think, fairly normal. He might disagree politically at times. But he is okay. And then I see the sacrifice. I know we have to trade off a balance.

But your heart goes out to these young kids who don't have the same protection we had. And I don't know if there is really a tradeoff where we should maybe—because of technology now—reintroduce that product because it could save—some estimates—millions of lives. And I would like to see it reintroduced under the controlled situations where we can make the molecules much smaller through atomizing the product.

Admiral ZIEMER. Sir, there are 12 approved insecticides on the WHO-approved list. DDT is on the list. And we were using DDT in three of our programs. We switched off of DDT because there was a resistance developing by the mosquitoes. So we alternate it to pyrethroid or another effective insecticide. So the issue of DDT is front and center, but I think what we need to do is continue to focus in on effective, safe insecticides that are approved and then look at the best application based on resistance, protocol, and the data that we have.

Mr. STOCKMAN. I also noticed they are taking—and indulge me a little bit, and I will yield back the time. But aren't they taking mosquitoes and injecting them so they don't bear other mosquitoes? I guess birth control for mosquitoes, which is kind of amazing. RU–486 for mosquitoes.

Colonel WEINA. We do have a number of very innovative strategies that are being developed by our entomologists that look at doing things besides insecticides, because we do know that, just like the parasite is going to be able to develop resistance to our drugs, the insects develop resistance to our pesticides and eventually will overcome the ones that we have available to them. So we need to be thinking, as it has been said, outside the box and to

other strategies, which include sterilized mosquitoes that are able to decrease the burden of the vectors that are present.

Mr. STOCKMAN. And lastly, my father used to do this. He was a zoologist, and what he used—I don't know if you can do this—he used vegetable oil on still ponds. As the larvae comes up to get air and then gets vegetable oil. Is that something that you can use widely?

Admiral ZIEMER. Larvaciding is an option.

Mr. STOCKMAN. You are being diplomatic.

Admiral ZIEMER. Yes, sir. But it is an important one because where we work, the application of larvaciding by WHO guidelines isn't the most costly, effective program.

Mr. STOCKMAN. I know they did it in Panama, too, right?

Admiral ZIEMER. Yes, sir. So there are certain parameters that WHO says ought to be used if larvaciding is considered an option. In the countries where we are working, we are not even looking at it because of the places and the conditions would not make it a cost-effective intervention for prevention purposes.

Mr. STOCKMAN. Well, thank you for your candor and your time. You guys have been great. Thank you so much.

Mr. SMITH. Thank you very much, Mr. Stockman.

Not to make light, but when Mr. Stockman was talking about the foggers, I grew up in Iselin, New Jersey. My friends and I, when we were 8, without our parents' knowledge or consent, used to follow the foggers on our bikes. We were covered with the stuff.

Mr. MEADOWS. Me, too, Mr. Chairman. That is our problem.

Mr. SMITH. That is when I decided to run for Congress.

Thank you so much for your great witness today, your testimony, and above all, your leadership. It is so greatly appreciated.

Admiral ZIEMER. Thank you.

Mr. SMITH. Pursuant to the rules of the committee, we will now have to end the formal part of the hearing and go officially to a briefing. It is part of the rules of the House and the committee, I should say, to receive testimony from Ambassador Mark Dybul.

[Whereupon, at 11:54 p.m., the subcommittee was moved to a briefing.]

Mr. SMITH. I will welcome the Ambassador to the witness table. Ambassador Mark Dybul—and it is a very high honor to welcome him here today—is the executive director of the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria. As an immunologist, as an administrator, as a teacher and as a leader, Ambassador Dybul has worked for more than 25 years to help prevent and treat infectious diseases.

Ambassador Dybul has written extensively in scientific and public policy literature. He is a founding architect and a driving force in the formation of the President's Emergency Plan for AIDS Relief, or PEPFAR. I know—and I say this firsthand because I was very involved with that legislation—it was Congressman Henry Hyde, who was the prime sponsor. It was a bipartisan bill. But Ambassador Dybul was absolutely critical in crafting that text, the language, the all important law and its reauthorization in 2008. So I want to thank him for that leadership.

He was formally appointed as U.S. Global AIDS Coordinator, with the rank of Ambassador from 2006 to 2009. Before joining the

Global Fund, he was codirector of the O'Neill Institute For Global Health Law program at Georgetown University, where he was also a distinguished scholar.

Welcome, Ambassador Dybul.

STATEMENT OF THE HONORABLE MARK DYBUL, EXECUTIVE DIRECTOR, THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS AND MALARIA

Ambassador DYBUL. Thank you, Mr. Chairman.

It is a great privilege to be back before this committee in a different role. Other members of the committee, thank you for your dedication and for being here. This committee, as I know firsthand, has had such long, strong bipartisan support for serving those in need.

And Mr. Chairman, thank you for your leadership going back so long in this fight. And I know now you have new friends and colleagues that will help support this effort with you.

You have heard a lot of the data and information. So if it is acceptable, I would like to enter my testimony for the record and highlight a couple of key points, including in response to some of the issues that have been raised. This is a very difficult financial time. We are very conscious of that. And coming before this body or any body, actually, around the world to ask for increased resources for foreign investment, we understand, is difficult to ask. And I think it is important to understand why we are doing this now. It is easy to say in these difficult financial times, we can wait 3 or 4 years, 5 years, until we have better economic times and better budgets. The reality is that because of the massive investment of the last 10 years and because of advances in science and our understanding of the diseases, we are at a critical tipping point in the history of malaria and HIV and tuberculosis. We now have the science and implementation understanding to actually end these diseases and public health threats and to put us in a position to ultimately eliminate them.

We have never had this moment in history before. Malaria has been with us as long as history has been recorded, as long as we know. We are the generation. You are the leaders that can actually put us on the course to end this disease as a public health threat. And that is why it is so important to act today. And I will expand a little bit on that.

The scientific advances, you have heard about: The new long-lasting insecticide treated nets, new indoor residual sprays, new treatments, much more effective combination treatments and eventually a vaccine, which I will come back to. One thing we have not talked about is the success of the interventions to date leading to a new understanding in epidemiology of the disease. We have had so much success over the last 10 years, which you have heard about, that high-transmission areas are becoming much more confined. A good example is South Africa and Swaziland. They now have malaria only on their borders with Mozambique. Not too long ago, they had malaria throughout their countries. We see this over and over and over again. Because of the success of the interventions, we now have areas that are being more and more contained with high transmission, which allows us to target our interventions

much more effectively. We are also understanding that high levels of the parasite in the body are very limited in geographic scope. So we are now focusing our efforts on those areas.

All of this has been made possible because of the experience of the last 10 years, because of the investments that have been made. We are now in a position to actually get for you a full return on that investment by completely controlling and ultimately eliminating malaria. If we succeed in what I just described, a partially effective vaccine would be enough in all likelihood. And that means some of the things the colonel talked about could be, in our lifetime, available. If we control the infection to such low rates, to such inefficient transmission, then you don't need an overly powerful vaccine. And that is the opportunity before us. But we are at a tipping point. And tipping points can go in two directions. You can continue on the course you are on or you can tip backwards. And you have already talked about some of that tipping backwards that has occurred. We have extraordinary data for how quickly—especially in malaria—you can tip backwards from success.

Zambia is an excellent example. It achieved fantastic coverage of interventions, significant declines in their infection rates. But because of funding issues were unable to replace nets and immediately saw an uptick in new infections. We have seen the same thing in Rwanda and other places. And while you have talked a little bit about what happens when the malaria comes back, one thing that is important to emphasize is if you have protected a child for a few years and then they no longer have protection, it is almost worse than never having protected the child because they were never exposed to malaria. They have no immunity to malaria. So if they then become infected, their malaria will be far worse and, as the colonel described, can lead to the meningeal, pulmonary, and other fatal forms of malaria because they were protected and became unprotected.

And that is why the data the chairman mentioned on the inability to just replace nets is so striking and such an important moral issue for us. And that is why the Global Fund dedicated $450 million this year to reduce that gap from 77 million to 24 million bednets. But we still have some gap. And that is just to maintain, not to achieve the vision we talked about, to drive toward complete control.

The bottom line of this is this is not a bottomless pit. This is not what we would have done for the last thousands of years in the fight against malaria. We are actually on the tipping point where today we can say we can completely control and ultimately end malaria in the world. But it is going to take resources.

And in that regard, we are very grateful to Congress for the 2013 budget. We know how difficult that was to maintain the financing for the Global Fund that allowed us to replace all of those bednets that otherwise we could not have replaced. We are very hopeful that the 2014 budget can meet the President's request, which is similar to the 2013 budget. In fact, it is the same. And one thing I believe is important for you all to know is that your contributions to the Global Fund are leveraged two to one from other donors because you can never give more than 33 percent. And we use that

to leverage two to one. So every $1 you give gets us $3 in the fight against malaria.

As has been mentioned, the Global Fund has committed about a third of its $23 billion portfolio to malaria. We work very closely with the President's Malaria Initiative. We support the same comprehensive approach. And more recently, we reorganized our structures so that we are focused on the high-impact, high-disease-burdened countries in a much more aggressive way, the countries that you all have mentioned where most of the malaria resides.

Partnership has come up a fair amount, and I would like to just say a few words about the close working relationship with PMI and others. One of the areas we are working aggressively—and to ensure that when you go to the taxpayers, you can tell them the money is being used well—is to increase efficiencies. Last week, the Global Fund hosted with PMI and UNICEF a new round of negotiations on the price of bednets to drive the prices of the nets down by using our collective buying power. It is the first time that has been done, that we worked together to use that collective buying power to drive those prices down.

A second example is to partner with the private sector and the U.S. Government through USAID. Yesterday, we announced a new innovative process that will allow us to more rapidly utilize the resources that you make available us to and to leverage the private sector's capability of guaranteeing resources to do that.

A third example and one that has come up is our work with PMI and other global partners in the Mekong Valley to address drug-resistant malaria. The Global Fund has committed $100 million to a regional partner there and has partnered with PMI and the technical expertise of the U.S. Government and other partners to ensure that our global investments are not threatened by the resistance that is developing there.

A fourth example is to partner with national malarial control programs to move toward that use of the science, use of the epidemiology to make sure the resources you commit are most effective and dedicated where the highest risk of transmission is. A final example I will give you relates to counterfeit drugs. Mr. Stockman, you asked who is working on this. Actually the Food and Drug Administration is working very aggressively on this. And there are several other international partners, including the private sector, that are developing new technology so that we can identify counterfeit products in a very rapid way through international consortia. And the Global Fund is actively involved this those efforts, which is something that a multilateral can do. It is more difficult for bilaterals to engage in.

I also want to point out that we are not just relying on you and your taxpayers for what we are talking about. Africa, itself, is stepping up in dramatically new and exciting ways, as is India and parts of Southeast Asia. The African Leaders Malaria Alliance brings together the heads of State of Africa at that level to focus on malaria. And in part, as a result of that, last year alone and annually, $625 million came from countries themselves to fight malaria. So they are partnering with you with their own resources as well as their commitment. A good example is Zambia, which in the last 2 years has almost tripled the resources they commit to ma-

laria. The private sector is also in the game heavily, in part with the commodities they provide, in part because of the delivery systems, but also with money. Chevron has provided the Global Fund about $55 million. Product (RED) is a partnership of CEOs and companies in the United States that provided the goal of funding over $200 million. The Bill & Melinda Gates Foundation has provided significant resources, and we are also targeting other high-net-worth individuals. So we are not looking to you all alone. We are developing financing partnerships that will relieve the burden on the American taxpayer in an exciting way. One of the reasons heads of state and the private sector are so involved is because of something that was touched on but not probed enough perhaps. And that is the impact of malaria on productivity. Nigeria alone estimates that they lose over $3 billion a year in lost productivity because of malaria. Globally, the estimates range as high as $40 billion. And most people think those are significantly underestimated. And that is why the private sector has gotten engaged, because Chevron, for example, in Nigeria, was losing so much time in their offices and in their production facilities because of malaria. So it was good business to intervene. That is good for the United States to have a rapidly growing economy in Africa to be a buyer of our goods and services.

So the opportunity before us is huge. The partnership that is responding is huge. But the most important opportunity is, in fact, for the first time, which we could not have told you 2 years ago, we are on the cusp of completely controlling this infection and ultimately eliminating it.

As it has been mentioned, we had malaria in this country. Eight United States Presidents have suffered from malaria, including Teddy Roosevelt and John F. Kennedy. John F. Kennedy of course was after 1951 when we eliminated it, but he served in Vietnam and came back with malaria. And as we talked about, that is a threat that is growing for us.

CDC in fact was created initially largely to respond to malaria and is still deeply involved. We have now eliminated it in the United States, but there is a risk it could come back. And we have the opportunity—if we invest wisely, if we use taxpayer dollars well, if we continue this partnership—to achieve something that has not been possible for thousands of years and is possible today: To completely control this infection, ultimately to have more scientific advancements and to move toward elimination. And if we don't do that, the cost in millions of lives is extraordinary. But more, the billions upon billions upon billions of dollars that you will continue to have to dedicate would not be necessary if we act today, if we act now. So we can leave for the first time a generation free of malaria that has not happened since recorded time in history. What an opportunity. What an opportunity. If we maintain our resolve, if we work together, if we capitalize on new scientific advancements, collectively we can accomplish one of the greatest feats in history, to defeat a plague that has been with us for thousands of years. Now is the time to act. Now is the time to invest so that we don't pay forever. Thank you very much for your attention. I look forward to answering your questions.

[The prepared statement of Ambassador Dybul follows:]

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Written Statement of Dr. Mark Dybul, Executive Director of the Global Fund
to the
House Foreign Affairs Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations

May 17, 2013

I would like to thank the Chair, the Honorable Chris Smith, the Ranking Member, the Honorable Karen Bass, and the entire Subcommittee for the honor of speaking to you today about U.S. and global funding in the fight against malaria, a disease that has been plaguing us for thousands of years, and continues, still, to impose a serious human and economic toll across the globe. In Africa alone, malaria takes the life of a child every minute.

I am here representing the Global Fund to Fight AIDS, Tuberculosis and Malaria and I would like to start by expressing my deep appreciation for the U.S. government's steadfast, bipartisan support for malaria and global health, in general, and for the U.S. Congress's support, in particular. This Subcommittee, Chairman Smith, and many Members in both parties in Congress have been deeply involved in and impassioned about saving lives through the President's Emergency Plan for AIDS Relief (PEPFAR), the President's Malaria Initiative (PMI) and the Global Fund – and the world has seen extraordinary progress from your investments. In malaria alone, the estimated annual number of global deaths has fallen by one-third over the last decade – from about 985,000 in 2000 to 660,000 in 2010 – even while the global population has grown. Thank you, truly, for saving these lives and for your continued leadership and support.

Now, I would like to turn to a discussion of U.S. investments in the Global Fund and what I see as the opportunities and challenges ahead of us in the continuing fight against malaria. The U.S. was the Global Fund's first donor and, today, remains its largest. Last year, and with thanks again to the Administration and the U.S. Congress, the U.S. provided more than a billion dollars to support Global Fund programs and partnerships around the world. With this and contributions from other countries, the

Global Fund provided about $3.5 billion in 2012 to the fights against HIV/AIDS, tuberculosis and malaria – including almost a billion dollars specific to malaria prevention, diagnosis and treatment. Global Fund programs currently provide 20% of the world's funding for HIV/AIDS, 80% of the world's funding for tuberculosis and, importantly, for this hearing, at least half of the world's funding for malaria.

In fact, the Global Fund, alongside PMI is the world's leading donor to malaria. Since its creation in 2002, Global Fund-supported malaria programs have distributed 310 million insecticide-treated nets worldwide, treated 290 million cases of malaria and provided 46 million indoor residual spraying services. More details on this can be found in Appendix A of my testimony, which presents a table of Global Fund–supported anti-malarial interventions over the past five years. To date, the Global Fund has disbursed $5.2 billion to support malaria control efforts in 97 countries.

The Global Fund and PMI work closely together to coordinate their efforts in-country and maximize their impact on the global malaria burden. PMI programs were conceived and designed, in fact, to build off of the in-country capacities supported by the Global Fund. Each entity has its own unique strengths, of course. Because the Global Fund does not have in-country technical staff, for example, it relies on PMI to coordinate and implement malaria activities and share information on the ground. Working hand-in-glove, alongside other partners, the Global Fund and PMI are making significant progress and shrinking the map on malaria.

When we talk about malaria, we should remember that malaria was once common right here in the U.S. In fact, at least eight U.S. Presidents are believed to have contracted malaria during their lifetimes, including, most recently, Theodore Roosevelt and John F. Kennedy. By the time of World War II, malaria had been eliminated in most places in the U.S. except for certain pockets in the southern part of the country. During the war, a number of military training bases were set up here – incidentally, an area infested with mosquitoes and rampant with malaria. To avoid spreading malaria to the civilian population, the U.S. government established the Malaria Control in War Areas initiative, which trained state and local health department officials in malaria control techniques and strategies. Borne out of this program, immediately after the war ended, was the precursor to today's Centers for Disease Control and

Prevention, then known as the Communicable Disease Center. Much of its early work was focused on control and elimination of malaria in the U.S. The CDC worked hand-in-hand with other government agencies and, together, the U.S. eliminated malaria inside its borders by 1951.

Today, as we focus our attention on other parts of the world still confronting this deadly disease, we should keep in mind this important piece of U.S. history. When this country faced malaria at home, the right blend of elements, including strong partnerships, political will, and aggressive public health interventions, among others, led to its defeat. Undoubtedly, the circumstances under which the U.S. eliminated malaria and the tools it used to do so are markedly different from the circumstances facing parts of the globe where malaria persists today, as are the efforts required in these areas to eliminate the disease. But, it is still possible to eliminate malaria in these parts; we just need to bring the appropriate pieces together, including robust funding, strong political leadership, and the right set of scientific and public health interventions. The world's fight against malaria has reached an historic inflection point. Scientific advances in anti-malarial treatment, prevention and diagnostics, coupled with current epidemiological data, and, importantly, the implementation knowledge gained by investments of the U.S. and other donors over the past 10 years have made it possible for us to stop malaria in its tracks.

We now know that when a country attains 80 percent coverage for key malaria interventions in at-risk populations there are significant health returns. Tanzania is a good example of a country that has had a dramatic scale-up of key malaria control interventions. Since 2008, it has seen a 47 percent reduction in malaria cases detected and a significant increase in insecticide-treated net coverage, with 91 percent of households in the country now owning at least one net. The scale-up of malaria control interventions has led, in part, to a 45 percent reduction in all-cause mortality among children under five between 2000 and 2010. So when a country has a well-resourced and implemented malaria control program, it can achieve astounding results.

Through the concerted efforts of the countries, supported by the Global Fund, PMI and other partners, scale-up of such malaria control efforts has occurred across the globe. Preventative interventions like insecticide-treated nets and indoor residual spraying have been implemented worldwide. [Please see

Appendix B: Insecticide-treated Net Coverage in Sub-Saharan Africa, 2002-2011] There have also been vast improvements in diagnostics, including the advent of rapid diagnostic tests, which now allow health workers to test and treat patients quickly and identify parasite-negative patients for whom another diagnosis must be sought and treated accordingly. First-line anti malarial mono-therapies have been replaced with highly effective combination therapies, which has helped to stump the serious and ongoing threat of drug resistance. Moreover, key interventions have decreased in unit costs by 30 to 40 percent. Altogether, the recent increase in delivery of key interventions, like insecticide-treated nets, means we are reaching levels in coverage that should lead to significantly reduced mortality and morbidity rates from malaria.

But recent history shows us that if we take our foot off the pedal, malaria incidence has the potential to rebound. We have seen this first-hand in Zambia. From 2006 to 2008, Zambia made remarkable progress in scaling up coverage of malaria interventions, including roll-outs of insecticide-treated nets to several provinces, primarily through antenatal care clinics and mass distributions. There followed a visible reduction in the burden of malaria. Between 2008 and 2010, however, the country experienced a resurgence of malaria in some areas, most notably in the Eastern, Luapala and Northern provinces. The likely explanation for the resurgence is that an intended, large influx of new insecticide-treated nets did not occur because of reduced funding and delays in procurement and implementation support. Meanwhile, the provinces in Zambia that did receive the majority of nets experienced decreases in levels of malaria. In 2011, the Global Fund used an emergency procurement mechanism to address the coverage gaps and sent nearly 2.3 million insecticide-treated nets to the Eastern, Luapala, and Northern provinces in Zambia. The situation in these areas has started to improve. The Zambia example highlights the very real danger in taking our foot off the gas pedal and the need to continuously maintain robust funding to sustain the gains that have already been made.

Net replacement is one specific example of a concrete financial need to maintain malaria coverage. The World Health Organization estimates that 150 million insecticide-treated nets are needed to protect all populations at risk of malaria in sub-Saharan Africa each year. These nets have an average

useful life of two to three years under field conditions. Though this coverage level was essentially met between 2004 and 2010, in 2011, only 92 million nets were delivered by manufacturers, largely due to funding constraints. Similarly, in 2012, only 66 million nets were procured. Thus, in February of this year, the Global Fund, the World Health Organization and other partners estimated that approximately 77 million nets will be needed to maintain coverage for communities that the Global Fund had previously protected, requiring approximately $450 million in funding in 2013 and early 2014. Without these replacements, entire populations and especially their children would be in jeopardy of dramatic malaria resurgences and death.

Accordingly, the Global Fund is in the midst of a big push to replace insecticide-treated nets in its new and interim funding grant streams, along with bolstering diagnostic and treatment needs. I am also pleased to report that there has, over time, been increased domestic spending on malaria control by recipient countries. The World Health Organization reported that in 2011 total domestic spending for malaria in the Americas and Africa had increased to an estimated $ 625 million, and there continues to be an up-tick. Zambia, for example, put $24 million of domestic funding in its 2013 budget for malaria drugs, an increase from the level reported by the WHO in 2011.

The global community has more work to do, however. Malaria partners have recently determined that the overall 2013-2015 funding gap in getting to near-zero deaths from malaria – including needs for commodities, management, communications, and monitoring and evaluation -- is approximately $3.5 billion, with an almost-$400 million dollar gap in providing essential commodities, like long-lasting insecticide-treated nets, artemisinin combination therapy drugs, and rapid diagnostic tests. Additional resources from the U.S., from increases in domestic resources and from other sources are necessary to maintain the remarkable results achieved so far and make full use of the new science and proven interventions.

The world currently faces an important choice: accelerate progress made or lose momentum, which means increased rates of malaria and not yielding the full return on investments of the past decade.

At present, our current tools remain remarkably effective in most settings, but resistance to artemisinins – the key compounds in artemisinin-based combination therapies – has been detected in four countries of South-East Asia and mosquito resistance to insecticides has been found in 64 countries around the world. Even though such resistance has not yet led to operational failure of malaria control programs, urgent and intensified efforts are required to prevent a future public health disaster. And if it gets to that point, we may not have the resources or the science to control it. The reality is "invest now, or pay forever."

The Global Fund, working with PMI and other partners, is better positioned than ever to help accelerate progress on malaria and target those areas most impacted by this disease. Over a year ago, the Global Fund launched a series of U.S.-driven reforms that focused on making the Global Fund a stronger, more efficient health financing institution. A product of the reforms, the new funding model that was recently launched is designed to direct resources to areas of the world most affected by the three diseases. In doing so, the Global Fund can leverage proven interventions and current epidemiological data to achieve greater impact; it can also achieve maximum value for money from the U.S. and other donors at a time when global economies and budgets remain significantly constrained.

Within the initial transition of the new funding model, the Global Fund will commit over $500 million of the $1.9 billion in available funding to malaria control efforts. There is a major emphasis on insecticide-treated nets, but as we well know, malaria control encompasses much more than sustained net replacement. Consistent with this, Global Fund resources will be directed to all the key interventions, including indoor residual spraying and improved malaria case management, including diagnostic testing and treatment with artemisinin combination therapy. The Global Fund will also target resources at intermittent preventative treatment of malaria for pregnant women and seasonal malaria chemoprevention, as well as supportive interventions like monitoring and evaluation, program management, and behavior change and communication. The Global Fund estimates that $14 billion is needed in total resources between 2014 and 2016 to support global malaria control efforts. If fully resourced, the world can avert 196,000 additional deaths each year between 2014 and 2016 through these

investments. Without these investments, however, we risk a malaria resurgence similar to what we saw in Zambia.

To achieve greater results in a tight budget environment, the Global Fund, through the new funding model, is also engaging more proactively in how it directs its resources: it is identifying problems and/or opportunities for high-impact and tackling them head on. This is entirely consistent with the two malaria-focused regional initiatives it is currently undertaking: one in Mesoamerica and Hispaniola that is focused on malaria elimination and one in the Greater Mekong sub-region that is aimed at artemesinin resistance.

The regional initiative in Mesoamerica and Hispaniola has obvious implications for the U.S. because of the close proximity in which the 10 countries this region comprises lie geographically. As a world health community, we must recognize that malaria is a global emergency that knows no borders. Therefore, eliminating malaria in these 10 countries not only helps this region achieve an important milestone, but it also helps to protect the health and safety of people in the U.S.

This regional initiative, and its focus on elimination, is also particularly well-timed because malaria rates have fallen in nearly every country in this region – often dramatically. Much of the region has already met the Millennium Development Goal for 2015 of reducing the number of diagnosed cases by 75 percent, and three countries have officially entered the pre-elimination phase. Of course, in some areas there is still a long way to go. But for many countries in this region, malaria elimination is entirely within reach.

To build on this momentum, the Global Fund is dedicating $10 million to this new regional initiative, with the hope of helping countries close to malaria elimination achieve that goal once and for all. In 2011, the Pan American Health Organization, together with donors, technical experts and other stakeholders, laid out a multiyear plan for malaria control in the Americas. At the same time, a regional plan in Mesoamerica and Hispaniola was in development, as were country-level plans to fight the disease. The Global Fund led regional malaria initiative will, therefore, leverage activities already taking place at

the country level, as well as regionally, and act as a catalyst, building upon progress already made and scaling up the efforts significantly.

In June, all 10 countries in this region will gather to craft the concept note for the initiative. This document will lay out the roadmap for malaria elimination between 2020 and 2025. It will look at what is needed to achieve this goal from a political, technical and country-coordination perspective before it is submitted to the Global Fund to review, approve of and disperse a potential $10 million grant.

The Global Fund is also trying to tackle the serious threat of malaria drug resistance through the new funding model. The Regional Artemisinin Resistance Initiative in the greater Mekong sub-region aims to help catalyze a coordinated response among partners to a major global threat to malaria control and to the Global Fund's investments over the last decade. The Global Fund has committed $100 million to this multi-country, multi-partner effort and will work with PMI, which already has a strong presence in this region.

As the Executive Director of the Global Fund, I am firmly committed to overseeing the continued implementation of these regional malaria initiatives under the new funding model, as well as other reforms that are allowing the organization to shift from an emergency response to one of long-term sustainability. Armed with these changes, the Global Fund, along with PMI and other partners, have a historic opportunity to stop malaria and save millions of lives from this devastating disease.

I will need the continued support of the U.S. government and other donors to fully realize this goal. Because, while malaria is treatable, preventable and curable, millions of people still die each year from this disease, principally children under the age of five in sub-Saharan Africa. I think we can all agree that no child should die for lack of a $1 insecticide-treated net, a $1 rapid diagnostic test kit, or a $7 drug treatment regimen.

As you know, the Global Fund is in the midst of a big international push on its Fourth Replenishment. We are profoundly grateful that the U.S. contributed $4 billion to the Global Fund during the last replenishment cycle from 2011 to 2013, including $1.65 billion in the Fiscal Year 2013 continuing resolution. We thank Congress for its support for the Global Fund and we are encouraged by

the Administration's recent request of $1.65 billion for Fiscal Year 2014. However, we are mindful that funding requests from the U.S. beyond Fiscal Year 2014 will depend largely on other donors stepping up to match the U.S. investment at least 2/3 to 1/3 over the course of the 2014 to 2016 replenishment; increased domestic investments by implementing countries during this same period; and the Global Fund's continuing implementation of its ambitious reform agenda.

We have reached a critical moment in history where we can see the end of malaria deaths. By investing now, the U.S. can help lead the world in shrinking the map on malaria by accelerating scientific progress and directing resources to people most impacted by this disease; however, if we lose momentum now, it will require even more costly investments to get back on track.

I would like to thank Chairman Smith, Ranking Member Bass, and the entire Subcommittee, again, for the honor of speaking with you today. I am now happy to answer any questions you may have.

APPENDIX A

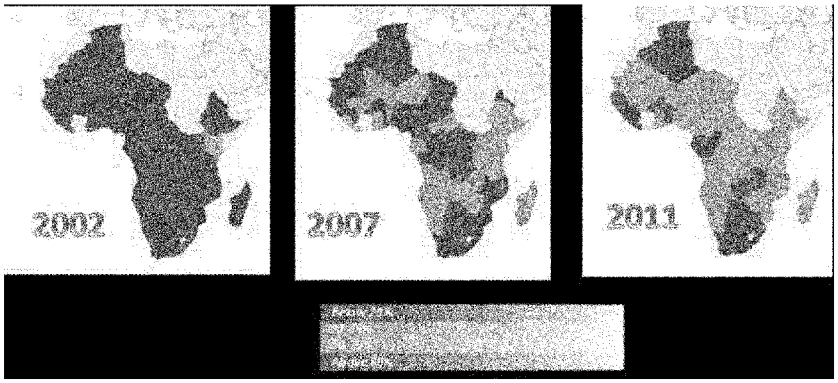
The table below shows the growth of results due to key interventions for malaria for Global Fund-supported programs through 2012.

Malaria Intervention	End of 2012	One year ago (end of 2011)	Five years ago (end of 2007)
Insecticide-treated nets distributed	**310 million**	**230 million**	**46 million**
Malaria cases treated	**234 million**	**187 million**	**44 million**
Indoor Residual Spray	**46 million**	**43 million**	**6 million**

Source: The Global Fund, 2012

APPENDIX B

Insecticide-treated Net Coverage in Sub-Saharan Africa, 2002-2011



Source: The World Health Organization, 2012

Mr. SMITH. Dr. Dybul, thank you very much for your testimony and for your leadership.

Your testimony is quite extensive. And I do hope that all members of the subcommittee, and the full committee as well, will read it, because you really lay out even more than what you have just done very well in your oral presentation.

You point out that we can all agree that no child should die for lack of a $1 insecticide-treated net—and I think that very low cost is under-appreciated. People don't realize how cheap it really is: A $1 rapid diagnostic test kit and $7 drug treatment regimen if, of course, the child is sick with malaria.

You talk in your testimony about the $3.5 billion gap. And I am wondering, in addition to the United States, and I frankly think we should do more, and I know maintaining current levels with the crisis in the budget that we face is job one, but certainly if we could go above that, obviously that is all value-added? What other countries are really stepping up to the plate? And, as you pointed out in your testimony, some of the affected countries, like Zambia, are doing more, which is greatly appreciated because they have resources, and they are prioritizing those resources. But what other countries typically in Europe and elsewhere are really stepping up to the plate?

Ambassador DYBUL. Thank you, Mr. Chairman.

And I think it is a really good question because it really does emphasize that the U.S. is not going it alone. The U.S. leadership has been out in front since the beginning of this fight on malaria. But it has not had to go it alone. So the Global Fund, as I mentioned, is a multilateral institution. We are not part of the United Nations. Actually, we are an independent multilateral. And we were created that way so we would have more flexibility. And through that mechanism, we have a board, which has the major contributors and countries represented on it. The United States is, by far, the largest single contributor to the Global Fund. But as I mentioned, you can never give more than 33 percent. And that leverage is two to one from others. Other countries that are large contributors: France is the second largest contributor to the Global Fund; the United Kingdom is the third. The United Kingdom also has a large bilateral program with a big emphasis on malaria. So they also have bilateral efforts in addition to their contributions to the Global Fund. Japan, Germany, Sweden—pretty much all of the Nordic countries have participated to very high degrees. We even have countries like Russia contributing to the Global Fund. India provides a contribution. Thailand provides a contribution. So it really is a way to have a shared responsibility, a global response to these epidemics.

But importantly, as you pointed out, African countries themselves—South Africa not only receives grants from us, they actually provide a gift to the Global Fund. Zambia is considering such a gift. Namibia provides a gift to the Global Fund. So, at the same time they are moving to fund their own domestic programs, they are trying to contribute to the broader effort globally. So it really is a shared responsibility.

I would also like to mention again the private sector contributions, which are critically important: The Gates Foundation, Chev-

ron, Product (RED). You are in there as a leader. But you don't have to go it alone. And we work very hard to ensure that your money is matched two-to-one.

Mr. SMITH. Let me just ask, on the insecticide-treated bednets, you have suggested that 77 million nets are needed just to get back where we were—especially because some of the nets wear out after a 2- or 3-year useful life.

The WHO says that to have complete coverage, we need 150 million such nets. Where are we in terms of actually getting to those numbers? And secondly, had President Bush not created the President's Malaria Initiative, or the PMI, where would we have been?

Ambassador DYBUL. So in terms of what is needed to get to that complete control we talk about, that is where the $3.4 billion gap comes from. If we are really going to contain the epidemic, if we are really going to get to that full control so that we can with a partially effective vaccine eliminate malaria, or at least eliminate it as a public health threat, we have the knowledge today, that is what that $3.4 billion would do. The 150 million nets a year is really to maintain. And we are not at universal coverage yet. We have a little bit to go. And we also need indoor residual spraying. We also need to treat people who do get malaria which actually contributes as a preventive tool as well because you reduce the parasitemia. And that is where the $3.4 billion would fill in and allow us to contain.

Again, I know that sounds like a lot of money, and it is a lot of money. But the opportunity cost not to invest today is to actually lose the return on investment of what you have invested for the last 10 years because, again, we are at that tipping point. And we can either continue to work to get to complete control or we can slide back down, in effect losing some of the return on investment—obviously not all of it since we have saved millions of lives.

President Bush's leadership was extraordinarily important. The President's Malaria Initiative has had a significant impact and really with the Global Fund and the UK's program are the major external funders, along with increasing domestic contribution, in the fight against malaria. But again, everyone is getting in the game, but it takes leadership to cause that effort.

Prime Minister Blair was actually a tremendous leader and worked closely with President Bush at Gleneagles, and the UK will be hosting the follow-on to the Gleneagles G–8 Summit this year. And we are hopeful that they will recognize the importance of this partnership through the G–8, going back to that Gleneagles, when President Bush and Prime Minister Blair were in office, that has led to where we are today with success in malaria.

Mr. SMITH. Thank you. I do have other questions, but in the interest of time, I yield to my good friend and colleague Mr. Weber.

Mr. WEBER. Thank you, Mr. Chairman.

Mr. Dybul you said that Swaziland had almost eliminated malaria, only had it in some areas on their border with Mozambique, I think. How did they do that?

Ambassador DYBUL. And South Africa is the same. And they did it through a strong national program with external financing and all the partners working together with a common objective to get to complete control. And so with long-acting insecticide-treated

bednets, with available treatment, with the correct treatment, the effective treatment, they were able to push it out so that it is really—because of the border, mosquitoes don't much follow geographic borders. They go wherever they want to go. So it is a very important issue because we are seeing this happen in country after country, where they are actually managing the infection in their own countries, but it is the bordering regions. So we are shifting to an approach that looks like a cross-border transmission and cross-border control so that we can do that.

But it really was through what we have been talking about, and you have been talking about all day, using the science, using the advancements in interventions, getting the ground game so that you get the coverage rates, using faith- and community-based organizations and make sure people are sleeping under the nets and that people are accessing services and having a national strategy and a national approach.

It is not just these two countries. Right now, Tanzania has had a 50 percent reduction. They have had 90 percent coverage of their bednets. They have had a 50 percent reduction in mortality and case detection and almost a 45 percent reduction in all caused child mortality because malaria contributed so much. So many countries are pursuing this effort. And what we know now is if we act in this coherent way, if we use all the interventions smartly, we can actually get to complete control.

Mr. WEBER. Let me ask you, are you able to quantify, when you look at that country, are you able to say the program cost X, they poured X amount of resources into it and their incidents went down, is that quantifiable?

Ambassador DYBUL. It is. It is. In fact, we have those data for you. We have the total dollar amount and we have the total impact. What we are doing now is actually combining all the spigots of funding. So what we have done in the past is look at what the Global Fund invested, look at what PMI invested, look what the country invested. What we are now doing is taking a country look and saying what should that cost be to actually achieve those results? And again, working with the U.S. Government to get the cost of the nets down, getting cost of the supply down, so I think what you are getting at is exactly right. We now have the knowledge of how much it should cost and to drive the cost down even further.

Mr. WEBER. All right. And then final question, Mr. Chairman, my colleague Mr. Stockman, had asked the previous panel could they give us the names of witnesses who knew who was doing the counterfeiting, and let me just say, tongue in cheek, we don't necessarily need those names. We need the names and the addresses of the counterfeiters so we can send Igor and Bruno over there with a No. 34 baseball bat and break their kneecaps.

Are there such a thing as sanctions? Or when you identify a country that has that kind of counterfeiting going on, is there a database that says this country has been participating, and is there such a thing as—how do you sanction them?

Ambassador DYBUL. It is rarely a country. It is usually people working within a country, and often——

Mr. WEBER. But if you were able to get with that government and say you-all need to shut this down.

Ambassador DYBUL. Which is exactly where it is going. And INTERPOL is actually actively involved in global counterfeiting with the FDA and others exactly for that purpose, so that people can begin to identify where people have refuge to do counterfeit activities, to track them with new technology, and then work collectively as an international community to shut them down.

Mr. WEBER. And so INTERPOL takes the information. There is a particular provider of medicine that is sending counterfeit drugs in and they can track that back and are keeping a database who not to buy from, for example.

Ambassador DYBUL. It is being developed. These programs are being developed because everyone has gotten so much attention for it. To Mr. Stockman's question, I think if you brought FDA in, they could give you a very full picture because they are very aggressively and actively involved in all of these conversations, and using these new handheld technologies where we can identify counterfeit and trace it back.

Mr. WEBER. Okay. Thank you, Mr. Chairman.

Mr. SMITH. Thank you.

Mr. Meadows.

Mr. MEADOWS. Thank you, Mr. Chairman, and thank you for your testimony and briefing, and I wanted to follow up a little bit in terms of, you know, you mentioned the Global Fund and I think you implemented a series of reforms, you know, due in part to a response from Congress. And as you have implemented those reforms, how would you say those have progressed since, you know, your leadership and what is still left to be done?

Ambassador DYBUL. Thank you for the question, because I think it is very important and really is a testament, in my mind, and the reason I was so interested in going into the Global Fund it that it is a true learning organization. It really looks at itself constantly to say how can we improve, how can we do better and let's change, and as we all know, that is not a typical approach in organizations.

Mr. MEADOWS. Right.

Ambassador DYBUL. And that is one of the most exciting things about it. So the reforms are really an evolution from looking to see where we are today, what the landscape looks like and how do we implement more effectively with higher impact. So some of the key things that have been done, and again, the board—the U.S. being an important member of the board and the U.S. Congress pushing, really—the board itself pushed for these reforms, and how rare is that that you have a governing body pushing for this type of change? Because often we think change means you made a mistake. Sometimes change is good because you are learning.

One of a few things we learned was that we didn't have the right—we don't have as much focus on high-impact grant management as we needed to and so we shifted so that now 75 percent of our staff is dedicated as a financing facility, which is what we are, to grant management, because that is our core business. And we are identifying what our core competencies are and partnering more with other organizations, which is what we were created to do for technical and other purposes.

Mr. MEADOWS. And so if you are looking at that grant management, what matrix do we use in terms of, one, the awarding of the grant, and then I guess the second part of that is the effectiveness once the grant has been given, what is the matrix, the area?

Ambassador DYBUL. So the matrix for how grants are given are based on disease burden, because that is where the impact is going to be. Co-investment is a key part of our—how we make——

Mr. MEADOWS. So the better co-investment, the more likely they are to get to the grant?

Ambassador DYBUL. And also a requirement for co-investment is based on economic situation. So even if you have a high disease burden but have a good economy, you need to be giving more, and we work on that in a formalized way as part of the grant-making identification.

Mr. MEADOWS. And there are no other political agendas or sidebars that evaluate it.

Ambassador DYBUL. No. Well, the other is ability to implement in terms of rapidity. We don't want to dedicate money and put it in a country when they don't have the capacity to move it. And then we have a risk management tool that is new, which looks at not only risks of misuse of funds so that we can ensure that—and go after any misuse of funds—but also risk in non-implementation, which gets to capacity a little bit, and what are those risk implementations. Is it the supply chain? Is it human resources? Is it the inability to reach certain parts of a country for various reasons? And then we dedicate our resources to alleviating those risks. So it is a very complex matrix across those areas, but it is leading to a much more impactful approach.

Mr. MEADOWS. So you are saying this is really more of a new funding model than you have had in the past; is that correct?

Ambassador DYBUL. In fact, we call it a new funding model.

Mr. MEADOWS. All right. So, and thus my question. And so as we look at this new funding model, what can we do in terms of the planning stages and the implementation stages, similar question that I asked the Admiral, what can we do from a legislative standpoint, knowing that we are only part of the pie, to help facilitate that and help encourage that to make sure that American taxpayers are getting what they pay for.

Ambassador DYBUL. Well, I am probably a little biased since, as the chairman pointed out, I actually was involved in the writing of the legislation, but I think it is pretty good.

Mr. MEADOWS. What tweaks would you make to your own writing; how about that?

Ambassador DYBUL. I actually believe currently that the language you have is very useful to us, and it actually helped the Fund, along with other people on the board, move toward this new exciting approach.

What we are really focused on is the partnership piece, and that is in the legislation that we should be focused on using the resources from the U.S. taxpayer from whatever source they come in the most effective way to have the greatest impact and partner and leverage. And that leveraging piece is something we have not always done well, none of us, and that is what is so exciting about this new funding model—we actually bring all the partners to-

gether to look at the epidemiology, look at the science, to ensure that the investments going in aren't duplicative.

Mr. MEADOWS. Right.

Ambassador DYBUL. Aren't ineffective and are going to the right outcome. And then, importantly, to the other part of your question, we evaluate it on a quarterly basis: How is the progress against the targets? And we can track it in a programmatic way so that we can adjust and reprogram as needed as we are identifying new realities on the ground. Grant management is not writing a grant. You start grant management when you write a grant. You then work to ensure that the money is used well. We also only disburse funds as the countries need them. We don't give them a pot of money and then 5 years later come back and see what they did.

Mr. MEADOWS. What a novel concept. Well, and so let me go back. You mentioned "tipping point" in your testimony here today. You mentioned "tipping point" four different times, and so as, as we see that, you say we are at a tipping point, we are at a tipping point and we can go forwards or backwards. And yet what you also said is that we are at a position where we can eradicate malaria. What is the timeframe, and what is the greatest barrier to—and I know that we are talking about science here. We are talking about—but probability, the probability of eradicating malaria within what period of time?

Ambassador DYBUL. There are different models, and I have to say a lot of this is mathematical modeling to predict——

Mr. MEADOWS. Sure.

Ambassador DYBUL [continuing]. When we intervene how we will do. The model so far over the last 10 years have held up pretty well, and really, eradication will require a vaccine in all likelihood. What we can do is eliminate it as a public health threat and completely control malaria. And what we have seen in the last 5 years, I think, makes us much more hopeful that the timeline could be even more compressed. But we are actually, and the World Health Organization reports on this, about 20 countries have eliminated malaria in the last 10 years—so you go from endemic or epidemic, to control, to elimination, and then ultimately eradication.

And if you look at the trajectory and the curves, we were seeing a 20-year horizon, 30-year horizon, but we are bending those curves down, including in countries, because of the success of the last 10 years. We are working on that precise type of modeling based on the new data to try to give us a better sense of that. But the wildcard in that, and this is why I emphasize it a little, what we are learning more and more is you can actually push the epidemic into corners, and that then means you throw everything you can at those corners to have the biggest impact to get everything down to low level. And if you can do that, then a relatively efficient vaccine should be enough. If you allow a couple of pockets somewhere, you are going to need a really highly effective vaccine, so a lot of it is going to depend on that variability.

The one thing we do know is that if we don't get down to complete control, near elimination, we will be continuing to fight this fight forever, and that is the tipping point, and that is the change that we have seen. Up until the last 2 years, we would have just had to keep doing the same thing and the same thing and the same

thing until we have a vaccine or until all countries had enough economic growth that they didn't have some of the issues around pooling of water and other things. But now we are seeing the opportunity to push, push the timeline forward strongly.

The reverse of that is if we don't stick in this game, we know what is going to happen. And malaria, more than any other disease, we know it will come back, and then we won't have the science or the tools to bring it back down, and a partially effective vaccine won't do it, and then we are going to have to just keep putting in more and more and more money rather than investing now, and that is the issue of the tipping point.

Again, I—you know, under most circumstances, I wouldn't—I have been around governments a long time, I have been around budgets a long time. I wouldn't come to you with a straight face to say we need more money today, given the current economic environment, except for this unique moment in history. It is a shame it is coming at a time of tough budgets, but it really is. We have never had in the thousands and thousands of years that we have had malaria.

Mr. MEADOWS. Well, I must admit, it was very unique testimony and thus why I followed up with a question, but with that, being sensitive to the other members, I want to yield back to the chairman at this point.

Mr. SMITH. Thank you, Mr. Meadows.

Mr. Stockman.

Mr. STOCKMAN. Mr. Meadows, you can keep going. Those are great questions. I enjoyed them. And following up on his line of comments and statements, you mention in your testimony, Mr. Ambassador, Zambia and Rwanda are reinfected. Can you tell me, in your mind, because you have been working with this for so long, what is the rationale behind that? What happened?

Ambassador DYBUL. So in both, neither country had eliminated, but they had significant control, very close to complete control in many areas. And that was because, like in Swaziland, they had national bednet campaigns, they had excellent care and treatment programs, they had an excellent program and a strategy that they implemented. But then they had some funding shortfalls and they weren't able to replace them, some nets, or couldn't complete some campaign.

Mr. STOCKMAN. Can I interrupt for a second? Was it the NGOs that had the shortfalls or the government?

Ambassador DYBUL. Both. So both NGOs and the government are involved. Basically it is one pot of money that gets divided out. Most bednets are distributed through national campaigns that are organized by the government because it is the only way you can do a national program, but implemented often through NGOs, especially the sleep-under-the-net campaigns. One important thing is you can't just distribute the nets. You make sure people know how to use them.

Mr. STOCKMAN. I was going to say, because don't they sell them or resell them or so?

Ambassador DYBUL. You know, sometimes that happens. With the national campaigns, that is rare because there is no reason to,

because your neighbor has one, too, but in the past, that actually did happen.

Mr. STOCKMAN. I saw them using it for everything.

Ambassador DYBUL. Yeah. And actually there was a big education campaign. I mean, in the early going, people were afraid to use them, didn't know how to use them. Actually in one case, I went into a home and I asked them where their bednet was because it wasn't hanging, and they pulled it out from under the bed in the plastic packets because they thought it was so beautiful and still in the plastic package. So you need to go in and teach people and encourage them, and that is where the communities are so important and the faith and faith-based communities and the community-based organizations.

In Nigeria, the Muslim community and the Christian community are working together to ensure that everyone in their congregation sleeps under their nets. It is part of their Sunday sermons. They do it all the time, and so that is really important. The funding shortfall was actually from external resources, but the governments couldn't make up and so they couldn't meet their deadlines to ensure that nets were replaced or campaigns were completed, and then we saw the increase. But then we all came back in, we moved heaven and earth to get the nets in and they came right back down.

So it tells you how rapidly with this disease, if you lose just a little bit, you lose a lot, but if you stay contained and you stay suppressed, then you start pushing to where you just have these little pockets of high rates of infection.

Mr. STOCKMAN. Why do you think in Vietnam they are drug resistant? What is the rationale behind that?

Ambassador DYBUL. So it is more than Vietnam. It is actually the whole Mekong Valley, so Myanmar, Vietnam, Thailand and really in that that nexus, again, because the mosquitoes and the resistance doesn't respect borders.

The resistance develops either because, as you pointed out, people get partially effective drugs, or they stop and start and don't take enough. And one of the key issues which has been raised is that, you know, if you are out in a village and you are in malaria season and your kid gets a fever, you are not going to walk the 2 days or the day—and the clinic may not even be open. You are going to go to a kiosk and you are going to pay for an anti-malarial drug, and the Global Fund actually has been engaged in a program to reduce the cost of the effective products in those kiosks. So what people do, they buy the cheapest product, which often is quinine or quinine-based products in an area that has quinine resistance or quinolone resistance and it just expands. Or they buy, rather than a combination artemisinin product, they buy a single artemisinin product, and we know it has to be in combination.

And so this single use of single artemisinin products rather than in combination develops resistance to the artemisinin, and so we are trying to get people in the private sector where people go to those kiosks so that when they go, they will still buy the cheapest drug, but it will be the effective drug. And then sometimes they just don't complete the course.

What we are working on internationally is bringing all partners together to really intensively address this resistance problem in this area so that it doesn't spread, threatening all our investments everywhere else, but there are multiple reasons. And we are hypothesizing because we weren't there as it developed, but we have a pretty good sense of how it developed and what is necessary to contain it.

Mr. STOCKMAN. Thank you. I know we are getting ready to vote, so I yield back the balance of what time we don't have.

Mr. SMITH. Thank you. Thank you, Mr. Stockman. Just a few final questions and maybe my colleagues might have a question or two before we go to votes over on the House floor.

In 2000 I authored legislation that became known as the Combating Autism Act. It took 3 years to get the bill passed, and one of the cores of that piece of legislation—as a matter of fact, I did the reauthorization in 2011 as well—was surveillance. At the time, we thought that the prevalence of autism in the U.S. was 3 out of 10,000, at least that was what we thought in the early 1980s, and CDC was spending $287,000, a drop in the bucket, per year, straight line for 5 years. We had essentially no real program on surveillance, and our legislation created centers of excellence; all of a sudden, now we know the number, at least on the spectrum, is 1 out of every 50. I held a hearing recently on what I call the global developmental disability pandemic autism. Sixty-seven million is one estimate worldwide, but we don't have reliable statistics, and reliable statistics are what drives, I think, good policy.

In the World Malaria Report for 2012, WHO suggests that in the 41 countries around the world that account for 85 percent of malaria cases, it is not possible to make a reliable assessment of malaria trends due to incompleteness or inconsistency of reporting over time. WHO concludes that surveillance systems seem to be the weakest where malaria's burden is the greatest and states that there is an urgent need to improve surveillance in those settings. I wonder if you might speak to that issue of surveillance, again, to drive the prioritization, the money, and of course, the deployment of resources.

Ambassador DYBUL. It is an extraordinarily important question because if we are really going to invest smartly and if we are really going to get toward this elimination, we need to know with very solid data how to invest and where to invest, and that requires surveillance, and that is part of what we are doing in the new funding model, and I think we are doing as a global community. Really, you know, 10 years ago, you could do anything and have a huge impact because there was just so much out there, and that is one of the reasons larvicides don't work in these communities. There is just too much malaria, and it is not going to do enough.

Now we have to be a lot smarter because of the impact, and that means better surveillance. So we are working with countries so that by the time they come in with a concept note, as the partnership, we will have invested in getting that data and those—that surveillance data so that we will know how to invest in the most impactful way. It is going to be a process to get there, but I do have to say, too, compared to where we were 10 years ago in these countries with surveillance to today, because of their work, because of

our investment, because of our partnership, it is night and day. And you have seen it, sir, I know, Mr. Chairman, I know many of the members have been and seen the radical transformation that has occurred that the American people have partnered with people in Africa to do. And part of it is in surveillance, but we are getting there in a way that was inconceivable 10 years ago, which is why I am much more optimistic than the models, because none of the models were able to predict that we would be today where we are today. And that is really because of the leadership of countries like the United States, but fundamentally because of the energy in people in Africa who are now looking to the United States and countries that have supported them in these diseases in a much different way and a much more positive way. And as we continue to work with them to support them, to identify their pockets with surveillance and improve their systems more broadly, that just expands and expands.

Mr. SMITH. Thank you.

On April 23, Dr. Thomas Frieden testified before our subcommittee. The title of our hearing was, "Meeting the Challenge of Drug-Resistant Diseases in Developing Countries." I know the Global Fund deals with PEPFAR, HIV/AIDS, as well as with tuberculosis. He did focus on MDR and XDR tuberculosis and all the challenges that are being faced going forward, but he did spend some time talking about artemisinin-resistant malaria and pointed out, and I would just quote in pertinent part his testimony:

> "Since 2008, malaria infections in parts of Southeast Asia have been shown to be resistant to artemisinin drugs. This is the last remaining class of antimalarial drugs and forms the basis of malaria treatment around the world. If these resistant parasites were to spread to sub-Saharan Africa (which has occurred with other forms of drug resistant malaria), the results could be devastating."

Could you speak to that?

Ambassador DYBUL. First, I would completely agree with Tom's assessment, and we have actually talked about this.

I would point out that there actually is a new—several new classes that are being created through remarkably brilliant public-private partnerships, the Gates Foundation is heavily involved, medicines for malaria and vaccines is involved, so we will have new classes of drugs, but we can't keep doing that, right, so we need to stamp out the resistance and that is why we are investing $100 million in that region to jump on it right away working with partners. It is estimated that it will cost about $400 million and we are basically leveraging and we are looking for people in that region who are interested in those countries to step up financially as well, and then coordinate across the countries because it is a cross-country effort. It is a regional effort because we have three countries that have the resistance. So, we are jumping on it immediately because of the threat.

MDR–TB is another big problem, and Global Fund is the largest funder of MDR–TB—external funder of MDR–TB—programs in the world, so we are very active there, but that is another committee hearing.

Mr. SMITH. Let me just ask, Ambassador Dybul, early on, and I have raised this repeatedly with Global Fund, I am not the only one, it had excluded, or largely excluded faith-based groups. I know that there is a renewed effort to try to be inclusive, if you might want to speak to that. Also, the challenges you face, the Global Fund's Web site indicates that malaria is the greatest cause of illness and death in the Democratic Republic of the Congo and that there are at least 10 million cases of malaria per year. Yet some of their programs get unacceptable ratings; of course, the challenges in the DRC are huge, namely the war. I have been to Goma myself. I know how the terrorism is, and the sexual violence is almost without precedent anywhere in the world, but if you could speak to that as well. Then I will go to my colleagues because we do have a vote.

Ambassador DYBUL. So on Congo, it is a difficult place, no question about it, but you can actually get things done even in difficult environments. And you know, Sudan actually has universal coverage of bednets, so it is possible, and we are intensively focused on Congo right now, and it is by working with more than the government. That is how you get the job done, by working with partners, including faith-based organizations, which is a segue into your other question.

We recognize that you cannot succeed, and then particularly when you are talking about getting to the last mile, getting to the people and making sure they stay in services and use their bednets and use the right anti-malarial drugs, that the communities and the faith communities are critically important to that.

We have changed the way we operate in a number of ways. We do have quite a number of faith-based implementers, Catholic Relief Services, World Vision. We also work with the faith community to raise additional resources. The large Lutheran group and Methodist group are actually trying to raise $40 million around malaria control right now with us. But it also about implementation and engagement, and so in our new funding model, we actually have shifted the process around, and it was always intended that faith-based communities be part of our country coordinating mechanisms, but it didn't always work well, and through our new mechanisms, we are actually working on that more and more, and actually welcoming people into our dialogue that leads to a country plan from all walks of life. And we are actually working with faith communities here in the United States to identify in these countries who should be at the table, who needs to be engaged in the conversation.

Now, that doesn't mean we have to fund them, but they need to be part of the conversation and part of the national planning because they do so much on their own. Even if we don't funnel money to them, they need to be part of the national plan and the national approach to ensure that we combat and actually ultimately eliminate malaria.

Mr. MEADOWS. So what you are saying—let me just follow up on that. So what you are saying is with these faith-based groups, there is no, in your matrix, when we were talking about funding matrix, there is no disqualifier in terms of providing funding for that?

Ambassador DYBUL. Absolutely not.

Mr. MEADOWS. Okay. And as we know in Africa, it is either faith or it is tribal or cultural, and so you are reaching out to all those different groups and the leaders of those groups to make sure we hit these pockets?

Ambassador DYBUL. We are, and our new funding model actually is designed to ensure that we do in a much more aggressive and effective way.

Mr. MEADOWS. All right. Well, I yield back. I thank you, Mr. Chairman. Thank you for your testimony.

Mr. SMITH. Thank you. Anybody else like to make any final comments? Ambassador Dybul, would you like to make any final comment?

Ambassador DYBUL. I would just like to thank the committee again and thank you, Mr. Chairman, for your many years of leadership and look forward to continuing to work with all of you.

Mr. SMITH. Well, frankly, we want to thank you for your extraordinary lifelong leadership. You have made an extraordinary difference, and I know it because the passage of PEPFAR was in no way a done deal. Its reauthorization, in which it was greatly expanded, there were lessons learned, and again, you were critical in the drafting of that legislation. So you have made an impact and saved lives. That really deserves a great deal of praise, so thank you for being here, thank you for the work that you do. This hearing, or briefing part of the hearing, is adjourned.

[Whereupon, at 12:42 p.m., the subcommittee was adjourned.]

APPENDIX

Material Submitted for the Hearing 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

May 10, 2013

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 www.foreignaffairs.house.gov):

DATE: Friday, May 17, 2013

TIME: 10:00 a.m.

SUBJECT: The U.S. Contribution to the Fight Against Malaria

WITNESSES: Rear Admiral Tim Ziemer
U.S. Global Malaria Coordinator
President's Malaria Initiative

Colonel Peter J. Weina, Ph.D., M.D.
Deputy Commander
Walter Reed Army Institute of Research
U.S. Department of Defense

BRIEFER: The Honorable Mark Dybul
Executive Director
The Global Fund to Fight AIDS, Tuberculosis and Malaria

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 *Friday* Date *May 17, 2013* Room *2172 Rayburn HOB*

Starting Time *10:00 a.m.* Ending Time *12:40 p.m.*

Recesses [1] (*10:30* to *10:55*) (____ 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 U.S. Contribution to the Fight Against Malaria

SUBCOMMITTEE MEMBERS PRESENT:

Rep. Weber, Rep. Cicilline, Rep. Bera, Rep. Meadows, Rep. Stockman

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.)*

TIME SCHEDULED TO RECONVENE _____
or
TIME ADJOURNED *12:40 p.m.*

Gregory B. Simpkins
Subcommittee Staff Director