FIGHTING MALARIA: PROGRESS AND CHALLENGES

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FIGHTING MALARIA: PROGRESS AND CHALLENGES

MONDAY, DECEMBER 5, 2011

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

The subcommittee met, pursuant to notice, at 3 p.m., in room 2172, Rayburn House Office Building, Hon. Christopher H. Smith (chairman of the subcommittee) presiding.

Mr. SMITH. The subcommittee will come to order, and good afternoon to everyone. I want to thank you for joining us for this very important hearing on malaria, one of the most serious health issues facing the developing world and particularly Africa today.

For the last century America has been a leader in the fight against malaria. While the United States and several other countries have been able to eliminate malaria, this deadly disease still persists and presents a serious challenge to other parts of our world. The World Health Organization estimates that 781,000 people died from malaria in 2009, and that 225 million people have suffered from infection. Malaria is the fifth leading cause of death from infectious disease worldwide. It inflicts a particularly severe toll on people of sub-Saharan Africa where 90 percent of the deaths caused by malaria occur.

Moreover, approximately 85 percent of malaria deaths occur in children under the age of five. Every 45 seconds a mother and father in Africa lose their child to malaria.

There is also a far-reaching impact on the wealth and the development of countries with endemic malaria. Africa may lose up to $12 billion in productivity due to malaria each year to the disease, while the disease in turn consumes about 40 percent of Africa's public health expenditures. These numbers and statistics are staggering, but they have a greater impact when one has been to Africa and met the individuals who must live with this dreaded disease.

Anyone who spends any meaningful time in Africa and mingles with the African people notices the prevalence of malaria. When you ask someone whether he or she has ever had malaria, they will likely respond not with a yes, but with how many times they have suffered from it. More astounding than the sad reality that malaria is killing or harming so many millions of people is the reality that malaria is preventable and treatable. The world has the tools to prevent and to treat malaria. No one in the 21st century should have to suffer from it, let alone die from it.

When I last visited Uganda, I visited several homes including a home in the remote region of Bushenyi. The three-room dwelling of white-washed walls and dirt floors was particularly empty, and this made the insecticide-treated mosquito net over the floor mats all the more striking. These nets may seem like insignificant items when listed on paper, but they are noticeably visible in the modest homes of these families who rely on them for protection from this ravaging disease.

What began in the United States as an effort to protect our troops abroad and citizens here at home has become for us a larger global health objective. In the last decade we have seen a renewed commitment by the United States, international organizations, and private foundations to eliminate all malaria deaths. The effort received a notable boost in 2007 when Bill and Melinda Gates renewed the challenge of worldwide malaria eradication.

While much progress has been made in combating malaria, as we have seen from past eradication efforts, malaria can resurge when treatment becomes ineffective through drug resistance. While the global commitment remains to beat this disease, and to beat it as soon as possible, the stakes are too high to bet it all on doing so before the tools we have lose their impact.

At today's hearing the subcommittee will receive an update on the progress toward malaria elimination in the most endemic countries with a focus on the vitality and the effectiveness of the treatment component. The hearing will examine the future of antimalarial drugs, vaccine development, and challenges in ensuring an adequate supply of effective medicines. We also will hear about the continued availability, affordability, and safe distribution of quality antimalarial medicines.

I look forward to hearing the testimony of our very distinguished panel, all of whom have made and are making an enormous difference in the lives of people who are being ravaged by this disease.

With that, I would now like to yield to my friend and colleague Mr. Payne for any opening comments he may have.

Mr. PAYNE. Thank you very much, Mr. Chairman, and let me commend you for calling this very important hearing on the international community's progress toward eradicating malaria. I would also like to thank our distinguished panel who are here with us for agreeing to come to testify and to give us an update of the current state of the epidemic.

I think you have heard the statistics just given by the chairman: 225 million cases, 781,000 deaths in over 100 countries. It is an area that we wonder why it took so long for the world to really get serious about malaria. But of course, we know that because malaria impacted on areas where there was not considered to be a return on the investment, many pharmaceutical companies just did not spend time trying to come up with a cure or a prevention, because they figured if they did, who could pay for it?

And so we have seen a sea change, though, in what is going on in the world today. We see many organizations now changing the manner in which they do, the fact that still though every 45 seconds malaria claims the life of an African child. The fact that even in our country many years ago when our Nation first began, ambassadors from foreign countries were paid hazardous pay to come

to Washington, DC, as ambassadors because of the problem of malaria, but we dealt with malaria and we eliminated malaria.

However, there are a number of unintended consequences with global warming going on, although people are saying it is not man-made, we still don't have the science, et cetera. With the climates warming up again, we may see the fact that malaria will once again start to come into temperate zone countries because of the global warming, and the whole question of malaria could once again become an issue in the Western Hemisphere.

The global fight against malaria is daunting, but it is winnable. This year I am pleased to welcome Congressman Fortenberry as my new co-chair of the Malaria Neglected Tropical Disease Caucus. We now have close to 60 Members in the House. Several years ago we were very excited when then-Congressman Boozman became co-chair and we launched the Malaria Caucus with Ms. Laura Bush coming to the House on one of her very few appearances here. And we launched the Malaria Caucus with a great deal of bipartisan support, and he is still continuing to fight the good fight over in the Senate.

The Senate Malaria Working Group led by Senator Coons and Senator Wicker, another former member of the House, is also enjoying bipartisan support. When we get bipartisan support we can conquer anything. I think we are doing that when we approach this question of malaria. In this time of difficult discussions on U.S. foreign assistance reform our malaria control and prevention commitments represents some of the strongest returns on investment for foreign assistance dollars.

In the last few years through proven effective and low-cost intervention, the global community has been able to slash disease burdens and deaths in Africa and elsewhere in the world. Over the last decade, Zanzibar has managed to reduce both the number of confirmed malaria cases, as well as malaria deaths by 81 percent.

Rwanda and Zambia have seen positive results through malaria control interventions as well, with Rwanda increasing the percentage of its population using net beds by 70 percent. Efforts to provide bed nets, indoor residential spraying treatment, and education are making a dramatic difference.

As our global partners are working to address drug quality and control concerns, World Health Organization prequalifications of essential medicines has been shown to be an effective mechanism to reduce the abundance of substandard drugs on the market in countries that have a weak domestic regulatory authority. In response to the findings of substandard quality and antimalarials in Africa, WHO had suggested and assisted in implementing key recommendations to empower countries to improve regulations at the country level. All of the tremendous progress we have made in the fight against malaria will not be possible without the United States' leadership and our global partnership. However, all of the groundwork that the United States and the international community has made in this fight currently is at risk. There are those in Congress who feel that the United States should cut back our already modest investment in life-saving global health programs.

I strongly disagree. The U.S. has a moral responsibility to be a leader in the fight and suffering worldwide through the Global

Fund Initiative, the President's Malaria Initiative. And let me just mention we have so many great organizations—Roll Back Malaria, Medicines for Malaria Ventures, the Malaria Vaccine Initiative, the Abuja Declaration, the Global Fund to Fight AIDS, Tuberculosis and Malaria, The Global Fund, One World Health, the President's Malaria Initiative, Malaria Control and Evaluation Partnership in Africa, the World Bank Booster Program for Malaria Control in Africa, Malaria No More, Malaria Vaccine Technology Roadmap of 2006, the Global Malaria Action Plan, the Affordable Medicines Facility, and the African Leaders Malaria Alliance—all are working together in a coordinated effort.

I have to commend Ray Chambers from my City of Newark who is the Special Envoy to the United Nations Secretary General for Malaria, and he and Peter Churnin are the ones who started Malaria No More; but Ray Chambers has done a fantastic job working on this, and of course, the Bill & Melinda Gates Foundation. Mr. Gates is involved in several of these organizations that I mentioned, and without him—I had the privilege to be at a meeting, it was like a fly on the wall, at the meeting with Mr. Gates and a number of people about 3 weeks ago, where they just talked about a war on malaria and the vision that there will be a vaccine created in our time in the future, in the near future.

And so once again there is nothing that is passionate as this to me, and I commend the chairman for calling this important hearing. Thank you, I yield back.

Mr. SMITH. Thank you very much. Mr. Turner.

Mr. TURNER. Thank you, Mr. Chairman. I am interested in hearing what our distinguished and expert panel has to say. I yield back.

Mr. SMITH. Thank you, Mr. Turner.

Without objection, I ask that the full remarks of Vice Chairman Jeff Fortenberry be made a part of the record. I would note for the record that he co-chairs the Congressional Malaria and Neglected Tropical Diseases Caucus, as noted by Mr. Payne. But he also authored an amendment to the State Department authorization bill that reaffirms our commitment to end malaria deaths by 2015. He is unable to be here today and his full statement will be made a part of the record.

I would like now to introduce our distinguished witnesses and again thank them for the Herculean efforts they have expended in trying to eradicate this vicious disease. Beginning first, welcoming back Ambassador Mark Green, former Member of the House, who served with great distinction here. Ambassador Green is a senior director of the U.S. Global Leadership Coalition and has had an extensive career in public office. He served as U.S. Ambassador to Tanzania from 2007 to 2009, where he worked closely with Tanzanian leaders to combat diseases such as malaria and HIV/AIDS. From 1999 to 2007 he served in the House of Representatives as a member of the International Relations Committee. He played a leading role in crafting the Millennium Challenge Act as well as other key legislation that addressed the global struggle to eradicate malaria. Ambassador Green has also served as managing director of the Malaria No More Policy Center right here in Washington, DC.

We will then hear from Dr. Dennis Schmatz who is president of the U.S. Board of Medicines for Malaria Venture, and has over 30 years of drug discovery experience. He was formerly the vice president of infectious disease research at Merck Research Laboratories. Dr. Schmatz has been involved with malaria research for his entire research career. He has served on and chaired a number of scientific advisory boards for the World Health Organization, including the tropical disease research program, and was founding member of the Medicines for Malaria Venture Expert Scientific Advisory Committee. He has a proven track record in managing large research teams across diverse therapeutic areas toward the successful delivery of novel medicines.

We will then hear from Dr. Regina Rabinovich, who is currently the director of Global Health Infectious Diseases at the Bill & Melinda Gates Foundation, where she oversees the development and implementation of strategies for the prevention, treatment, and control of malaria. Dr. Rabinovich joined the Foundation in 2003. She previously served in various positions at the U.S. National Institute of Allergy and Infectious Diseases, where she participated in Children's Vaccine Initiative, and served as liaison to the National Vaccine Program Office. Dr. Rabinovich has also served as chief of the Clinical and Regulatory Affairs Branch of the Division of Microbiology and Infectious Diseases.

Then we will hear from Dr. Roger Bate who is the Legatum Fellow in Global Prosperity at the American Enterprise Institute and a founding director of Africa Fighting Malaria. He researches international health policy with special interest in counterfeit medicines and malaria control. Dr. Bate has conducted extensive research in India and numerous African countries on the public health consequences of the counterfeit drug trade. He writes extensively on topics such as endemic diseases in developing countries as well as access and innovation in pharmaceuticals and international health agreements. He is author or editor of 14 books, 2 dozen peer-reviewed journal articles, and hundreds of newspaper articles.

We will then hear from Dr. David Bowen who is currently the CEO of Malaria No More. Until November 2011, Dr. Bowen served as the deputy director for Global Health Policy and Advocacy at the Bill & Melinda Gates Foundation. In this role he had the responsibility for interactions between the Foundation and governments worldwide on global health. Dr. Bowen was previously staff director for health of the Senate Committee on Health, Education, Labor and Pensions. From 2000 to 2002, he held a joint appointment as a visiting fellow in the Department of Health Care Policy at Harvard Medical School.

And finally, we will hear from Dr. Richard Steketee, who is the science director for the Malaria Control Program at PATH. He previously served as an active-duty member of the U.S Public Health Service and has served in a number of positions at the Centers for Disease Control and Prevention. These positions, including chief of the Malaria Epidemiology Section, branch chief of the Prevention Services Branch, and chief of CDC's Malaria Branch. During his tenure with CDC, he lived in Malawi for 4 years working on malaria research. Dr. Steketee also provided expertise on malaria to a number of international consortia.

Without objection, the fuller resumes of our very distinguished panel will be made a part of the record.

I would like to now yield to my good friend and colleague, Ambassador Green, for such time as he may consume.

STATEMENT OF THE HONORABLE MARK GREEN, SENIOR DIRECTOR, U.S. GLOBAL LEADERSHIP COALITION

Ambassador GREEN. Thank you, Mr. Chairman and Ranking Member Payne and members of the subcommittee. I am truly honored to be appearing before this subcommittee and to have this chance to talk with you about an underpublicized success story, a great success story in American development policy. I also want to respectfully commend you for holding this hearing, because the final chapters in that story have yet to be written. As lawmakers such as yourselves, who obviously care deeply about Africa and the developing world, you are going to be the ones with pen in hand as we go forward in writing the final chapters.

Very quickly, in terms of my own background, I myself suffered from malaria when I served as a teacher in Kenya in the mid-1980s. One of my students died from malaria shortly before I came back. I have also had the honor of helping to craft malaria policy from my days as your colleague on this committee, to my days as Ambassador to Tanzania, which is one of the original President's Malaria Initiative Focus countries. I have also had the privilege of advocating for malaria programs as a member of Malaria No More, and you will hear shortly from that organization's distinguished new CEO, Dr. David Bowen.

Since you will be hearing from experts like Dr. David Bowen who are far more conversant than I am on the numbers and research associated with this great success story, I will try to confine my remarks to what I believe is in many respects the most exciting development in this long battle, and that is leadership, leadership right here in the U.S. and, more importantly, exciting leadership in Africa itself.

As you have laid out very well, Mr. Chairman, malaria has been with us for centuries and it has claimed millions of lives. And there have been times when the world has scored remarkable victories, truly important victories, eliminating the killer disease from places like the U.S. and Europe. There have been times when it seemed that victory was in sight in some of the world's hardest-hit regions. Only to fall short.

Members of the subcommittee, I honestly believe that this time the fight is different. These days the world is making real and sustainable progress. We have never been this close and we have never come this far in providing hope for generations of children and families all across the sub-Saharan Africa. Millions of lives have been saved and millions of lives can be saved in the years ahead. Most importantly, a new generation of strong African leaders is rising to take on the malaria challenge. While it is true that Africa cannot conquer malaria alone, it is just as true that the killer disease cannot be defeated unless Africans lead the way, and they are.

At the 2009 United Nation's General Assembly, 14 African heads of state in government came together to rededicate themselves to

the goal of ending malaria deaths by 2015. They launched a new coalition called the Africa Leaders Malaria Alliance, or ALMA. Just 2 years later, ALMA has grown to 41 heads of state and government, including membership by the African Union itself. It has become an invaluable forum for leaders to share ideas and best practices and to collaborate on common challenges.

In just its first year of existence, ALMA tackled important issues like securing universal access to artemisinin-based combination therapies to prevent drug resistance, removing taxes and tariffs on essential antimalarial products, increasing local production of high-quality, safe and effective antimalaria interventions, and the banning of monotherapies. That would not have been possible just 4, 5, 6 years ago.

As you will hear today, the world's public health experts are armed with effective new tools and technologies. Just as with man's struggle against killers like smallpox and polio, our scientists have labored long and hard in pursuit of a vaccine against malaria. While, as you will hear more today, researchers can now report historic progress. The first ever large-scale phase 3 trial of a malaria vaccine is underway right now in Africa.

Some of the most exciting developments in our drive to end malaria deaths come not from new technology, but new uses of existing technology, and that to me is truly exciting. Take the example of the simple mobile phone, something that I think all of us here take for granted. Mobile phones are commonplace in sub-Saharan Africa. In fact, most experts tell you that is the great growth market. But now, thanks to innovative ingenious leaders in both the public and private sector in Africa, they have become not just simple mobile phones but amazing logistical and analytical tools to address global health challenges. Perhaps one of the best examples is the Malaria Early Epidemic Detection System, known as MEEDS, which is funded in part by the American people through USAID, the Centers for Disease Control, and PMI.

The islands of Zanzibar, as you probably know, are part of Tanzania. They have almost eliminated malaria from their shores. To help them cross the finish line of totally breaking malaria's death grip, the tool called MEEDS was created. Working with the Zanzibar Malaria Control Program, it was developed to detect the early stages of an epidemic within 2 weeks of onset. Every single Monday, health leaders from 53 different stations in Zanzibar use text-messaging technology to send into an automated server any positive tests that they have of malaria. If in fact there is a positive test or a tick up, if you will, they pounce on the epidemic with all of the interventions that we know about and work to erase it, to wipe it out. It is a partnership between pubic health leaders and Selcom Wireless. It is a remarkable example of taking an existing technology, bringing together the public sector, bringing together the private sector, and putting it to work. That is great leadership.

Leadership in the fight is also coming from communities of faith. Nowhere in the world are faith networks more important or more influential than in Africa. Faith institutions, Christian and Muslim in particular, can reach towns and villages that are cut off all too often from limited infrastructure. And the message is that faith

leaders express—well, let's face it, they carry a lot more weight than any of us as politicians could ever hope to do.

With one-fourth of the world's malaria deaths occurring in Nigeria, a coalition of interfaith groups, international organizations, and Nigerian health officials are working hard to deliver interventions.

The Sultan of Sukoto, the most powerful Islamic leader, who represents 70 million Muslims, and the Catholic Archbishop of Abuja, his counterpart among Christians, launched an effort to train 300,000 imams, priests, pastors and ministers to carry the malaria prevention message to villages throughout the country. I don't have to tell you how important this unity is, not only for public health reasons and in fighting malaria, but quite frankly for what it means for our national security interests.

In 2002 world leaders created the Global Fund to Fight AIDS, Tuberculosis and Malaria. The Global Fund now funds nearly two-thirds of the world's malaria projects. Launched in 2005, the President's Malaria Initiative has increased funding from $30 million to $618 million. These extraordinary investments have enabled a rapid scale-up of proven interventions such as insecticide-treated nets and rapid diagnostic tests. That is American leadership that works, and it is American leadership that shows the world what we stand for, and it shows the best that America has to offer.

You have tough choices to make, obviously, in the months and years ahead, but what I can say to you is investments we make in malaria are working, their success is measurable, verifiable, and predictable. We know these tools work, we know how to conquer malaria, a disease that has killed so many millions.

In the last 5 years deaths from malaria have fallen by over 20 percent, and malaria cases have dropped by 50 percent in over 40 countries worldwide, and that translates into millions of lives saved. There are always challenges and malaria is not exempt, but I continue to be impressed by the innovative efforts from the public sector and private sector. It is a remarkable success story.

One last success story I wanted to point out to you that again shows the strength of leadership, public and private, and that is the challenge that Tanzania faced in trying to take care of its logistical challenge, how you actually get those interventions, those medical supplies, out to different parts of the country.

The Global Fund helped the Government of Tanzania reach out to the private sector, and the result was a public-private partnership with an American organization that knows a thing or two about getting effective supply chains in place, an organization called Coca-Cola. Now Coca-Cola is providing technical expertise to individuals in Tanzania to develop stronger, more effective, and more extensive supply chains, better delivery to more places. That is a great success story that we can celebrate.

So as we look to the future it is with a sense of great hope. We have come a long way in this fight. And those of us who were in the field 20 and 30 years ago, quite frankly if you would have told us then about the success that we would see, I am not sure that we would have believed you. This is a story of Republicans and Democrats coming together, this is a story of Americans working together with African leaders. This is a story of security experts,

faith leaders, the world, truly coming together and it is a story to celebrate and to publicize because it is absolute proof that we can make a difference. Thank you, Mr. Chairman.

[The prepared statement of Ambassador Green follows:]

Testimony to the Subcommittee on Africa, Global Health, and Human Rights
Mark A. Green
Congressman and Ambassador (ret.)
Senior Director, U.S. Global Leadership Coalition

Mr. Chairman, Ranking Member Payne, and distinguished members of the Subcommittee: Thank you for this opportunity to talk with you about an under-publicized success story—a success in American development policy, but more importantly, a success for poverty relief and the human condition in Sub-Saharan Africa. Let me respectfully commend you for holding this hearing at this moment in time because the final chapters in this story have yet to be written and lawmakers such as yourselves, who obviously care deeply about Africa, will be among those with "pen in hand."

In terms of my own background on the subject, I myself suffered from malaria when I served as a teacher in Kenya in the mid-1980s. From those days to the days when I served on this Subcommittee; from the days when I oversaw the President's Malaria Initiative in Tanzania as Ambassador to my work with Malaria No More and now with the U.S. Global Leadership Coalition (USGLC), I have come to believe that remarkable progress has been made in battling malaria, and that America's leadership in the cause serves our national interests on the world stage.

As you know, Malaria has been with us for centuries, and it has claimed millions of lives. There have been times when the world has scored important victories – eliminating the killer disease from places like the U.S. and Europe. There have been times when it seemed that victory was in sight in some of the hardest-hit regions of the world only to fall short.

But, members of the Subcommittee, the good news is that this time the fight is different. Armed with strong leadership in the United States and nations equipped with exciting new technologies, unprecedented faith partnerships, and historic pledges of financial resources, the world is making real and sustainable progress. We have saved millions of lives and helped provide new hope to generations of children and families who might otherwise have fallen victim to this scourge as generations past have done.

Most importantly, a new generation of strong African leaders is rising to take on the malaria challenge. While it's true that Africa can't conquer malaria alone, it's just as true that the killer disease can't be defeated unless Africans lead the way. And they are.

At the 2009 United Nations General Assembly, 14 African heads of state and government joined together to rededicate themselves to the goal of ending malaria deaths by 2015. They launched a new coalition called the African Leaders Malaria Alliance, or ALMA.

Just two years later, ALMA has grown to 41 heads of state and government, including membership by the African Union itself. It's provided an invaluable forum for leaders to share ideas and best practices, and to collaborate on common challenges. In just its first year of existence, ALMA tackled important issues like securing universal access to artemisinin-based combination therapy to prevent drug resistance; removing taxes and tariffs on essential anti-malaria products; increasing local production of high-quality, safe, and effective anti-malaria interventions; and the banning of mono-therapies.

But, as I said earlier, it isn't just strong leadership that's making the difference. More than ever before, this time our public health experts are armed with effective new tools and technologies.

Just as with man's struggle against killers like smallpox and polio, our scientists have labored long and hard in pursuit of a vaccine against malaria. Researchers can now

report historic progress: the first ever, large-scale Phase 3 trial of a malaria vaccine is underway in Africa.

Some of the most exciting developments in our drive to end malaria deaths come not from *new* technology, but from new uses of existing technology. Take the example of the "simple" mobile phone.

Mobile phones are commonplace in Sub-Saharan Africa. Now, thanks to innovative, ingenious leaders in both the public and private sector, they've become amazing logistical and analytical tools to address global health challenges. Perhaps one of the best examples is the Malaria Early Epidemic Detection System – better known as MEEDs. The islands of Zanzibar, part of Tanzania, have almost eliminated malaria from their shores. To help them cross the finish line of totally ending malaria's grip, a tool called MEEDs was created. In collaboration with the CDC and the Zanzibar Malaria Control Program, MEEDs was developed to detect the early stages of an epidemic within two weeks of onset by measuring weekly changes in frequency and incidence rates of laboratory-diagnosed malaria cases at health facilities in Zanzibar.

A public-private partnership with Selcom Wireless facilitates the data transmission from health facilities via SMS messages on cell phones and the delivery of weekly updates to the Zanzibar Malaria Control Program as well as other Ministry of Health officials. One example of their success is a MEEDs detection of an increase in malaria infections in Bumbwini. Zanzibar Malaria Control officials responded with a multi-faceted intervention including indoor residual spraying, delivery of long-lasting insecticide treated mosquito nets and provision of anti-malarial treatment. Community mobilization was set in place within one week.

Leadership needed in the fight against malaria is also coming from communities of faith. Nowhere in the world are faith networks more important or more influential than in Africa. Faith institutions – Christian and Muslim in particular – are able to reach towns and villages that often seem cut off because of limited infrastructure. And the messages that faith leaders express often carry more weight with believers than anything that health or political officials can say.

With one quarter of the world's malaria deaths occurring in Nigeria, a coalition of interfaith groups, international organizations and Nigerian health officials are working hard to deliver malaria interventions across the country. The Sultan of Sokoto, the most powerful Islamic leader who represents 70 million Muslims, and the Catholic Archbishop of Abuja, his counterpart among Christians, launched an effort to train 300,000 imams, priests, pastors and ministers to carry the malaria prevention message to villages throughout Nigeria. I don't have to tell you how important this unity between Christian and Muslim's in fighting malaria impacts not only the health and well being of Nigerians – but what it means for U.S. national security.

The truth of the matter is that in order for this dramatic success to continue and to meet the goals of stopping deaths from this preventable disease by 2015, there must be the necessary financial resources. Funding gaps clearly remain, but this time is different because the financial tools to defeat malaria are within reach.

In 2002, world leaders created the Global Fund to Fight AIDS, Tuberculosis and Malaria. The Global Fund now funds two-thirds of the world's malaria projects. Launched in 2005, the President's Malaria Initiative has increased funding from $30 million to $618 million in just a few short years. This incredible investment of resources

has enabled a rapid scale-up of proven malaria interventions, such as insecticide-treated nets and rapid diagnostic tests. While you obviously have tough choices to make in setting spending priorities, and development funding is part of that, malaria tools are proven. Their success is measurable, verifiable, and predictable. We know these tools work. We know how to conquer malaria—a disease that has killed many millions over the years.

The story is remarkable: in the last five years deaths from malaria have fallen by over 20% and malaria cases have dropped by 50% in over 40 countries worldwide. This translates into the lives saved of three quarters of a million children.

There are always challenges, and fighting malaria is not exempt. However, I am continually impressed by efforts to find innovative solutions to fighting malaria. In Tanzania, the government wanted to find a way to increase their scope of delivery of medical supplies by their supply chain to all 5,000 of their health centers in an effort to reach more of their population. However, Tanzania needed some help to develop the expertise necessary to create more effective supply chains. Smartly, the Global Fund turned to the private sector and they have now started a public private partnership pilot project together with an American organization that knows a thing or two about developing effective supply chains – Coca-Cola. Coca-Cola in partnership with the Global Fund is piloting a project to provide technical assistance to individuals in Tanzania to develop stronger, more effective and extensive supply chains. Better delivery to more places means we can fight malaria more aggressively. Truly remarkable.

So as we look to the future, it's with a great sense of hope. We've come a long way in this fight. One of my proudest achievements when I served in Congress and had the honor of sitting on this Subcommittee was our bipartisan work creating the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act.

I would argue that the commitment we made in the Lantos-Hyde legislation was and still is in our national interest. It helps us to continue to show the world who we are and what we stand for. The great news as we meet here today is that we have an opportunity to finish the job.

Thank you again for indulging me with the chance to testify today – it's nice to be on this side of the dais!

Mr. SMITH. Thank you very much for your very encouraging testimony, but also the focus you put on leadership, and when that leadership is truly creative and determined, the huge benefits and consequences it actually yields. So thank you so very much.

And personally, I want to thank you again for your personal leadership on this. You know how this place works, you know how the executive branch works, and you having lived in Africa both before and during your ambassadorship, you know what really works there. So your advice and counsel has been very, very helpful to the committee, to the Congress, and to the executive branch. Thank you.

I would like to now yield such time as he may consume to Dr. Schmatz. Please proceed.

STATEMENT OF DENNIS SCHMATZ, PH.D., PRESIDENT OF THE BOARD, MEDICINES FOR MALARIA VENTURE NORTH AMERICA, INC.

Mr. SCHMATZ. Mr. Chairman, Congressman Payne, and members of the subcommittee, my name is Dennis Schmatz. I am president of Medicines for Malaria Venture's U.S. Board, and I chair the MMV Expert Scientific Advisory Committee. Thank you for the opportunity to testify on the role that drug development plays in combating malaria in Africa and around the world.

Since World War II when malaria disabled hundreds of thousands of our troops, the United States has been a key player in the development of malaria drugs. Those treatments originally deployed for our troops were used in the 1950s and 1960s to assist in the first global wave of malaria eradication. As those drugs became less and less effective due to growing resistance to the parasite, the U.S. again became involved with malaria drug development for our troops in Korea and Southeast Asia.

Since then, the United States has continued its leadership role in malaria drug research, in part to protect our continued interests around the world and in part to care for the greater than 200 million people who contract the disease each year. When these people sicken, they are unable to earn wages, unable to care for their children, and countries lose billions of dollars in GDP per year. Over 800,000 die each year, the most vulnerable being children under 5, and pregnant women in Africa.

Continued investment in malaria drug research benefits both the U.S. and its allies, both troops and civilians, around the world. MMV receives funding from the U.S. Government from USAID and NIH, as well as from other foreign governments, including the United Kingdom, Switzerland, and Ireland.

MMV is a private-public partnership based in Switzerland and registered as a 501(c)(3) in the U.S. Our mandate is to discover, develop, and deliver effective and affordable medicines to those who need them most. We need lead collaborations around the world to protect the most vulnerable, and to find new treatments that make management of malaria better, cheaper and easier, and to prevent transmission and relapse of malaria to finally help eradicate this disease.

Protecting the most vulnerable, MMV can point to two recent successes. First, in 2009 we launched Coartem Dispersible in part-

nership with Novartis. Coartem D is a cherry-flavored pediatric formulation of the effective but bitter adult drug, Coartem. Before the development of this pediatric medicine, adult tablets were crushed and given to children, and dosing was approximate since children often spit or vomit it up, leading to suboptimal treatment.

Since the launch of Coartem D, over 92 million doses have been distributed in 35 countries and it is rapidly becoming the preferred treatment for young children in Africa.

MMV also partnered to manufacture and deliver injectable artesunate to treat severe malaria. Studies published in the UK journal, "The Lancet," demonstrated that there were significantly fewer deaths using injectable artesunate versus the commonly used IV quinine. It is also much easier to administer than quinine and it has fewer side effects. Because of these other factors, Doctors Without Borders independently estimates that this drug could save some 195,000 lives each year.

Since its launch in January, our partnership has been responsible for delivering over 1.1 million vials of this lifesaving drug, enough for 237,000 severely ill patients. However, there is still a number of unmet medical needs. Resistance to artemisinin, the primary compound in all the front-line drugs, appears to be developing along the Thai-Cambodian border, the same location where the last great wave of malaria resistance to chloroquine developed.

The last time this happened, the world was caught empty-handed, with millions of people exposed to malaria and with no effective drug to cure their disease, our citizens among them. We simply cannot be caught empty-handed again. We must have new drugs at the ready to combat resistance when it develops. Those drugs simply are not there right now and should resistance emerge with no treatment to combat it, we will lose much of the successful work that has been accomplished to roll back malaria around the globe.

Unfortunately, today's drugs are imperfect, either because the full treatment takes too long to complete or the cost of treatment prohibitive for those who need it the most. To solve this dilemma, MMV is working on a single-dose cure that is not based on artemisinin, and it could dramatically change the way that malaria is treated throughout the world.

Such a drug, known as OZ439, is now in phase 2 studies. OZ439 originated from an MMV-sponsored partnership in Nebraska, also in collaboration with other partners around the world. If it lives up to its promise, OZ439 could be one of the most valuable gifts the United States has brought to the fight against malaria. In truth, though, because drug development is a complex scientific process and because there are often unexpected events during clinical development, neither MMV nor its partners can take the risk of depending on just one new molecule. Therefore, we are nurturing a portfolio of promising projects around the world, including several in the U.S., which can supply the next two generations of drugs to combat malaria.

My distinguished colleagues on the panel will discuss the crucial places that preventions, such as nets and vaccines, vector control such as insecticides, and diagnostics play in fighting against malaria. These interventions and the continued development of new drugs against this parasite would be crucial in order to eradicate

the disease. If there is anything the world learned in the last great foray into eradication is that overreliance on too few tools to fight this disease quickly led to defeat.

The United States Congress and the executive branch to the President's Malaria Initiative, USAID, NIH, CDC and the Walter Reed are all key players in this arena. A future without malaria is within reach, but only if we stay vigilant. Without a continuous supply of innovative medicines, defeating malaria will not be possible.

Thank for the opportunity to testify.

[The prepared statement of Mr. Schmatz follows:]

Written Testimony of
Dr. Dennis Schmatz
President of the USA Board of Medicines for Malaria Venture
and Chair of MMV's Expert Scientific Advisory Committee

Before the
House Foreign Affairs Subcommittee on Africa, Global Health, and Human Rights

December 5, 2011

Mr. Chairman, Congressman Payne and Members of the Subcommittee, my name is Dennis Schmatz, I am President of Medicines for Malaria Venture's (MMV) U.S. Board and I Chair the MMV Expert Scientific Advisory Committee. I thank you for the opportunity to testify on the role that drug development plays in combating malaria in Africa and around the world.

Since WWII, when malaria played a major strategic role in disabling hundreds of thousands of our troops, the United States has been a key player in the development of malaria drugs.[1] Those treatments, originally deployed for our troops, were used in the 1950s and 1960s to assist the first global wave of malaria eradication. As those drugs became less and less effective due to growing resistance of the parasite, the US again became involved in malaria drug development for our troops in East and Southeast Asia.

Since then, the United States has continued a leadership role in malaria drug research, in part to protect our continued interests around the world, and in part to care for the millions of people who contract the disease each year. When these people sicken, they are unable to earn wages, and countries lose billions of dollars in GDP per year.[2] In addition, malaria remains a

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[1] Malaria affected US soldiers during World War II throughout Europe and Asia. For example, according to the US Army Department Office of Medical History, from 9 July to 10 September 1943, during the fierce Sicilian campaign, there were 21,482 hospital admissions for malaria compared with 17,375 battle casualties. Because most of the infections were with P. *vivax*, there were many incapacitating relapses during the spring of 1944. (citation: http://history.amedd.army.mil/booksdocs/wwii/Malaria/chapterI.htm) According to one military historian, there were as many as half a million cases of malaria among the military during the war.

Malaria continued to threaten troops in Korea but became even more of a problem in during the Vietnam War, as the parasite developed resistance to the frontline treatment of chloroquine. (citation: http://www.npr.org/2011/09/01/139641878/at-walter-reed-military-medicine-fights-malaria) Although the treatment and prevention of malaria for troops has improved significantly from these earlier wars, Walter Reed Army Medical Center continues to be very active in the field of malaria treatment and prevention, and MMV has worked with the Center in its development of new medicines.

[2] "Taking into account initial poverty, economic policy, tropical location, and life expectancy, among other factors, countries with intensive malaria grew 1.3% less per person per year, and a 10% reduction in malaria was associated

leading cause of death in many developing countries despite being a preventable and entirely treatable disease. While recent global efforts have made significant progress against the malaria parasite, the burden of malaria remains staggering, especially on the very young, as illustrated by the following facts:

- An estimated 781,000 people died from malaria in 2009
- 85 percent of people dying are children under the age of 5
- A child dies every 45 seconds from malaria and disease accounts for approximately 20% of all childhood deaths in Africa
- 125 million pregnancies are at risk of malaria every year, and up to 200,000 infants die as a result

As both the subcommittee and the Congress has recognized, continued investment in malaria drug research benefits both the United States and its allies, both troops and civilians, around the world. MMV itself received $2.5M from USAID in 2011, and $1.15M from the NIH. In turn, we will invest approximately $10M in work in the United States in 2011 distributing additional funds from other donors such as the Bill and Melinda Gates Foundation, and the governments of the United Kingdom, Switzerland and Ireland.

MMV is your expert partner in this life-saving work.

As a public-private partnership based in Switzerland and registered as a 501(c)(3) in the United States, our mandate is to discover, develop and deliver effective and affordable medicines to those who need them most. We lead collaborations around the world to do three things:

- To protect the most vulnerable people, including children and pregnant mothers
- To find new treatments that make management of malaria better, cheaper and easier
- To prevent transmission and cure relapse of malaria to help finally eradicate this disease.

In protecting the most vulnerable, MMV can point to two recent successes. First, in 2009, we launched Coartem® Dispersible in partnership with Novartis. Coartem® Dispersible is a cherry flavored pediatric formulation of the effective but bitter adult drug Coartem®. Before the

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with 0.3% higher growth," Gallup, John Luke and Jeffrey D Sachs, "The Economic Burden of Malaria". Am. J. Trop. Med. Hyg., 64(1, 2)S, 2001, pp. 85–96.

development and distribution of this pediatric drug, adult tablets were crushed and given to children. The dosing was approximate, and children often spit or vomited it up, making dosing, and thus a cure, even more difficult. Since the new drug's launch in 2009, however, the situation has changed: over 92 million doses have been distributed in 35 countries and it is rapidly becoming the preferred treatment throughout Africa for young children.

Following up on this breakthrough drug, MMV partnered with Guilin Pharmaceutical Company, to manufacture and deliver an injectable artesunate to treat severe malaria. Studies published in the U.K. medical journal The Lancet show that injectable artesunate results in 22.5% fewer deaths than the commonly used IV quinine.[3] It is much easier to administer than an IV drip, and it has many fewer side effects. Because of these and other factors, Doctors Without Borders estimates that some 195,000 lives could be saved each year with this drug.[4] Since it was launched in January of this year, our partnership has been responsible for delivering over 1.1 million vials of this life-saving drug, enough for 237,000 severely ill patients.

Most recently, MMV developed Eurartesim with sigma-tau Pharmaceuticals and received European Medicines Agency approval in October, 2011. Eurartesim is highly effective against *P. falciparum* malaria in adults and children, has a simple dosing regimen (only three administrations over three days) and has significant protection against new infections for at least two months after treatment. Developed to high international standards, DHA-piperaquine meets WHO clinical treatment recommendations as it combines two active antimalarial ingredients in a single tablet: the highly potent artemisinin-derivative (dihydroartemisinin) with a second antimalarial (piperaquine) which protects the first one against the emergence of resistance.

MMV is very proud of what we have accomplished with all of our partners to date.[5] Despite our best efforts, however, there are acute medicine needs that are still unmet. Key

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[3] .Dondorp AM, Fanello CI, Hendriksen IC, Gomes E, Seni A. Chhaganlal KD, et al. Artesunate versus quinine in the treatment of severe falciparum malaria in African children (AQUAMAT): an open-label, randomised trial. Lancet 2010;376:1647-57.

[4] *Making the Switch: Ensuring Access to Improved Treatment for Severe Malaria in Africa.* Medecins Sans Frontiers. April 2011

[5] Among our partners in the United States are Rutgers University, Merck and Company Inc. in Whitehouse Station, New Jersey, the University of Nebraska Medical Center, Drexel University College of Medicine, the University of Pittsburgh, Columbia University, Cornell University, Anacor Pharmaceuticals Inc. of Palo Alto, California, Bio Ventures for Global Health in San Francisco, the University of South Florida, and Walter Reed Army Institute of Research.

among them is that resistance to artemisinin, the primary compound in all of the frontline drugs, appears to be developing on the Thai-Cambodian border.[6] This is the same location where the last great waves of malaria resistance to chloroquine developed.

The last time this happened the world was caught empty handed, with millions of people exposed to malaria and no effective drug to cure them. Our own citizens were among them.

We simply cannot be caught empty-handed again. We must have new drugs at the ready to combat resistance when it develops. Those drugs simply aren't there right now. And should resistance emerge with no treatments to combat it, we will lose much of the successful work that has been accomplished to roll back malaria around the globe.

The current drugs are imperfect, either because the full treatment takes too long to complete, or the cost of treatment is prohibitive for those who need the treatments the most. In order to solve this dilemma, MMV is working on a single-dose cure that is not based on artemisinin. A single-dose cure could dramatically change the way that malaria is treated throughout the world. Such a drug, currently known as OZ439, is currently in Phase II studies. Incidentally, the number 439 refers to the number of different compounds we had to develop in order to get to such a promising molecule.

And this is where I circle back to where I began discussing the role of the United States as OZ439 originated at the University of Nebraska, was developed in a collaboration with partners on two other continents, and was funded and nurtured by MMV. If it lives up to its promise, OZ439 could be one of the most valuable gifts that the United States has brought to the fight against malaria.

In truth, though, because drug development is a complex scientific process, and because there are often unexpected events during clinical development, neither MMV nor its partners can take the risk of depending on just one compound in development. Therefore we are developing a

[6] According to the World Health Organization's Global Plan for Artemisinin Resistance Containment "Artemisinin resistance has been confirmed in a limited area within the Greater Mekong subregion, and evidence from other potential foci in this region is under review. Experts agree that we have a limited window of opportunity to contain or eliminate the resistant parasites before they spread to higher-transmission areas, putting at risk recent progress in malaria control. The urgency is increased by the fact that no other antimalarial medicines are available that offer the same levels of efficacy and tolerability as ACTs, and few promising alternatives are available in the immediate research and development pipeline." *Global Plan for Artemisinin Resistance Containment*, WHO 2011. p. 15.

portfolio of projects around the world, including other very promising projects in the United States which can supply the next two generations of drugs to combat malaria.

You have heard, and you will hear, my distinguished colleagues on the panel discuss the crucial places that preventions such as nets and vaccines, vector control such as insecticides, and diagnostics play in the fight against malaria. These interventions and the continued deployment of new drugs against this parasite will be crucial in order to eradicate the disease. If there is anything that the world learned in its last great foray into eradication, it was that over-reliance on one weapon quickly led to defeat.

In conclusion, Ladies and Gentlemen, the United States Congress, and the Executive Branch through the President's Malaria Initiative, USAID and NIH, are all key players in this area. MMV, is pleased to be a partner with you in this arena, and looks forward to our eventual victory in this fight.

Without a continuous supply of innovative medicines, defeating malaria will not be possible. A future without malaria is within reach, but only if we stay vigilant toward completing the mission.

Thank you for the opportunity to testify.

Mr. SMITH. Thank you very much, Dr. Schmatz. Thank you for the encouraging news but also telling us about the ongoing challenges faced by all of us in finding the drugs that will truly mitigate and hopefully eradicate and treat this disease.

I would note parenthetically that sitting right behind you is Mark Tavlarides. As Ambassador Green said earlier, he once served up here where Mark used to sit right here as chief of staff for the human rights subcommittee under Gus Yatron. He did a great job. He was Democrat staffer, worked very well with the minority. We became great friends over the years, and I want to thank him for his leadership in helping this hearing come into fruition.

Dr. Rabinovich, you are next.

STATEMENT OF REGINA RABINOVICH, M.D., DIRECTOR, INFECTIOUS DISEASES, GLOBAL HEALTH PROGRAM, BILL & MELINDA GATES FOUNDATION

Dr. RABINOVICH. I want to thank you, Mr. Chairman, Mr. Payne, Mr. Turner, and other members of the subcommittee for taking the time to focus on malaria and for your commitment over the years to robust U.S. investment in global health and development.

We have come a long way in malaria from just 10 years ago. Since 2000, more than 1 million African children have been saved from malaria. Approximately half of all countries with malaria have reduced malaria cases and deaths by 50 percent or more. This tremendous progress against malaria has been due to innovation and prevention and treatment, increased funding, and political will.

New tools such as long-lasting insecticide-treated bed nets, and artemisinin-based and combination therapy, along with prevention during pregnancy, and indoor residual spraying, all of these have made this progress possible.

The U.S. President's Malaria Initiative, the Global Fund to Fight AIDS, TB and Malaria, and the World Bank are essential to the remarkable successes in malaria control. The Global Fund alone has distributed 190 million bed nets to protect families from malaria.

I was trying to think about how big you would require a container to hold 190 million, to make that clear, but it is a tremendous effort and one that is worthy of note.

The President's Malaria Initiative provides lifesaving prevention and treatment to millions of people in Africa and Southeast Asia. However, even today, malaria has a disproportionate impact on the world's poorest and most vulnerable individuals and still kills far too many children each year. Our children here in the U.S. do not have to suffer from malaria. No child anywhere should.

Maintaining the gains achieved today in malaria control is essential, but it is not assured without the continued commitment of multiple partners, including the U.S. Government. Guided by the principle that all lives have equal value, the Bill & Melinda Gates Foundation works to help all people lead healthy and productive lives. Our Global Health Program seeks to ensure that lifesaving advances are developed and that they reach those who need the most.

In malaria we focus our efforts on improving existing tools, on discovering new ones to reduce and prevent malaria transmission, and, in the long term, to eradicate malaria worldwide.

Existing interventions have contributed to a 20-percent decline in mortality due to malaria. We must continue to improve access to intervention like long-lasting insecticide-treated bed nets, indoor residual spraying, and treatments that save lives. The impact of tools available right now is very real. However, the malaria parasite has a history of adapting to drugs and adapting to insecticides. Drug resistance to the most effective drug available, artemisinin-based and combination therapy, is developing and has been recognized in Southeast Asia.

Research and development is essential because the preventive tools available today that are so effective at controlling malaria are not sufficient to control malaria in the long term or for eradication, due in part to the development of the resistance. Today the world has the strongest research and development pipeline for malaria that has ever existed, and we must ensure that it stays this way. Significant credit goes to the National Institutes of Health, which is one of the primary funders of malaria research and development.

When I left the National Institutes of Health to join the Malaria Vaccine Initiative, I was asked why I would bet my career in creating a malaria vaccine, something that did not exist and which had been troubling to many initiatives previously. At the time, I didn't really have an answer based on impact. Most researchers were not convinced that the scientific path to a malaria vaccine was clear. And even if our work resulted in promising candidates, we did not know how we would finance or how we would deliver them. After all, at the time, which was about a decade ago, even the cheap and broadly available measles vaccine was not being used worldwide.

In the last 10 years a lot has changed. We are much closer to having a malaria vaccine that works, through significant efforts by the PATH Malaria Vaccine Initiative and by many partners. It is possible a malaria vaccine will be available by 2015. We have seen interim results for the RTS,S malaria vaccine, which were announced in October and published in the "New England Journal of Medicine." It showed that that vaccine, so far, prevents clinical malaria in 56 percent of the trial participants over a period of 1 year, and these are the first results. Those results are exciting. We now have proof it is possible to create a vaccine that is effective against malaria.

The U.S. Government, through funding through the Department of Defense and USAID, has played an important role in development of this vaccine.

Research is also underway on other vaccine candidates, including transmission-blocking vaccines which would prevent people infected with the malaria parasite from passing the disease on to mosquitoes, who would then infect other people, or, if vaccinated, not infect other people. In the effort for malaria eradication, these vaccines will ultimately be invaluable. However, significant work is still needed on the development of vaccines, and the U.S. Government will continue to play an important role in supporting these efforts.

The Gates Foundation also invests in development of new drugs and methods to control mosquitoes. And there are today significant potential on both fronts. Medicines for Malaria Venture, as we heard from the previous speaker, is developing new drugs with entirely new classes of action, including a potential single-dose cure which would radically improve our ability to treat malaria in the field.

The Innovative Vector Control Consortium and other partners are working on new insecticides for bed nets and entirely new methods to control mosquitoes that could look like the mosquito coils we use in our backyards or wall linings, with insecticides that are easier to use than bed nets. We must continue to support the development of new treatment and preventive measures to ensure that we stay a step ahead of the evolving parasite.

We have reached an inflection point, a moment in which we either forge ahead and ensure permanent progress in the fight against malaria, or we slide back and run the risk of losing much of what we have already achieved. This is not the time to relax our guard. We cannot afford to accept partial success. To fight malaria we have to maintain momentum. We are either gaining ground or we are losing it. Resistance to drugs and insecticides is a very real threat. We have come too far to accept backsliding in the fight against malaria.

In the face of today's challenges, there is one primary reason that I am optimistic for the future of malaria, and that is the commitment and dedication of so many people here in the U.S. and around the world, from scientists and researchers, program managers in the field, political leaders, and partnerships faith-based organizations and nongovernmental organizations that have emerged to fight this disease. I am optimistic that we must face the current situation with urgency. Malaria fights back and recent gains could be lost. We need to be smarter, we need to act faster. We must continue to fund the President's Malaria Initiative and the Global Fund. This funding saves the lives of children, women, and entire families.

We also recognize funding is needed to develop new treatments and methods of prevention and to deliver more effective and affordable interventions. The Gates Foundation's long-term objective is the eradication of malaria, but we can only achieve eradication if we act urgently and maintain attention and funding today. We are committed to fighting malaria for the long haul. Commitment and leadership by diverse partners, including the U.S. Government, African leaders, nongovernmental and faith-based organizations, and the private sector is critical.

It has been an honor to appear before you today. I appreciate your time and I look forward to a productive conversation.

Mr. SMITH. Thank you very much for your testimony and leadership.

[The prepared statement of Dr. Rabinovich follows:]

Dr. Regina Rabinovich
Director, Infectious Diseases, Global Health Program, Bill & Melinda Gates Foundation

Fighting Malaria: Progress and Challenges
Monday, December 5
House Committee on Foreign Affairs, Subcommittee on Africa, Global Health, and Human Rights

I want to thank the Sub-Committee for taking the time to focus on malaria and for your commitment over the years to robust U.S. investment in global health and development.

We have come a long way in malaria from just 10 years ago.

Since 2000, 1.1 million African children have been saved from malaria. Approximately half of all countries with malaria have reduced malaria cases and deaths by 50 percent or more.

This tremendous progress against malaria has been due to innovation in prevention and treatment, increased funding and political will.

New tools such as long-lasting insecticide treated bed nets and recently developed drugs—along with prevention during pregnancy and indoor residual spraying—have made this progress possible.

The Global Fund to Fight AIDS, Tuberculosis and Malaria, the U.S. President's Malaria Initiative and the World Bank are essential to the remarkable successes in malaria control. The Global Fund's impact is profound: it has distributed 190 million bed nets to protect families from malaria. The President's Malaria Initiative provides life-saving prevention and treatment to millions of people in Africa and South-East Asia.

However, malaria still has a disproportionate impact on the world's poorest and most vulnerable individuals, and still kills far too many children each year. If our children here in the U.S. do not have to suffer from malaria, no child anywhere should. Maintaining the gains achieved to date in malaria control is essential, but it is not assured without the continued commitment of multiple partners, including the U.S. government.

Guided by the principle that all lives have equal value, the Bill & Melinda Gates Foundation works to help all people lead healthy and productive lives. Our Global Health Program seeks to ensure that life-saving advances are developed and reach those who need them most.

In malaria, we focus our efforts on improving existing tools and discovering new ones to reduce and prevent malaria transmission, and in the long-term, eradicate malaria worldwide.

Existing interventions have contributed to a 20 percent decline in mortality due to malaria. We must continue to improve access to interventions like long-lasting insecticide treated bed nets, indoor residual spraying, and treatment that save lives. The impact of the tools available right now is very real.

However, the malaria parasite has a history of adapting to drugs and insecticides. Drug resistance to the most effective drug available, artemisinin-based combination therapy, is developing in South-East Asia.

Research and development is essential because the preventive and curative tools that are available today – and are so effective at controlling malaria today – are not sufficient to control malaria in the long-term or for eradication, due largely to the development of resistance.

Today, the world has the strongest research and development pipeline for malaria that has ever existed and we must ensure that it stays this way. Significant credit goes to the National Institutes of Health, which is one of the primary funders of malaria research and development.

When I left the National Institutes of Health to join the Malaria Vaccine Initiative, I was asked why I would bet my career on creating a malaria vaccine. At the time, I didn't have a good answer based on impact. Most researchers were not convinced that the scientific path to a malaria vaccine was clear. And even if our work resulted in promising candidates, we did not know how we would finance or deliver them. After all, at the time, even the cheap and broadly available measles vaccine was not being used worldwide.

In the last ten years, a lot has changed.

We are much closer to having a malaria vaccine that works, through significant efforts by the Malaria Vaccine Initiative and many partners. It is possible that a malaria vaccine will be available by 2015. The interim results for the RTS,S malaria vaccine, announced in October, show that the vaccine prevents clinical malaria in 56 percent of trial participants over a period of one year. These results are exciting. We now have proof that it is possible to create a vaccine that is effective against malaria. The U.S. government, through funding from the Department of Defense and USAID, has played an important role in the development of this vaccine.

Research is underway on other vaccine candidates, including transmission blocking vaccines, which would prevent people infected with the malaria parasite from passing the disease on to mosquitoes, who would then infect other people. In the effort for malaria eradication, these vaccines will be invaluable. However, significant work is still needed on the development of malaria vaccines and the U.S. government will continue to play an important role in supporting these efforts.

The Gates Foundation also invests in the development of new drugs and methods to control mosquitoes. There is significant potential on both fronts. Medicines for Malaria Venture, a non-profit organization that we support, is developing new drugs with entirely new classes of action, including a potential single dose cure, which would radically improve our ability to treat malaria. They also recently developed a malaria drug for children.

The Innovative Vector Control Consortium, and other partners, are working on new insecticides for bed nets and entirely new methods to control mosquitoes that could look like the mosquito coils we use in our backyards or wall linings with insecticide that are easier to use than bed nets. We must continue to support the development of new treatment and preventive measures to ensure we stay a step ahead of the evolving parasite.

We have reached an inflection point – a moment in which we either forge ahead, and ensure permanent progress in the fight against malaria; or slide back, and run the risk of losing much of what we have already achieved.

This is *not* the time to sit back and relax our guard. We cannot afford to accept partial success.

To fight malaria, we have to maintain momentum. We are either gaining ground, or we are losing it. Resistance to drugs and insecticides is a very real threat. We have come too far to accept backsliding in the fight against malaria.

In the face of today's challenges, there is one primary reason that I am optimistic for the future of malaria – the commitment and dedication of so many people here in the U.S. and around the world – from scientists and researchers, program managers in the field, and political leaders, and the partnerships that have emerged to fight this disease.

I am optimistic, but we must face the current situation with urgency. Malaria fights back and recent gains could be lost. We need to be smarter and act faster. We must continue to fund the Global Fund and the President's Malaria Initiative. This funding saves the lives of children, women, and entire families. Funding is also needed to develop novel treatments and methods of prevention and to deliver more effective and more affordable interventions.

The Gates Foundation's long-term objective is the eradication of malaria, but we can only achieve eradication if we act urgently and maintain attention and funding today. We are committed to fighting malaria for the long haul. Commitment and leadership by diverse partners, including the U.S. government, African leaders, non-governmental organizations, and the private sector, is critical.

It has been an honor to appear before you today. I appreciate your time, and I look forward to a productive conversation.

Mr. SMITH. We now turn to Dr. Bate.

STATEMENT OF MR. ROGER BATE, LEGATUM FELLOW IN GLOBAL PROSPERITY, AMERICAN ENTERPRISE INSTITUTE

Mr. BATE. Mr. Chairman, members of the committee, thank you very much for inviting me to testify on this extremely important topic. Just over 7 years ago, I testified before the committee on what was then a relatively weak effort against malaria. The United States Government and other donors were not funding all viable control measures. The most politically charged was the lack of the use of insecticide DDT, but, as important, was the lack of support for the best malaria drugs.

Not long after that hearing, the reforms and funding began in earnest. The U.S. Government started implementing all interventions. The Global Fund ramped up spending on both preventative and treatment efforts, including the best drugs to fight malaria the artemisinin combination therapies (ACTs), which have already been mentioned.

Progress was swift and impressive, particularly in locations targeted by the President's Malaria Initiative, particularly the island the Zanzibar. And for those efforts and other efforts, the President's Malaria Initiative in my estimation is deserving of continued, even increased, support.

The Southern African Development Community is targeting malaria elimination in eight countries, starting with Botswana, Namibia, South Africa, and Swaziland. With enough political will, elimination is a real possibility relatively soon. So overall there is good news. I would echo every comment that has been made by every speaker so far. And I stress it is good news, because I intend on spending the bulk of my time discussing some of the significant challenges that I see that remain. And those discussions are going to revolve around problems related to drug resistance. There are others I could mention; mission creep in certain agencies, and procurement problems which is increasing mortality in certain occasions. We may get to those in questions.

But as has already been mentioned, the artemisinin combination therapies are the best treatment available. Resistance is being noticed on the Thai-Cambodian-Burmese borders, and resistance is likely to increase.

I am going to cover a few reasons as to why I see that to be the case. The first is fake and substandard antimalaria medications are a significant, and probably a growing, problem. It is uncertain how many poor-quality antimalarials there are on the market in Africa, but it is certainly not a negligible amount. Many of these inferior-quality products are not illegal in the countries in question.

Of the sampling that my research team and colleagues around the world have done, we found that roughly about half the drugs that failed quality control contain artemisinin, so they are directly contributing to resistance. There is also an increasing proliferation of brands, legitimate and otherwise, in many countries in the world. Nigeria has already been mentioned. Nigeria and Kenya have over 200 different brands of artemisinin therapy on sale.

Working with the American Enterprise Institute, you would not be surprised to know that I am in favor of free trade and open mar-

kets, but this is not a controlled market. There is a considerable free-for-all in these markets and its quality control is bad because the medical regulation authorities in those countries have limited capacity.

There is a significant positive note that the U.S. Government is supporting via the U.S. Agency for International Development—the very excellent program on quality medicines at U.S. Pharmacopeia, which is combating fake and substandard drugs, and helping developing-country medical regulatory authorities to identify unregistered illegal medicines and whether they cause problems. Most will on the market.

Again, from different research that colleagues of mine have undertaken, unregistered medicines on the whole fail quality control tests five times more often than registered medicines. So simply getting the medical regulatory authorities to control what is on the market for antimalarials, I think, is important. The U.S. Pharmacopeia program, to the tune of $35 million, is in my opinion deserving of continued and increased support.

The second major problem related to increasing resistance has already been mentioned. That is the sale of monotherapies. Coordinated action and attempts for the last 6 years to remove these from the markets, in Africa in particular, have had some success. But there are still some companies, a few companies in China, Vietnam, and to a lesser extent India, that are still producing them. This is a major contributor to resistance.

In order to combat those monotherapy sales and replace them with ACTs, a team at the Institute for Medicine suggested subsidizing ACTs in the private sector, where most people buy their drugs. In the poorer regions, probably around 70 percent of drugs are bought privately.

The Affordable Medicine Facility for Malaria is currently being piloted by the Global Fund in eight countries. This is an interesting idea. It may have a significant impact where it works well, but from my assessment of it, this is a project that has run ahead of itself. It is not achieving its aim. Even though we are in the first year and the first pilot phase, we are already beginning to see significant problems. For instance, the AMFm is exacerbating existing problems with diagnosis. This is not unique by any means to the AMFm, but it is increasing the number of people being treated with malaria drugs who do not have malaria.

Secondly, there are ordering practices going on. We have already heard Zanzibar has almost eliminated the disease, yet 243,000 ACT treatments were authorized by the Global Fund for Zanzibar, and 70 percent of all of the orders for AMFm are for adult treatment. Malaria is primarily a childhood disease.

So there are significant problems that we are noticing out there. The subsidy is supposed to massively reduce the price of these drugs. Looking in 37 pharmacies in Nigeria and Ghana, my research team found that the drugs were two to five times higher in price than had been expected. Yes, they are lowering the price of ACTs, which is good. They are driving out some of the monotherapies. But the impact is still very worrying. Perhaps most worrying of all is that four pilot countries—Kenya, Nigeria, Ghana, Tanzania—account now for 80 percent of the annual global ACT

production capacity if all of those orders are fulfilled. That is a major problem.

The United States Government so far has boycotted the AMFm, and I think for good reason. And you might wonder why I am mentioning the AMFm if the U.S. Government isn't funding it. Well, I think the U.S. Government procurement program of malaria treatments are going to be seriously curtailed. I already know that there will be serious problems in procuring medicines over the next 6 months.

All in all, the AMFm is disrupting distribution systems and causing medicine procurement to operate on a first come/first served basis, creating huge problems. The Global Fund already doesn't have enough funding to fund its round 11, and it is probably short of funding for the AMFm. In my opinion, it should probably be stopped now before it completes the initial phase. I like experiments, I like to try and find out when things work. This is an innovative idea. If it continues through the first phase, we might learn enormously interesting information. In my opinion, the U.S. Government should work harder to end the AMFm, or at least limit its scope, before even greater damage is done to distribution systems, and it has a harmful effect on drug resistance.

I could go on on other potential challenges, but I will end there, thank you.

Mr. SMITH. Dr. Bate, thank you very, very much.

[The prepared statement of Mr. Bate follows:]

SUBCOMMITTEE HEARING
COMMITTEE ON FOREIGN AFFAIRS
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, D.C. 20515-0128

SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, AND HUMAN RIGHTS
Christopher H. Smith (R-NJ), Chairman

Fighting Malaria: Progress and Challenges
December 5, 2011

Congressional Testimony by Dr Roger Bate, Legatum Fellow in Global Prosperity at the American Enterprise Institute in Washington DC, and a Director of Africa Fighting Malaria, a research organization based in Washington and South Africa.

Mr Chairman, members of the committee, thank you for inviting me to testify on this important topic.

Seven years ago I testified before this committee on what was then a relatively weak domestic and international effort against malaria. United States Government (USG) and other donors were then not funding all viable preventive measures, most notably refusing to support the use of the insecticide DDT. International donors were also supporting out of date medicines which exacerbated significant resistance problems and failed to treat malaria cases effectively. Leading malaria scientists, ably lead by Dr Amir Attaran, exposed this folly and pressured for change. But with limited funding available at both the domestic and international level, change was slow to materialize.

Reforms then came about rapidly. Within fourteen months of that hearing, the WHO publicly defended the use of DDT at a press conference in Washington chaired by my colleague, Richard Tren.[1] President Bush announced the billion dollar President's Malaria Initiative (PMI) and PMI began buying DDT and promoting its use.[2] The Global Fund to Fight AIDS, TB and Malaria (Global Fund) ramped up spending on both preventative efforts as well as treatment efforts that included the best drugs to fight malaria, artemisinin-based combination therapies (ACTs).[3]

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[1] *Africa Fighting Malaria Annual Report January 2007*, Annual Report, page 2, http://www.fightingmalaria.org/pdfs/2006%20AFM%20Annual%20Report.pdf.
[2] "WHO gives indoor use of DDT a clean bill of health for controlling malaria," World Health Organization, last modified September 15, 2006, http://www.who.int/mediacentre/news/releases/2006/pr50/en/.
[3] *REVIEW OF THE GLOBAL FUND GRANT PORTFOLIO – FUNDING THE RIGHT THINGS?*, A TERG Technical
Report August 2006, page 4,
http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&ved=0CC4QFjAB&url=http%3A%2F%2Fwww.theglobalfund.org%2Fdocuments%2Fterg%2FTERG_FiveYearEvaluationPortfolioReview_Paper_en%2F&ei=yD-5Tr3fOaW22gXqzr2pBw&usg=AFQjCN G49sIEC3d0fIvDr9u8RTTeCEV-Hw.

Progress was swift and impressive, particularly in locations targeted by PMI such as the Tanzanian island of Zanzibar. Where all available preventive and treatment measures were used, cases and fatalities plummeted. By 2007, the disease had almost been eliminated from the island.[4] In all PMI-targeted countries, child mortality fell impressively by between 23% and 36%.[5] Since malaria is often the leading cause of child mortality, improved malaria control significantly lowers all cause child mortality, and in PMI countries the only major public health program in recent years was for malaria control.[6] For this reason, the PMI can take credit for a large portion of these saved lives. Across the board malaria rates have fallen, although it is difficult to know the magnitude of the decrease because reporting is sparse and health systems across the region are poor. According to the Lives Saved Model (LiST), supported by the Roll Back Malaria Partnership, over 1 million malaria related deaths have been prevented since 2000.[7] Most of these deaths would have been prevented since the reforms began in the latter part of the last decade.

Nigeria and the DR Congo, home to half of the continent's malaria cases, were recently added as PMI focal countries. At the same time, the Global Fund and other donors began scaling up their programs in these two nations in the hope that success is possible there too. Reductions in disease can be achieved in both nations, but it is not yet possible to contemplate eliminating malaria because health systems are so weak in these countries.

Parts of southern Africa are attempting disease elimination. The Southern African Development Community (SADC) has agreed to a Malaria Elimination 8 (E8) program that targets malaria elimination in Botswana, Namibia, South Africa and Swaziland and scales up interventions in support of (with the long term goal of) elimination in Angola, Mozambique, Zambia and Zimbabwe. If governments demonstrate strong political will at the highest levels, donors sustain funding, and the two partner to effectively utilize all available techniques, there is a chance that these efforts will succeed in eliminating malaria, as Mauritius and the United Arab Emirates have.[8]

So overall there is good news, but significant challenges remain.

Challenges:

Artemisinin-based Combination Therapies (ACTs) are the best treatment available for falciparum malaria, but resistance to current artemisinin has already been noted in the Thai,

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[4] Peter McElroy, "Zanzibar: Beyond Malaria Control ," President's Malaria Initiative, http://www.pmi.gov/countries/profiles/zanzibar.html.
[5] Katie Todd, "The President's Malaria Initiative: Success Stories from Senegal," Malaria Policy Center, last modified June 19, 2011, http://www.malariapolicycenter.org/blog/?tag=pmi.
[6] "Countries," President's Malaria Initiative, http://www.pmi.gov/countries/index.html.

[7] *A Summary of Regional Progress from A Decade of Partnership and Results*, Roll Back Malaria Partnership Progress & Impact Series, page 2, http://www.rollbackmalaria.org/ProgressImpactSeries/docs/report8factSheet2-en.pdf.
[8] *Progress Against Malaria: Winning the Fight Against a Deadly Disease*, Gates Foundation Progress Sheet, page 3, http://www.gatesfoundation.org/livingproofproject/Documents/progress-against-malaria.pdf.

Cambodia,[9] and Burmese borders.[10] While new versions of ACTs, such as the Wellcome Trust supported DHA-PPQ drug,[11] are being developed, there are no effective substitutes for ACTs yet. Early trial results for the new malaria vaccine have generated significant hype, but even if the vaccine becomes available in the next few years, it will only afford a 50% protection level for approximately one year.[12,13] Limiting resistance to the most effective current treatments for malaria is therefore vital.

There are several reasons that resistance is likely to increase:

Substandard and fake medicines. Fake and substandard antimalarial medications are a major problem in Africa. In the first study my research team did in 2007, we found that nearly a third of the drugs failed basic quality control tests. Many of these were fakes and contained no active ingredient. [14] While these medicines are potentially lethal, fakes with no active ingredient do not increase drug resistance. But fakes with some active ingredient and substandard medicines are likely to increase drug resistance. Substandards are badly produced medicines made by legal manufacturers. They do not work properly because they contain some of the wrong ingredients, the right active ingredients in the wrong amounts, or the right ingredients in the right proportions but improperly formulated. Substandard drugs threaten the patient's life and may contribute to drug resistance. It is impossible to know the extent of the effect but it may be significant, particularly given the increasing proliferation of brands.[15] A report from 2004 found more than 200 different antimalarial brands in Kenya alone.[16] Across all of our studies we found that perhaps 15% of the dozens of brands of artemisinin therapies were substandard. Cutthroat competition is driving prices downwards, increasing pressure on small manufacturers to cut corners to keep costs low enough to stay in the market.

N.B. I should add one point of good news and that is USG's funding of efforts to limit fake and substandard drugs directly. USG through USAID funds the US Pharmacopea program on quality medicines (PQM). This program, totaling $35m over five years aims to improve the medical regulatory authorities in emerging countries so as to improve oversight and lessen likelihood of

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[9] *Progress Against Malaria: Winning the Fight Against a Deadly Disease*, Gates Foundation Progress Sheet, page 3, http://www.gatesfoundation.org/livingproofproject/Documents/progress-against-malaria.pdf.

[10] Chansuda Wongsrichanalai and Steven R Meshnick, "Declining Artesunate-Mefloquine Efficacy against Falciparum Malaria on the Cambodia-Thailand Border," *EID Journal*, 14th ser., no. 5 (May 2008.

[11] "Malaria treatment approved for use by the European Medicines Agency," Wellcome Trust, last modified October-November 3, 2011, http://www.wellcome.ac.uk/News/2011/News/WTVM053342.

[12] Martin Enserink, "New Hope for 'Crazy' Malaria Vaccine," Science, last modified September 8, 2011, http://news.sciencemag.org/sciencenow/2011/09/new-hope-for-crazy-malaria-vacci.html.

[13] "Part II: The Global Strategy," in *Global Malaria Action Plan*, Roll Back Malaria Action Plan, http://www.rbm.who.int/gmap/2-4a.html.

[14] Roger Bate, Philip Coticelli, Richard Tren, and Amir Attaran, "Antimalarial Drug Quality in the Most Severely Malarious Parts of Africa: A Six Country Study," *PLoS One* (May 7, 2008).

[15] *Fact Sheet N°275: Counterfeit Medicines February 2006*, World Health Organization Fact Sheet, http://www.gphf.org/images/downloads/library/who_factsheet275.pdf.

[16] Kaur, Harparkash, Michael D Green, Dana M Hostetler, Facundo M Fernandez, and Paul N Newton. Antimalarial drug quality: methods to detect suspect drugs.http://www.actconsortium.org/data/files/kaur_et_al_in_therapy012010.pdf.

fake and substandard medicines in these markets.[17] While this applies to all medicines, poor quality antimalarials are often rife in some of these markets. My team's research found that unregistered medicines were five times more likely to fail quality standards than registered medicines.[18]

Monotherapies. Six years ago the WHO demanded that manufacturers stop making and selling artemisinin monotherapies[19] since the likelihood of artemisinin resistance developing is much higher if malaria strains are exposed to it alone. When combined with another less effective but still useful drug, the odds on the parasite developing resistance to both simultaneously is far lower. But it appears this warning was not heeded. My research team found over a dozen brands of artemisinin monotherapies for sale in 2007.[20] In another study earlier this year in Accra and Lagos, my colleagues found several monotherapy brands still on sale.[21] According to WHO data from November of last year, 53 of the 78 nations in need of ACTs have outlawed these products, but the other 25 nations have been less proactive.[22] Additionally, producers from China, India and Vietnam in particular ignore WHO policies and demands, and continue manufacturing these drugs.[23]

Over supply – AMFm . In many highly malarial countries, most people purchase malaria treatment from private shops and pharmacies. The Affordable Medicines Facility malaria (AMFm) was established in an attempt to increase access to the most effective medicines and drive out the ineffective and proscribed treatments (such as oral artemisinin monotherapies) by providing highly subsidized ACTs via the private sector. AMFm is currently being piloted in 8 countries. It holds some promise because it recognizes the important role played by the private sector in malaria treatment; however, its implementation leaves a great deal to be desired. Although the first year of the pilot phase is not yet completed, significant problems are already evident. For instance, AMFm does not address diagnosis problems, which could exacerbate the inappropriate use of these valuable treatments (notably non-malarial fevers being treated with antimalarials). Furthermore, the Global Fund has authorized and subsidized ACT deliveries that can only be described as inappropriate. For instance, the Global Fund authorized the delivery of 240,000 ACT treatments to Zanzibar, which as I have already described, has almost no malaria. AMFm orders that have been approved for just four countries account for 80 percent of the total annual global ACT production capacity. Over 70 percent of these approved orders are for adult treatments – which is odd as malaria is mostly a childhood disease (adult dose packs often

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[17] Phil Taylor, "USAID, USP launch counterfeit meds programme." Securing Pharma, last modified October 27, 2009, http://www.securingpharma.com/usaid-usp-launch-counterfeit-meds-programme/s40/a265/.
[18] Roger Bate, Loraine Mooney Kimberley Hess, Medicine Registration and Medicine Quality, Research and Reports in Tropical Medicine, December 2010 Volume 2010:1 Pages 89 - 93
[19] *WHO informal consultation with manufacturers of artemisinin-based pharmaceutical products in use for the treatment of malaria: August 24, 2007.*
http://www.who.int/malaria/publications/mtgmanufacturersartemisininderivatives.pdf. (page 8)
[20] Roger Bate, "One in Three Malaria Drugs Failing in Africa," International Policy Network, http://www.policynetwork.net/health/media/one-three-malaria-drugs-fai
[21] Richard Tren et al., *Africa Fighting Malaria Policy Paper-September 2011*, http://www.malariaworld.org/sites/default/files/AMFmPolicyPaper.pdf.
[22] *Marketing of oral artemisinin-based monotherapy medicines at country level: November 19, 2010*, page 1, http://www.who.int/malaria/monotherapy_NDRAs.pdf.
[23] "WHO Launches Effort to End Misuse of Malaria Drug," Daily News Central, last modified January 20, 2006,http://health.dailynewscentral.com/content/view/0002070/58/.

contain four-fold the number of pills at only a bit more in price, and so I speculate that each pack is being split up and sold to treat more than one child - increasing profit but increasing risk of inappropriate dosing and even product degradation). My colleagues repeatedly asked the Global Fund for the rationale behind subsidizing so many adult treatments for a childhood disease, but have not been given any answers. There is no medical or public health justification for it. Based on leaked documents exposed by Africa Fighting Malaria in its recent report, this one treatment program will soon contribute to a global shortage of ACTs. The report[24] describes several instances of mismanagement of public funds and an apparent disregard of how the malaria treatments will be used. While the US Government has refused to fund AMFm, tightening global ACT supply is affecting US Government programs and hindering their ability to purchase the best quality malaria treatments.

The AMFm also aims to lower resistance. In highly malarial countries, most people presumptively treat fevers with malaria drugs, in part because the cheapest malaria drugs are less expensive than the cheapest diagnostic test. But a study from 2007 found that up to half the cases presumed to be malaria were in fact something else.[25] Such self-diagnosis and over-prescription is an extreme waste of scarce resources and may also further create resistance. This is inevitable to some degree given levels of poverty, lack of education and lack of access to free diagnostics (at government clinics).

While in principle the AMFm could work, and in some locations it may be doing so, it is flooding the market with ACTs, some of which are being stolen and diverted (often degrading as they are transported in poor conditions) to other markets. Ignoring its disruption to systems, it is also increasing stock-outs in other areas. And while all the producers are prequalified by WHO, there is doubt as to whether quality is being maintained as production dramatically increases. My colleagues and I have a paper passing through peer review at this moment, which will support this statement. Previous research touched on the theft of drugs of which the latest research also comments.[26] Finally, in my team's recent research, we found that domestically produced drugs (notably antimalarials made by African companies) had the worst quality problems.[27] AMFm drives increased production by such companies, who hope that at some stage they will be able to compete for AMFm funding. African country representatives are lobbying hard for their companies to take part and African companies are aware of, if not financing, this lobbying.

All in all, AMFm is disrupting distribution systems and causing medicine procurement to operate on a first-come, first-served basis, creating huge problems for donors (including PMI).

Insecticide resistance. The World Health Organization is rightly concerned about the rise in insecticide resistance and is currently formulating a comprehensive strategy to deal with the problem. To address this challenge, resistance management programs will require the use of

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[24] Available at: http://www.fightingmalaria.org/pdfs/amfmpolicypaper.pdf

[25] Africa in an era of combination therapy," World Health Organization, http://www.who.int/bulletin/volumes/86/2/07-042259/en/index.html.

[26] Roger Bate Lorraine Mooney and Kimberly Hess , Antimalarial Medicine Diversion, Research and Reports in Tropical Medicine, September 2, 2010

[27] Roger Bate, Lorraine Mooney, and Julissa Milligan, "The Danger of Substandard Drugs in Emerging Markets: An Assessment of Basic Product Quality," *Pharmacologia* 3, no. 2 (2012): page 46-51, http://www.aei.org/docLib/Pharmacologia-Published.pdf.

several different insecticides with different active ingredients and modes of action to break the spread of resistant genes. However, decades of anti-insecticide activism have deterred research into this vital area of public health; even with the rise in malaria research and development funding in recent years, only 4 percent has been spent on disease vector control[28] (mosquito control) and only a fraction of that would be devoted to insecticides. This is a challenge that must be addressed sooner rather than later, and it will be difficult to root out since anti-insecticide activism reaches the highest echelons of the United Nations bureaucracy.[29]

Malarial country support. Malaria control requires ongoing and sustained funding. The United States has led the way and is the most generous nation when it comes to malaria control.[30] It is time, however, for malarial countries to start contributing to their own programs. While some malarial countries have genuinely limited budgets, others, particularly those in West Africa, have massive oil reserves and for several years have enjoyed windfall revenues thanks to high oil prices. US taxpayers have, for the most part, been happy to support life saving programs abroad, but it is time for these relatively wealthy malarial countries to start acting as true partners and begin funding some or all of their own programs.

USG funding of other agencies. The Global Fund is to be commended for its transparency, but it has failed to act on the information it has gleaned, and continues to allow its funds to be used by governmental distribution systems known to be corrupt. The recent High-Level Independent Review Panel recommended the Global Fund "Mandate the outsourcing of drug storage and delivery as the norm, except where the Fund certifies a local institution according to international standards."[31] The Global Fund Board decided at its 24th Board Meeting to merely give consideration to this recommendation rather than to begin its implementation.[32] It has also used, and continues to use, UNDP as an intermediary even though it has no idea how UNDP has used its funds (since UNDP will not allow audit internal reports to be seen by the Global Fund[33]). UNDP's role as a principle recipient has been a significant barrier to Global Fund OIG audits.

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[28] Program for Appropriate Technology in Health. "Staying the Course – Malaria Research and Development in a Time of Economic Uncertainty," June 2011, PATH, available: http://www.malariavaccine.org/files/RD-report-June2011.pdf

[29] Roberts, D. and Tren, R. "International advocacy against DDT and other public health insecticides for malaria control," *Research and Reports in Tropical Medicine*, Vol 2011:2, pp 23-30, January 2011, available: http://www.dovepress.com/articles.php?article_id=6101

[30] "Who Gives Money to the Global Fund?" Avert: Global Fund, http://www.avert.org/global-fund.htm#contentTable2.

[31] The Global Fund to Fight AIDS, TB and Malaria. Turning the Page from Emergency to Sustainability. The Final Report of the High-Level Independent Review Panel on Fiduciary Controls and Oversight Mechanisms of the Global Fund to Fight AIDS, TB and Malaria. Page 66. September 19, 2011. http://www.theglobalfund.org/en/highlevelpanel/

[32] The Global Fund to Fight AIDS, TB and Malaria. 24th Board Meeting Decision Points. September 26, 2011. http://www.theglobalfund.org/en/board/meetings/twentyfourth/

[33] The Global Fund to Fight AIDS, TB and Malaria. Turning the Page from Emergency to Sustainability. The Final Report of the High-Level Independent Review Panel on Fiduciary Controls and Oversight Mechanisms of the Global Fund to Fight AIDS, TB and Malaria. Page 17. September 19, 2011. http://www.theglobalfund.org/en/highlevelpanel/

Overcoming these problems:

1. The US Government should continue to control its own financing for malaria, targeting focus countries that agree to play by the rules and maintaining quality standards on drug quality and procurement. It must continue to use its own distribution systems where recipient governments are incompetent or corrupt. USG should encourage others (notably Global Fund) to do likewise or risk losing funding.
2. Future USG funding to the Global Fund must only continue if the Fund genuinely addresses the problems it has: the Fund should stop using UNDP in any role until UNDP provides audit reports on its spending; it must use different distribution systems when current systems have led to theft or corruption; USG should also pressure the Global Fund to prohibit medicine procurement from companies that manufacture and market oral artemisinin monotherapies[34].
3. USG should formulate policies to encourage investment in much needed new public health insecticides and to combat anti-insecticide activism.
4. USG should continue to fund the US Pharmacopea program on quality medicines through USAID. USP's PQM program is a good value for US taxpayers. This program could be expanded or at least extended in time.
5. USG should continue to boycott AMFm; indeed, it should provide regular updates on how AMFm distribution problems are negatively affecting its own programs and publicize such failings.

It is important that these actions are taken, and all entities including PMI are even more transparent (especially with information provided by contractors, which is often limited and highly redacted for external reviewers). Great progress is being made and thousands, maybe millions, of lives have already been saved. In the past, aid fatigue brought on by slack performance and measurement and sheer laziness reversed great gains made against malaria. It would be tragic if the excellent advances made against malaria in the past seven years were undermined by what are at the moment minor, but expanding, self-serving policies of African governments and producers, western producers and some western donors.

[34] See WHO for latest list of official positions of companies – some of these may not be complying with their own policies - http://www.who.int/malaria/monotherapy_manufacturers.pdf

Mr. SMITH. Dr. Bowen, please proceed as you would like.

STATEMENT OF DAVID BOWEN, PH.D., CHIEF EXECUTIVE OFFICER, MALARIA NO MORE

Mr. BOWEN. Chairman Smith, Ranking Member Payne, Mr. Turner, and members of the subcommittee, thank you for the opportunity to testify on the great strides we have made and are making toward eliminating malaria as a public health threat. Members of this committee on both sides of the aisle have been great champions in the fight against malaria and your support has helped save countless lives.

I would like to echo Ambassador Green's comment that this is an under-publicized and under-appreciated success story against a disease literally as old as humanity itself.

I am David Bowen, the CEO of Malaria No More, an advocacy organization which was established 5 years ago, at the White House Summit on Malaria. Thank you, Ambassador Green, for that very generous introduction. Yours are very, very big shoes to fill.

Malaria No More works to raise awareness and build support for the fight against malaria among policymakers, the public, businesses, and we have helped provide 2.7 million lifesaving mosquito nets. Thanks to a global partnership of government, the private sector, faith-based organizations, and community leaders across the world, there have been remarkable advances in the fight against malaria. Global malaria deaths have fallen by over 20 percent, and in less than 5 years malaria cases have been halved in over 40 countries, and childhood deaths from malaria fell by over 200,000. Yet the fact remains, the unacceptable fact remains that malaria still kills a child every 45 seconds.

To address this major health threat, the President's Malaria Initiative was launched in 2005 by President George W. Bush, with strong bipartisan support from Congress, and has been continued and expanded under President Obama. Since its founding, PMI has distributed over 30 million insecticide-treated mosquito nets, provided over 67 million lifesaving antimalarial treatments, and protected more than 27 million people as a result of indoor residual spraying.

The successes of PMI have been many, and a fuller list of examples is provided in my written testimony. But here I will mention just two. In Senegal, PMI documented a 40 percent reduction in child deaths between 2005 and 2010; and in Tanzania, child deaths fell by 28 percent in the same period.

The success of PMI is inextricably linked to the efforts of the Global Fund. In his annual report the leader of PMI, Admiral Ziemer, stated, "Coordinating PMI investments with local initiatives financed by the Global Fund is critical to the success of both the Global Fund and PMI."

Under the leadership of George W. Bush and with bipartisan support in Congress, the U.S. pledged the founding donation to the Global Fund in 2001, and the U.S. continues to be its largest single donor. By law, the U.S. does not contribute more than 33 percent of the total funding, thereby leveraging $2 from other donors for every $1 invested by the U.S. taxpayer. The Global Fund provides nearly two-thirds of all malaria funding and has provided approxi-

mately 200 million bed nets and treated 230 million cases of malaria.

Through PMI and its contributions to the Global Fund, the U.S. is helping win the battle against malaria today. And U.S. support is just as indispensable to the effort to develop new ways of fighting malaria in the days to come. A remarkable innovation in this fight, as you have heard and you will hear further, is the RTS,S vaccine which has proven that additional protection against malaria is possible.

Since the days of Walter Reed himself, the U.S. has been a leader in malaria research. And this proud tradition has been carried on with distinction by the Walter Reed Army Institute of Research which worked with GlaxoSmithKline and PATH to develop this impressive new vaccine. Sustained support for malaria R&D is crucial in developing new ways to prevent and treat malaria, as well as in combating the threat of drug and insecticide resistance.

The remarkable progress made in recent years is critically dependent on robust funding. We are making major progress toward the day in which the world can say that malaria, like smallpox, is a disease of the past. This dream cannot be realized unless U.S. bilateral and multilateral funding remains strong. Through an investment of less than 1 percent of our budget, the U.S. saves and improves millions of lives, helps build robust current and future trading partners around the world, and contributes to our national security.

Just this week AFRICOM published a statement indicating that malaria remains a direct threat to the health of U.S. personnel in that command. More indirectly, but just as crucially, widespread disease can contribute to the destabilization of a society, leading to failed states. According to the National Intelligence Strategy published under President Bush in 2005, "Failed states are a refuge and breeding ground of extremism."

Investing in global health is critical to advancing our economic interests and building jobs at home. History has shown us that today's aid recipients often become tomorrow's consumers of American goods.

Eleven of the 15 largest importers of American goods and services are former recipients of U.S. foreign aid, including South Korea, Taiwan and Brazil.

A recent African Development Bank report states that Africa's income is expected to triple in the next 50 years. African countries as potential markets for American products can only be successful if their consumers are healthy and productive.

The road to eliminating malaria deaths will not be easy. A fundamental requirement is the proper use of taxpayer funds. We must and will work against misuse of funds in any form and must also employ every feasible mechanism to guard against counterfeit or substandard medication.

Malaria No More is dedicated to achieving measurable results. That is why we have partnered with the African Leaders Malaria Alliance, ALMA, through which African nations are holding themselves accountable by scoring their progress on country led efforts and sharing best practices.

You have already heard from Ambassador Green about the leadership ALMA has shown in the fight against malaria. I just want to highlight one thing, which is the scorecard that ALMA has produced, ranking each country on their progress against definable measures.

These kinds of scorecards provide clear public evidence about who is doing well and who needs to improve. We are optimistic that with robust support from the U.S. Government, we can continue the remarkable momentum of the last 5 years and bring forward the day which no child dies of this preventable disease. As a result of U.S. leadership, more children than ever before are surviving to see their fifth birthday and spending more time in school, giving them hope for a brighter tomorrow. More parents are able to spend time working to improve the lives of their children, their families and their communities. Thank you for the opportunity to testify, and I would be happy to take any questions.

[The prepared statement of Mr. Bowen follows:]

PREPARED STATEMENT OF DR. DAVID BOWEN, CEO, MALARIA NO MORE
House Committee on Foreign Affairs, Subcommittee on Africa, Global Health, and Human Rights"
Monday, December 5, 2011, 3:00pm

Mr. Chairman, Ranking Member Payne, and Members of the Subcommittee: Thank you for this opportunity to testify on the successful progress made possible by U.S. contributions and those of our partners in the fight against malaria as well as the challenges that lie ahead. Your committee has provided strong bipartisan support for global health, and the Members of this committee have been ardent champions in the fight against malaria. You should be proud that your work has saved the lives of millions of men, women and especially children around the world. Your continued bipartisan support is needed now more than ever to sustain the progress which has been made in the fight against malaria.

As President George W. Bush eloquently stated in 2007 proclaiming April 25th as World Malaria Day, "As a compassionate nation, we are called to spread awareness about malaria -- and we're called to act. That's what compassionate people do. When they see a problem, they act." As President Obama stated before the Ghanian Parliament, "We are called to act by our conscience but also by our common interest, because when a child dies of a preventable disease in Accra, that diminishes us everywhere. And when disease goes unchecked in any corner of the world, we know that it can spread across oceans and continents."

Mr. Chairman, since the founding of our great nation, Americans have fought this debilitating disease. George Washington, Abraham Lincoln and Teddy Roosevelt all suffered from malaria. In the 1930s, 30 percent of the American population in the area covered by the U.S. Tennessee Valley Authority was affected by malaria. In fact, the Centers for Disease Control was created, in 1946, with the sole mission of fighting malaria. Thankfully, due to a robust eradication effort under the National Malaria Eradication Program, malaria was eliminated from the United States in 1951. If we remain steadfast in our resolve, similar success can be achieved in Sub-Saharan Africa.

Mr. Chairman, I am the CEO of Malaria No More, an advocacy organization which was established five years ago at the White House Summit on Malaria with the goal of helping reach near zero malaria deaths in Africa by 2015. Malaria No More works to raise the profile of the disease among the public, policymakers, and businesses, while engaging the private sector to provide life-saving mosquito nets and other critical interventions to families in Africa. Thanks to contributions from the American public and private companies, Malaria No More has distributed 2.7 million long-lasting insecticide treated mosquito nets in the past five years -- enough to protect 5 million people at risk of malaria.

Over the past five years, there have been remarkable advances in the fight against malaria. According to the World Health Organization, the estimated number of global malaria deaths has fallen from approximately 1 million in 2000 to roughly 781,000 in 2009 due to the generosity of the American people and that of many other nations around the world. Our commitment has helped to ensure that in less than five years, malaria cases have been halved in over 40 countries, and childhood malaria deaths have dropped by 200,000. The ancillary public-health benefits

resulting from these successes in the fight against malaria include reductions in co-morbidity from pneumonia and malnutrition, freeing-up health system resources and contributing to local country ownership and sustainability through capacity-building, thereby mobilizing local governments, the private sector and civil society to assume responsibility for health services. Simply put, our investments have paid off tremendously and enabled countries to engage in fighting the diseases themselves by increasing their own capacity to fight malaria.

Despite this progress, malaria remains one of the major global health challenges in the world, and specifically on the African continent, with approximately 80% of malaria deaths occurring in African children under five years of age. The human and economic toll of malaria in Africa is devastating. The mortality and health impact that the malaria burden imposes in sub-Saharan Africa, predominantly on pregnant women and children under the age of five, is well known. In addition, the malaria burden imposes a high cost on macroeconomic growth and 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 that up to $12 billion is lost in economic productivity due to malaria in Africa annually.[1]
- **Malaria is imposing costs on families that are already living on the very edge of survival**: Economic studies have shown that the total cost (direct and indirect) imposed by malaria can cost families up to 32% of household income in Malawi[2].
- **Malaria imposes an enduring legacy of lost opportunity on the children it affects:** Malaria negatively impacts childhood cognitive development, which can lead to reduced educational attainment and earning potential in adulthood. A recent study in Uganda concluded that an episode of cerebral malaria was associated with a 3.7 fold risk of cognitive impairment compared to unaffected children.

Mr. Chairman, over the past five years, the international community has come together to advocate, innovate, and deliver on key life-saving interventions. Critical innovative partnerships have been created between donor governments such as the United States' President's Malaria Initiative (PMI), developing country governments, the private sector, local communities, nongovernmental organizations, foundations, the scientific community, and the faith-based community. These stakeholders partnered over the past five years to tackle this preventable, but highly deadly disease, which disproportionately affects women and children globally, but particularly in sub-Saharan Africa. Through these efforts we have made real progress, and that is why with continued efforts and resources we have an opportunity to eliminate malaria as a public health threat within this decade.

[1] The Malaria Burden and Africa; Ebrahim Samba; WHO January 2001

[2] Ettling, et. al. Economic Impact of Malaria in Malawian households, 1994

U.S. Leadership through the President's Malaria Initiative

Mr. Chairman, the President's Malaria Initiative (PMI), launched in June 2005 by President Bush with strong bipartisan support from Congress, was established to help reduce the burden of malaria across Africa. PMI, a bipartisan initiative, is led by the U.S. Agency for International Development with the Department of Health and Human Services' Centers for Disease Control and Prevention as its major partner. The Initiative was established with a vision of five years of funding between fiscal years 2006 through 2010 and represented a $1.265 billion expansion of U.S. government resources to reduce the malaria burden and help relieve poverty in Africa. President Obama, with the continued bipartisan support in Congress, has reaffirmed U.S. leadership in the fight against malaria and his support for PMI through the expansion to two additional countries, Nigeria and the Democratic Republic of Congo. The goal of PMI is to reduce malaria deaths by 50 percent in 15 focus countries in five years. In some cases, the goal has been to reduce deaths by as much as 70 percent. PMI has assisted the focus countries to increase access to four proven malaria prevention and treatment measures: insecticide-treated mosquito nets (ITNs); indoor residual spraying with insecticides (IRS); intermittent preventive treatment for pregnant women (IPTp); and improved laboratory diagnosis and appropriate treatment, including artemisinin-based combination therapies (ACTs).

Since its establishment, PMI alone has distributed over 30 million insecticide-treated mosquito nets; provided over 67 million lifesaving anti-malarial treatments, and protected more than 27 million people as a result of PMI-supported indoor residual spraying. PMI has provided support to countries to improve the management of anti-malarial drugs and other essential medical commodities which has resulted in significant improvements in supply chain systems in all 15 original PMI-focus countries.

In addition, malaria is one of President Obama's six priority areas under the Global Health Initiative, which was announced in May 2009. In April 2010, USAID, the Department of Health and Human Services, and the Department of State released a joint "Lantos-Hyde United States Government Malaria Strategy." The strategy outlines key targets for the U.S. malaria program from 2009 to 2014. Key goals and principles include the following:

- halving the burden of malaria (morbidity and mortality) in 70% of at-risk populations in sub-Saharan Africa;
- limiting the spread of anti-malarial multi-drug resistance in Southeast Asia and the Americas;
- assisting host countries to revise and update their National Malaria Control Strategies and Plans to reflect the declining burden of malaria; and
- linking U.S. malaria efforts with host country malaria plans.

Success Stories

Mr. Chairman, five years after PMI was launched, dramatic improvements in the coverage of malaria control measures are being documented in nationwide household surveys. During the past four years, nine PMI countries, **Ghana**, **Kenya**, **Malawi**, **Mali**, **Rwanda**, **Senegal**, **Tanzania**, **Uganda**, and **Zambia**, have reported increases in household ownership of one or

more insecticide-treated bed nets from 33 to 85 percent in 2007–2010. At the same time, usage of a bed net more than doubled from an average of 21 to 50 percent for children under five years and about the same amount for pregnant women. Over the same time period, the proportion of pregnant women who received interventions for the prevention of malaria increased from an average of 24 to 43 percent.

Of the nine PMI focus countries **(Ethiopia, Ghana, Kenya, Madagascar, Malawi, Rwanda, Senegal, Tanzania, and Zambia)** where baseline and follow-up health surveys have been conducted, all-cause mortality among children under five has dropped by 16 to 50 percent. While several factors could account for these reductions in under-five mortality, according to PMI, the timing of these reductions, in close association with the massive scale-up of malaria prevention and treatment measures, strongly suggests that reductions in malaria prevalence and death are playing a major role in the improvement.[3]

In **Tanzania**, all-cause, under-five mortality fell by 28 percent between 2005 and 2010. Over the same time period, household ownership of at least one insecticide-treated bed net increased from 23 to 64 percent and usage among children under the age of 5 and pregnant women increased from 16 percent (both groups) to 64 percent and 57 percent, respectively. Nationwide prevalence of severe anemia in children six months to five years of age also fell by 50 percent between 2005 and 2010. Malaria control has also been extremely successful on the island of Zanzibar where less than 2 percent of patients at the 90 health facility surveillance sites have blood smears that have tested positive for malaria parasites.[4]

In **Senegal**, a 40 percent reduction in all-cause mortality in children under five was documented between 2005 and 2010. This dramatic reduction is due, in part, to rapid increases in the coverage of malaria interventions. Household ownership of one or more ITNs increased from 36 percent in 2006 to 60 percent in 2008. After the 2009 national ITN distribution to children under the age of five, a post-campaign survey found household ITN ownership had increased to 82 percent. The proportion of pregnant women who received two or more doses of IPTp rose from 12 to 52 percent between 2005 and 2008. In late 2007, Senegal introduced rapid diagnostic tests (RDTs) for malaria in all of its health facilities, and in 2008, 73 percent of all suspected malaria cases were tested. The U.S. Government has supported malaria control in Senegal since 1999, including $2.2 million in FY2006. For the period FY2007-2010, PMI provided $75 million in funding.[5]

In **Ghana**, in 2010, under the leadership of the National Malaria Control Program (NMCP), PMI partnered with Malaria No More UK; Comic Relief; UNICEF; the World Health Organization (WHO); Nets for Life; ADDRO, a local nongovernmental organization; and others to launch the first in a series of long-lasting ITN distribution campaigns designed to reach all the regions in the country by the end of 2011. In May 2010, more than 10,000 volunteers walked door to door in every community in the Northern Region, distributing and hanging 560,000 long-lasting ITNs to cover children under the age of five and pregnant women. In 2010, PMI contributed 955,000

[3] The President's Malaria Initiative, Fifth Annual Report to Congress, April 2011
[4] Id
[5] Id

long-lasting ITNs, logistics support, training, technical assistance, and post-campaign evaluations to the Ghanaian ITN program.[6]

Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund)

In addition to bilateral assistance for malaria, the U.S. provides multilateral assistance to the Global Fund. Under the leadership of President George W. Bush and with bipartisan support in Congress, the U.S. pledged the founding donation to the Global Fund in 2001 and we continue to be the largest single donor to the Global Fund. However, the U.S. shares the burden with donors worldwide by capping its contributions at 33% of the total contribution, which effectively leverages $2 from other international donors for every $1 invested by the U.S. taxpayers. The Global Fund is an independent international financing institution, which pools funding from donors to provide grants to low-and middle-income countries to combat malaria (as well as HIV and TB). The Global Fund has committed $22.6 billion in 150 countries, and has distributed 230 million bed nets and treated 230 million cases of malaria.

PMI and the Global Fund Collaboration

All 17 PMI countries have received significant financing from the Global Fund for malaria prevention, treatment and control programs. In its 2010 annual report, PMI stated "coordinating PMI investments with local initiatives financed by the Global Fund is critical to the success of both the Global Fund and PMI." As PMI Coordinator, Admiral Tim Ziemer put it, "The incredible progress we have made against malaria is due in large part to effective partnerships with host governments and the Global Fund to Fight AIDS, Tuberculosis and Malaria…" In addition the Global Fund provides an additional mechanism for U.S. malaria support through PMI by financing programs developed by recipient countries and by reaching many countries beyond the PMI focus and non-focus countries.

PMI works in many countries with the Global Fund, and the programs build upon and complement each other. For example, in **Liberia**, the combined efforts of PMI, the Global Fund, and UNICEF supported the procurement and distribution of malaria drugs throughout the country. PMI and the Global Fund also supported the development of a supply chain national master plan for the Ministry of Health in Liberia. In **Madagascar**, PMI collaborated with the Global Fund, the National Malaria Control Program, and other partners to distribute more than 5.6 million long-lasting ITNs (PMI provided 2.5 million of these nets) in 71 districts in the country in 2010. The Global Fund and PMI also both fund the National ITN Coordination Committee to carry out training and net distribution. In **Benin**, PMI and other partners including the Global Fund contributed to the success of Benin's ITN campaign. In the **Democratic Republic of Congo**, in collaboration with the World Bank, Global Fund, DfID, PSI, and UNICEF, PMI is contributing to substantial progress toward achieving long-lasting insecticide-treated nets universal coverage. In **Malawi**, PMI successfully piloted IRS in the central region of the country for the past three years, and as a result, the Government of Malawi scaled up the program to seven districts with assistance from the Global Fund. Finally, in **Uganda**, PMI, the Global Fund, and the World Bank were able to negotiate an agreement to address a delay in the

[6] Id

procurement of 7.2 million ITNs for a mass campaign targeting children under the age of five. The agreement allowed the campaign to move forward on time.

U.S. Leadership in Malaria Research & Development

Mr. Chairman, of critical importance, is the research and development that is being done by the U.S. government, academic and research institutions, philanthropic organizations, and the private sector to develop our current and future tools to end malaria deaths. A remarkable example, the RTS,S vaccine, has proven that additional protection against malaria is possible with the creation of new tools through U.S. leadership in research and development (R&D). The Walter Reed Army Institute of Research, in continuing the malaria-fighting work of its namesake, U.S. Army physician, Walter Reed, began development of the vaccine in collaboration with GlaxoSmithKline and PATH's Malaria Vaccine Initiative (PATH MVI) in 1987. This new malaria vaccine candidate offers hope that not only will millions of lives be saved and stability brought to countries fighting malaria; it will also increase our ability to protect our troops serving overseas in malaria-endemic regions.

U.S. government agencies have been leaders in malaria R&D, with the National Institutes of Health, Department of Defense, and USAID representing more than a quarter of global malaria R&D funding in 2009. And the private sector's collaboration with Walter Reed is not unique. Many other private sector, academic, non-governmental, and philanthropic organizations, such as the Bill and Melinda Gates Foundation, have contributed significantly to this long-term effort.

Although global funding for malaria R&D has increased over the past two decades, sustained investment is needed given the challenges of drug and insecticide resistance. This resistance means that our best drugs and insecticides are likely to be ineffective eventually, and here again, the U.S. is rising to the challenge. The National Institute of Allergy and Infectious Diseases, the Walter Reed Army Institute of Research, and many academic and private organizations around the U.S. conduct research to develop innovative new drugs and insecticides that will last longer and save more lives.

Of course, given the recent increase in treatment candidates for malaria, clinical and field-based studies are critical in evaluating the effectiveness of these new interventions. USAID plays a critical role in providing U.S.-based agencies, as well as private companies, with developing world knowledge, and PMI supports operations research into malaria interventions. In **Tanzania**, a PMI study looked into whether indoor residual spraying can be withdrawn in areas with high ITN ownership without a rebound in transmission. And PMI's partner, the Center for Disease Control and Prevention, helped to lead the RTS,S vaccine candidate trial at one site in **Kenya**.

Key Challenges

Despite the successes in the fight against malaria, several key issues present challenges to achieving the goal of near zero deaths by 2015. First and foremost, continued progress is in jeopardy without sustaining funding on a bilateral and multilateral basis for malaria prevention, treatment and control. In addition, the emerging problem of poor quality and counterfeit drugs is

putting lives at risk and contributing to incidence of drug-resistant strains of malaria. The good news is that hearings such as today's help us to shine light on the challenges, and allows us to explore solutions to become even more effective in eliminating malaria.

Funding:

Mr. Chairman, significant strides have been made in the fight against malaria over the last ten years, as noted above. Those strides could be reversed. The current economic environment clearly presents significant budgetary constraints that require immediate attention -- but as Congress faces difficult decisions in its negotiations over federal spending levels, we urge Congress to continue to provide an appropriate level of funding to ensure that the world is able to capitalize on the gains made in recent years.. We are making major progress toward the day in which the world can say that malaria, like smallpox, is a disease of the past. The promise of eliminating malaria, however, cannot be fulfilled if bilateral and multilateral funding is flatlined or substantially reduced.

As a result of strong bipartisan support over the past five years, congressional appropriations for malaria have consistently increased since FY2004, which has driven the recent successes. Congress is in the midst of critical negotiations on the FY2012 appropriations, deciding the fates of both domestic and international programs. As that debate continues, millions of lives are being saved by the less than 1% of the U.S. budget that is spent on development assistance and global health programs. Global health and other development assistance programs are on the chopping block as they are misperceived as being wasteful and contrary to U.S. national interest. That is simply not the case. Through an investment of less than 1% of the U.S. budget, the U.S. saves and improves millions of lives, reflecting America's fundamental humanitarian values. Funding for malaria is also quantifiable, meaning we can measure inputs, outputs, and the impact that our tax dollars are providing, which is critically important in ensuring we are making efficient and effective use of our resources. In addition, these programs are critical in advancing our national security and economic interests. Our country benefits from global stability — but stability is difficult in nations and regions weakened by malaria, AIDS, and starvation. As you know, Mr. Chairman, these nations are not only fragile but have the potential of becoming failed states creating a vacuum for extremism and violence, which is also why our military community has a strong interest in malaria beyond force protection.

Moreover, history has shown us that investing in today's aid recipients will help convert them to tomorrow's consumers of American exports. Eleven of the 15 largest importers of American goods and services are former recipients of U.S. foreign aid — including South Korea, Taiwan and Brazil. The U.S. Department of Commerce estimates that for every $1 billion in goods the U.S. exports, 6,000 manufacturing jobs are supported here at home. And 95% of the world's consumers live outside the United States. Research released in October by the African Development Bank shows that Africa's income is expected to triple in the next 50 years, and that most African countries "will attain upper middle income status" by then. These potential markets can only be successful if their consumers are healthy and productive.

Funding malaria control and other global health programs has demonstrated real progress, saving hundreds of thousands of lives, particularly the lives of children and pregnant women. As I

noted earlier, supporting PMI and the Global Fund has yielded real results and cutting funding will have a significant impact on people's lives. The math is as grim as it is inescapable – for every $50 million cut to global health funding from FY2011, approximately 1 million fewer bed nets will be provided and 2.5 million fewer people will receive ACT treatment for malaria through PMI.

Drug Quality:

An increasing problem throughout much of the developing world is the sale of counterfeit, adulterated, and poor-quality drugs. These drugs do not deliver the appropriate treatment for malaria patients, thus putting their lives at risk, and contributing to the emergence of drug-resistant strains of malaria. We fully appreciate the threat that sub-standard and counterfeit drugs represent to the progress being made to reach near zero deaths from malaria by 2015. We are encouraged, however, by the efforts of the U.S. government, the Global Fund, and African leaders to address these challenges, and we strongly urge them to continue to investigate these issues to shed light on individuals seeking to profit on the lives of those in dire need of lifesaving assistance.

PMI Efforts to Address Sub-Standard Quality Drugs

PMI is taking concrete steps to assist countries in addressing these challenges. It is providing support to strengthen the capacity for malaria case management, including ensuring a steady supply of high-quality, essential drugs and supplies, and providing support to train and supervise health workers in management of patients with fever. PMI also ensures that all medical commodities that are procured with U.S. taxpayer dollars undergo rigorous quality assurance/quality control testing prior to delivery. In addition, only those ACTs that have been approved by a stringent regulatory authority or the WHO prequalification program are procured with PMI funding.

In **Ethiopia**, PMI helped the Drug Administration and Control Authority establish a drug quality monitoring program. In addition, PMI supported similar post-marketing anti-malarial drug quality control programs and assessments in **Benin, Ghana, Madagascar, Senegal,** and **Uganda**. Finally, PMI also implements end-use verification programs whereby PMI funds quarterly surveys of commodity stocks in a sample of health facilities in PMI focus countries to verify that malaria commodities are available in health facilities and are reaching their intended beneficiaries. PMI has carried out surveys in 12 PMI countries and are seeing encouraging results such as in **Kenya** where, during 2010, 80 percent of 174 public health facilities visited had adequate stocks of ACTs on the day of the survey.[7]

Combating Substandard and Counterfeit Drugs: Actions by the Global Fund

The Global Fund is dedicated to preventing procurement and/or introduction of counterfeit or substandard medicines in its grant portfolio. The Global Fund employs a coordinated approach, including multiple and reinforced quality control measures throughout the supply chain, careful

[7] Id

review of pre- and post-shipment quality, and strengthened collaboration with technical partners to manage and prevent quality failures.

In order to ensure that donor dollars are used as effectively as possible in aiding needy recipients and combating the three diseases, the Global Fund takes an uncompromising stance toward counterfeit or substandard medicines. It employs a range of comprehensive strategies to prevent quality failures and constantly strives to update its safeguards.

Nonetheless, those who seek to profit from counterfeit medicines show unrelenting resolve in their efforts, and the global community must be equally determined to defeat them. African governments, PMI, the Global Fund, and other donors must continue efforts to mitigate all cases of malfeasance. These efforts are critically important to the international community's mission to save lives and promote good governance.

African Leaders Malaria Alliance (ALMA)

The African Leaders Malaria Alliance (ALMA) was launched during the UN General Assembly in September 2009 to provide African leaders with a high-level forum to promote universal coverage with effective malaria interventions. ALMA is a coalition of 41 African heads of state and government as well as the African Union, who are working to maintain momentum in Africa to end malaria deaths by facilitating the sharing of effective malaria control practices. Under the leadership of President Kikwete of Tanzania, who has served as chair for the past two years and will hand over the reins to President Ellen Johnson-Sirleaf of Liberia later this month, ALMA's member states are holding themselves accountable by scoring their progress on country-led efforts and sharing best practices to increase effectiveness in the fight to end deaths from malaria.

ALMA is partnering with stakeholders to address key challenges to universal coverage; has called on all African countries to waive taxes and tariffs on all malaria drugs and commodities; is working to prevent stock outs of rapid diagnostic tests (RDT) and ACTs; and is promoting the ban by its member-states of the production, importation, and use of mono-therapies. ALMA is taking concrete steps by ensuring regulatory measures are implemented to stop marketing oral artemisinin-based montherapies and to promote broad access to artemisinin-based combination therapies. To date, 31 ALMA member-states have banned the use of monotherapies. The ALMA Secretariat is run from Africa by Executive Secretary Johannah-Joy Phumpahi, a former Minister of Health and Member of Parliament from Botswana. She was also an Assistant Director General to the World Health Organization and Vice President to the World Bank before taking up her role as ALMA Secretariat.

Conclusion

Across Africa, individual families, mothers, and children are winning the fight against malaria. As a result, countless inspiring stories are being written across the African continent where there used to be stories of heartbreak. The statistical success has been evident across Africa. Nations across Africa have demonstrated remarkable results. But what can be lost in the

recitation of statistical success is the very real difference these interventions are making in the lives of individual people.

Children are surviving to see their fifth birthday and spending more time at school instead of being sick. Family members do not have to spend as much time caring for the sick and workers can spend more time producing at their respective professions because they are not spending multiple days per year fighting this deadly disease.

These stories serve as a reminder to the rest of the world that funding levels must continue and increase, and the miniscule amount of the U.S. budget apportioned for these programs not only saves lives, but builds futures.

Mr. SMITH. Dr. Bowen, thank you very, very much.

Now our final witness. I do thank for your leadership as well, so please proceed.

STATEMENT OF RICHARD W. STEKETEE, M.D., SCIENCE DIRECTOR, MALARIA CONTROL PROGRAM, PROGRAM FOR APPROPRIATE TECHNOLOGY IN HEALTH

Dr. STEKETEE. Thank you very much, Chairman Smith and Ranking Member Payne and Mr. Turner and other members of the subcommittee.

It is a real pleasure to be here and I appreciate following a number of strong reports from each of my colleagues here at the table. Let me highlight a couple of things. One is that this progress has also shown us the incredible speed of change and innovation as we have gone forward, and it has been done through a remarkable partnership both within this country and across many nations. The second issue that I will come to, though, is that this progress is fragile and we need to pay attention because while there is speed in change and progress, holding that and going forward with it is and will be the true test for all of us.

So just a little history: 1,000 years ago, we had just a name for this. Malaria comes from mal air or bad air, and that is what we thought caused it. It was just over 100 years ago that we actually identified the parasite and recognized that humans transmit them to mosquitoes and those mosquitoes transmit them to other humans. It was just over 50 years ago that we embarked upon a malaria eradication program globally. With actually huge success—and you may hear different stories about that—but included in that was the United States eliminated malaria. And I was 19 years old when it certified its malaria eradication in the United States with the World Health Organization.

Since that time, we actually had a hiatus after that global malaria eradication program. The scientists didn't stop working, but there were essentially no resources. And in addition to that, the global malaria eradication program had never really gone to Africa. It had left out the hardest place in the world.

At the end of the 1990s, particularly with the attention from leadership in Africa, we ended up with new leadership amongst the U.N. agencies and then that followed with resources. So this last decade, the first 5 years was essentially countries coming together and getting better plans, and we have that documented actually quite nicely.

But the subsequent 5 years mark when the money came, the Global Fund was developed, the U.S. President's Malaria Initiative and the World Bank Booster Program all came together and funding went from about $100 million a year of external assistance to malaria in 2000 to $1.6 billion in 2009 and 2010. Unfortunately, $1.6 billion is actually still relatively small, but it has made an enormous difference in what has occurred.

That is a more than tenfold increase in the funding and that has been followed by essentially a tenfold reduction in the incidence of infection and that has led to the saving of essentially 1.1 million child lives in sub-Saharan Africa in the last decade, almost all of which has occurred since 2007. The hospitalizations and the out-

patient visits for malaria have been reduced by 50 percent in at least 10 African countries and essentially almost all of the countries outside of Africa.

That burden of all of those health visits actually saves money. The number of blood transfusions has markedly reduced; and to walk into a ward that used to be full of children getting blood transfusions and today seeing that work with one or two patients, sometimes empty, is the remarkable progress that has occurred. The countries show their ability to deliver this, and that is part of the partnership that has gone forward.

So we have had many interventions out there, and we have always had concerns about whether or not this could go forward with actual country leadership and countries demonstrating that they could do the work. And as Dr. Rabinovich mentioned, the concept of 190 million bed nets into homes is a remarkable logistics effort. It is not perfect. There is still much work to be done, but that is truly remarkable.

Another issue in this is the fact that this money has gone widely, and it has come from wide places. So U.S. leadership in this and particularly the President's Malaria Initiative and the combined contribution also to the Global Fund have allowed us to do the right thing as Americans and the right thing to influence global donors because it is through the Global Fund that we have additional leverage to encourage other donors to come forward. And that has proven to be remarkable.

In addition to that, the Global Fund has reached out and essentially supported programs in, I believe, 82 countries for the malaria control and that is 82 out of the 100 nations that have malaria. With all due respect to the 18 that didn't get resources, they are the ones that are almost ready to eliminate.

So, in addition to saving more than 1 million child lives in this last decade, we also have eliminated malaria transmission in four countries and certified that under WHO leadership. We have set goals between now and 2015 to eliminate in 10 additional countries, all of which is thought to be entirely doable as long as resources are available.

Another aspect to be aware of is that some companies have invested in this, and we have actually been able to document that. Sugar industries in these countries, some mining companies, both for copper or for precious metals. Where the company provided prevention to their workforce and the families of their workforce, and then realized that the decreased number of health visits and the improved productivity of their workers meant that they got a return for every dollar invested. They essentially made back an additional dollar in lower costs and improved productivity. And that is a pretty good return on investment. So there has been a huge amount of work and investment by many people.

The financing nations, ours included, the many agencies, the scientists and the countries themselves, where we have a little bit of trouble counting the money that individual countries have put into malaria control. That is a hard number to come up with because they pay the salaries of all their health workers. They support the facilities that they work in. And it is through that and the logistics systems that are supported by external funding and the commod-

ities that are supported that actually allow them to deliver really important services.

This demonstrated and remarkable success is just as fragile as it has been innovative and fun. What we do today is actually categorically different than what we did just one decade ago. We didn't use insecticide-treated nets in hardly any homes. While we knew about indoor residual spraying, we weren't doing it. We didn't actually have ACTs to provide as the best drug. And we didn't have a good rapid diagnostic test which we have today. We actually have many of them today that we can take out into communities and know where malaria is. And as was mentioned earlier, we have cell phones that allow people to send text messages and either alert us of outbreaks or tell us about cases and their needs for the supplies that are so important. But that progress is incredibly fragile and while the speed of change is remarkable, if we let our guard down and stop the resource flow, the speed of reversion will be, I am afraid, in our face. So, as has been mentioned, this has been through bipartisan leadership in our country. It has actually been bipartisan leadership across the globe or multipartisan leadership across the globe it has been an incredible health success.

And let me just highlight the Roll Back Malaria Partnership produced and launched just 2½ months ago this document on a decade of partnership and results in malaria control. And I refer the committee to this should there be additional questions about the extent and the numbers related to the success. We do this as people and the number of us have actually come down from the American Society of Tropical Medicine and Hygiene annual meeting being held in Philadelphia. That is actually a remarkable meeting. Many of the people there are malaria experts, certainly not all of them. A number of them work in other—particularly the neglected tropical diseases. But they provide huge leadership and have for a generation now and will continue to do so for subsequent generations.

That leadership on the science side has finally turned to incredible success on the program side. And that is what makes me proud as a scientist, as somebody who cares about malaria and as an American citizen about our country's investment in this because I don't think there is any better. Thank you very much.

[The prepared statement of Dr. Skeketee follows:]

COMMITTEE ON FOREIGN AFFAIRS
Subcommittee on Africa, Global Health, and Human Rights
Testimony on Malaria,
December 5, 2011

Richard W. Steketee MD MPH
Science Director, Malaria Control Program
PATH, Seattle

Malaria Control Saves Lives – one of the very best investments in Global Health of our generation

The parasite that causes malaria, its life cycle, and its mode of transmission were identified just over 100 years ago. In the 1950s and 1960s, the global public health community attempted an ambitious program to eradicate malaria, which produced many successes in countries but never reached its stated global goal. In the decades that followed, malaria became an enormous problem, unchecked by any substantive program interventions. In the 1990s, the malaria science community recommitted itself to identifying, testing, and demonstrating the efficacy of a set of improved affordable interventions that could be delivered on a wide scale to homes and communities. And, in 1997, African Heads of State made a call for a renewed effort against malaria in the Harare Declaration on Malaria.

Building on the enthusiasm for effective interventions and in recognition of the enormous growing burden, the Roll Back Malaria (RBM) "movement" was launched in December 1998 with leadership from the World Health Organization (WHO), the United Nations Children's Fund (UNICEF), the World Bank, and the United Nations Development Program (UNDP). As RBM was organizing and a new millennium beginning, the year 2000 was taken as the baseline for measurement of the anticipated progress. Momentum grew over the next several years, but it was the remarkable increase in investment by global donors and multilateral agencies beginning in 2005 that transformed partners' collective understanding of what was possible. Many donors had long supported countries in their malaria control efforts, but major shifts in the mid-2000s changed what was possible and inspired an urgent sense of responsibility to bring this deadly disease to a halt, and simultaneously contribute to the achievement of the Millennium Development Goals (MDGs).

From modest beginnings, the RBM Partnership has rapidly evolved into what it is today: a superior example of global partnership with ambitious, yet achievable, aspirations. A disciplined commitment to strategy, evidence, and the prioritization of country support and leadership were central partnership principles that were fuelled by funding sufficient to bring about impact.

Major changes have occurred in every aspect of malaria control since 2000, including the control measures themselves, global and national policies and strategies, partnerships, financing, and systems for monitoring program scale-up and progress. The evolution of new tools (such as long-

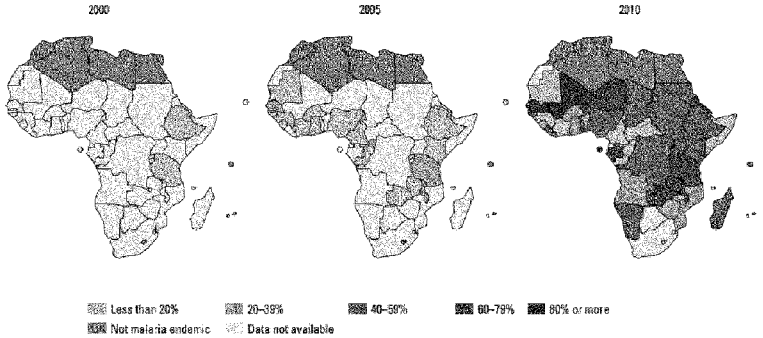
lasting insecticide-treated nets, rapid diagnostics, and better drugs) and new strategies (scaling up for impact, expanding from a narrowly targeted approach to reach all at risk, and targeting elimination where possible) indicates a partnership that has quickly matured and responded to diverse and rapidly changing needs and situations. Moreover, the partnership has placed the greatest attention on Africa where the infections, illnesses, and deaths from malaria make up more than 85 percent of the global burden.

Around the world, many countries have rapidly scaled up their programs and compiled remarkable evidence of impact. This represents clear evidence that the malaria control community, led by national governments and their national malaria programs, can deliver the services to people in need (Figure 1 shows this dramatic change in the last five years).

Figure 1

Proportion of households with at least one ITN, based on the latest survey data available by the end of 2000, 2005 and 2010

Steep increases were seen in the proportion of African households with at least one ITN.



Countries have accomplished this with substantial national leadership and hard work and with a broad partnership supporting them. This partnership—the RBM Partnership—has evolved as a range of collaborative national, regional, and global partnerships. Its underpinnings include high level political support from the UN Secretary General's Special Envoy for Malaria, technical guidance from the WHO Global Malaria Program, remarkable growth in program financing from key donors (the Global Fund to fight AIDS, Tuberculosis and Malaria [Global Fund], World Bank, the US President's Malaria Initiative [US-PMI], UK Department for International Development [DFID], the Bill & Melinda Gates Foundation, and others), development of new interventions by the science

community and private sector, and support for program action by national and international nongovernmental public health organizations.

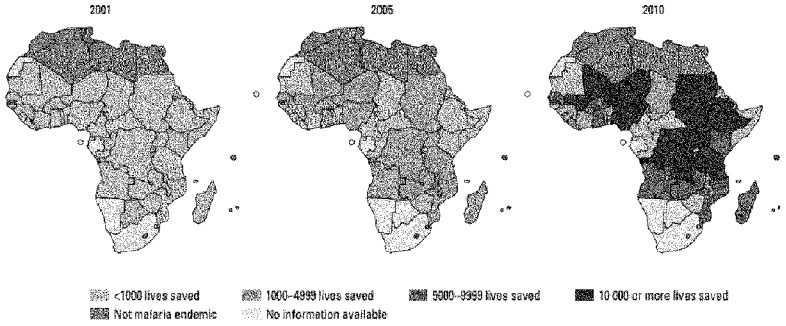
It is this powerful partnership that has established the foundation on which malaria control today is achieving unprecedented results, including:

- A more than ten-fold increase in resources available for malaria control since the beginning of the decade, with most money raised over the past three years.
- An estimated 1.1 million child malaria deaths averted in sub-Saharan Africa since the start of the RBM Partnership (see Figure 2).
- A more than 50 percent reduction in malaria cases and deaths in more than ten African countries that achieved substantial intervention scale-up.

Figure 2

Estimated number of children's lives saved by malaria prevention in 2000, 2005 and 2010

Using the Lives Saved Tool (LiST), a health impact model that estimates the under-five child mortality impact of key interventions based on coverage data from surveys and intervention efficacy from randomized controlled trial research, modelled estimates suggest that compared to mortality in 2000, a substantial number of child malaria deaths have been prevented each year and this has occurred largely since 2005. In 2010 alone, an estimated almost 300 000 child malaria deaths were averted in Africa due to malaria control.

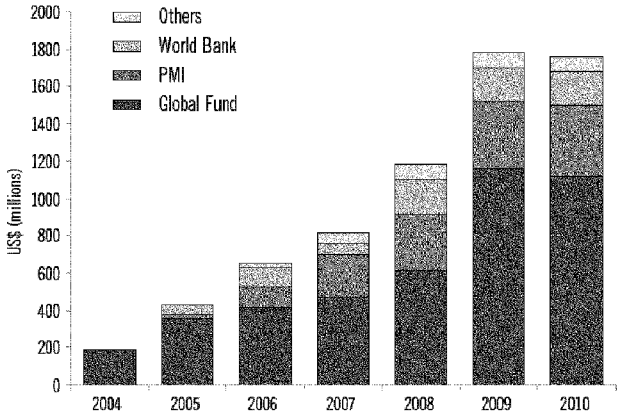


Source: LiST modelling done by Tulane University School of Public Health and Tropical Medicine and Johns Hopkins University Bloomberg School of Public Health, based on Stover J et al., 2010.[22]

- A more than 50 percent reduction in malaria cases and deaths in the majority (but not all) of the malaria-endemic countries in the other (non-African) malarious regions of the world.
- Four countries over the past four years (United Arab Emirates, Morocco, Turkmenistan, and Armenia) certified by WHO as having eliminated malaria—the first countries to achieve this distinction in 20 years.

Global funding of malaria control clearly has been one of the most productive health investments ever. The following figure shows the dramatic increase in commitments for malaria control globally from the three main donors (the Global Fund, US-PMI, and the World Bank) and other partners. The increase starting after 2004 has led to the interventions being delivered and lives being saved.

Figure 3
Funding commitments for malaria from the Global Fund, the U.S. President's Malaria Initiative, the World Bank, and Others – (2004 –2010)



But the work is still far from done. Some countries have not yet begun to fully scale up malaria interventions; other countries that have scaled up are now struggling to achieve the efficiencies required to sustain high coverage rates and to take next steps to further reduce malaria transmission, illness, and malaria-associated deaths. And the global partnership is challenged by the global economic downturn and donors' shifting funding priorities, placing at risk even this successful health initiative.

Based on the successes to date, the RBM Partnership has updated its goals for end-2015 to align with the MDGs, identifying the elimination of malaria deaths, the marked reduction of malaria cases, and the elimination of malaria transmission in ten countries and the European Region as major objectives. Indeed, the next phase of the RBM Partnership is upon us. It will require yet another remarkable effort in the near term, requiring significant financial, technical, and human resource commitments from countries and all existing and new partners.

Key Messages

Message 1. Rapid intervention scale-up has resulted in remarkable global and regional reductions in malaria illness and death. The first decade of Roll Back Malaria has witnessed remarkable impact of malaria control in countries where interventions have been scaled up. Child survival has improved around the world and across Africa. Estimates provided here suggest that malaria prevention has contributed to saving more than 1 million children from a malaria death in Africa since the inception of the RBM Partnership. National population-based surveys, facility surveys, routine health information, and special studies demonstrate consistently fewer malaria cases, less anemia, and fewer blood transfusions, less severe disease, less death, and marked reduction in transmission including elimination of malaria in three countries.

Malaria control impact was achieved across all endemic regions:[1] Global goals focused on reducing the burden of malaria by one-half have brought about dramatic impact in all regions.

In the African region: Malaria control has saved the lives of more than 1 million African children from malaria deaths between the creation of the RBM Partnership and the launch of this report. In countries with substantial scale up of interventions, remarkable progress has been seen and at least 11 countries have recorded a more than 50 percent reduction in cases or deaths due to malaria.

In the European region: There has been remarkable progress in malaria control; malaria mortality has essentially been eliminated and the region is poised to eliminate transmission in the coming five years.

In the Americas: The majority of countries have demonstrated substantial progress and more than one-half have achieved a more than 50 percent reduction in malaria cases and/or deaths.

In the Eastern Mediterranean region: Remarkable progress has occurred here with elimination having been achieved in several countries and marked progress in others. But some larger countries with considerable burden such as Sudan and Somalia have experienced limited progress over the decade linked to political and economic strife (however Sudan is reporting very recent successes in scale-up of malaria control).

In the South-East Asia Region: Half of the ten malaria-endemic countries have shown a greater than 50 percent reduction in cases or deaths; but several large countries and/or

[1] This report uses WHO Regions.

heavily populated countries such as India, Bangladesh, Indonesia, and Myanmar still suffer a considerable burden.

In the Western Pacific Region: Half of the countries have achieved a greater than 50 percent reduction in cases or deaths; but again, major scale-up efforts are required in countries such as Cambodia and Papua New Guinea to advance regional progress.

Message 2. The malaria control landscape has been transformed in the last decade. The first decade of Roll Back Malaria has seen a major change in every aspect of malaria control including global and national policies and strategies; partnerships; financing; interventions—including new systems for insecticide-treated nets (ITNs), indoor residual spraying (IRS), prevention in pregnancy, diagnosis, and treatment; and systems for monitoring program action and progress. Malaria control today is unrecognizable from just ten years ago and we can anticipate that this rapid pace of change will continue and be required in the coming decade to sustain and grow the impact.

Evolution in the RBM Partnership: The RBM Partnership emerged in a global public health context where partnerships were seen as the way forward, yet there was limited experience with core requirements for effectiveness. Today, the RBM Partnership offers a robust platform for discussions and harmonization of partners in malaria programming, resourcing and advocacy, and its structure and function appear to be one of the stronger partnership examples in global public health—undoubtedly aided by its experience and focus on country work.

Improvements in malaria control policies and strategies: Between 2000 and 2010, countries moved aggressively to align their malaria control policies with WHO recommendations and to embrace the global strategy as laid out in the Global Malaria Action Plan and to respond to the UN Secretary General's call for achieving universal coverage, particularly with ITNs in sub-Saharan Africa. Policies initially targeted the most vulnerable populations (women and young children) but have evolved to address entire populations in order to reach all people at risk, especially those potentially transmitting infections to others. And, because of the recognition that malaria prevention is a global public good and that the poorest must have access, there has been a dramatic evolution to provide interventions that are affordable (often needing to be free) to the end user.

Growth in malaria control financing: Starting in earnest by the middle of the decade, financing commitments and disbursements for malaria control increased seven- to nine-fold, although they remain below required levels to achieve full scale-up across endemic countries. Funding increases have resulted in marked increases in program coverage resulting in considerable health impact. This success is fragile and inextricably tied to funding; in some areas, gains were quickly lost when financing fell off. Particularly in the current unstable global economic environment, consistent and sufficient funding is required to ensure continued success.

Improvements in interventions and delivery systems: During the course of the decade, interventions have changed. ITNs are now long-lasting ITNs (LLINs) and don't need retreatment. IRS is much more widely applied beyond urban and peri-urban settings and protects many more families. Intermittent preventive treatment for pregnant women (IPTp) and ITNs reach many more pregnant and reproductive-age women through antenatal clinics. With recent clarity on the quality, utility, and decreasing price of rapid diagnostic tests (RDTs), WHO now recommends universal diagnostic testing of suspected malaria with RDTs as a first line diagnostic test in peripheral health facilities and in communities, representing a true paradigm change for malaria control. Much more effective treatment with ACTs has reached wide-scale acceptance, distribution, and use. Finally, additional new interventions are poised to help even more: recent evidence from malaria vaccine trials shows important promise; new drugs are under development and testing in the field; new diagnostics are also becoming available.

Improvements in measuring progress: In 2000, there was a distinct lack of information to guide programs. Over the decade, attention to the collection and synthesis of accurate information has blossomed. A "malaria module" was introduced into national surveys (DHS, MICS) and the Malaria Indicator Survey facilitated data collection where these other surveys were not available. National surveillance systems have been pushed to improve timeliness and quality of information. Malaria diagnostic testing is transforming surveillance as countries change to reporting "confirmed malaria" rather than "suspected malaria" or simply "fever presumed to be malaria." New phone and internet technologies are facilitating novel approaches to surveillance that incorporate real-time feedback to front line health workers. And, as transmission is reduced, it is this improved surveillance and timely local information that will be critical to further contain and ultimately stop malaria transmission.

Message 3. Policy and action supporting intervention scale-up is broadly accepted and prioritized as integral to stopping malaria. Efforts to achieve universal intervention coverage, as declared by the UN Secretary General in 2008 have been a shining success in many countries.

Vector control: To date, near-full coverage of populations with LLINs has been achieved in many African countries. IRS has been markedly expanded as well in many countries. But some countries remain in the early stage of scale-up; and resources, infrastructure, technical capacity, and commodities are required in those countries to achieve and maintain high coverage.

Prevention in pregnancy: While policy adoption for the prevention of malaria during pregnancy progressed rapidly during the decade, coverage of women with IPTp has been slower and not as well supported as might have been possible. Efforts in this area need to be redoubled to protect susceptible women and their newborns.

Diagnostic testing: In 2010, WHO recommended diagnostic testing for all suspected malaria cases prior to treatment. This is revolutionary for the field of malaria control—both knowing where the malaria is and treating confirmed malaria rather than all febrile children. It is anticipated that, as with other recommendations, the full adoption of this policy into daily practice will progress rapidly.

Case management: While policy adoption for malaria treatment with ACTs has progressed rapidly, deployment and coverage with ACT treatment has been slow until the last two years. Recently, several African countries have turned the corner and treatment using ACTs is becoming the standard practice. Aligning appropriate treatment with confirmed malaria and reaching all those in need remain important next steps in malaria control.

Message 4. The continual upgrading of the RBM Partnership's goals, objectives, and targets is a demonstration of progress. The 2011 update of the RBM Partnership's malaria control vision and objectives tightens the focus specifically on action required to achieve the 2015 MDGs. There have been four updates over the course of the decade and this recent update, with its increasingly ambitious targets, highlights the sense of urgency accumulating as countries build on their successes.

RBM Vision, Objectives, and Targets updated in 2011

Vision: Achieve a malaria-free world.

Objective 1. Reduce global malaria deaths to near zero by end-2015.

Objective 2. Reduce global malaria cases by 75% by end-2015 (from 2000 levels).

Objective 3. Eliminate malaria by 2015 in ten new countries and in the WHO Europe Region.

Targets include: Achieve universal access to and utilization of prevention measures; sustain universal access to and utilization of prevention measures; accelerate development of surveillance systems; achieve universal access to case management in the public sector; achieve universal access to case management and referral in the private sector; achieve universal access to community case management of malaria.

Message 5. Continued success requires building on what works, rapidly anticipating the need for and developing new strategies and tools, addressing threats head on, and ensuring that successful investments are not lost due to global competing priorities.

Build on what works: The rapid impact of population-based intervention scale-up is now well-established. Strengthening the intervention delivery planning processes, procurement and logistics and supply systems, and financial management mechanisms remains essential

to further progress. In addition to ensuring continued universal coverage of LLINs (and IRS where appropriate), special focus on increasing coverage of IPTp, diagnostic testing, and treatment is required.

Rapidly anticipate the need for and develop new strategies and tools: This next decade is likely to bring us a first malaria vaccine, new diagnostic tests, new drugs and drug combinations, new insecticides and new ways to deliver them, and new enthusiasm for reducing and containing malaria to smaller and more focal areas and then eliminating those foci as well. These new and emerging tools will introduce challenges for countries and partners in keeping national policies updated, allocating needed budgets, and implementing more and more at local levels.

Directly address threats to progress: There will be threats to the progress in malaria control. These include: waning efficacy of tools; challenges inherent in supporting large, complex countries that are early in their efforts to scale-up or countries with political instability or conflict; strengthening systems for both scale-up and keep-up efforts; supporting countries to further reduce transmission and enter pre-elimination or elimination work; and providing predictable support in an environment of fluctuating global health resources.

Ensure that successful investments are not lost due to global competing priorities: Malaria control has been an excellent investment. Sleeping under an ITN and having a home sprayed with insecticide are now normal expectations in many millions of households and in most national malaria control programs. But if financing commitments falter, these gains will quickly be lost. RBM partners must continue producing results and communicate these successes to decision-makers in and beyond the health sector so that it will be unthinkable to reduce global commitments of support. As with global immunization, this set of essential and highly effective child survival interventions must become uniquely prioritized in a way to guarantee that they are always in reach for the poorest and most rural or marginalized at-risk populations.

Sustain investments in research and development of new tools: The recent successes in malaria control are due in part to past investments in product development, whether safe and effective insecticides, improved drug treatments, or diagnostic tests. Knowing what we do about the adaptive abilities of the malaria parasite and its mosquito host, maintaining the flow of funds for the development of the tools of tomorrow is imperative, whether new classes of insecticides and drugs, more accurate diagnostic methods, or (assuming a first vaccine is within reach) a more highly effective, second-generation vaccine.

Political momentum, particularly among the endemic countries, will be essential to maintain the gains and keep malaria high on the international agenda. The recent formation of the African Leaders Malaria Alliance (ALMA), a coalition of 39 African Heads of State focused on ending deaths from malaria represents a groundbreaking opportunity to ensure that successful investments are maintained.

Status of Funding: The Critical Role of the United States and the Global Fund to Fight AIDS, Tuberculosis and Malaria

The combination of the global economic crisis and competing global health priorities has created an acute crisis in the continued financial support of the Global Fund. And, like many health sector programs supported by the people of the United States, the U.S. President's Malaria Initiative is at risk even when it has demonstrated excellent progress. The most recent Global Fund Board Meeting (November 2011) led to decisions to revise the strategy to further limit financial support risk because funding was simply not available; this puts successful malaria control programs on the brink of losing ground after demonstrated success.

Mr. SMITH. Thank you very much, Doctor.

Let me begin with the questions. And again, I want to thank all of you.

Your full testimonies, without objection, will be made a part of the record, and they are very much filled with recommendations and good data that this subcommittee, and all interested parties here in Congress, ought to become very well acquainted with.

Let me begin with Ambassador Green, if I could. You spoke of leadership, the importance of it, and others who might want to step in and speak to this as well, please do. How much U.S. funding is needed in the immediate term, this fiscal year, and going out into the near term, to ensure that there is no speed of reversion that I think we have to be very concerned about. We are in combat, as Dr. Rabinovich said, with the danger that this terrible parasite, as you put it, malaria, fights back and recent gains could be lost. I thought that was very telling and obviously very true.

So if you could start with that. And secondly, Ambassador Green, you talked about the malaria early epidemic detection system. You talked about how MEEDs has been created and how well it worked. And I am wondering if this best practice is being replicated—and if anyone else would like to touch on it? Anywhere else, it seems to me when you prove something and prove it well, it ought to be rolled out as quickly as possible.

Then you also spoke about the importance of faith-based collaboration, and I, too, believe that with the HIV/AIDS pandemic, without full cooperation with the faith-based community, particularly in Africa, where it represents 70 percent of all health care that is delivered via a health care institution or clinic. To bypass that would mean that fewer people get antiretrovirals, in the case of HIV/AIDS, as well as testing and all the other important things. You highlighted how the Catholics and the Muslims are working so well together to train 300,000 imams, priests, pastors and ministers to carry out the malaria prevention message to villages throughout Nigeria.

If you could maybe elaborate on that a bit, because it seems to me that is not only an important health care initiative but also mitigates some of the unnecessary and deleterious animosity between Muslims and Christians in Nigeria, where there has been a flare up, as we know, in recent months and years.

Ambassador GREEN. Well, thank you, Mr. Chairman.

I will attempt to partially duck the first two questions you asked, particularly with respect to funding. What I would rather do is defer to my colleagues. And Dr. Bowen can talk to you a bit about the state of funding and the funding request. What I can say is that what separates the malaria challenge and our approach to it from some of the other challenges and choices that, respectfully, you face and you face here in Congress is, again, we know precisely what to do; that this is a question of our willingness to invest the necessary resources. Again, technologies are fairly proven. It is a financial challenge and a challenge in our commitment and leadership.

A name that has come up a couple of times in the testimony that I would commend to you is Rear Admiral Tim Ziemer, the head of the President's Malaria Initiative, who I believe is an outstanding

leader in not just global health, but also in logistics. And what he can tell you is, take a look at the map of Africa and tell you in those countries in which PMI is operating, precisely what we—we being the world community—will get for the investment of resources. In other words, you can boil down to the bed nets that can be purchased, the rounds of indoor residual spraying that can be purchased, precisely what we will be able to get with resources invested.

He can also tell you geographically, and one of the things that I think is remarkable about his leadership is when he takes a look at that map, he is able to tell you precisely what we need to be able to go into certain countries and add them to the list of those nations that will see a reduction in malaria of 50 percent or more.

And the same is true with respect to your second question. MEEDs was a project that was developed and piloted in cooperation between the President's Malaria Initiative, the country director, Dr. McElroy, working in Tanzania with public health leaders in Tanzania and Zanzibar, in particular. And it was launched just a couple of years ago but, again, has already shown remarkable progress. One thing you can count on from Admiral Ziemer is that he will, in fact, take and use those best practices and spread them wherever we can.

One of the things that maybe—one of the reasons it was pioneered in Zanzibar—is because we had seen such progress down to the point of below 1 percent infection rate. And the question was, what does success look like? You know, when is it that we can say we have crossed the goal line. MEEDs is an effort to do just that. MEEDs is an effort to take the remarkable efforts that have been made, lock them in and to take those final steps to stamp out whatever, God willing, minor infection outbreaks that we see.

With respect to the faith-based story, Nigeria in particular, but in other parts of Africa, it really is remarkable, just as you pointed to. It is remarkable for two reasons, or its advantages are really twofold. In terms of being able to deliver a product, I was always amazed as Ambassador when organizations from the West would come to me and talk about reaching out to other parts of the country and having no concept whatsoever about the logistical challenges that that presents. These are remote areas that are oftentimes completely cut off in terms of modern media access, in terms of the traditional infrastructure that, you know, we have become accustomed to. Faith leaders, of course, are well established in every corner of the land. So when you are able to enlist the armies of compassion that come from our faith leaders, you have a built-in distribution network that can move product very quickly.

But the other part to it, that I really want to focus on, is faith leaders are able to pierce through the lack of education and knowledge that in some ways is the most daunting challenge that you face in some countries. When I taught school in Kenya, my students were absolutely convinced you got malaria from rain. And you could see how they would jump to that conclusion, and that would be relatively harmless, except if it comes from rain, why would you sleep under a bed net? So enlisting respected faith leaders, whose voice and opinion is held in high regard and trusted and listened to, they are able to pierce through that.

I faced a similar situation last year when I went to Liberia, and part of the reason for that was with Malaria No More, where we did a focus group and asked young mothers why they didn't sleep under a bed net. And a lady said to me that she couldn't sleep under a bed net because at night when her spirit left her body and went out into the village, that if she slept under a bed net, it might not be able to come back. An American recovering politician can say over and over again, that is not what happens, and that of course is to no avail. But when the local faith leader comes and says, this is why we need to do this, that is the voice that makes a difference.

The Nigeria story is the most remarkable in terms of numbers, and it really is a model to hold up as a success. And I think we all owe a debt of gratitude to the Center For Interfaith Action Against Global Poverty, another Gates funded institution, which has spearheaded this from our perspective. But the best news is it is not just confined to Nigeria. The story is in many other parts of the continent as well.

Mr. BOWEN. If I might just pick up on two points from Ambassador Green. First, very briefly, on the faith-based organizations. I, until quite recently, worked for the Gates Foundation. And one of my most memorable experiences there was traveling to northwest Nigeria and working with the sultan and the amirs. And I had the privilege of being able to address a meeting called by the amir of Gwandu in a room that felt like it was about 120 degrees, where the entire leadership from northwestern Nigeria was there. And when the amir said, you know, please cooperate with the polio vaccination campaign, that message went from the amir, to the district's head, to the village heads. It is an extraordinary reach. Just on the funding.

We certainly strongly support the President's request of $691 million for PMI and $1.3 billion for the Global Fund. And the math here is grim, but inescapable. For every $50 million cut under the 2011 levels, that means a million fewer bed nets distributed and 2.5 million fewer combination therapies.

Mr. BATE. I would concur with my panelists that the funding request from the PMI should indeed be met as best as possible. I think we also need to think tangentially about funding efforts that will improve malaria treatment.

And so I will refer to the remarks I made before about USAID's funding of the U.S. Pharmacopeia project on quality medicines, an extremely important role in building up. They have the competence to help the medical regulator authorities in these countries that is very important to control for quality of drugs.

Where I may part company is on the funding of the Global Fund. I think the Global Fund is a fantastic organization, but recently, the high level independent review panel recommended that the Global Fund—and I quote—"mandate the outsourcing of drug storage and delivery as the norm, except where the fund certifies a local institution according to international standards." At the Global Fund's 24th board meeting, it merely decided to give consideration to this recommendation rather than begin its implementation.

In certain parts of Africa, where my colleagues and myself to a certain extent, have looked at the private sector ACTs markets. In one study we published in the peer-reviewed literature, 28 percent of the drugs on sale, the ACTs on sale in the private sector, were stolen and diverted from the public sector. That is because of poor management.

Now, I think that the U.S. should be pressuring the Global Fund as far as it can to not only look into the recommendations of that high-level panel but actually enact them or perhaps potentially restrict the funding from the U.S. Government.

Mr. SMITH. Dr. Schmatz, you identified, as did other panelists, the growing threat of resistance to artemisinin as a key challenge to controlling malaria.

Dr. Bate, you talked about monotherapies, and that 6 years ago the WHO demanded that manufacturers stop making and selling artemisinin monotherapies. And you point out that producers in China, India, and Vietnam in particular, ignored WHO policies and demands and continue manufacturing these drugs.

And, Dr. Bowen, you also talk about drug quality in your testimony, and you note, I think, some progress being made. But what about those countries that continue? It seems to me that China, which increasingly is garnering the market on the manufacture of drugs of all types, you know, this could be a serious detrimental effect of trying to use the ACTs, as you talked about in your testimony? Why are the WHO policies being ignored and resisted by these manufacturing countries?

Mr. BATE. The extremely good manufacturers in China and India and perhaps in Vietnam—I know them less well—are brilliant at getting their products into the market. And that is one of the reasons why there are so many different brands and so many good antimalarials out there. And that needs to be stressed. And I probably should have stressed that before.

The problem that you identified correctly is that they are not adhering—some of the manufacturers are not adhering to that. The only immediate thing I can think of doing is to in every sense limit donor support for any manufacturer that is selling a monotherapy, even if it is also selling an ACT. So do not fund the ACTs from those manufacturers that still are in breach of the guidelines. That is the only short-run thing I can think of doing.

Mr. SCHMATZ. One aspect of that that I think does work is that for the Global Fund and other donor organizations, in many cases, countries cannot buy drugs that are not pre-qualified by WHO. And so I think that is a really important standard to set and to stick with. I mean, not that you can totally enforce that everywhere. But the funding that is used from these donor organizations, if it can't be used for those other products, it won't be. And at least they will focus you toward the ones that are quality drugs.

Our mandate in everything we do is to focus on quality drugs that are approved by rigorous regulatory agencies, like the FDA or the DMA, and all the things we are bringing forward in the future and make sure those quality standards are met and that again those drugs would be pre-qualified by the World Health Organization to be the ones that could be bought with those funds. It is

much more difficult, of course, in country to deal with drugs coming from other sources.

Mr. BOWEN. And I would add just one comment which is that the ultimate response to resistance is really two-prong. One prong is to implement the safeguards that were identified against the use of counterfeit and substandard medications, but this is ultimately an arms race with the disease itself. And you can slow the pace of that through adequate controls, and we certainly should. But the other prong of the response is robust research and development so there is a constant stream of new approaches and new treatments.

Ambassador GREEN. Mr. Chairman, just a couple of quick additional thoughts.

You have put it the right way with respect to monotherapies, and that is focusing on the producers. Some might be tempted to ask, why can't we ban these in-country? Of course, the difficulty is if you are a poor family in Tanzania and you have access to a monotherapy of artemisinin, which you are told will, in fact, address malaria for you, although in the future, it may lead to resistance, but it is much less expensive; it is very difficult to expect that family not to take the less expensive drug because, of course, in so many cases, they have profound challenges of poverty. So you are focusing on this issue in the right way.

Secondly, I would hearken back to ALMA, the African Leaders Malaria Alliance, and really the banding together of heads of state from all across Africa has been a remarkable development and I think offers great hope in this area. Dr. Bowen put up the scorecard.

I have been very impressed with how strongly they have tried to share best practices and quite frankly hold themselves and their colleagues accountable for those standards. So, again, I think the emerging African leadership does offer some real hope in this area.

Mr. SMITH. Dr. Steketee, in your testimony you raise so many questions. You all do. Time does permit—we will submit a number of written questions for all of you. But, Dr. Steketee, you, in your Message No. 3, talk about prevention in pregnancy and you point out that coverage of women with intermittent preventive treatment for pregnant women has been slower and not as well supported as might have been possible. Efforts in this area need to be redoubled to protect susceptible women and their newborns. We all know that malaria contributes to 8–14 percent of low birth weight in malaria endemic countries. Obviously, that decreases significantly the child's chances of survival. And I am wondering what your recommendations would be there. Is that something that from a policy point of view has not been emphasized?

Dr. STEKETEE. Thank you very much for that question. I actually spent much of my science career looking at malaria and pregnancy and its prevention. It is interesting. This is actually a relatively easy and low-hanging fruit, and where people have paid attention to it, the programs have done quite well. That is, we have gotten both the insecticide-treated nets and the intermittent preventive treatment to those pregnant women.

It is typically administered through existing antenatal clinics, and antenatal clinics actually are some of the best attended health facilities by the target population. So the women come, and one of

the challenges has been that it has been just a little off the radar. It hasn't been quite as important as the insecticide-treated nets or indoor residual spraying. And everybody, of course, needs drugs to treat the acute infection. And it is relatively inexpensive because it is two doses, maybe three doses in the course of a pregnancy of sulfadoxine/pyrimethamine, which is one of our least expensive drugs out there. And we are looking for new drugs as well.

But in the scheme of things, having said that, this was actually raised at the Gates Malaria Forum last month. And it was highlighted, and there is a process underway as we speak about looking at some of those policy issues and some of the performance issues in solving them, and experience says that they are relatively easily solved. It is just a bit more attention that needs to be paid.

Mr. SMITH. Dr. Rabinovich.

Dr. RABINOVICH. Yes, actually, tomorrow morning at 7 o'clock o'clock in the morning, in Philadelphia, a meeting of the partners will occur because I think this one fell off the radar due to lack of attention. The drug is cheap. This is really doable. Prenatal care is happening. It should be delivered, and the resources exist because of the Global Fund and PMI funding in country. So we just need to make sure we pay attention, work with the leaders and hold ourselves accountable. And tomorrow morning we are on our way.

Mr. SMITH. Thank you.

Mr. SCHMATZ. I just want to comment on the resistance question that you asked earlier, and that is I think one of the big problems we have with the current resistance we are starting to see in the ACTs now is the drugs that are—the combinations in those, those fixed-dose combination drugs, all of those components at one time were used as monotherapy well before the time when people decided—actually it was HIV that kind of led into the understanding that putting two different drugs and two different mechanisms together, you can delay resistance against both of them and extend the life of both of those drugs.

We unfortunately didn't have that luxury in the malaria world because the ones we had available to do these combinations with had already been used quite frequently before that for many years as monotherapy, leading to resistance of both of them in the parasite population. So when you put them together, there is still that potential for that. The goal now going forward is the new drugs we develop need to be made as fixed-dosed combination immediately and never be sold and available as single entities. That would definitely extend the life of any of those new drugs that we develop going forward.

Mr. SMITH. Dr. Rabinovich, you mentioned that we are much closer to having a malaria vaccine that works through significant efforts by the Malaria Vaccine Initiative and many partners. You said it is possible that the malaria vaccine will be available by 2015. Now is that possible or probable? And how far are we in terms of—and, Dr. Bate, you talked about this and all of you did really—the whole resistance problem? At what point does our current ACT treatment, or whatever the best treatment is, become obsolete? We are in a race with time. How much of a race are we in?

And finally, to Dr. Rabinovich, if I could, you said the Gates Foundation also invests in the development of new drugs and methods to control mosquitoes. The BBC in August—and I am sure you all saw it—did an article about a spermless mosquito holding the promise to stop malaria. And, of course, it talked about developing 10,000 mosquito embryos with tiny fragments of RNA designed to turn off the gene that is essential for normal sperm development in mosquitoes. Is this something that is promising? Do we give much weight to this as a way of controlling the very population of mosquitoes?

Dr. RABINOVICH. Thank you for those questions. Let me take them one at a time. The first question you asked is about a vaccine. And the results that were published in October are the preliminary results, just the 1-year result of the RTS,S vaccine, which has been tested in—at 11 sites, 7 countries in Africa. That trial is ongoing. And I think for full transparency, the first year results were presented. But really we need the full results, not only from the toddlers but from the babies that were just recruited. And we are going to have those results able to look at in 2014. Now, it needs to be evidenced-based. If it works and it protects children for a number of years, we want to make sure there is no rebound. It is something that the advisory committees, the WHO and the countries will consider for use.

But it is not a perfect vaccine. The evidence so far is that it is about 50, 55 percent efficacious at preventing malaria and preventing clinical illness from malaria. So we are going to have figure out how that compares and how it adds to bed nets and to the other measures that are available when those data are available. So the story still is still to be told, but it is the first time that we have really shown in a large enough population is that you can have an impact with a vaccine.

The second question you asked was about resistance. And the place where resistance has been shown has not been in Africa. We are all scared to death that it will actually move over to Africa. Historically, resistance for reasons that are not totally clear to us I think have begun in Vietnam, Thailand, Cambodia and Asia and then migrated over to India and then hopped right over into Africa. It was recognized by planned studies looking for resistance. These have to be small piloted studies to evaluate how well the drugs are working, recognized along the Thai-Cambodia border. And the partners of bilaterals have gotten together to actually work to decrease the amount of malaria there, ideally eliminate it, because of fear it would move onward, and that really is a global crisis if it did. We would lose ACTs.

We are very excited about the portfolio that sits at MMV. You call it OS. I call it "Oz" because it would really be a wonderful thing to have. But they are not available yet, and so we really have to pay attention to resist intense ACTs today. The third thing you asked was about mosquitoes. And I think it is important to consider innovation, not only in new drugs and vaccines but also in ways to control mosquitoes, because we know that bed nets right now—bed nets and indoor residual spraying are at the core of our impact in Africa today. And there are several approaches.

The one that you refer to is they have genetically modified the mosquito so that it cannot be reproduced. That is one idea that is being tested.

Another is to have ways of having a Wolbachia, which is actually an infection within the mosquito that requires to attack it through Wolbachia-based approaches. There may be other innovative approaches, not just insecticides that would ultimately help us in the fight of decreasing the risk of getting bit by an infected mosquito.

And all I can say is we need to look at their safety. We need to make sure that they work and then evaluate them to see which one gets introduced. And there will be concerns in the global stage about genetically modified organisms, and I think that is why I am saying that the data needs to drive their full evaluation for inclusion in the global program.

Thank you.

Mr. SMITH. Yes, Dr. Bate.

Mr. BATE. Just one point on the research agenda. Although this is a hearing primarily about treatment, I think it is somewhat worrying that only about 4 percent of the global malaria budget is spent on areas of insecticide research. And regardless of whether it is indoor residual spraying or bed nets, we are going to need better insecticides, and with the exception of the Gates Foundation, which funds the IVCC, there is very little effort in that area.

It is probably more contentious and people don't like insecticides. But I think that is going to be an area in the short run that needs to be ramped up because until we have—this is not to downplay the vaccine. I think it would be fabulous. Until we have a much more effective vaccine, then I think we are going to continue to need insecticides and new ones at that.

Mr. SMITH. Just one last question before yielding to my friend, Mr. Payne. With regards to vector control, which Dr. Steketee also spoke about in his testimony, are malaria-bearing mosquitoes spreading, despite all of our efforts? Obviously, bed nets protect individuals during the most fearful times, at night, during sleep, when children and adults could get bit. But are the mosquitoes that bear and carry malaria spreading in their borders? I chair the Lyme Disease Caucus here in the United States Congress, and we know that the Lyme disease-bearing tick, particularly the deer tick, just every year expands, and, unfortunately, mal-affects people with disease. Should Americans be concerned that malaria has come to our shores, for example, from countries that are in Africa and other endemic areas?

Dr. STEKETEE. Thank you very much for that question. You also raise the issue of borders and which becomes an interesting thing. This is—and I just highlight this because I think one of the potential progresses here and particularly with ALMA, the idea of African leaders actually banding together for leadership purposes and allowing them to cross their own borders with the right ideas. So I just put that aside as really a critical issue.

Most mosquitoes actually would like to move as little as possible. It is a pretty tough life out there for them. It is a fragile little woman mosquito, because those are the ones we care about. She would like to go and find a very close body of water to lay her eggs in and then return to the house where she came from. So she has

very little incentive to go across borders. So, for the most part, the mosquito itself will not be the big transmitter going across the borders.

It is actually us people that move the parasite and make us concerned about that.

Having said that, we think of populations of mosquitoes. And if you have a very good intervention, which we do with insecticide-treated nets and indoor residual spraying, that intervention has been shown to essentially kill all of that population that have the particular behavior of feeding indoors and on those people sleeping at night and essentially kills all of those. Now there may be in the midsts of that population a few that didn't read the textbook, and they go out, and they bite somebody outside, and they get their blood meal and they are able to continue, and they stay outside of that immediately targeted area of insecticide. So we end up with actually an evolving population because of how good our intervention is. We have left remaining those few that don't have that behavior, and they start to look like we have created the wrong thing, that is we now have allowed them to survive, but we have killed all the others. Mind you, those are the ones that are a little less likely to bite indoors, and they are a little less likely to transmit ongoing. So they actually become a weaker and weaker transmission for the malaria. We may need to go after those.

And as insecticide resistance evolves in a population, it evolves because we are using just one, and we are learning to do and discussing, and it is going on again as we speak, there is a—WHO has produced a draft document for controlling insecticide resistance, which includes the idea of rotating, which is a lot like using combination therapy for drugs, but of rotating insecticides so that we are not allowing a population of resistant mosquitoes to evolve.

So I think there is actually a lot of work being done on that. And as long as we don't lose sight, and I will highlight the idea that research ongoing on insecticide is actually critical in the midst of this. We do need that.

Mr. SMITH. Thank you.

Dr. Bowen, did you want to comment?

Mr. BOWEN. Just one very brief comment. A lot of the previous comments have focused on sort of the high-tech methods for mosquito control, and those are all very, very important but there is a lot of low-tech work that can be done. For example, we are working with an organization in Senegal with a French acronym of PECADOM, which trains people to be community leaders and just do very simple things to stop mosquitoes from breeding; making sure that there aren't tires lying around that can serve as pools of standing water and that sort of thing. So it really is a partnership of both the very high tech, the transgenic mosquitoes, with the very low tech of just making sure there aren't tires lying around in the village.

Mr. SMITH. Mr. Payne.

Mr. PAYNE. Thank you very much.

It is a very in-depth discussion.

According to WHO—and anyone can answer—insecticide-treated nets that were distributed between 2007 and 2008 need to be replaced. What steps does your organization take to ensure that the

nets will be replaced as needed? And in your opinion, what steps should the donor community take to ensure that the nets are replaced? And also if you could even, preceding that question, there was always some question about the treated nets, and there was, I think, initial opposition in some countries. Could you tell me how that has been overcome? I suppose it has been. But do you still find some resistance to that? And secondly, how do you keep a count of the replacement needs for the nets after several years of use?

Dr. STEKETEE. Let me take that question on. We have actually worked with a number of countries now in that process, and this is where the country logistic systems have really dramatically changed in the last few years. I would say that from 2005 to 2007, we had a hard time understanding exactly where the nets were needed, where they were, where they weren't and how to understand when to replace them.

We have now gotten to the point where almost village by village in many countries, they have a roster of nets in households, which ones are short of nets, which ones are—ways of measuring—picking up on who lost a net, maybe it burned last night under the stove for the kitchen; maybe it is just now torn too much and registering its loss. So the systems are categorically better. For example, we have been working in Zambia a lot. Zambia has district-by-district, regularly-updated numbers as to how many nets they have in stock, how many nets are in households, how many they anticipate needing to replace in the coming year and what the resources are.

I will just highlight one challenge in the midst of that, and that is, unfortunately, the ups and downs of funding that determine that tranche of insecticide-treated nets comes to the country. If the country doesn't have the money to procure, they hold off. And because this is so seasonally tied in many places, if you miss one season, you allow your entire population to just be inadequately protected for that season.

So one of the challenges for the countries has been to take that information and to try to match it with some consistent funding so that they have supplies when they need them.

Mr. PAYNE. Thank you very much.

So the question, just listening to your answer, really has a lot to do with the manner in which the individual countries have worked on their health systems, delivery systems and—how have your—any of your organizations worked with the basic things that you mentioned, keeping inventory, making sure that people know that a program is going to start? Are there any programs—I am sure you do have that—that go into communities to build that kind of very basic infrastructure up?

Mr. BOWEN. One of the areas that we are working in is—again, innovation doesn't just happen in the lab. We are trying to find innovative ways to communicate with communities, and having cell phone technology and other kind of mass media to let people know about the need to use bed nets properly is another way to just make sure that families are using the bed nets every night and are using them adequately. And I am sure others can comment on some other things that are being done to build up the health systems.

But also, I think your question highlights the fact that ongoing funding really is needed because it is not adequate simply to buy one tranche of bed nets, as you pointed out. There is an ongoing need to replace as they get worn and as the long-lasting insecticide ultimately wears out.

Ambassador GREEN. I think, first off, the most important thing to remember is that no program, no plan will be successful if it isn't a partnership between donors and leaders in-country.

I mean, I think a basic rule is you can't want it more than they do. In other words, these programs have to be built around in-country, innovative leadership that is committed, top to bottom, to getting this done. And when I do take a look at those countries where the success has taken place, those are the countries.

In Tanzania, when President Kikwete talks publicly about sleeping under a bed net himself, when he takes to the stage at concerts with malaria messages, when that kind of leadership is shown and when clear signals are sent throughout the ministry of health and leadership all over the country, where faith leaders are enlisted, that is where success takes place.

Also, in terms of our response to malaria interventions, I think a very innovative program that really hasn't gotten enough attention is the involvement of the Peace Corps. Peace Corps volunteers—in some ways, this was pioneered in Senegal, and Malaria No More played a huge role in that. Peace Corps volunteers have been very effective in using the typical volunteer's ingenuity and sense of can-do in malaria messaging, in working with leaders, in keeping track on the logistics front. So it is partnerships across borders and across oceans, and it is partnerships across cultural sectors inside the country that is making the difference.

Mr. PAYNE. There is the debate I think in the millennium development goals on the question of control versus elimination. And when we get into, you know, limited funding, especially now that we understand that the Global Health Fund, a number in Spain and Italy, some are going to be unable to reach their goals because of their financial situation. We have the two to one—and by us actually reducing our appropriations proposal, we restrict how much the others can give. How do you see this—us being able to kind of get through with the combination of the European problem and the possibility for the Global Fund in particular of the cut in funding?

Dr. RABINOVICH. I think there are a number of things that can be done and are being done. The first is to look for efficiencies in countries, and the Global Fund has prioritized this and they call it value for money. But it is actually looking for the most efficient way to use the dollars and to make sure that you are getting the impact that you want. The second is—and I think was announced at the Global Fund board a couple of weeks ago, which is to focus on the most fragile countries so that lower-middle-income countries are no longer—or fewer of them are receiving funding; Brazil offered not to receive funding, China will not receive funding—allowing them to focus on the poorest countries that actually don't have a lot of alternative ways of funding the sustainability of bed nets and of treatment. I think those things go part of the way toward dealing with the temporary gap in any single country to give. But I think we have to look at the bigger picture, given the impact not

only on malaria, but HIV and TB, that this is a priority program that has really been recognized for its effectiveness and for its impact and to figure out how to sustain it for the longer term. And I think that must be a priority.

Mr. PAYNE. Yes.

Mr. BATE. Looking whether it is nets or spraying or treatment, it is a bit like removing garage; it is only sustainable if it is paid for. And the real question is how it is paid for. And whilst I actually do concur with nearly every remark that has been made in answer to these questions, I do think there are some African countries that are in a parlous state and really not that able to contribute as much. But some of the countries have significant wealth and have significant corruption problems. Maybe we have an opportunity here—I am thinking of Nigeria and Angola with their considerable oil wealth—to step up a little more than is currently the situation.

That is not to deny that there aren't major problems and that the aid community should not do what it can. But given strained conditions, these may be opportunities to press harder for the nations most affected to step up a little more themselves.

Mr. PAYNE. Yes, Dr. Bowen.

Mr. BOWEN. Just to pick up briefly on that. There clearly is a great need for financial transparency. That is why one of the things that ALMA is doing, the measures are not just about public health measures. They are things like financial transparency, removal of tariffs on antimalarial goods and preventive bed nets and products such as that. So I couldn't be more supportive of Ambassador Green's comments about the leadership of President Kikwete, and we are delighted that Ellen Johnson Sirleaf is coming in as the leader of ALMA.

And I would also agree with Dr. Rabinovich's comments, that it is important to get the most—to squeeze the most valuable for money out of every dollar, euro, yen that goes into the Global Fund. But ultimately, of course, the United States is the indispensable nation in this. If the United States isn't there, the effort there will be significantly imperiled.

Ambassador GREEN. If I can, just a couple of thoughts I think are important to put on the record. Remember, this challenge is unlike some of the other development challenges that we are taking on. Half measures don't work. This is not a situation where you can extend out, you know, filling the jar with pebbles over more years. There really is a premium on the mobilization of resources. You either do it, or you don't do it. But sort of crawling along slowly, you won't get the return on investment.

One of the remarkable things about the malaria challenge is, again, we know what to do. And in Zanzibar and other parts of the world, there is clear evidence of that. And one of the things that we have learned is an integrated mobilization of resources is what makes the difference. And so one of the things I admire about what PMI is doing is when they take a look at those countries, they can go into, they don't simply take their resources and divide it up by 50. They instead look and say, okay, here is leadership; here is a definable challenge. You know, we look at the math. We can do this. Let's do it.

And what that means in some cases is there are terribly impoverished countries where there are huge problems that we would like to go into and try to make a difference, but we are resource constrained. There are other countries that we look at and perhaps they aren't as poor, but we look and we say, okay, we can do this, you know, we can defeat this here. And as you take a look at the overall challenge, those are the choices you have to make. But it is important that we understand you have got to mobilize, you have got to mobilize fully, you can't simply extend this out and go on the cheap. If you do, sadly, we won't get there. We won't be able to fill the promise.

Mr. PAYNE. With the new ALMA project that you mentioned—and I was very impressed with just looking at the schematic there—how long have they been putting out that report that complicated—I mean, that thorough?

Mr. BOWEN. This is the initial scorecard, but the plan is to keep it going and to use this as a touchstone for responsibility for accountability in the fight.

Mr. PAYNE. I think that measures like that—NEPAD was supposed to be a move in that direction, and it has kind of had some stumbling blocks. But I think that once nations are held accountable, that they are compared to others—I think what Mo Ibrahim is doing with his whole question of rating, you know, heads of state I think is really putting the spotlight on, and I do believe that we will get to the point where, you know, 15, 10 years ago, people didn't even discuss corruption and these things that had been going on, you know, for decades.

And of course, we also have to work more on the European countries. As many of you may know, the corruption has not been illegal in most of those countries, and as a matter of fact, I think it was in Germany, you could make it a tax deductible item; you just had to declare it. But it was not—it was not considered criminal. It was considered the cost of doing business. So if we can work more on the corrupters, you know, it is a two-way street, it doesn't condone those who take corruption, but I think that those who are offering it and like I said, I travelled in Africa for decades and decades, and it seemed like a practice that was just a part of a business portfolio for a number of the European countries. So I think that it is a two-way fight. We have got to continue to work in exposing it, having reporting, have things that are verifiable, having things that are out in the public so that people can be judged on what they do or do not do.

Just lastly, how rife as a problem is the sale of counterfeited or adulterated or poor quality drugs? Do we have any fix on that? Is there anyone who is really monitoring that? Do we really know how bad it is.

Mr. BATE. Yes. The short answer is, no, we don't have a good handle on the size of the problem. A lot of the data that has been collected is not easily comparable. There is no doubt that there is a significant both substandard and falsified drug problem, products which are either intentionally there to mislead people or, more likely I think in the poorest countries in Africa, drugs which have been made legally but are just not up to the standards. And also, in ad-

dition to that, you have a problem with storage, transportation, which leads to degradation of products.

So it depends how you define it as to the numbers you get, but most of the studies that have been published which do any level of comparison from one location to another, follow reasonably tight protocols, you are seeing at least 10 percent of the products failing in quality control. And in some markets for some drugs and antimalarials, it is considerably higher than that, but we don't really have a good handle on the exact numbers.

Mr. PAYNE. Yes, Doctor.

Dr. RABINOVICH. If I could give you an example from the diagnostic field, we funded the Foundation For Innovative New Diagnostics to work with WHO to evaluate how good were the diagnostics. And of the first more than 100 diagnostics, only about a third were working the way that they should.

Now that information was fed back to the Global Fund and PMI and other funders so that they focused on the use of good diagnostics which then becomes the basis for credible diagnosis at the field level which is necessary for adequate and appropriate use of drugs. But it is these quality systems, not only for—I mean, the same thing can be said for vector control tools. Do they really have an insecticide that will really least 3 or 4 or whatever the advertised number of years? These regulatory systems and validation systems are really important to the ongoing credibility of the program and really needs to be part of what is maintained.

Mr. PAYNE. Well, let me thank you very much. We will certainly continue to focus on this issue. Actually, Thursday of this week we are going to be cohosting an event with PATH and Roll Back Malaria, where the whole question of RTS,S, the discussion about malaria vaccination that continues on and was really at the 15th anniversary celebration of IABI, where Mr. Gates and some of his folks were about a month ago—where the whole question, as you may you recall, dealing with the vaccine, I think that is the goal that we really need to continue to move forward on, and then we won't have the debate, the question that I almost asked about, you know, should we spend money on trying to prevent, or should we put it on research? We get a vaccine, and we don't have to worry about it. So, once again, let me thank you all, and I yield back to the chairman.

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

Just a few follow-up questions and final questions if I could.

Dr. Schmatz, could you discuss more the single-dose cure for malaria that was in your testimony that is in development? How long are the clinical trial phases?

Mr. SCHMATZ. Currently in phase 2A, getting prepared to do bigger trials now. And the projection is that if everything goes smooth, which in our discovery that is not always the case, but we are very hopeful here from what we are seeing, that that product could be potentially available around 2016, going through all the steps along the way in the regulatory process and pulling all the stops out as well to get there.

Mr. SMITH. Let me ask Dr. Steketee, you in your testimony point out that four countries over the past 4 years—United Arab Emirates, Morocco, Turkmenistan, and Armenia—certified by WHO as

having eliminated malaria, are the first countries to achieve this distinction in 20 years. Are there other nations that may be getting close to that distinction? Are any of those nations in sub-Saharan Africa? And if anyone would like to talk about this, which countries in Africa—and I know Dr. Bowen, you did raise up a very detailed chart, which I will read very carefully later, as I am sure others will—but which countries are doing the best across the whole broad range of strategies to combat malaria and who are the laggards? Dr. Steketee?

Dr. STEKETEE. Well, thanks very much. Because this issue of eliminating malaria is obviously where many, many nations have put that in their current plans, that is what they are wanting to do. In the discussions that led to the updated Roll Back Malaria goals for 10 countries to eliminate in the coming 5 years, they actually did that because there are nine countries that are in the WHO European region—this is not only Western Europe. This is a set of relatively small countries that have almost no malaria, but they have little pockets of it. And those are slated within the next 5 years to hopefully eliminate malaria. Armenia was actually part of that group and just declared elimination 2 months ago. So, yes, there are a number of countries in that stage.

In terms of other places, you ask specifically about Africa, as Ambassador Green has mentioned, a small part of Tanzania, that is the islands off the coast, are actually not very far away. And this is the case of making a decision, do you go for it, and when do you go for it? In that sort of sub-national setting, but because they are islands, clearing islands tends to be both easier and something that you can continue to sustain.

Now among the other places in sub-Saharan Africa, first of all, South Africa still has transmission, but in focal areas along its boarders with Zimbabwe and Swaziland and Mozambique. And that is a lot because, not the mosquitoes moving across the border, but people move across those borders. And they are in particular trying to pay attention to whether or not they can eliminate it. And this is actually a pretty important discussion because that southern cone of Africa—Botswana, Namibia, Zimbabwe—once it gets beyond its political strife, has an incredibly strong health system, or did, and it has been hampered in the recent years, particularly from the political strife, but that could turn around. And if that does, you could have Namibia, Botswana, Zimbabwe, South Africa, and Swaziland actually quite close to eliminating malaria.

Just north of that, I mentioned we had worked a fair amount in Zambia. There are parts of Zambia where you can now count cases in districts on hands and maybe hands and toes, and that is new. And that is why I am talking about the speed of change here and the innovation has gotten us thinking and gotten countries talking about what it takes to do elimination.

The other places in sub-Saharan Africa are in West Africa. Particularly Senegal and Gambia have recently shown remarkable progress. Northern Senegal has districts where over the past year they have had trouble finding any malaria. So this elimination happens in these countries step by step, district by district, but both Senegal and Gambia are now meeting and talking about how they can work both across their boards and jointly against the parasite.

And lastly, I will mention, outside of Africa, in the Americas, we have—the Americas have made incredible progress. And if you look country by country, particularly in Central America, but also in South America, they are not very far away. We are talking about a few deaths left. Just as an aside, Mexico is a huge place for U.S., you know, visitors to go on holiday. And we used to identify that we would recommend from the U.S. that our citizens take prophylaxis when they go to Mexico, and that was actually the largest number of use of prophylaxis for the citizens of our country. And that malaria in Mexico is almost gone.

So the progress and the possibilities out there are really exciting, and they take attention, but that group of South American countries, they formed a coalition to try to do this, and they are close. And whether it is just moral support and applause from the sidelines or ways of figuring out how to emphasize that would be hugely helpful.

Lastly, out in, again, back to the island issue in the Western Pacific, there are a number of islands that are working toward elimination. So while we haven't called those countries out for the next 5 years, it is—this is what is in abeyance here, that is if the global community backs off of malaria as a priority, then you can imagine that these places will say, hmm, not sure where the help is coming from and maybe we have to go do something different now.

Mr. SMITH. Thank you very much for that very extensive answer.

We have talked a lot today about the importance and efficaciousness of insecticide-treated bed nets, indoor residual spraying and intermittent preventive treatment for pregnant women, three of the best tools that we have for prevention.

And I am reminded, Dr. Steketee, that you mentioned earlier that the treated bed nets actually help kill the mosquitoes, which I think is a very important point to underscore. It reminds me in the whole fight against the pandemic of HIV/AIDS that antiretrovirals, ARVs, actually have capability of reducing the viral load, which becomes a way of defeating that terrible virus. Here we are defeating the actual parasite and the carrier of parasite.

But let me ask anyone who would like to answer this, how and by whom are decisions made regarding what prevention strategies to promote in any particular region or country or even a specific area within that country? Who makes those decisions right now? Is it the Health Department? Is it the collaboration of the partners, or what?

Dr. RABINOVICH. I think any of us could answer. There is a global process, and WHO is entrusted with technical assessment of the data and making policy recommendations for the countries. But then there are regional WHO offices. And the responsibility really sits with the country to figure out how it is and what it is going to implement.

And there are differences. Malaria is not a single disease. It demonstrates and has different patterns of transmission and different things that must be emphasized in different places. Trying to segment that into a pattern that would be easier to attack is something WHO is doing.

But it really is a partnership between the many partners, including WHO, the Roll Back Malaria Partnership, which brings every-

one to the table, and most important of all is the countries, because that is where the key decisions, not only at the national level but down to the district level, must be made. I don't know if anyone has anything to add. It is a little complicated, but it works.

Dr. STEKETEE. I will just add this as an example where the U.S. President's Malaria Initiative sits with the country, country by country where they work and look at their plans and then look to see how they can help support the implementation of those plans. And it has been that set of years actually where there was very little money where people spent a lot of time figuring what the strategy should be that got us a solid set of national programs that could speak to this is our strategy.

And then those evolve over time as we get new information. And so, for example, if we got a new vaccine or if we got a new drug that was a single-dose therapy with high cure rates, those would be rapidly discussed at WHO. And they would be rapidly discussed with the regional offices and then country by country. And experience has shown that we now have enough people with enough knowledge at country level that the uptake of that information is both thoughtful and relatively expeditious.

Mr. SCHMATZ. If I could add to that, the immediate approach and reaction to dealing with malaria is procurement, optimizing the current interventions you have, and in-country activities, and all of those are critical and have made a huge impact already. The long gain is clearly going to come from R&D. And when you look at the actual investment that is made in R&D, it is a long sustained expensive process. But I would argue, and I think most of the people in the room would agree with me, without that, the end game—you won't win the end game. So while the immediate interventions are critical, you are saving lives today with the tools you have now; you won't win that long game without sustained effort to really support the R&D that is out there. That is a very small component of the investment that is made today on the actual R&D part.

Mr. SMITH. I just want to note for the record, and mention was made of the $691 million request for Fiscal Year 2012. But in 2004, it was $89 million; 2005, $99.9 million up to $111 million; in 2007, $256 million; $358 million in 2008; $391 million in 2009; and it went up rather significantly in 2010 to $594 million. So the glide slope is a build out that needs to be sustained, and I think all of you have made your cases extremely persuasively, backed by your knowledge and your expertise, and very, very important information.

I have a final question, and Mr. Payne may have a final question as well.

Ambassador Green, again getting back to your original point about leadership and the importance of it, you did talk about how Coca-Cola is partnering with the Global Fund on a technical assistance project with regards to supply chains. I would note parenthetically that I travel often to Africa and elsewhere often to places that are way out of the way. All of you do even more so, I am sure. I am always amazed because once I am jet lagged by day 2, I drink a Coca-Cola for breakfast, and there is always one available at the hotel wherever I may be. So their supply chain is second to none. Could you elaborate on how well that is working and

whether or not that expertise will be shared as a best practice for others?

Ambassador GREEN. Yes, it is quite extraordinary, you can get a Coca-Cola just about anywhere in the world and certainly all over Africa. The early returns are good. But I want to build on that, and it is not just Coca-Cola. I want to point out another remarkable project that is current currently run by Barbara Bush, President George W. Bush's daughter, in which she came up with the idea, gee, we have lots of business expertise here in the U.S. and we have lots of young business executives who are dedicated to changing the world, so we have got expertise, we have got challenges, what do we do? And the Global Health Fellows, which is the name of her organization, matches up young business executives with development opportunities overseas.

On Zanzibar, a young executive from The Gap spent a year helping the ministry of health in Zanzibar doing supply chain management on meds and was able to put his expertise and experience to work in remarkable ways. So have you Coca-Cola, which is doing things on a grand scale, and you have young entrepreneurs, business executives, doing it on a microscale. And the combination of those is truly uplifting. Because at the end of the day, it is going to be leadership. It is going to be that can-do sense that I think we are all very proud of, and that will make all the difference. Thank you.

Mr. SMITH. Thank you.

Mr. Payne.

Mr. PAYNE. Just that I really appreciate the fine work that all of you do.

I agree that it is the will of the individual country and the community. About 3 or 4 years ago, I went to Rwanda, where they were starting this big initiative, maybe 2 years ago, and they started in the churches and in the community centers. And they had someone discussing it every week that this event was going to start. I happened to be there when we were out in a village where they were starting. Everyone had to take their furniture out of the house. They had to put their curtains up. I put on a suit. They thought I was a guy that had the job, but they were worried because they knew a local guy was supposed to do the job, so they thought I came and bumped him out or something. But I put on my suit, and we did the spraying around the house, and it was just like a community event. Everybody was involved. They knew what was going on. They were alerted. They knew when they had to have things out. They knew how long it had to be, have the kids out while the spraying went on. They put the nets up, and so I think it is very important how we work on the very local communities.

One other issue that shows how I think it is catching on, I was in Djibouti at a military installation and there was a border dispute with the other country—I won't mention because they deny there was a border dispute. But there were 21 prisoners of war from the opposite country. And I wanted to meet them to see how they were being treated, and they were all being treated okay, well and so forth, and we had a conversation with them. But the thing that was most impressive is when I went into their housing facility,

lo and behold, they had bed nets. And that really said something, that they, in Djibouti, the government felt it was important enough to have bed nets around prisoners of war. You know, then, they thought this was an important issue. Same way in Rwanda where we have seen—I have talked to Ray Chambers. As I mentioned he is from Newark, New Jersey, and he talks about going to some of those pediatric wards and infant—in Rwanda where they used to be packed with kids, and now they have virtually no one there, which shows that in certain parts, it is really working.

So what you are doing is fantastic and I commend the chairman for having this very important hearing, and we will keep pushing for elimination with the vaccine. Thank you very much.

Mr. SMITH. Would any of you like to make a final comment? You have been very gracious with your time. This couldn't come at a more timely period during consideration of the 2012 budget, so thank you for that.

Yes, Dr. Rabinovich.

Dr. RABINOVICH. On behalf of this group, I would like to thank you for holding this session. We are but a fraction of the partners that are involved in this. And as I think about the Rotarians in Zambia, the Methodists as principal; recipient of the Global Fund Award, Exxon Mobil talking about malaria at the Olympics, Nothing But Nets bringing in every sport that has a net of any kind into the fight. Under the partnership model, this has really been already an incredible decade, but there is really so much more that needs to be done over the next decade. When I visited the Gambia 10 years ago, there were three children to a bed for a disease that has almost disappeared from the Gambia 10 years later. This is possible. This is possible, but it really takes that kind of partnership, commitment, and steadfast attention to make it happen. Thank you.

Mr. SMITH. On that final very wise note, the hearing is adjourned.

[Whereupon, at 5:23 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, D.C. 20515-0128

SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, AND HUMAN RIGHTS
Christopher H. Smith (R-NJ), Chairman

December 5, 2011

You are respectfully requested to attend an OPEN hearing of the Subcommittee on Africa, Global Health, and Human Rights, to be held in **Room 2172 of the Rayburn House Office Building (and available live, via the WEBCAST link on the Committee website at http://www.hcfa.house.gov):**

DATE: Monday, December 5, 2011

TIME: 3:00 p.m.

SUBJECT: Fighting Malaria: Progress and Challenges

WITNESSES: The Honorable Mark Green
Senior Director
U.S. Global Leadership Coalition

Dennis Schmatz, Ph.D.
President of the Board
Medicines for Malaria Venture North America, Inc.

Regina Rabinovich, M.D.
Director, Infectious Diseases
Global Health Program
Bill and Melinda Gates Foundation

Roger Bate, Ph.D
Legatum Fellow in Global Prosperity
American Enterprise Institute

David Bowen, Ph.D.
Chief Executive Officer
Malaria No More

Richard W. Steketee, M.D.
Science Director
Malaria Control Program
Program for Appropriate Technology in Health

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, and, Human Rights* HEARING

Day *Monday* **Date** *December 5, 2011* **Room** *2172 Rayburn*

Starting Time *3:00 p.m.* **Ending Time** *5:23 p.m.*

Recesses *0* (____to ____) (____to ____) (____to ____) (____to ____) (____to ____) (____to ____)

Presiding Member(s)

Rep. Chris Smith

Check all of the following that apply:

Open Session ☑
Executive (closed) Session ☐
Televised ☑

Electronically Recorded (taped) ☑
Stenographic Record ☑

TITLE OF HEARING:

Fighting Malaria: Progress and Challenges

SUBCOMMITTEE MEMBERS PRESENT:

Rep. Chris Smith, Rep. Donald Payne, Rep. Robert Turner

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.)*

Prepared statement from Amb. Green
Prepared statement from Dr. Schmatz
Prepared statement from Dr. Rabinovich
Prepared statement from Dr. Bate
Prepared statement from Dr. Bowen
Prepared statement from Dr. Steketee
Prepared statment from Rep. Fortenberry
Statement from Africa Fighting Malaria

TIME SCHEDULED TO RECONVENE _____
or
TIME ADJOURNED *5:23 p.m.*

Sheri Rickert
Subcommittee Staff Director

United States Congressman — First District, Nebraska

JEFF FORTENBERRY

Fighting Malaria: Progress and Challenges

December 5, 2011

Thank you Mr. Chairman for convening this important hearing. As the co-Chairman of the Congressional Malaria and Neglected Tropical Diseases Caucus, I am glad to see a focus on this pernicious disease that takes the life of a child every 45 seconds.

America does not struggle with malaria, and there are all manners of tragedy, poverty, and disease across the globe. But the detrimental impact of one single disease—a preventable and treatable disease-- is staggering. It is hard for good Americans to sit idly by while the vulnerable are afflicted by a disease that the United States defeated in the 1950's. The majority of those killed are pregnant women and children under five years old. Ninety-eight percent of all malaria deaths occur in just 35 countries, the majority of which are in Sub-Saharan, and malaria costs Africa at least $12 billion in lost annual GDP. The economic impact is dire, and also becomes entangled with global stability and national security. Malaria, interestingly, is the top health threat to our troops overseas.

Thank you to those here to testify today about this important lifesaving work. Through your remarkable achievements, the humanitarian generosity of the American taxpayer, the ideals of our country, and also because of our position in the world as an exceptional world leader, the United States is helping to help change the course of malaria.

For example, a recent partnership between Medicines for Malaria Venture and the University of Nebraska Medical Center, led by Dr. Jonathan Vennerstrom, has led to a very promising potential single-dose cure for malaria. As that drug advances through clinical trials, Dr. Vennerstrom has his eye on another target—liver-stage malaria. Noting this tremendous research going on in my backyard, in the congressional district that I represent, illustrates how much, and how personal, of a stake the American people have in continuing the last decade's progress and ending malaria deaths. I met recently with a group of Methodist Church members from Lincoln who show the civic impact of American citizens doing their part to combat malaria as well. For as little as $10, lifesaving bed nets can be purchased. Good Americans are connected to good causes with ease, and these ordinary citizens have aided significantly in the delivery of more than 400 million bed nets, doing their part to help the international effort.

On the federal level, the President's Malaria Initiative (PMI), a US Government interagency initiative begun in 2005 and led through USAID, has set a goal of reducing malaria

transmission and deaths by 50 percent for 450,000,000 people, representing 70 percent of the at-risk population in Africa, by 2015. PMI has had tremendous success since its inception, and recently expanded to begin working in Nigeria and the Democratic Republic of the Congo, two high-malaria death areas in which the United States was previously unable to provide assistance. In all 17 countries in which it operates, PMI is doing good work like indoor residual spraying, environmental management of pesticides at the country level, health care delivery systems for malaria rapid diagnostic testing and care, and, significantly, a new, concerted focus on malaria maternal care programs.

As a father of five young girls, I've been very encouraged by the shared emphasis by the international community on addressing maternal mortality as it relates to malaria control. The transfer of malaria to children during pregnancy is a serious concern. Most commonly, it manifests in very low birth weight, feeding issues, and other developmental challenges. It can pose greater health risks, causing deadly complications during delivery. Malaria infection causes 400,000 cases of severe anemia and from 75,000 to 200,000 infant deaths annually in sub-Saharan Africa alone. Quite seriously, with one particular form of malaria, pregnant women have a fourfold increase of stillbirth. I look forward to learning more about progress in addressing malaria maternal care.

Even with these challenges, global malaria deaths have decreased by 38%, with 43 countries cutting malaria cases or deaths by 50% or more. And the World Health Organization reports that in 2010, the percentage of African households owning at least one insecticide-treated mosquito net increased to 42 percent. More children under 5 years of age are using these nets than in previous years. The progress is clear: we are reversing the trend of the previous decade and saving more than a million lives. And I am happy to note that the Foreign Affairs Committee recently approved an amendment to the State Department Authorization bill that reaffirms our commitment to working to end malaria deaths by 2015.

While our nation's leadership in this lifesaving work is clear, so are the fiscal realities confronting America. We need to have an honest and creative conversation about how we can retain the best of our efforts but still get America's fiscal house in order. We must continue to pressure other members of the international community to sustain and scale up their support and financial contributions for efforts worldwide to combat malaria. That's why I'm glad to see new partnerships springing up across the globe, and seeing the commitments of many countries to implementing best practices. Together, as the responsible community of nations, we can continue the progress we have seen over the last decade.

Global leadership is yielding remarkable results. I remain committed to this essential component of our global health work, where investments truly reap significant dividends in lives saved and populations made more stable. Serious work remains in the years ahead. But we can end this disease.

MATERIAL SUBMITTED FOR THE RECORD BY MR. ROGER BATE, LEGATUM FELLOW IN GLOBAL PROSPERITY, AMERICAN ENTERPRISE INSTITUTE

Submitted Testimony to US House of Representatives
Sub-Committee on Africa and Public Health
Hearing
December 5th, 2011

Fighting Malaria: Progress and Challenges

Africa Fighting Malaria thanks Chairman Smith, Ranking Member Payne and all the Members of the Africa and Public Health Sub-Committee for holding this important hearing and for allowing us to submit this written testimony.

In recent years remarkable progress has been made in the fight against malaria, thanks in very large part to US leadership and funding. In 2004 and 2005, thanks to hearings held by the Sub-Committee on Africa and Public Health and several hearings in the US Senate, far-reaching reforms were made to the US malaria control and treatment programs. Prior to these reforms, US support for malaria control was limited in scale, was poorly measured and monitored, was lacking in transparency, and seemed geared more to giving advice and paying consultants than procuring life-saving commodities and truly controlling and treating malaria. Since the malaria reforms and the launch of the US President's Malaria Initiative the US response to this disease has been bold, well funded, transparent and results-oriented. We believe that the impressive results achieved by the PMI – available at www.fightingmalaria.gov - are a testament to US leadership for malaria control. It is also a testament to the importance of Congressional oversight and an insistence that US taxpayers' money be spent in the most appropriate, efficient and effective way.

The US taxpayer is also the largest funder of the Global Fund to Fight AIDS, TB and Malaria. By most measures the Global Fund has been remarkably successful in funding the scale up of malaria control programs, particularly in Africa. There is no doubt that thanks to increased funding, many lives have been saved from needless deaths from malaria. According to Roll Back Malaria's LiST model, since the scale-up in malaria control almost three quarters of a million lives have been saved from malaria, most of these in Africa and almost all in the past five years.[1]

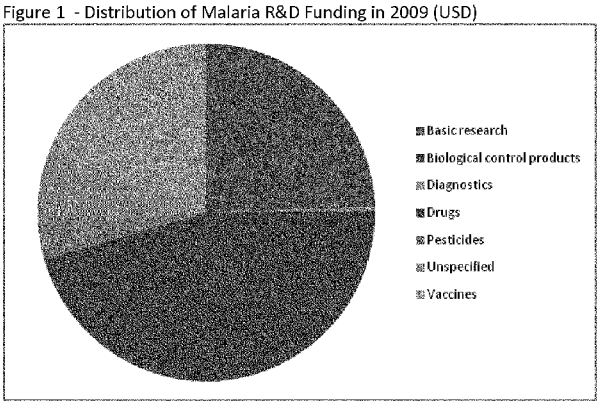
Notwithstanding this recent progress, there remain some serious obstacles to sustained and improved malaria control and treatment programs. Of particular concern is the ongoing anti-insecticide activism from within the United Nations, the anemic political leadership and funding in the search for new and effective public health insecticides, and insufficient support for comprehensive vector control programs that include indoor residual spraying. In addition, we are very concerned about the aggressive political support for a recently launched and controversial malaria drug subsidy program that is already proving to be highly disruptive to malaria treatment programs.

Vector Control

[1] Roll Back Malaria, "Saving Lives with Malaria Control: Counting Down to the Millennium Development Goals," World Health Organization, Geneva, September 2010

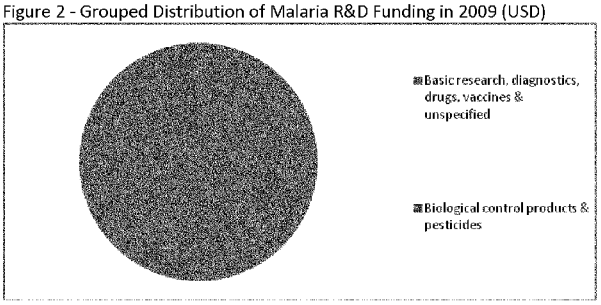
Increased access to insecticide treated nets (ITNs) and long lasting insecticidal nets (LLINs) as well as scaled-up indoor residual spraying (IRS) programs account in very large part for the recent reductions in malaria transmission. Yet although vector control forms the very basis of any malaria control program, research and development funding for new vector control products is totally inadequate. An analysis of the research and development (R&D) spending for malaria contained in the G-FINDER database and given in Figures 1 and 2 below shows that vector control attracted only 4% of the total R&D spending in 2009.

Figure 1 - Distribution of Malaria R&D Funding in 2009 (USD)



Data extracted and adapted from G-FINDER survey data for malaria

Figure 2 - Grouped Distribution of Malaria R&D Funding in 2009 (USD)



Data extracted and adapted from G-FINDER survey data for malaria

Of the limited funding for vector control only a fraction is actually spent in trying to find new public health insecticides. With the exception of the Gates Foundation-funded Innovative Vector Control Consortium (IVCC) there has been no substantial effort to bring new public health insecticides (PHI) to market. We believe that this is due to the well funded and aggressive anti-insecticide activism from environmental groups as well as an almost complete failure among malaria advocacy groups to

campaign for new insecticides.[2] As a result there has been no new insecticide for public health in at least 30 years. With the limited market for PHIs one would expect UN agencies, such as the World Health Organization (WHO), to champion enlightened public policies that would create incentives to develop new products. Yet leadership from within the UN has been limited at best and counterproductive at worst.

In January 2011, Africa Fighting Malaria published a paper explaining how anti-insecticide activism within the UN resulted in claims being made that malaria can be controlled without the use of public health insecticides.[3] As our paper explains, these claims were false and based on a deeply flawed and highly problematic project in Mexico and Central America. Yet the lack of scientific evidence did not stop the UN Environment Program (UNEP), the Global Environment Facility and, regrettably, the environmental sector of the WHO from stating in a joint press release in 2009 that the project utilized "pesticide-free techniques and management regimes" to "cut cases of malaria by over 60 per cent".

Such statements are purely political and designed pander to anti-insecticide activism. As WHO's own records reveal, this activism resulted in a World Health Assembly Resolution (50.13) in 1997 that calls on member states to "take steps to reduce reliance on insecticides for control of vector-borne diseases."[4] There is no evidence to support the idea that diseases such as malaria can be controlled without insecticides.

In addition to generalized anti-insecticide activism, UNEP and the Stockholm Convention Secretariat continue to campaign for an early elimination of DDT. While DDT is only one of the dozen PHIs approved by WHO, it plays a very important role for several malaria control programs worldwide. Furthermore as countries grapple with the problems of insecticide resistance, it makes little sense to reduce the range of available chemicals. Rather, the number of chemicals should be kept as large and diverse as possible. Yet UNEP has publicly stated that it seeks the elimination of DDT by 2020.[5] The Stockholm Convention permits the use of DDT until a safe, affordable and effective alternative is made available. To date no such alternative has been developed and therefore UNEP is in fact violating the Convention and the will of the Parties to the Convention.

Along with inadequate support for the development of new PHIs, we have found that, with the exception of the PMI, most donors are reluctant to fund IRS programs. This may be due to ignorance about the importance of IRS to an integrated vector control program or it may be due to political reticence to fund any program that involves spraying insecticides. While the Global Fund has certainly funded some highly successful IRS programs, this intervention barely features in its reports as a progress indicator or on its website. Much more advocacy and political leadership is required to ensure that malarial countries are able to adopt truly comprehensive vector control strategies that go beyond the

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[2] For more details see, Roberts, DR. and Tren, RJ, *The Excellent Powder, DDT's Political and Scientific History*, DogEar Publications, IN, 2010

[3] Roberts, DR & Tren, R, "International advocacy against DDT and other public health insecticides for malaria control," *Research and Reports in Tropical Medicine*, Jan, 2011, **2011;2**, pp 23-30.

[4] World Health Assembly, "Resolution 50.13. Promotion of chemical safety, with special attention to persistent organic pollutants." WHO, May 1997, Geneva. Available: http://www.who.int/ipcs/publications/wha/whares_53_13/en/index.html

[5] Stockholm Convention on Persistent Organic Pollutants (POPs). Future plans for work on DDT elimination - A Stockholm Convention Secretariat Position Paper [Internet]. 2007 Nov, Available from: http://www.pops.int/documents/meetings/ddt/plan.pdf

provision of ITNs and LLINs.

Decades of woeful under-investment in public health systems by malarial country governments have resulted in worryingly few vector control specialists on the ground. These public health professionals are needed to monitor the effectiveness of insecticides and undertake field entomology that will feed into an evidence base to guide policy. While donors can and probably should play an important role here, it is vital for malarial country governments to start funding these positions so that malaria control can be sustained well into the future.

Regrettably with anti-DDT pressure and while Resolution 50.13 remains WHA policy, there is little hope in truly advancing broad based and well-funded efforts to create new safe and effective public health insecticides. In addition to sound science-based statements and sound leadership from WHO on vector control, it would be of enormous value for the governments of donor nations to consider legislation that would create incentives for insecticide developers to create new PHIs. Such legislation has been adopted to encourage investment in drugs and vaccines for neglected diseases and it is high time that the same attention be given to PHIs. If the US Congress were to consider low-cost legislation that would help to create such incentives we believe it would assist greatly in the neglected search for new PHIs.

Treatment Policies

As stated above, vector control forms the very basis of any malaria control program. Reducing transmission of the disease is essential to reducing the selective pressure on parasites that will lead to malaria drug resistance. Currently, and thankfully, artemisinin-based combination therapies (ACTs) remain highly effective in Africa, which bears most of the global malaria burden. However in addition to reducing malaria transmission, the emergence of drug resistance can be forestalled and perhaps avoided if donors and malarial countries ensure ACTs are of high quality and are used appropriately and only to treat positive malaria cases.

Improving access to safe and effective malaria treatments so that people, especially children and pregnant women, can be treated promptly is obviously vital. However we fear that some policies that are designed to improve access to treatment may actually be undermining this important goal. Below we address Global Fund procurement policies as well as a new malaria drug subsidy managed by the Global Fund that are problematic.

Global Fund procurement policies.

As the largest funder of malaria control and treatment programs, the Global Fund and its procurement policies are enormously important. It is essential that scarce funds be spent in the most appropriate and effective way. The evidence of misappropriation of funds and possible fraud are serious and should not be tolerated. We are very pleased that the Global Fund's board appears to be open to proposed reforms based on the recommendations made by the Global Fund's High Level Review Panel report.[6]

It is of course very important to remember that the only reason legislators, public health advocates, and all other stakeholders are aware of these problems is because the Global Fund is more open and transparent about its funding and procurement than any other donor or funding agency. We hope that this policy of openness and transparency will remain in place.

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[6] Report available here: http://www.theglobalfund.org/en/highlevelpanel/

In 2009 Africa Fighting Malaria published a paper in *Malaria Journal* highlighting the impact of problematic Global Fund procurement policies on access to ACTs. As we explained in this paper,[7] in an effort to increase competition, the Global Fund encourages principle recipients to use international competitive bidding practices for drug procurement. Competition between suppliers is probably the best method of reducing prices and is something that we would support. However in the case of Kenya, these policies encouraged the country to procure ACTs from a firm that was incapable of actually supplying sufficient high quality products in the required time.

The outcome of procuring from a supplier that was incapable of delivering the product was, predictably, stockouts of ACTs. As a paper by Mary Hamel et al. explains, one of the consequences of this stockout was a dramatic increase in mortality ratios for children under the age of five.[8] After falling from 241 to 137 deaths/1000 live-births between 2003 and 2007, the ratio increased by around 54 percent to 212 deaths/1000 live-births.

The point here is that the importance of sound procurement policies that focus on price as well as ability to deliver and sustain access to high quality anti-malarials should never be underestimated. Finding ways of increasing and sustaining access to ACTs is therefore essential. However, we believe that policies should be pursued based on evidence rather than advocacy. Regrettably we believe that the Global Fund's Affordable Medicine Facility for malaria (AMFm) fails in this regard.

Affordable Medicines Facility malaria (AMFm)

As we explain in our recent report attached in the Annex, the AMFm is an innovative scheme designed to increase access to ACTs by subsidizing the price at a global level. The concept of providing subsidized medicines through the private sector is interesting and has merit. However, the way in which the AMFm was first aggressively promoted and is currently being managed is highly problematic. Phase 1 of the AMFm involves providing $225m in subsidies for ACTs that are procured cheaply by first-line buyers in eight countries. As our report explains:

As of August 2011, approved AMFm orders for just four countries, Ghana, Kenya, Nigeria and Tanzania, account for around 80 percent of the total global ACT production capacity. This overwhelmingly high demand for ACTs in just four countries threatens the availability of ACTs in all other malarial countries. The prospects of ACT stockouts for non-AMFm participants are real and imminent and the rapid increase in demand may result in a shortage of artemisinin.

An AFM survey in two AMFm countries and an examination of AMFm demand and supply records reveal some serious anomalies. For instance:

Though malaria is mainly a childhood disease, 70 percent of AMFm treatment orders are for adult doses.
Three ACT manufacturers are also acting as first-line buyers in Nigeria, Ghana and Uganda with potential conflicts of interest.

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[7] Tren, R, Hess, K and Bate, R, "Drug procurement, the Global Fund and misguided competition policies, *Malaria Journal*, 2009, **8:305**

[8] Hamel, M.J. et al. "A reversal in reductions of child mortality in Western Kenya, 2003 – 2009," *American Journal of Tropical Medicine and Hygiene*, 85(4), 2001, pp 596-605

Zanzibar, a country that has almost zero malaria transmission, has ordered over 240,000 AMFm ACT treatments.
Our survey in West Africa revealed AMFm products being sold in non-AMFm countries. The threat of leakage of AMFm drugs to non-AMFm countries is real and requires urgent action.

The evidence is growing of a looming shortage of ACTs as USAID has confirmed that it is concerned about its ability to procure sufficient quantities of these medicines.

The Global Fund has already warned that it lacks sufficient financial resources to complete Phase 1. Demand for the ACTs from the first-line buyers may have been very high and perhaps higher than expected, but all orders were approved by Global Fund staff. The fact that the Global Fund approved the order and payment for over 240,000 treatments to a country with almost no malaria (Zanzibar) suggests that the Fund was less than careful about managing the resources it was allocated.

Our organization approached the Global Fund on several occasions to enquire about the anomalies we found in AMFm orders. Their eventual response (copies of correspondence are given in the Annex) declines to answer any of our questions, stating that the independent evaluation of Phase 1 will provide information on how successful the scheme has been. We believe however that the looming shortage of ACTs requires a more urgent assessment of the AMFm and, if necessary, a halt to any further disbursements until the ACT market has stabilized.

The AMFm Ad Hoc Committee (AHC) met in October 2011 and the Global Fund Secretariat confirmed that it has applied for additional funding of $124m in the short term ($50m to be raised from UNITAID and $74m from the UK Government) to complete Phase 1. Given the fact that the Global Fund is experiencing a critical shortage of funding and that it announced a delay to Round 11, and given the limited resources of the Fund as a whole, we find it wholly inappropriate for it to fundraise for this specific project. Fundraising for the AMFm alone, while all grant applications are being delayed, is highly questionable, but it is all the more so given the serious concerns raised above and in our report.

While the AMFm remains an interesting and novel idea, there are considerable opportunity costs imposed in devoting such considerable sums to this project alone. We believe the AMFm must be urgently and carefully reassessed to ensure that it does not further disrupt established malaria treatment programs. US Congressional appropriations language forbids any US funding of the AMFm. We feel that under the circumstances and given the evidence to date, this is entirely appropriate and justified and we would encourage the US Congress to retain the language and even strengthen it.

Conclusion

Welcome progress has been made against malaria, however these gains are fragile and as we describe above there are several issues that could disrupt and even reverse this progress. While funding for malaria control is important and is known to be a good public health 'investment' there can be no room for complacency. We believe that with growing evidence of insecticide resistance and limited alternative PHIs, now is the time to think boldly and creatively about legislation and political leadership that would challenge the harmful anti-insecticides agenda and create viable incentives for the development of new PHIs.

The lead US malaria control program, the PMI, has been highly successful in most of its endeavors and we would encourage legislators to continue to fund this program. At the same time, during this age of substantial public deficits, we would encourage ongoing Congressional oversight to ensure that US taxpayer's money is being put to best use.

The Global Fund is a vitally important source of funding for most malaria control programs and while we would like to see the Fund continue its work, it must be reformed and should return to its original purpose of being a funding mechanism. The fact that the Global Fund took on the AMFm is evidence of the Fund's willingness to stray from its mission. The Global Fund's current funding crisis creates opportunities for the Fund's major financial supporters to insist on reforms