S. Hrg. 109–614

BILATERAL MALARIA ASSISTANCE: PROGRESS AND PROGNOSIS

HEARING

BEFORE THE

FEDERAL FINANCIAL MANAGEMENT, GOVERNMENT INFORMATION, AND INTERNATIONAL SECURITY SUBCOMMITTEE

OF THE

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS UNITED STATES SENATE

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

JANUARY 19, 2006

Printed for the use of the Committee on Homeland Security and Governmental Affairs

U.S. GOVERNMENT PRINTING OFFICE

26–748 PDF WASHINGTON : 2006

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2250 Mail: Stop SSOP, Washington, DC 20402–0001

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

SUSAN M. COLLINS, Maine, *Chairman*

TED STEVENS, Alaska
GEORGE V. VOINOVICH, Ohio
NORM COLEMAN, Minnesota
TOM COBURN, Oklahoma
LINCOLN D. CHAFEE, Rhode Island
ROBERT F. BENNETT, Utah
PETE V. DOMENICI, New Mexico
JOHN W. WARNER, Virginia

JOSEPH I. LIEBERMAN, Connecticut
CARL LEVIN, Michigan
DANIEL K. AKAKA, Hawaii
THOMAS R. CARPER, Delaware
MARK DAYTON, Minnesota
FRANK LAUTENBERG, New Jersey
MARK PRYOR, Arkansas

MICHAEL D. BOPP, *Staff Director and Chief Counsel*
JOYCE A. RECHTSCHAFFEN, *Minority Staff Director and Chief Counsel*
TRINA DRIESSNACK TYRER, *Chief Clerk*

FEDERAL FINANCIAL MANAGEMENT, GOVERNMENT INFORMATION, AND INTERNATIONAL SECURITY SUBCOMMITTEE

TOM COBURN, Oklahoma, *Chairman*

TED STEVENS, Alaska
GEORGE V. VOINOVICH, Ohio
LINCOLN D. CHAFEE, Rhode Island
ROBERT F. BENNETT, Utah
PETE V. DOMENICI, New Mexico
JOHN W. WARNER, Virginia

THOMAS CARPER, Delaware
CARL LEVIN, Michigan
DANIEL K. AKAKA, Hawaii
MARK DAYTON, Minnesota
FRANK LAUTENBERG, New Jersey

KATY FRENCH, *Staff Director*
SHEILA MURPHY, *Minority Staff Director*
JOHN KILVINGTON, *Minority Deputy Staff Director*
LIZ SCRANTON, *Chief Clerk*

CONTENTS

BILATERAL MALARIA ASSISTANCE: PROGRESS AND PROGNOSIS

THURSDAY, JANUARY 19, 2006

U.S. SENATE,
SUBCOMMITTEE ON FEDERAL FINANCIAL MANAGEMENT,
GOVERNMENT INFORMATION, AND INTERNATIONAL SECURITY,
OF THE COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:30 p.m., in room SD–342, Dirksen Senate Office Building, Hon. Tom Coburn, Chairman of the Subcommittee, presiding.

Present: Senators Coburn and Carper.

OPENING STATEMENT OF SENATOR COBURN

Senator COBURN. The Subcommittee will come to order.

I would like to thank our witnesses for taking the time to testify and the tremendous effort that some of them made to get here, the long distances they traveled.

This is a follow-up hearing to a hearing we had some 6 months ago, and it is important for America to realize that malaria sickens somewhere around 500 million people a year. It kills nearly 2 million people every year. Of those, 85 percent of the victims reside in Sub-Saharan Africa. As we sit here for the next 2 hours, 240 more children will die from malaria. The United States will spend $105 million to fight malaria this year, and the President has a new initiative where he has committed $1.2 billion over the next 5 years to fight this dreaded disease. With plans to scale up spending so dramatically and in such a short period of time, it is all the more important that we get it right, that our program saves lives in a measurable way.

After our hearing on this subject last year, U.S. Agency for International Development (USAID) went through its books and reported that less than 8 percent of the bilateral malaria budget went toward life-saving commodities such as $2 drugs that cure the disease, insecticides to kill the mosquitoes that carry the disease, and nets to keep the insects off people while they are sleeping. What is worse is that the majority of that 8 percent was spent to sell bed nets rather than to give them to the people who could not afford to buy them.

When we brought some sunshine to the budget on this project, we discovered that the vast majority of the malaria money was going to advice-giving programs, administrative overhead, travel, and conferences. In other words, we spent most of our money tell-

ing people how to use the cheap and effective tools to fight malaria and very little money actually providing them those tools and very little money actually saving lives.

Despite good intentions all around by those dedicated workers at USAID, our priorities have been out of whack. But things are changing, and I want to commend President Bush and those at USAID for recognizing the problem and announcing the major reforms over the past 6 months to change course. The President's plan targets a few focus countries at a time for nationwide coverage with life-saving interventions, including insecticide spraying in homes and drug procurement. But even in countries not initially targeted, USAID recently announced an overhaul of its malaria programming so that by next year 50 percent of its budget in those areas will go towards purchasing commodities and 25 percent of its budget will be spent on spraying. This is ground-breaking movement, and I am encouraged to think how many children and pregnant women might be spared death from this preventable and curable disease.

I want to congratulate the President for his leadership, and especially Assistant USAID Administrator Kent Hill and his deputy, Michael Miller, who is here today, for their courage and commitment in the face of the grueling task of implementing reforms at the programmatic level. It is very easy for Members of Congress to throw stones and criticize. It is quite another thing to actually turn a program around and change an international bureaucracy and move it in a different direction. We are having a follow-up hearing today because the sound policy and planning that have been achieved so far are only the beginning. So what I would like to do is get into some of the details of what we will be looking for over the coming months to carry out the new initiatives:

Accountability. One of the first principles we aim for here is transparency. We have been assured that a website would be launched that tracks all the money and the progress made with that money toward measurable indicators. So far, the website is not up and is not running, but I will be interested to hear a firm date for that launch so that taxpayers and congressional overseers can perform our job of seeing where the U.S. dollars are actually carried out in action.

Second, the President's initiative sets an ambitious goal: 85 percent coverage in focus countries of vulnerable populations with life-saving interventions, as appropriate. And it is that "as appropriate" that provides wiggle room, some of which is very legitimate. But we do not want to open loopholes that allow for those who are content with the status quo to rest on their laurels. So far I haven't seen any of the technical guidelines or the criteria that govern when, where, and for whom certain interventions should and should not be used. It seems that these decisions are being made on an ad hoc basis for each country, which makes it difficult to compare the results across countries, to assess the scientific soundness of those decisions, and also for other donors and other countries who are looking to us for guidance about how to fight malaria in other countries and to imitate what we hope may be the most successful anti-malaria campaign since the world eradication effort last century.

Let me outline some of the basics we are looking for: Insecticide spraying in homes virtually everywhere; the use of the cheapest and most effective insecticide, which almost always turns out to be DDT. The World Health Organization (WHO) and others have stigmatized DDT long enough, even as environmental groups now concede that the chemical should be used for malaria control. No human or wildlife harm has ever been demonstrated when DDT is used for spraying of homes. The unnecessary death toll caused by a bias against DDT needs to end right here and right now. I will be expecting USAID to reverse years of damage caused by an anti-DDT message by enthusiastic and vocal support with dollars and words for spraying with DDT.

Next, a bed net distribution strategy that can realistically reach 85 percent coverage for vulnerable populations. Since almost every household contains a child under five or a woman of child-bearing age, that means you have to get at least one, maybe two or three bed nets into most houses in focus countries. That is going to involve a lot of free bed net distribution, and not a marketing campaign to sell nets.

We will want to see artemisinin-based combination chemotherapy used where there is resistance to older drugs greater than 10 percent. If we do not know what the resistance levels are in a given area, we should use artemisinin until we can establish what those resistant levels are.

USAID can streamline the use of indoor insecticide spraying through lifting of regulatory barriers. Massive environmental impact assessments for public health initiatives were never the intent of Congress in the National Environmental Policy Act. I suggest that USAID carefully review these laws and regulations. Rather than trying to justify the onerous regulations as not as problematic as they seem, I would rather see the Acting Administrator of USAID exercise his authority to remove the barriers altogether.

Finally, setting numerical goals for commodity allocations will further validate this Administration's commitment to saving the lives of Africans. While a commitment was made for countries not targeted by the President's initiative, I would like to see some targets set for the President's focus countries as well. You see, what we saw and what we do does echo around the world. We are only one player vitally concerned with the welfare and health of those on the continent of Africa. But we are the biggest player when you count both our bilateral and multilateral contributions to malaria control. If our message and our money go out in a science-based, unapologetic, reformist way, the whole world will change with us.

Given the death toll from this disease, nothing short of dramatic change by every donor and every host country's malaria program is necessary. We are losing generations in the meantime.

You will see on this other photograph a few of the children who died in one year at one school in Uganda from malaria. Tremendous potential wasted because we have not been effective in helping those that are dependent upon us. Every minute we take to get these programs up and running is precious time lost for millions of children just like them.

[The prepared statement of Senator Coburn follows:]

Chairman's Statement
Sen. Tom Coburn, M.D. (R-OK)
Bilateral Malaria Assistance: Progress and Prognosis
January 19, 2006

Malaria sickens somewhere around 500 million people and kills nearly 2 million every year. Of those, 85% of victims reside in sub-Saharan Africa. As we sit here for the next two hours, 240 more children will die from malaria.

The United States will spend $105 million to fight malaria this year, and the President has committed $1.2 billion over the next five years. With plans to scale up spending so dramatically in so short a period, it is all the more important that we get it right – that our program saves lives in a measurable way.

After our hearing on this subject last year, USAID went through its books and reported that less than 8% of the bilateral malaria budget went toward life-saving commodities such as the $2 drugs that cure the disease, insecticides to kill the mosquitoes that carry the disease and nets to keep those bugs off people when they're sleeping. What's worse is that the majority of that 8 percent was spent to SELL bed-nets to poor Africans rather than providing them free in quantities enough to make a dent in the malaria problem. When we brought some sunshine to the budget, we discovered that the vast majority of the malaria money was going to advice-giving programs, administrative overhead, travel and conferences. In other words, we spent most of our money telling people how to use the cheap and effective tools to fight malaria, and very little money actually providing them those tools.

Despite good intentions all around, our priorities have been out of whack. But things are changing. I want to commend President Bush and USAID for recognizing the problem and announcing major reforms over the past 6 months to change course.

The President's plan targets a few focus countries at a time for nation-wide coverage with life-saving interventions, including insecticide-spraying in homes and drug procurement. But even in countries not initially targeted, USAID recently announced an overhaul of its malaria programming so that by next year, 50 percent of its budget will go toward purchasing commodities. Twenty-five percent of funding will be spent on spraying.

This is ground-breaking movement, and I'm encouraged to think how many children and pregnant women might be spared death from this preventable and curable disease. I want to congratulate the President for his leadership, and especially Assistant USAID Administrator Kent Hill and his Deputy Michael Miller, who is here today, for their courage and commitment in the face of the grueling task of implementing reforms at the programmatic level. It's very easy for Members of Congress to throw stones and criticize. It's quite another thing to actually turn the ship of a large, international bureaucracy in a different direction.

We're having a follow-up hearing today because the sound policy and planning that have been achieved so far are only the beginning. So let's get into some of the details of what we'll be looking for over the coming months to carry out the new initiatives.

Chairman's Statement
Sen. Tom Coburn, M.D. (R-OK)
Bilateral Malaria Assistance: Progress and Prognosis
January 19, 2006

One of the first principles we aim for here is transparency. We've been assured that a web site would be launched that tracks all the money and progress made with that money toward measurable indicators. So far, the web site isn't quite up and running. I'll be interested to hear a firm date for that launch, so that taxpayers and Congressional overseers can see U.S. dollars in action.

Second, the President's initiative sets an ambitious goal: 85% coverage in focus countries of vulnerable populations with life-saving interventions, as appropriate. It's that "as appropriate" that provides wiggle room, some of which is legitimate. But we don't want to open loopholes that allow for those who are content with the status quo to rest on their laurels. So far, I haven't seen any set of technical guidelines or criteria that govern when, where and for whom certain interventions should and should not be used. It seems that these decisions are being made on an *ad hoc* basis for each country, which makes it difficult to compare results across countries, to asses the scientific soundness of those decisions, and also for other donors and countries who are looking to us for guidance about how to fight malaria in other countries to imitate what we hope may be the most successful anti-malaria campaign since the world eradication effort last century.

Let me outline some of the basics we're looking for:

- Insecticide-spraying in homes virtually everywhere.
- The use of the cheapest and most effective insecticide, which almost always turns out to be DDT. The WHO and other elites have stigmatized DDT long enough, even as environmental groups now concede that the chemical should be used for malaria control. No human or wildlife harm has ever been demonstrated when DDT is used for indoor spraying of homes. The unnecessary death toll caused by anti-DDT bias needs to end right here and right now. I'll expect USAID to reverse years of damage caused by this anti-DDT messaging by enthusiastic and vocal support, with dollars and words, for spraying with DDT.
- Next, a bed-net distribution strategy that can realistically reach 85% coverage for vulnerable populations. Since almost every household contains a child under 5 or a woman of child-bearing age, that means you have to get at least one, maybe 2 or 3, bed-nets into most houses in focus countries. That's going to involve a lot of free net distribution and not just a social marketing campaign to sell nets.
- We'll want to see artemisinin-based combination therapy, or "ACT" drugs used everywhere where resistance to older drugs is greater than 10%. If we don't know what the resistance levels are in a given area, we should play it safe and use ACT anyway until we get that resistance data.
- USAID can streamline the use of indoor insecticide spraying through lifting regulatory barriers. Massive environmental impact assessments for public health initiatives were never the intent of Congress in the National Environmental Policy Act (NEPA). I suggest that USAID carefully review these laws and regulations. Rather than trying to justify onerous regulations as not as problematic as they seem, I'd rather see the Acting Administrator of USAID exercise his authority to remove those barriers altogether.

Chairman's Statement
Sen. Tom Coburn, M.D. (R-OK)
Bilateral Malaria Assistance: Progress and Prognosis
January 19, 2006

- Finally, setting numerical goals for commodity allocations will further validate this Administration's commitment to saving African lives. While a commitment was made for countries not targeted by the President's initiative, I'd like to see some targets set for the President's focus countries as well.

You see, what the U.S. ***says***, and what the U.S. ***buys*** echoes around the world. We're only one player, but we're the biggest player when you count both our bilateral and multilateral contributions to malaria control. If our message and our money go out in a science-based, unapologetically reformist way, the whole world will change with us. Given the death toll from this disease, nothing short of dramatic change by every donor and every host country's malaria program is necessary. We are losing generations in the meantime. These photographs are just a few of the children who died in one year at one school in Uganda from malaria. Every minute we take to get these programs up and running is precious time lost for millions of children just like them.

I know our witnesses share my passion, and I'm grateful for their time and hard work to end the scourge of malaria on the world's children and families. Thanks for being here today.

Senator COBURN. I know our witnesses today share my passion, and I am grateful for their time and their hard work to end the scourge of malaria on the world's children and families. And I want to thank you for being here.

Michael Miller has been with USAID in his present capacity since 2004. We welcome him back to the Subcommittee for the second time. He serves in various interagency capacities for USAID in the implementation of the President's Emergency Plan for AIDS Relief, PEPFAR, and is directing the implementation of the President's Malaria Initiative.

Mr. Miller, you are welcome. Your testimony has been read. It will be introduced into the record as submitted, and you will be recognized for 5 minutes. And thank you again, personally, for being here.

TESTIMONY OF MICHAEL MILLER,[1] DEPUTY ASSISTANT ADMINISTRATOR FOR GLOBAL HEALTH, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

Mr. MILLER. Senator, it is my pleasure to be back, and we really appreciate your support and your interest in this. When we make big changes like that with any institution, it is never easy. And having the support of Congress is going to be essential as we go forward to maintaining those and building on those successes.

Since this Subcommittee's last hearing on the topic, the President has changed our global malaria strategy fundamentally in scope, size, and structure. Additionally, USAID has implemented necessary, complementary changes to its ongoing malaria programs. These changes, I believe, ensure greater effectiveness and accountability, provide critically needed global leadership, and will ultimately save more lives.

The most important development is the President's Malaria Initiative—or PMI, as we call it—which is a multi-agency program led by USAID. The PMI will reduce significantly the number of Africans who die from malaria and will challenge other donors to make similar commitments. President Bush's commitment of an additional $1.2 billion over the next 5 years is unprecedented in the fight against malaria. Accordingly, the goals of PMI are ambitious: Reduce by 50 percent the number of deaths from malaria in target countries. The program will eventually include up to 15 countries and benefit 175 million Africans.

The speed with which we have begun to implement the PMI is also unprecedented. In less than 6 months after the President's announcement, USAID was already in the field implementing programs that differ considerably in scope and size and focus from their predecessors. Right now, the PMI is conducting an indoor residual spraying campaign in southern Angola to protect over 500,000 people from epidemic malaria outbreaks. We recently distributed 130,000 long-lasting insecticide-treated nets in Zanzibar, which we will also follow up with indoor residual spraying. And in about a week, we will begin the distribution of 270,000 free long-lasting insecticide-treated nets in war-ravaged northern Uganda, among many other activities.

[1] The prepared statement of Mr. Miller appears in the Appendix on page 00.

PMI is a very different way of doing business than past practice. The hallmarks of the PMI are first and foremost programming based on clearly defined numerical targets for outcomes. Second is transparency in how the money is being spent. Third is a robust and effective monitoring and evaluation plan to make sure that we are, in fact, reaching our goals. This approach provides assurances that taxpayers' money is being spent effectively.

PMI's size and structure also provide opportunities to fight malaria in Africa in ways we could not just imagine a few years ago. In the past, USAID used the relatively small amount of funds to implement programs focused on issues such as policies to adopt artemisinin combination therapies over failing treatments, among other things. Much of that work is now done. With the PMI, we have the opportunity to design and implement many simultaneous, large-scale, comprehensive—meaning providing commodities as well—country-wide programs throughout Africa.

But that opportunity also necessitated changes to the programs currently outside the PMI, as we call it, the non-PMI, the existing USAID malaria programs. These are the structural changes we announced in December. One of the most visible changes is the elimination of programs that were simply too small to be effective on a scale we require. That was set at $1.5 million for this year. It will go up to $2.5 million for next year. Second is a correction of the imbalance between technical assistance and commodities, which we spoke about at length. Third is the opportunity to push the dialogue and think about indoor residual spraying as a frontline tool for fighting malaria in Africa, and we believe it has been under utilized.

The rapid scale-up of PMI means that next year more resources and more coverage of people will be inside the program than outside the program, since there is a very rapid graduation in. As a consequence, having two parallel but different programs side by side is as impractical as it is undesirable. Because PMI will expand rapidly, any real distinction between the two has to be temporary, and the programs that now fall outside the PMI have to start making critical adjustments now, including emphasis on life-saving commodities, reporting on planned activities and allocations, and programming more money.

In the case of Indoor Residual House Spraying (IRHS), this year we will spend approximately $20 million on spraying, and I would note that is two times the entire amount of the global malaria programs in 1997 just on spraying alone this year, and about a 20-fold increase over fiscal year 2004. In at least three of the eight countries where USAID will support IRHS this year, DDT will be the primary insecticide. As some countries move into the matrix of PMI countries—in other words, they move off the list of outside PMI and into PMI—the specific numerical targets and the monitoring and evaluation regime will also apply to them as well. In short, the changes we instituted to the non-PMI are part and parcel of the creation of a single, large-scale, target-driven strategy to fight malaria in Africa and to demonstrate those results.

What we have begun to do with PMI, as we have done with the President's Emergency Plan for AIDS Relief, PEPFAR, is to judge and plan our programs based on outcomes, not simply on how

much money we put in at the beginning. The difference is simple but profound in terms of how we plan and how we go about it. It demands a level of new programmatic transparency and documentation that in turn provides confidence in the effectiveness that allows the President to make the multi-year commitments and ramp up funding accordingly. Targets keep agencies, individuals, and entire governments focused. With accurate data, targets provide unambiguous measures of success or failure and allow informed judgments about whether the program is effective, whether it should continue to be funded or not, or that money should be moved elsewhere. Ultimately, that not only makes for good management and good governance, it is much more satisfying for those of us who are charged with implementing the programs. It also makes them more effective. In the case of the PMI, that means the opportunity for the United States to fill a global leadership role in the fight against malaria and to save millions of lives that might otherwise have been lost to a preventable and curable disease.

Thank you.

Senator COBURN. Thank you so much for coming. One of the things you alluded to was the transparency and accountability of this new program, and we have talked about having a way for the American public to track that. And this is not just with USAID. The American people ought to be able to see where all their money is going all the time, except in national security issues. And the idea of having that available to the American public, when do you perceive that will be available?

Mr. MILLER. I will make a distinction between the fiscal year 2004 data and the fiscal year 2005 data, because we have collected them at different times. The fiscal year 2004 data is complete. We have put what we call the aggregate or the composite spread sheet of expenditures up on the website yesterday or the day before. And then as we actually make the typed corrections, if you will, to the data sheets that we corrected by hand as we conferred with the field, did mathematical corrections and things like that, those will be posted subsequently. I think the last time I asked the staff was doing it. There were five up.

So the 2004 data is complete, and it is starting to be posted. The 2005 data is going to take a little longer simply because when the fiscal year ended, we sent out the questionnaire, I believe, on October 31. So the missions received it presumably that day and were able to start collecting that data themselves and sending it out to their grantees for them to return data back to the mission.

That will take a while because of a couple factors: Simply because they have not closed their books, they are still spending some 2005 money. They have to rely on the grantees to send the information back, which, of course, you cannot always guarantee. Not much happens over Christmas in many of these countries, including here.

Senator COBURN. Well, the point I am getting to is there is going to be created a continual expectation that there is going to be data collection and transparency, where the money is spent and the results of the money.

Mr. MILLER. Absolutely. Our goal is to have by February 10 the complete 2005 data. If it is not accurate, we will not post it. We

will continue to go back and make sure it is accurate. We do not want to rush it. But 2006 and beyond, it is built into the system, and that is the benefit that we do not have to do a retrospective.

Senator COBURN. Under the President's Malaria Initiative, the goal is 85 percent coverage of vulnerable populations as appropriate. How would you define "vulnerable populations"?

Mr. MILLER. Children under five, people living with HIV/AIDS in malarious areas, and pregnant women.

Senator COBURN. OK. And what four interventions are essential to achieve malaria control?

Mr. MILLER. Insecticide-treated nets and indoor residual spraying as prevention measures at the household level; treatment, ACTs, and treatment of expectant mothers with intermittent preventive treatment. That is four.

Senator COBURN. When we go back to the goal of 85 percent coverage of vulnerable populations as appropriate, can you define to me what criteria you all are going to use for this "as appropriate"?

Mr. MILLER. There will be some cases where—it is rare, but in general you can say in most areas in tropical Africa, in the countries that we are focusing on this year and next year, everybody within those categories will be vulnerable; almost 100 percent in Angola I think you can say. There will be parts of—well, almost 100 percent, but there are parts of Angola, in the highlands, where it may not be. There are parts of—people who live in the cities perhaps are not vulnerable. But, in general, I think you can say almost anybody who fits in those three categories of HIV/AIDS positive, children under five, or pregnant women is more than likely going to be in the vulnerable population.

Senator COBURN. The ultimate goal is to fund adequately all four interventions.

Mr. MILLER. Right.

Senator COBURN. How are you going to make the decisions for priority, for which comes first?

Mr. MILLER. Well, the idea is to do all simultaneously. We want those levels of coverage on all of them. The one distinction I will make is between nets and spraying. Whereas, at the home level, if you can achieve coverage of one of those two at 85 percent, we believe we will be meeting our targets.

Now, there are cases where, in fact, in Zanzibar, we will do what we call the suspenders-and-belt approach, which is spraying and nets made available. And we will see what the effect of that is. What we do know is in the case of if you have proper and effective use of a net or the proper and effective use of IRHS, you can reduce the incidence of malaria for the protected person by 90 percent.

Senator COBURN. But the difference is you can do IRHS once a year and have a variable use of net of not use of net, where somebody takes the net and goes fishing with it instead of using the net for prevention. So I guess I presume by your answer you all have scientific data to say that nets, if you get an 85-percent coverage, are just as effective as IRHS?

Mr. MILLER. The way I would characterize it is we do know that nets are effective, we do know that IRHS is effective. What I don't think we, the world, really have a sense of is exactly what the distribution should be, how much IRHS versus how much nets.

Now, there are practical considerations as well, some areas where it would be conceivable that it simply just becomes cost-ineffective to do IRHS, which does have a logistical train along with it. You do have to have acceptance rates and stuff like that. But you are correct, there are clear advantages in some cases of IRHS over nets. And what we hope to find out is—take the issue of IRHS, which we believe has been underutilized, and start to push the issue to have people asking the question how much IRHS can we do, where is it cost-effective to really get the data on this, we have some data, and we know from places like South Africa, and I am sure in Swaziland, a place like that, that it can be very cost-effective. But what we don't know in these countries that are hyperendemic countries like Uganda, where 95 percent of the country has transmission almost all year round and they have not done spraying in decades. Where is it that we can cost-effectively do spraying before we start running out of money or where in the case—or if that is the case, where nets would be more appropriate.

Additionally, we also have net distribution networks up and running. One of the tragedies, if you think of IRHS, is because it has been underutilized—and it is not just DDT. I think it is IRHS across the board. There is very little institutional capacity in these countries. For the case of Uganda, I had a very interesting conversation with the National Malaria Control Program and with the Vice President himself, who is also a physician like you. They are very inclined to use IRHS. They are leaning heavily towards DDT. But in this first year, they have chosen, under the PMI, in fact, to choose one district, Kabali District, do spraying in one district, and then see how—get their feet under them, essentially, start moving out to the other 14 districts that they have targeted, and then make a decision as to whether they think in that case they can rotate DDT in instead of synthetic pyrethroid. Their preference would be to use DDT simply because it is more effective in their case.

Senator COBURN. It is also markedly less expensive.

Mr. MILLER. It is a fourth of the cost, is what they told me.

Senator COBURN. For the same amount of dollars, you get four times the amount of coverage. Once you have the infrastructure there.

Mr. MILLER. Right. I don't think the math would work out exactly, but, yes, you can presumably get much more coverage because the largest single cost in that program, speaking of Uganda specifically, if I remember right, it was the insecticides. So if you cut that by a fourth—now you do have additional transportation costs. DDT is bulkier, but you also have cost savings where DDT can have a longer residual effect——

Senator COBURN. It is twice as long.

Mr. MILLER. Yes, and that is also the case in some other countries. We found that you could spray once a year with DDT or potentially——

Senator COBURN. Well, I think that is pretty well known. We are going to have some testimony today about that, and the fact is it is significantly less in cost, it lasts twice as long, and it is more effective. They are not equal in effectiveness.

Mr. MILLER. Right. And there are cases where the building material, if it is a finished wall or a painted wall, you really have to

make a judgment because there are adherence issues, residual issues, and streaking apparently is a problem when they wipe it off the wall.

Senator COBURN. Is there still a plan in the new Malaria Initiative to subsidize nets rather than just giving them out?

Mr. MILLER. The principle that USAID has established that economics should never be a barrier to net ownership, I think, is a sound principle. It is not the only—that in itself is not a net plan. It is a good principle, and we will stick to it. But my personal belief is at the levels of coverage we are looking at and the fact that so many people in malarious areas, particularly in rural areas, people who are destitute, who simply never will be able to afford a net under any circumstances, or people who possibly could but will have no exposure to a socially marketed message or very little contact with a formal marketplace, that those people—we cannot realistically expect that we can reach the kind of levels we want to by selling nets alone. And, yes, I think we will have to—we are prepared to, as the situation warrants, provide free nets, as we are in Uganda already, in large amounts.

Senator COBURN. Other than infrastructure to do indoor residual spraying, the infrastructure limitations to be able to train people to do it, when is IRHS inappropriate in your view? I am hearing that bed nets equal IRHS, and from what I have read, I do not read that in the literature.

Mr. MILLER. No.

Senator COBURN. I am going to learn some of that today, but from what I have heard from you—and I have a little bit of concern—is that we are liable to not use the most effective, and the variable is if you have a bed net in your home and you don't use it, you don't have coverage.

Mr. MILLER. You don't have coverage, yes.

Senator COBURN. If your home has been sprayed with DDT, you have coverage for a year.

Mr. MILLER. Correct.

Senator COBURN. There is a big difference. You take a variable out of the equation.

Mr. MILLER. Yes, I agree that IRHS has many advantages in many situations. What we do not know—generally, IRHS has been underutilized. I think there is a big question mark about how much we can get—the cost-effectiveness, what kind of coverage levels—with the money we have. I think that just requires doing a lot more of it. I think we have commissioned a study that will look at all the available data on cost-effectiveness, but I do not have confidence that alone will really give us the picture. I think we have to put more money against it and see what the data is, because there are a lot of questions about how effectively we can use it. And I think we can use it much more effectively, and that is sort of less of a question. But in the single home—I should clarify. What I meant is in a controlled situation, if you are using a net properly in a controlled situation, if you are in a home that has been sprayed properly, that individual, that vulnerable individual, can enjoy certain amounts of coverage. Now, I suspect that there are situations—and from past experience people say in urban areas, in peri-urban areas, there are these sort of diffuse, quasi-urban areas

around the big cities in Africa, that spraying is much more advantageous. And that is what we are really aiming to find out, is put money behind that and see what really are the cost-effectiveness numbers that we can take to the bank and really plan against in future years.

Senator COBURN. In November of this year, the South African Health Ministers, it was resolved that member states should support IRHS with insecticides. And, recently, Ugandan scientists urged their government to support IRHS with DDT. Is there some outside barrier to indoor residual spraying with DDT?

Mr. MILLER. With DDT? Yes, I think there is. There is a lot of ignorance about DDT, as I think we have seen. People are afraid of it, and that is not just here. Again, I will go back to my Ugandan experience. I had a very fascinating conversation with Vice President Bukenya, who said they, for example, have started a net retreatment program in the area around where he is originally from, and they had very little uptake—uptake meaning people actually accepting the service for free. And they found out a rumor had gone around that the retreatment was with DDT, which, of course, first, is false, we don't treat nets with DDT; and, second, it is false that it is harmful to humans in indoor residual spraying.

So there is ignorance we have to fight and——

Senator COBURN. So do you all have a plan to address that in terms of remove the barriers to IRHS with DDT?

Mr. MILLER. Absolutely. Well, the first part of the plan is simply do more of it. In fact, in the non-PMI programs, when we dedicated that 25 percent to IRHS, what we were able to do is go through and essentially cherrypick countries where we knew they had very robust IRHS plans and national malaria control plans, which is not true for every country, and where we had a reasonable number of them that would use DDT.

Now, one of the main ones that does not in that roster of four—five if you count Madagascar, and I will come back to that—Kenya does not. And they have the same problem that Uganda does, which is essentially if I—this is my own characterization. They feel like they are over the barrel in terms of exports, particularly to the EU, and they think it is a real concern, and I think it is, that the standard is very high that if there is any DDT detected in the cut flower industry, in the vegetable exports, freshwater fisheries, all of which are common to those countries and to Tanzania, then they face potentially a ban to exports to the EU. That would cripple their economies. In their minds, there would be no advantage.

In Uganda, DDT is not illegal. But as I mentioned, they are essentially going to get themselves back into the IRHS program, understand what they want to do, make sure there is no seepage out in the agricultural community, make sure the security around sprays are adequate. In Kenya, they still have a ban. We have not had any dialogue with them as to whether they would lift that. I think they are going to have to make that decision on their own.

But to answer your question, yes, there are. There are many considerations for them.

Senator COBURN. I am going to turn this over to Senator Carper, but it is interesting when you look at the signs and you look at the death rate in Africa and you look at the effectiveness of DDT, and

we are going to hold people hostage to not do the most effective, the most efficacious treatment and public health strategy because we are going to threaten them with poor science because we don't understand the poor science. And I think there is an obligation on your part to bear the pressure to change that with the EU. When 500,000 kids die a year because there is not IRHS and there is not artemisinin and there is not the medicines made available, and the IRHS isn't there because somebody is afraid—not on the basis of scientific but on the basis of emotion—that it is going to have an impact on somebody, that is hijacking the world's poorest people in the worst way.

[The prepared statement of Senator Carper follows:]

U.S. SENATE COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
SUBCOMMMITTEE ON FEDERAL FINANCIAL MANAGEMENT, GOVERNMENT INFORMATION, AND INTERNATIONAL SECURITY
Ranking Member, Tom Carper
Opening statement for Hearing on
"Bilateral Malaria Assistance: Progress and Prognosis"
January 19, 2006

Thank you Mr. Chairman for calling this hearing. While we often hear of the devastation that the AIDS epidemic has caused on the continent of Africa, we hear much less about a disease that has proved to be equally as deadly – malaria.

3,000 people die from malaria each day on the continent of Africa. Most of them are children.

This hearing today allows us to follow up on a previous hearing that examined how our government has proposed to address this deadly disease.

I am encouraged by the numerous changes that have taken place since that May 11th hearing that I think can help to put us back on track for meeting the Roll back Malaria goal of halving malaria deaths by 2010.

These changes since our last hearing include the President's Malaria Initiative, which is the first time that this administration has openly committed to fighting this disease and means that we now have:

- A Malaria coordinator tasked to oversee all of our malaria initiatives,

- A commitment of $1.2 billion over the next 5 years to fight malaria,
- A requirement that a percentage of those funds be spent on commodities like (nets, drugs, and spraying) and,
- An oversight plan that will make sure that African governments and organizations have a larger role in planning and implementing malaria programs in their countries and that allows the public to monitor our malaria activities

While I am pleased by this new focus on malaria, I am somewhat concerned about the permanency and sustainability of this initiative as, I am told that the President created this malaria initiative in the same year that he initially proposed to cut malaria funds.

My hope is that this will be a permanent and sustainable initiative that our expert witnesses here today can give us further insight on so that we can ensure that our efforts are a success.

I look forward to hearing their views on the effectiveness of current U.S. and global efforts to fight malaria.

Most importantly, I'd like to hear about best practices on the ground and how with increases in funding for drugs, nets, and spraying, we can begin to work more closely with African governments and organizations. This will ensure that they are able to use all of the tools at

their disposal to fight malaria while simultaneously receiving the skills and training that are needed to implement these programs long term.

Thank you, then, to our witnesses for taking the time to be here today to educate us on these issues and to you, Mr. Chairman, for taking them on.

OPENING STATEMENT OF SENATOR CARPER

Senator CARPER. Thank you, Mr. Chairman. Good to be with you again. And, Mr. Miller, thank you for joining us.

I think you were before us back in May. Is that right?

Mr. MILLER. I was.

Senator CARPER. I thought so. If you would start with a little bit of a timeline for me, please, and take it from May when we had our hearing, and I think the President maybe offered his initiative in, I want to say, early summer, maybe June, can you walk me through the timeline from where we were back in May and sort of chronologically what is different today and when did that occur.

Mr. MILLER. Yes, sir. I believe the hearing was May 12. By that time, we were already in very early planning stages with the White House in terms of what kind of program we could potentially propose to the President in the lead-up to the G–8. And a lot of the planning around the President's Malaria Initiative really was from the G–8. As you know, last year at the Gleneagles Summit, the United Kingdom had as their theme, if you will, global health. And so one of the global health initiatives we had was a series of options on what we thought we could do in malaria. Ultimately, the President chose it because it could be—it is doable. Malaria is beatable. There is plenty of room for global leadership on this. And it is something we can do—with relatively reasonable amounts of money, we can have a huge impact. And that is why he chose it.

He chose that leading up to the G–8, and by June 30, we had a completed proposal that he had approved, and he announced on June 30. We were up and running pretty fast. Certainly by December we had the spraying program started in Angola. We had net distribution started in Tanzania, and we will start the programs in—the jump-starts in Uganda as well.

Also by December, we had our country teams make two trips to the region. The first was to make a needs assessment, and that is an assessment where a team, some of the malariologists that are with me here, went to Tanzania, Angola, and Uganda, and along with other donors, with the World Health Organization, and with the governments of those countries, the National Malaria Control Programs, made an assessment of who is doing what where and who is not doing what where and where we can start planning to put our resources against that. That was in August. The second would be a series of planning trips, both by country staff that is already there and our expertise here going out as needed, to pull together a country proposal, essentially. This is modeled, if you are familiar with PEPFAR COPs, the country plans that they submit every year, which show what they are going to do, with who, and where. We had a small version of that submitted to us. We had an interagency team that included Secretary Leavitt's office, the Centers for Disease Control, DOD, State Department, Office of Management and Budget, the White House, the National Security Council, and us.

We reviewed those and approved them in large part on December 20. So just in that 6-month period or so, less than 6 months, we actually had approved programs, money behind them, and activities going on in the field.

Senator CARPER. That is pretty fast.

Mr. MILLER. Very fast, yes. And I should add——

Senator CARPER. Do you think it was largely instigated by our hearing, probably? [Laughter.]

That is probably giving us more credit than we deserve.

Mr. MILLER. It certainly did not hurt.

Senator COBURN. Let me answer that. There are a lot of people that are interested in this. Senator Brownback has been working in this area for a long time. There are people in USAID that want to see it more—the people that work at USAID want to see success. And so highlighting it helps raise the pressure on it, but the leadership, both in USAID and at the President's level, is responsible for this change, not us. And you did not hear my opening statement, but I said that.

Mr. MILLER. But we do certainly appreciate your interest and support on that.

I should also add that also in December Administrator Natsios signed a fairly comprehensive and fundamental restructuring of our programs, malaria programs within USAID that currently fall outside the President's Malaria Initiative but are in the process of graduating in. So that was all within a 6-month period. We started the Presidential initiative, got it up and running, and independently made pretty fundamental reforms internally.

I do have to give a tip of the hat to PEPFAR. The fact that we in the U.S. Government, we had exceptionally good leadership within PEPFAR from Ambassador Tobias, so we are very pleased to hear the news about him today—that is right, if the Senate confirms him, of course. And we also had the benefit of seeing where the barriers were, where things were easy, what kind of numbers we had to collect, what kind of data we needed in the end to prove that we were meeting our goals. And then the most basic point is that you have a program that is based on targets. You set a target that is realistic, you say how you are going to get there, and then you start programming against that with a program that can prove it is getting there. And that is the real innovation with PMI that PEPFAR really led the way on, and we have benefited tremendously. The people in the countries that have already gone through the process of making a country plan and that kind of planning and that kind of reporting was much easier for them and much easier for us. We have already been through that. So very much benefited from that.

Senator CARPER. Just take a very short while on this one, and I know you spoke of this in your statement, but how are we doing? It has been 6 months since the President unveiled the initiative.

Mr. MILLER. I think we are doing great. I am very satisfied——

Senator CARPER. How are we doing and how do you measure success?

Mr. MILLER. We measure success in lives saved at the end of the day. The end of the day is actually at the end of 5 years, but we do have within that 5-year period ways to measure our progress. And it is very important.

At the end of year two, or halfway in—first we establish baselines, what the coverage is in a country, what gaps we need to fill, what the mortality is from malaria, particularly in children under five. And halfway in, about the end of year two, we make an as-

sessment of what our coverage rates are with preventions and with treatments. That data also provides for us what the deaths are within that sample area, what the under-five deaths are. And halfway through, we can go through and send people out to track down those deaths and do what we call a verbal autopsy. In other words, you take an expert that goes back to those homes where the child died and ask the mother a series of questions, because a child in Africa to have a fever, it can be any number of things. Half the time it is going to be malaria in these areas. But it could be meningitis, it could be any number of things, so they ask: Was the child vomiting? Did their neck hurt? Were they stiff? And they collect that data, they send it back to a panel of experts, who will do what they—that is part of the verbal autopsy, who make a pretty accurate determination of whether they think it was a malaria death or not.

With that data, what we can—coverage data, is IRHS being implemented effectively? Is the insecticide being watered down, diverted, or are people missing, are people not understanding what we are doing? Are people using their nets for other things? Sometimes people leave nets in the bags. It is the only thing they own. It is the only thing that has been produced that is new, and they would rather keep it than use it because they don't have the education. So we make sure people understand how they have to do this on their own. We can make corrective adjustments then, and also at the end of the year three, we can also go back and do another assessment of what the coverage issues are, whether IRHS, nets, and the treatments are doing what we say we need.

So we have several chances within that time to make corrective actions, so that plus the surveillance data, which will take a little more time to explain, we have a pretty good sense of where we are. So by the end of year five, at the end of the day, I think we can say with a pretty high level of confidence if we are meeting those targets or not, or even at the end of year two, if we need to take corrective actions that soon.

Senator CARPER. All right. Thanks very much.

Mr. MILLER. You are welcome.

Senator CARPER. Thanks, Mr. Chairman.

Senator COBURN. I have three real quick additional questions. You related to our staff that the programmatic environmental assessment should be completed in March, and you still feel comfortable with that? The programmatic environmental assessment?

Mr. MILLER. Right, we do, yes, and that is probably worth explaining real quickly. That is, in the environmental assessment period for leading up to spraying, what we have decided to do is try to make life a little easier on these country plans and take and do one large assessment, the types of assessments that we need across the board, a toxicity, chances of leakage—we use international standards—potential harm to fisheries, things like that. So the country plans can go and have a greatly reduced assessment burden.

Senator COBURN. Right.

Mr. MILLER. So, yes, we are still sticking by that.

Senator COBURN. And I understand there is underway a search for a malaria czar, somebody to take charge of this. As a country,

we are going to have three times the investment on an average. We are going to go to about $350 million a year in terms of malaria.

I am wondering, what are the characteristics for the person that you are going to fill that? I sit and look as a physician at the failed strategies in Africa, and I am wondering if we ought to be choosing an infectious disease expert that was not associated with a failed strategy.

Mr. MILLER. Right.

Senator COBURN. I would just put that out as a comment. If we go from back inside of the failed strategies, I think we lose confidence, first. I can tell you I will lose confidence. Second, is new ideas, fresh ideas, and new invigoration will be helpful. So I am interested in that.

Then, finally, my final question is one of the other big problems that we are facing in Africa is tuberculosis. And can you relate to me—and I know this hearing is not on that, but are there plans ongoing in USAID to expand our help on that dreaded disease?

Mr. MILLER. I will start backwards, on the TB. I can't tell you off the bat what our projections are on TB. But I agree that, when we were planning PEPFAR—I was actually in a different position at that time—and also here on the Hill, people identified—we used to call them "the big three" in Africa. They are very commonly associated with each other. If someone has HIV, there is a good chance you are going to die of TB or malaria. So it is very reasonable to say that as we are dealing with AIDS and malaria, we would also benefits from taking a look at TB. I am not offering any criticisms right off the bat, but I do want to recognize that, yes, it makes sense.

Now, on the coordinator, I agree with you. We are not looking to enforce or reinforce the status quo. We are looking to change the way Americans view our role in fighting malaria worldwide, the way the world views our role. So we have to have a leader. Someone with public health expertise I think would be helpful, but as we have seen with many leaders in public health, it is not necessary. I do not come from a public health background. My boss does not. Ambassador Tobias does not. So it is not required. If you surround yourself with real professionals—and we do—it is really qualities of leadership, someone who understands opportunity, someone who can push the issues for IRHS, for example, someone who can do that not just here within USAID or within an interagency but also globally.

That search is ongoing. There are some candidates, but presumably we have our own leadership change coming up, and it will have to be at least connected to that.

So I would have liked to have had one by now. That is not for lack of trying. And certainly by next year, when we ramp up to $135 million within the PMI and go up to presumably—potentially up to $200 million overall, it is an incredible amount of responsibility. We have to staff up some more internally. We will want somebody that has leadership and has the experience, and our job now, I think we see it as we get a program up and running that we can hand over to that person, that there is minimal distractions, minimal corrective action that will have to be taken.

Senator COBURN. All right. Thank you. I am going to have about four or five other questions that I will submit to you in writing, if you would get those back to us in a couple of weeks.

Mr. MILLER. I would be happy to, yes.

Senator COBURN. I would appreciate it

Senator Carper, do you have additional questions?

Senator CARPER. Just one, if I could.

In your opinion, what role should malaria experts and African governments be playing in defining where house spraying should be used? But before you answer, let me give you sort of a second part. Do you have any concerns that legislating that a percentage of U.S. funding be for spraying, taking out of the equation both African governments who may better understand logistics in their particular part of the world, and experts who may best understand which sprays or which nets or other tools may work best?

Mr. MILLER. I think in any circumstances, answering generically, we want to have experts as closely associated with the planning as possible. I think the best way to go about it is to start with the idea that we believe spraying has been underutilized in Africa. Personally, I believe everything has been underutilized in Africa. That is part of the problem.

In the 1950s, when a panel of experts, a WHO panel of experts, and the donors decided that Africa was simply too difficult to undertake the eradication—and eradication was the aim then—to undertake the eradication programs in Africa, as we did on many other continents, we were literally decades behind. And what we found is in these countries, as the Ugandans told us very clearly, there is very little expertise on indoor residual spraying. Some people remember it. Some people are very enthusiastic about it. A lot of people don't know about it. And the expertise within the National Malaria Control Programs varies quite a bit. And I think the attitudes toward indoor residual spraying varies quite a bit.

One thing that we have observed internally is that the National Malaria Control Programs' posture toward indoor residual spraying very often reflects the prevailing opinions of outside experts who are hired as consultants to help write them. So it's going to be a real grab bag of opinions. Predominantly, the opinion is that IRHS does not have a role. We don't agree with that. Most Africans don't agree with that. It is not universal.

In the case of Tanzania, for example—Zanzibar, rather, it was USAID staff that said, Why don't we try an indoor residual spraying campaign here as well? They said that is a good idea. In Uganda they have a very clearly defined plan where they have planned over long periods what to do, and we come in behind that without much questioning. It can be expanded or it can be limited, depending on it. But I think it is fair to say that the level of expertise on IRHS worldwide, particularly in Africa, is pretty spotty, and we need to support that. We need to support more interventions across the board, not just IRHS but more interventions, more attention on malaria from all donors.

Senator CARPER. All right. Thank you very much. And thank you for the report.

Mr. MILLER. Thank you.

Senator COBURN. I would just note that there is great scientific data that proved the effectiveness of IRHS in terms of controlling malaria.

Mr. MILLER. I agree.

Senator COBURN. Reductions by 50 percent in the death rate among those where it has been utilized properly. And that is what we are talking about. We are talking about saving those kids' brothers' and sisters' lives. And it is effective. And it is not about mandating the percentage. It is about having more than 8 percent of the budget go to actually making an impact in the disease.

Mr. MILLER. Right.

Senator COBURN. That is what it is about. Mr. Miller, thank you very much.

Mr. MILLER. My pleasure, sir.

Senator COBURN. We will submit some questions. Thank you for coming before us, and congratulations on a job well done.

Mr. MILLER. Thank you very much. Thank you, Senator.

Senator COBURN. I would like to thank our next panel. We have three witnesses. I want to personally express my appreciation for you coming. We have Simon Kunene, Malaria Program Manager, Swaziland Ministry of Health. Mr. Kunene has directed Swaziland's National Malaria Program since 1993. He is the Chairperson of the Southern African Development Community Subcommittee on Malaria. He also serves as a consultant to the World Health Organization on vector control and indoor residual spraying for malaria control. I appreciate very much the distance that he has traveled to come to be with us. I know what that long ride is like, and to share the lessons that you have learned from being involved with this in the field.

Next is Dr. Don Roberts, Professor at the Uniformed Services University of the Health Sciences. Since 1986 Dr. Roberts has been a professor at the Division on Tropical Public Health. He has authored over 100 peer review publications. Much of his research is focused on malaria control methods, specifically on indoor residual spraying. I appreciate the scientific expertise he will share with the Subcommittee.

Next is Dr. Andy Arata, Vector Control Specialist. Dr. Arata serves as a consultant to USAID and the World Bank projects involving vector-borne disease and their control. He has previously held a post as professor in the Department of International Health and Development at the Tulane School of Public Health and Tropical Medicine. He has served as the Deputy Project Director of the Environmental Health Project funded by USAID, and has over 30 years of experience consulting, managing, teaching, and researching in the field of tropical diseases and vector control. I look forward to hearing about lessons learned from his extensive career.

I want to welcome you all. Your full testimony will be made a part of the record, and you will be recognized. We would like for you to limit to 5 minutes. If you go over, we are OK. We do not have any votes that we are going to have to worry about today.

Mr. Kunene.

TESTIMONY OF SIMON KUNENE,[1] MALARIA PROGRAM MANAGER, SWAZILAND MINISTRY OF HEALTH, AND CHAIRMAN OF THE SOUTHERN AFRICAN DEVELOPMENT COMMUNITY SUBCOMMITTEE ON MALARIA

Mr. KUNENE. Thank you, Mr. Chairman. Thank you very much for inviting me to give this testimony today, and I hope this hearing will lead to a better understanding of what Swaziland is doing or has done in malaria control, and how the U.S. Government can better assist other African countries, including Swaziland, to save lives.

As my written testimony explains, Swaziland's main intervention in malaria control is indoor residual house spraying, and this method of control has been highly effective for many years, and was first introduced shortly after the end of the Second World War.

As a result of the successes and a reduced pattern of malaria, funding for malaria control was reduced significantly in the 1980s. Indoor residual house spraying coverage declined, and malaria cases and deaths increased.

In 1986 and 1987, the government of Swaziland, along with some partners, which included the World Health Organization, the South African Trade Mission and USAID, reinvigorated malaria control. This relaunched program was, and is still, mainly based on indoor residual house spraying and provision of effective drugs. And recently we have introduced insecticide treated nets in our program.

We now have a very wide coverage, Mr. Chairman, of IRHS, and with more than 90 percent in targeted areas is now coverage achieved. We use DDT and synthetic pyrethroids, which continue to be highly efficacious and cost effective.

An innovation of our program is to use geographical positioning system, GPS, to enhance planning, monitoring and evaluation of our malaria control activities. The introduction of GPS in our program ensures that limited resources are put to the best possible use. With support from the Global Fund we recently introduced ITNs, targeting pregnant women and children under five years of age.

To ensure that we achieve the appropriate targets, these nets are distributed to the high risk groups free of charge. We strongly believe that IRHS and ITNs complement each other. In other words, ITNs are not a replacement for IRHS and vice versa.

Malaria case management remains very critical if we are to reduce malaria morbidity and mortality. This requires that health personnel are properly trained in the management of the disease, and there should be a consistent supply of drugs. The Kingdom of Swaziland, over the years, ensured that all anti-malarial drugs are available at health facilities, and the distribution and administration of these drugs remains the responsibility of health professionals.

The consistent implementation of IRHS and the limitation of antimalarial drugs to health professionals have probably contributed to the slow development and spread of chloroquine resistance in the country. It is against this background that the chloroquine remains the drug of choice. However, the country has taken a deci-

[1] The prepared statement of Mr. Kunene appears in the Appendix on page 00.

sion to introduce ACT in the country, not because of resistance, but because of the added advantages of ACTs.

Malaria is very unstable in Swaziland and epidemics are very common in the years of favorable conditions for transmission. It is, therefore, crucial that we have a very sound disease surveillance system in place to pick up any abnormal situations.

Our decisions on malaria control are based on scientific evidence. Therefore, we monitor drug and insecticide resistance, and we work with international institutions in this regard.

The effective implementation of the above has ensured that the pattern of disease is maintained at acceptable levels. For example, clinical malaria cases have been reduced from 45,000 in 2000 to over 5,000 in 2004. Malaria admissions have fallen from about 1,800 in 2001 to fewer than 200 in 2004. There were less than 10 malaria deaths in 2005. We now have a situation where a single malaria death becomes a news item.

The Kingdom of Swaziland works closely with other partners in the Southern African Development Community. An important factor in our success has been the inter-country collaboration with South Africa and Mozambique in Lubombo Spatial Development Initiative. This is an initiative that has been highly successful and is based on IRHS, effective drugs, good disease surveillance and capacity building. These interventions have resulted in significant reduction in the pattern of the disease in the three countries.

The inter-country collaboration shows what can be achieved when the right interventions are chosen, and when good operational research supports decisionmaking.

We would like to see a situation where a far greater proportion of U.S. Government support for malaria control goals on commodities. That will have an immediate impact on malaria cases and deaths. We would also like the U.S. Government to promote policies that will provide essential commodities, such as ITNs, free of charge to the vulnerable groups. I would also like to see the U.S. Government taking a more active role in positively promoting this intervention, which has been degraded over the years. We also need a clear position on the use of DDT, whether or not U.S. funds can be used to purchase this insecticide. We also would like to appreciate U.S. support in the research, development of alternatives to DDT.

Finally, Mr. Chairman, we strongly believe that U.S. Government supported malaria initiative should fit with country's own strategic framework instead of being imposed on them for sustainability.

Thank you for the opportunity to give evidence today, and for your interest and leadership on this issue. I thank you.

Senator COBURN. Thank you very much. Dr. Roberts.

TESTIMONY OF DONALD R. ROBERTS, Ph.D.,[1] PROFESSOR, DIVISION OF TROPICAL PUBLIC HEALTH, DEPARTMENT OF PREVENTIVE MEDICINE AND BIOMETRICS, UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES, BETHESDA, MARYLAND

Mr. ROBERTS. Thank you, Chairman Coburn, for the opportunity to present my views on malaria and DDT this afternoon. As a government employee, I am required to state that my comment should not be construed as reflecting the opinions of my university, the Department of Defense, or the U.S. Government.

In preparing my comments I was reminded of a statement often used in discussions of controversial issues, namely, that each of us is entitled to our own interpretations, opinions, and ideologies, but we are not entitled to our own facts. Certain basic facts about DDT and malaria control might help focus our thoughts and discussions.

DDT is sprayed on the inner walls of houses to control malaria, and this is referred to as indoor residual house spraying, or IRHS. When sprayed on walls, DDT acts primarily as a spatial repellent. This spatial repellent action stops mosquitoes from entering houses and transmitting malaria while people sleep. DDT is moderately toxic to mosquitoes, but toxicity is not its primary mode of action. Our research shows that mosquito resistance to DDT toxic actions does not neutralize DDT's spatial repellent action. Thus, DDT is effective in the control of malaria even when the mosquitoes are resistant to its toxicity.

Some people argue against house spray programs and the use of DDT solely on the basis that poor or less developed countries do not have the infrastructure or people trained to administer such programs.

To the contrary, many malaria endemic countries started malaria control program operations on their own initiative in the 1940s. Those pioneering programs were quick-starts, and the managers learned valuable lessons as the programs progressed, and the programs progressed quickly. It seems reasonable to me that if poor countries created such programs 60 years ago, governments can do the same thing today.

Another argument against indoor spraying is expense, that it's OK for urban areas, but that indoor spraying is just too expensive for rural areas. Well, malaria is a rural disease. The truly significant value of DDT in the 1940s was that it offered, for the very first time, an affordable method of protecting rural households from malaria. In fact, any claim that indoor spraying is ineffective or cannot be used in rural areas because of cost, is simply not consistent with the historical experience.

There has been a lot of discussion about DDT's usefulness in areas where mosquito vectors show variable levels of resistance. I have already explained that DDT does not function by killing mosquitoes, so DDT resistance does not impair its mode of action, that of spatial repellency.

Regardless, let us assume there is evidence that DDT resistance is a problem. The best way to evaluate the problem is to spray DDT and monitor its effect on malaria cases. I suppose we could

[1] The prepared statement of Mr. Roberts appears in the Appendix on page 00.

call this a trial and error method. If DDT does not control disease, then use another chemical. If it controls disease, then it works, regardless of any finding of resistance.

I propose a similar method to address claims that DDT is not effective under some epidemiological conditions. This trial and error method is consistent with advice of one of the world's most famous malariologist. In a presentation before the Royal Society of Tropical Medicine and Hygiene in 1949, Dr. Arnoldo Gabaldon admonished the audience that DDT's effectiveness should be judged on reducing malaria cases, not on reducing mosquitoes.

Additionally, this trial and error method is in line with funding objectives of the President's Malaria Initiative, that is, disease control, not mosquito control.

I will end my testimony with a historical perspective on leadership for USAID's new malaria program. Before DDT house spraying began, almost 2 billion lived in malaria endemic areas and were at risk of malaria. Even before the global malaria eradication became functional in 1959, DDT house spraying freed roughly a third of a billion people from endemic malaria. By 1969, only 9 years later, DDT house spraying had freed another two-thirds of a billion people from endemic malaria, almost one billion people living without the daily threat of endemic malaria.

Now, let's look at the Roll Back Malaria Initiative, which began in May 1998 and is now in its eighth year. I cannot figure out what the initiative has accomplished, and numbers of malaria cases have actually increased during the last 8 years. Eight years is a precious long time for those who are at constant risk of disease and death from malaria.

In concluding my comments, I want to say that I hope the person selected to lead USAID's malaria program will not be wed to the Roll Back Malaria approaches to malaria control.

Thank you.

Senator COBURN. Thank you, Dr. Roberts. Dr. Arata.

TESTIMONY OF ANDY ARATA,[1] VECTOR CONTROL SPECIALIST

Mr. ARATA. Thank you, Chairman Coburn and Members of the Subcommittee on Federal Financial Management, Government Information and International Security, for the opportunity to speak before you today and to present my perspective on malaria control and progress in malaria control programs.

As you mentioned in your statement, I have spent over 35 years working in malaria and vector-borne disease control, working for a number of international organizations in over 30 different countries.

I began my WHO career at the actual peak of the Malaria Eradication program in the 1960s, and worked for WHO on new control methods, particularly biological control in the 1970s, and I have served as a consultant evaluating malaria control programs in Africa, Latin America and Asia, for USAID, WHO, and the World Bank.

I am really quite pleased to see that U.S. foreign aid in malaria control is reconsidering the use of indoor residual spraying and

[1] The prepared statement of Mr. Arata appears in the Appendix on page 00.

DDT. For a number of years I have felt that the almost sole approach to vector control through the employment of insecticide treated nets, the ITNs, was very shortsighted, producing positive, but limited, results.

In general, I and many field-oriented colleagues have proposed integrated control measures, employing more than one approach to vector control, depending upon the ecology of the vectors in each specific area. This approach is employed not only for malaria control but for the control of other vector-borne diseases such as dengue, yellow fever, West Nile, as well as nuisance insects. Integrated control is also used extensively in agriculture, and we have a lot to learn from that. For malaria vectors, integrated control may include larval control by chemical or biological insecticides, elimination of breeding sites, especially man-made, in irrigation ditches, ponds, rice paddies, etc., housing improvements, ITNs, depending on the characteristics in vector ecology in a given area.

Malaria is a very variable disease. There are four different parasitic species and numerous anopheline vectors—40-50 vectors more or less, and a range of transmission intensities from endemic to stable to unstable, to variable biting patterns in terms of where and when the mosquitoes prefer to bite, resistance potential for both the parasites to anti-malarial drugs and the vectors to insecticides. We also have both forest and urban transmission patterns. In other words, measures that work in Southern Africa may not necessarily work in the Congo. The variety of circumstances facing the control program manager in the field is huge. On top of these factors, there are other complexities; differences in housing construction material, whether wood, mud, etc. These will modify the efficacy of any insecticide, so depending on only a single compound or a single method of application is, in my opinion, a recipe for failure.

My career in malaria control has spanned from the eradication era through the reemergence of IRHS as a major control measure. To my mind, the overriding lesson of the malaria eradication period, has been that there was no "magic bullet." Local variations mattered, and a flexible approach, what I have called "integrated control" was the most effective. In many instance malaria programs of the past were problematic and what we might refer to as cookie-cutter. They tried the same thing in country after country without any variation or consideration of local problems.

Sole reliance on IRHS with DDT did not work well, and we now have more tools available to us than we did earlier. The bed nets and the newer drugs for malaria treatment offer new opportunities for effective control measures using integrated approaches tailored to local circumstances and vector-specific variables. Integrated control also implies the development of infrastructure and management practices, as well as community participation, and even appropriate diagnosis and treatment.

I hope that those charged with the development of new malaria control programs will see their way to employ DDT as they would any other insecticide, to be tested and evaluated for efficacy, for safety and cost in each situation. I think DDT has a role to play in malaria vector control, and if it is used particularly as a component in integrated control systems. Thank you, sir.

Senator COBURN. Thank you, Dr. Arata.

Mr. Kunene, you have an integrated program, do you not? You have impregnated nets and indoor residual spraying. We saw from the data you presented to the Subcommittee this marked reduction in infection, marked reduction in hospitalization and marked reduction in deaths. Is that correct?

Mr. KUNENE. Yes.

Senator COBURN. When Dr. Arata talks about an integrated, would you describe the system in your country as an integrated system?

Mr. KUNENE. Yes. I think we fully support an integrated approach. As I mentioned in my presentation, we use IRHS, then we use ITNs. ITNs are targeting pregnant women, which are considered a vulnerable group, and children under five. So if we were to use ITNs and ignore IRHS, we probably would be covering about 20 percent of the total population at risk because pregnant women plus children under five, I think they contribute about 20 percent. So you will have about 80 percent of the population not covered or not protected.

So with the IRHS we are able to cover the 80 percent, which is not covered by the ITN program. So integrated, we fully support.

Senator COBURN. And it is true, the same program you are using has been used in South Africa as well. Where you have countries today, where we are not doing anything, we are not seeing anything done, does it makes sense to apply what is being done until we figure out an integrated strategy? Nobody is wanting to use a cookie-cutter approach, we understand that, but we also understand that a lot of the buildings in your country have disparate different materials that are part of it, and there is no question they absorb at a different rate, it lasts varying lengths of times in terms of the application of indoor residual spraying with DDT. But the fact is it acts as an irritant and repellent in very small quantities. Is that true?

Mr. KUNENE. Yes.

Senator COBURN. So what is working somewhere now is better than nothing happening where people are dying by the thousands.

Mr. KUNENE. I think there is attempts—as the Chairman has mentioned, we are treating it as a solution, that these two interventions will never replace each other. They complement each other. And as the region, South Africa, I strongly believe that is what even our minister has decided, and DDT remains the insecticide of choice, not only for South Africa, Botswana and Namibia. Zambia has just relaunched IRHS, and they have seen significant results in terms of reduction of malaria mortality and morbidity.

We are now moving towards maybe Malawi, Tanzania, the whole sort of region, I think will move towards IRHS, IRHS as method, that the choice of insecticide, we leave that to the countries. They can do their own recommendations. What would be affordable to us, and what would be more effective, but IRHS as the method.

Senator COBURN. Thank you.

Dr. Roberts, Dr. Arata asserted that DDT should be tested like other insecticides and evaluated. Do you have any comment on that?

Mr. ROBERTS. I do believe that there is a role for pilot testing in areas where there are no recent test data for the effectiveness of DDT in an indoor residual spray program. So it seems to me that would be an intelligent way to proceed, doing pilot testing.

On the other hand, it is somewhat difficult to reconcile a slow approach in a setting where just literally thousands of people are dying. So it seems to me that this is one of those situations where outsiders should step back and let the countries make those decisions, how do they want to proceed, and then support them in any way possible, whether it is DDT or another insecticide.

Senator COBURN. Mr. Kunene, you testified that DDT has been your primary insecticide, is that correct?

Mr. KUNENE. Yes.

Senator COBURN. And how many years since your program began? That is 6, 7 years ago; is that correct?

Mr. KUNENE. It was introduced in 1946.

Senator COBURN. I understand that, but the reuse of it really started, your numbers started coming down starting in 2000, correct?

Mr. KUNENE. Yes.

Senator COBURN. Have you all seen adverse health impacts from the use of DDT in your country?

Mr. KUNENE. As I mentioned, we are working in collaboration with the Swaziland Environmental Authority, which is a government wing, and they are the ones monitoring our responsible use of the product. And over the years they have not indicated that there are any adverse health effects as a result of the use of DDT in the country.

Senator COBURN. Dr. Roberts, do you know of any publication of scientific data, peer-reviewed, that shows adverse health effects from indoor residual spraying of DDT?

Mr. ROBERTS. I do not. Could I amplify?

Senator COBURN. Sure.

Mr. ROBERTS. I do not know of a published peer-reviewed article that shows that there is an adverse human health effect from indoor residual spraying with DDT. But I would like to add to that that I have actually been told by, for example, the head of the NIH in Mexico, that they have looked at that extensively because of the very considerable environmental pressures that were applied in Mexico to stop the use of DDT in malaria control. His comment to me—this was March of last year—was that they have found nothing.

Senator COBURN. Dr. Arata, are you familiar with any peer-reviewed scientific data that would suggest that?

Mr. ARATA. No, I am not. We do know, of course, from an environmental standpoint, there are risks to be taken, but even there, the vast majority of the problems are associated with excessive use in agriculture, forestry, and the like. In general, public health use of insecticides in most of the countries that I am familiar with, developing countries, usually amounts to only about 10 percent of what is used in agriculture, and used within the houses in IRHS. It is really unlikely that it would cause any environmental damage.

Senator COBURN. So you would agree with the program. There is not any peer-reviewed literature out there on DDT when used in indoor residual spraying offers any threat to the environment?

Mr. ARATA. Not that I know of.

Senator COBURN. There is not any. We have looked at it.

Mr. ARATA. There is none.

Senator COBURN. There is no search that would show that.

So one of the things I wanted to establish for this hearing is, we do not want to use DDT because it is cheap and because it works if it harms the environment and truly will make things worse; we want to use DDT is because it is very effective in certain areas at controlling the disease. And we have to get over the hump of the environmental bias against it because of the lack of understanding of the confined use of this and the diluted quantities that are used compared to what our experience was in this country.

When I was a young boy, they used to come down the streets spraying. The fogs would be out and they would be spraying it. As a young boy I can remember the massive use of it, and the massive use of it in terms of agriculture for cotton, things like that.

Mr. Kunene, would you comment on the importance, what would it mean in the continent of Africa if America would aggressively support indoor residual spraying?

Mr. KUNENE. Mr. Chairman, I think we would see a significant reduction of mortality and morbidity as a relate of malaria in the country. Just IRHS as a principal. If you add the DDT, I think that will even make it even more successful, Mr. Chairman.

Senator COBURN. From your perspective, is there something that our USAID folks can do as they roll out this new program, looking at it from Africa, what can they do to be quicker, more efficacious, more effective, and attain greater results other than what you've heard here today? If you were to sit down and had a chance to give them advice, what advice would you give them?

Mr. KUNENE. I do not know what the approach is now—I strongly believe that for when you put money, you must be able to evaluate whether you are making success or not. Baseline surveys I think are critical. We do not just come and spray, then start evaluating later. Let us determine the situation now from an etymological perspective. What species or vector species are available, and what is the parasite prevalence for now, the hospital data? Then will come in with the interventions.

But when it comes to IRHS implementation, as my colleagues say, that initial cost will be on the high side considering the equipment, considering the recruitment of personnel, and we must invest on personnel. People must be properly trained. I think in Africa we have the expertise now. And since we are using some of the insecticides which are very sensitive like DDT, the responsible use remains very critical, so that is why the training of personnel is critical.

Ensuring that you establish a very good database. You should know where to spray. We have moved a step forward because we are now on GPS. We are plotting all homesteads or all houses that are sprayed, but that is a very good planning, monitoring and evaluation tool.

Insecticides, equipment and human resource, that is where most of the money will come. So I am happy when—I was happy when I looked at the fact that USAID or the U.S. Government is considering increasing the cake for IRHS. That is welcome. Thank you.

Senator COBURN. Thank you.

Dr. Roberts, in your testimony you talked about what history has taught us what happened in the 1940s and 1950s and the effective use. And your proposition was, let us do it and see what happens with the trial and error approach. One of the things I have heard, as I followed this issue for a couple of years, is integrated control sometimes is a code word for everything except IRHS. We will do everything, but we are not going to do indoor residual spraying. When you hear the words "integrated program," what comes to mind?

Mr. ROBERTS. Unfortunately, that is what comes to mind, that it is a code word for let us do anything but IRHS. And there are some examples out there that vividly illustrate that. There is a program going on in Central America. The Global Environment Facility funds, I think it is a $7 million project. There is no question, if you read through the document for the GEF project in Central America, there is no question that the design and the goal of that project is to eliminate the use of insecticides in malaria control.

And there have been statements even in WHO literature, and the WHO staff, in exchange of communications with me, that show very clearly that the goal is with integrated vector management, IVM, is that the goal is to reduce the use of insecticides for disease control.

Furthermore, there is a World Health Assembly resolution that specifically calls on the countries to reduce their reliance on the use of insecticides for disease control.

My own personal opinion is that it is an awful resolution, and I do not understand how it was ever adopted by the World Health Assembly. That is the ultimate governing body for the World Health Organization, a decisionmaking body, so the World Health Organization is functioning under a resolution that calls on countries to reduce reliance on the use of insecticides.

Senator COBURN. I would like all of you to answer this, given your extensive experience. If we had a program as outlined—it looks like we are going to—which is really going to be a balanced program to use for interventions to impact this, and it would end up being dominated by impregnated nets and IRHS and then treatment, would the rest of the world follow? What do you think?

Mr. ROBERTS. I will comment. I think so. I gave a presentation before the Ministry of Health in Thailand in November, and I was talking about the need for the use of DDT. This is not a specific answer to your question, but in general I think it is, and an individual from the political section of the Ministry of Health stood up and said that the world is not going to make any move at all to restarting the use of DDT in these critical programs unless the United States shows leadership. I take it from that, is that it will make a difference if we can show change and flexibility.

Senator COBURN. I think Dr. Kunene testified to the fact that you have to have—we are not talking about indiscriminate use of DDT, we are talking about trained use and utilization of DDT in

terms of indoor residual spraying. I believe you also testified earlier that we saw tremendous results from the use of DDT in the rural areas in terms of IRHS in the 1940s, 1950s and 1960s. Dr. Arata, would you want to comment?

Mr. ARATA. Regarding the role and the position of WHO, I do not speak for WHO, but I might mention a couple of things. The resolution reducing the amount of insecticide usage has to be taken into context. For one thing, programs like the onchocerciasis control program (OCP), used a large amount of insecticides, which was replaced by ivermectin as a drug, so therefore, they no longer needed the same amounts of insecticides. The same thing is happening with control of other filarial diseases, with diethylcarbamazine being used for treatment in urban areas, for example, rather than vector control, so no need to specify which vector-home diseases that may also use insecticides are we talking about.

Integrated programs do not come as code words to me, nor to most of the people that I work with. Integrated vector control just means using more than one type of vector control measure. Then you can have integrated malaria control, which integrates vector control and the diagnosis and treatment. And then you can have integrated health programs where through sentinel sites and through clinics, one treats a multitude or a number of different problems.

So really, integration is, for me at least, not a code word for not using something, but rather a very positive thing, and is really copied after some of the integrated control measures in agriculture, which are very advanced in terms of economic analysis and economic modeling, which is a level we have not reached in public health at the present time.

As far as whether other countries will follow us, I think that there is a very good chance that they will, but I think the only way they will do that is if we give them an opportunity to get involved fairly early in the game, rather than sending them a program of saying, "This is what we are going to do now. Come and join us." So I think if we ask for some cooperation and collaboration in some of the planning, at least opinions, then I think we will have the leadership role that we would like. So thank you.

Senator COBURN. Dr. Roberts, one last question. What happens when we replace IRHS with drugs only? What is the natural history of that? We do not see resistance for parasites to ivermectin yet, but it does not mean we will not, correct?

Mr. ROBERTS. Right. We could look back at our uses, for example, chloroquinized salt. That has been tried in more than one location in the world. The one that I am most familiar with was in Surinam and Guyana and Brazil. The result was almost immediate resistance to chloroquine, and in that case it was falciparum malaria, which is the more deadly form.

When you start suppressing the use of insecticides in malaria control, the truth is, we really only have one major option for preventing malaria transmission, and that is the use of insecticides, and breaking man/vector contact inside of house. And when you eliminate that as an option, really the government will have only one option or alternative, and that will be to go with mass drug distribution, what I refer to as chemoprophylaxis, and that is pre-

cisely what has happened in Central America with this GEF project.

Senator COBURN. Then you have the propensity to develop resistance.

Mr. ROBERTS. Exactly.

Senator COBURN. Could I also comment? In many ways I agree with Andy about integrated vector management. The problem that we have with the concept of integrated vector management is that it has, in fact, been used in the wrong way. The concept is valid. The concept is good, but it has been used to eliminate the use of insecticides.

Senator COBURN. That has been the goal, rather than to eliminate disease?

Mr. ROBERTS. Right.

Senator COBURN. I want to thank each of you. There will be several questions that will be directed to you. If you would be so kind as to respond to those, we will not take more time in the hearing. Our goal is to not see a picture like that, where it is not there. And if there is anything, $2 for ACT treatment, $2 to cure somebody of a disease, to spray a room for a buck, fully absorbed cost, we do not have any reason not to be successful. I will assure you that we will follow up. I am very pleased with USAID's response.

Just so they will know, and the others, we had 21 Subcommittee hearings on ineffective spending of the Federal Government's money last year. We are going to have over 40 this year in terms of the follow up, and the whole goal is not to be critical, but to make sure that when we intend to help somebody, that we really help them, and that we get the most value for every dollar that the American taxpayer pays, because in the long run what it does, it makes a difference in those people's lives. You can see those young children, we did not make a difference. We did not impact. If 98 percent of what we spend ends up impacting somebody, then we are the better for it and so are they.

I thank you for coming, appreciate it very much. Mr. Kunene, again, the long trip here, thank you for the testimony of what you are doing in your country, and we congratulate you on your success. Thank you.

The hearing is adjourned.

[Whereupon, at 4:07 p.m., the Subcommittee was adjourned.]

APPENDIX

Michael Miller
Deputy Assistant Administrator for Global Health
U.S. Agency for International Development

Testimony before the
Subcommittee on Federal Financial Management,
Government Information and International Security
Committee on Homeland Security and Governmental Affairs
United States Senate
January 19, 2006

Senator Coburn, Senator Carper, thank you for again allowing me to testify on behalf of the Administration regarding the United States' malaria prevention and treatment programs. Since this subcommittee's last hearing on the topic, the President has changed our global malaria strategy fundamentally in scope, size, and structure. Additionally, USAID has implemented necessary, complementary changes to its ongoing malaria programs. These changes, I believe, ensure greater effectiveness and accountability, provide critically-needed global leadership, and will ultimately save many more lives.

The most important development is the President's Malaria Initiative, or PMI, which is a multi-agency program led by USAID and including HHS/CDC, State Department and others. The PMI will reduce significantly the number of Africans who die from malaria and will challenge other donors to make similar commitments. President Bush's commitment of an additional $1.2 billion over the next five years is unprecedented in the fight against malaria. The goals of PMI are ambitious: in five years of implementation, reduce by 50 percent the number of deaths from malaria in the target countries. The program will eventually include up to 15 countries and provide prevention and treatment for 175 million Africans.

PMI's life-saving activities will help motivate other donors, and private, public and voluntary organizations to complement the United States commitments by providing additional funding.

PMI is a comprehensive and sustainable approach to saving lives. Its methods include purchase and distribution of medicines for treatment

(ACTS), distribution of medicines for prevention of malaria in pregnancy, distribution of long-lasting insecticide-treated bednets to prevent insect bites and to kill mosquitoes, and indoor spraying with insecticides to kill mosquitoes.

The speed with which we have begun to implement the PMI also is unprecedented. In less than six months after the President announced the initiative, USAID and our partners were in the field implementing programs that differ considerably from their predecessors. Right now, the PMI is conducting an indoor spraying campaign in southern Angola to protect over 600,000 people from epidemic malaria outbreaks; we distributed 130,000 long-lasting insecticide-treated nets in Zanzibar; and in about a week we will begin the distribution of 395,000 free long-lasting insecticide-treated nets in war-ravaged northern Uganda, among many other activities.

PMI is a very different way of doing business than past practice. The hallmarks of the PMI are first and foremost programming based on clearly defined numerical targets for outcomes. Second is transparency in how the money is being spent. Third is a robust and effective monitoring and evaluation plan. This approach provides assurance that taxpayers' money is being spent effectively.

PMI's size and structure also provide opportunities to fight malaria in Africa in ways we could not just a few years ago. In the past, USAID used the relatively small amount of funds to implement programs focused on issues such as policies to adopt artemisinin combination therapies (ACTs) over failing treatments, and efforts to address the lack of production capacity for ACTs and insecticide-treated bed nets. Much of that work is now finished. With the PMI, we now have the opportunity to design and implement many simultaneous, large-scale, comprehensive, country-wide programs throughout Africa.

But that opportunity also necessitated changes to those programs currently outside the PMI – sometimes called the "non-PMI" programs. These are the structural changes to the malaria program that USAID announced in December of last year. One of the most visible changes is the elimination of programs that were simply too small to be effective on a scale we require. Second is a correction of the imbalance between technical assistance and commodities within country programs. Third is the opportunity to push the

dialogue and thinking about indoor residual spraying as a frontline tool to fight malaria in tropical Africa.

The rapid scale-up of the PMI means that next year more resources and more coverage will be inside the PMI target countries than outside of the PMI. As a consequence, having two parallel but different malaria programs running side by side is as impractical as it is undesirable. Because PMI will expand rapidly, any real distinction between the two is temporary, and the programs that fall outside the PMI have to start making critical adjustments now, including the emphasis on life-saving commodities, reporting on planned activities and allocations, and programming more money. In the case of IRS, this year we will spend approximately $20 million on spraying – about a twenty-fold increase over fiscal year 2004. In at least three of the eight countries where USAID will support IRS this year, DDT will be a primary insecticide. As some countries move into the matrix of PMI countries, the specific numerical targets and the monitoring and evaluation regime will also apply. In short, the changes we instituted to the "non-PMI" are part and parcel of the creation of a single, large-scale, target-driven strategy to fight malaria in Africa and demonstrate results.

What we have begun to do with the PMI, as with the President's Emergency Plan for AIDS Relief (PEPFAR), is to plan and judge our programs based on outcomes, not simply on how much money we put in. The difference is simple but profound. It demands a new level of programmatic transparency and documentation that in return provide confidence in effectiveness to allow the President to make multi-year commitments to ramp up funding accordingly. Targets keep agencies, individuals, and entire governments focused. With accurate data, targets provide unambiguous measures of success or failure and allow informed judgments about whether a program is effective and whether it should continue to be funded. Ultimately, that not only makes for good management, and is more satisfying for those of us charged with implementing them, but also makes for more effective programs. In the case of the PMI, that means the opportunity to fill a global leadership role in the fight against malaria and to save millions of lives that might otherwise be lost to a preventable and curable disease.

Written Testimony of Mr. Simon Kunene to the Senate Subcommittee on Federal Financial Information, Government Information and International Security on malaria control at 2pm on Thursday 19 January 2006, Dirksen Senate Building.

Dear Mr. Chairman,

Thank you for inviting me to submit written testimony and to give oral testimony to this most valuable hearing. I am the manager of the Swazi Malaria Control Program and am also the chairman of the Southern African Development Community (SADC) Sub Committee on malaria.

I would also like to this opportunity and thank the US Government for the contribution it has made towards malaria control in the countries affected by malaria in the African region and beyond.

I hope that this hearing will help to improve understanding of what is involved in malaria control and how the US Government can contribute to effective control of this preventable and curable disease more especially in Sub Saharan Africa. Your Government's contribution towards malaria control has been direct (bilateral President Malaria Initiative) or indirect (Roll Back Malaria and Global Fund).

1. Introduction

The Kingdom of Swaziland is a landlocked Southern African country bordered by Mozambique to the east and by South Africa to the north, south and west. Swaziland's population is approximately 1.2 million people. Like many African countries, we face significant socio economic challenges that includes high (>42%) HIV Prevalence Rate among pregnant women and poverty as a result of persistent drought situation. The economy of the country is depends on agriculture and tourism.

In Swaziland, like in many other African countries, malaria remains a threat or impediment to socio economic development of the population. It should however be mentioned that as a result of rigorous malaria control program the disease burden and its impact in the general population has over the years been maintained at near acceptable levels. It is estimated that 30% of the population is at risk of malaria and the risk levels varies within the malarious areas.

I would like to give a brief history of malaria control in Swaziland, describe the malaria control program and suggest ways that the US

Government can assist other countries in achieving the results that we have achieved.

2. Historical background of malaria control in Swaziland

The Kingdom of Swaziland has a long history of malaria control having been established in the year 1946. The main interventions for malaria control at the establishment of the program were indoor residual house spraying with Dichlorodiphenyltrichloroethane (DDT) and proper case management.

The parasite prevalence among < 5 years was 65% at the time of initiation of Indoor Residual House Spraying (IRHS). At the initiation of the malaria control >50% of the country was considered malarious. It was also estimated that about 60-70% of the population was at risk of the infection. The parasite prevalence was reduced to about 5% within 5 years of implementation of the intervention.

By 1972 there were no indigenous malaria cases reported in the country and as expected the disease was no longer considered a priority health problem and the disease was almost declared as eradicated. This unfortunately resulted in significant reduction in resources allocated for malaria control. For example the number of environmental technicians was reduced from 36 to 14 and the budget for insecticide for indoor residual house was significantly reduced hence indoor residual house spraying was discontinued.

The shift in priority and lack of resources led to the collapse of the national malaria control program and the disease incidence started increasing by 1978. The malaria situation in the country worsened in 1983 as a result of Cyclone Domonia and increased Chloroquine resistance levels.

The malaria situation had reached unacceptable incidence levels by 1986/87 and as a result the Ministry of Health sought assistance from partners including World Health Organization (WHO), South African Trade Mission (SATM) and USAID to re establish the national malaria control program. It should be mentioned that at the time of re establishing the program 90% of the financial resources came from the partners indicated above. The assistance from partners included procurement of insecticides drugs and equipment, training of health workers on malaria case management and information education and communication (IEC)

Indoor residual house spraying was re-launched during the period 1987/88 and DDT was the insecticide of choice for traditional structures and synthetic pyrethroids for oil painted surfaces. The agreement between

Government and the partners was that Government would gradually increase the budget for malaria control to be able to absorb the cost of running the program once the partners pull out.

The partners (USAID-CCCD and SATM) finally pulled out during the period 1992/93 and Government had not significantly increased the budget to absorb the costs of running the program and as a result the program was struggling because of limited resources. The country as a result of poor indoor residual house spraying coverage and above average rainfall received during the period 1994-1996 experienced a serious epidemic of the disease 1995/96 season.

In an effort to address the unacceptable malaria situation the Government included malaria as one of its priority diseases in the Economic and Social Reform Agenda (ESRA) and committed herself in increasing the malaria budget by 30% per year for three years (1996/97 to 1998/1999).

The increase in the allocation of resources for malaria control by the Government resulted in increased indoor residual house spraying coverage in the country and a significant reduction in the burden of the disease. The Government of Swaziland is allocating about 90% of the recurrent expenditure for malaria control and the rest comes from partners.

The country recently benefited from the launch of the Roll Back Malaria (RBM) initiative. The RBM initiative resulted in increased resources for the national malaria control program.
The country also got support from the Global Fund to fight HIV/AIDS, Tuberculosis and Malaria Round 2.

3. Current strategies

The implementation of malaria control activities are guided by the national malaria control policy. The major strategies are based on the global malaria control strategy and they include vector control, case management, disease surveillance, information education and communication, epidemic preparedness and response, operational research and program management

3.1 Vector control

In the area of vector control the national malaria control program has over the years relied on indoor residual house spraying and recently 2004 adopted use of insecticide treated nets.

3.1.1 Indoor residual house spraying

The planning, implementation, monitoring and evaluation of indoor residual house spraying activities at all levels (national, regional and local) remains the responsibility of the national malaria control program. At national level the national malaria control program, at the end of each malaria season in consultation with the entomological and disease surveillance sections of the department prepares a list of areas to be sprayed.

The inclusion criteria for areas to be sprayed is based on updated and sound entomological and epidemiological data. Areas which have not report indigenous malaria cases in the 2 consecutive malaria transmission seasons are not included in the indoor spray program.

The implementation of IRHS is always preceded by intensive training of all personnel to be involved in the exercise. This is done to ensure that the insecticide is properly applied on wall surface. The training also covers the responsible use of DDT which has been the insecticide of choice over the years.
The national malaria control program has over the years maintained a high (92%) spray coverage.

The NMCP has recently (2004-2005) introduced the use of Geographical Positioning Systems (GPS) in the planning, implementation, monitoring and evaluation of indoor residual house spraying activities. The GPS programme is funded through the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria (GATM) with technical assistance from WHO and Medical Research Council (MRC) in Durban South Africa. Coordinates (Longitude and Latitudes) of all homesteads are taken and entered into Health Mapper for spatial distribution (see fig 1).

Information collected in the GPS also includes the type of surfaces and number of rooms per homestead. This information is very important for future planning of the intervention because it will be easy to quantify the amount and type of insecticide that will be required. Information on the number of people in each homestead sprayed is also collected and this allows the program to effectively determine the proportion of the population protected by indoor residual house spraying.

Fig 1 Homesteads with mud surfaces at Matsanjeni Mambane

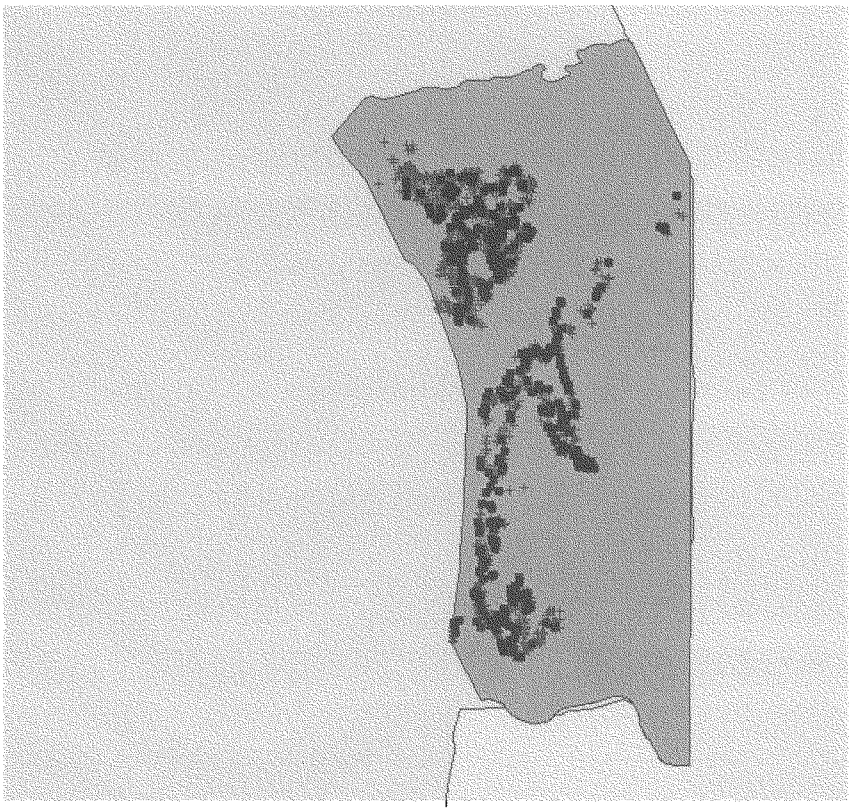
3.1.2 Insecticide Treated Nets

The country as mentioned early has recently adopted use of insecticide treated nets. With funding from GFATM the national malaria control program started distributing bed nets to pregnant women and children under 5 years.

The nets are distributed free to the target groups. The objective based on the 2000 Abuja Declaration on malaria is to reach 60% of the target groups with the intervention. The country also received support from JICA who procured Long Lasting Nets (LLN) for distribution.

Recent 2005 surveys found that 40% and 13% pregnant women and children under 5 years respectively in targeted areas reported to have received ITNs.

The program during routine IRHS activities also identifies all households with ITNs and the information is included in the GPS. The figure below shows households with ITNs.



3.2 Case management

Case management forms one of the cornerstones of malaria control as it is able to significantly reduce morbidity and mortality due to malaria. Whilst pregnant women, infants and young children in endemic areas, and 'non-immune' persons traveling to malaria endemic areas, have traditionally been considered to be the high risk groups, it is important to note that due to the unstable nature of malaria in Swaziland, most patients presenting with malaria in this country are non-immune regardless

of age, sex or area of residence. Severe and complicated malaria is therefore not uncommon even in adults living in malarious areas in Swaziland. Due to the low levels of acquired immunity, severe malaria can develop rapidly and, hence, early presentation and diagnosis are very important.

Effective case management of uncomplicated malaria can greatly reduce the incidence of severe malaria. Prompt referral and effective management of severe cases will minimize malaria mortality.

The national malaria control program has over the years invested on in-service training of health workers on malaria case management. This has resulted in improved performance of health has significantly contributed or resulted in reduction in mortality.

It is also worth noting that the Government of Swaziland has always ensured that anti-malaria drugs are available in all health facilities. The country is still using Chloroquine because studies have not shown any evidence of existence of resistance. It should however be mentioned that the country is in the process of changing Chloroquine to more effective drugs because of added advantages of using combination therapies.

3.3 Disease Surveillance

The NMCP operates an effective weekly malaria surveillance system, which is timely and has a high coverage. This has been successfully used to detect malaria outbreaks at the local and national levels.
There is a national malaria database that summarizes the range of malaria data available.

At the health facility level, capacity building in malaria data management, mapping and analysis has been achieved.
The effective disease surveillance system is very critical and it ensures that the available scarce resources are used where the greatest impact will be realized.

3.4 Operational research

Operation research is an integral part of the program. The major areas of research include routine monitoring of drug and insecticide resistance. Community Knowledge Attitudes and Practices studies on malaria are conducted on a regular basis.

Annual parasite prevalence studies are conducted to monitor the burden of the disease at community level. The national malaria control

program collaborates with a number of institutions both locally and internationally.

4. Impact interventions on burden of the disease

The effective planning, implementation, monitoring and evaluation of IRHS and other interventions have over the years maintained the burden of the disease at near acceptable levels in the country.

In the last 5 years the country has realized significant reduction in mortality and morbidity of malaria. The country has actually achieved the Abuja Target of reducing malaria morbidity and mortality by 50% by 2010. The biggest challenge now is how to sustain the achievement to 2010 and beyond.

The achievements can be attributed to a number of factors including the maintenance of high indoor residual house coverage and population protected by IRHS and consistent availability of drugs in all health facilities in the country.

The number of clinical malaria cases has been reduced from above 45000 in 2000 to less than 10 000 in 2005. This indicates a more than 75% reduction.

The number of laboratory confirmed cases has also been significantly reduced from about 4000 in 2000 to less than 300 in 2004/5 season.
The number of malaria attributed admission has been reduced from about 1800 in year 2000 to less than 200 in 2004/5 season.

5. Regional collaboration

The Kingdom of Swaziland is a member of a number of regional organizations. These organizations include the Lubombo spatial development initiative (LSDI) and Southern African Development Community (SADC).

5.1 Lubombo Spatial Development Initiative

The Governments of South Africa, Swaziland and Mozambique in conjunction with some key private partners, launched the Lubombo Spatial Development Initiative (LSDI).

The LSDI malaria control program is coordinated by the Regional Malaria Control Commission comprising of program managers, pubic health specialists and scientists in the three countries.
The major activities in the LSDI as outlined in the protocol are indoor residual house spraying, introduction of effective drugs, strengthening

health information and strengthening capacity by training of health workers on malaria control.

Baseline parasite prevalence surveys among 5-15 years conducted in the three countries in 1999 showed rates of up to 80% in Mozambique, 40% in South and 5% in Swaziland.

The low parasite prevalence in Swaziland can be attributed to the fact the program has been consistent in indoor residual house spraying using DDT where as in South DDT use was stopped during the period 1996-2000 and the program in Mozambique because of a political unrest.

The LSDI malaria control program has been implementing IRS in the last 5 years. ACT has been introduced in most parts of the ISDI area (Mozambique and South Africa).

The impact of the implementation of these interventions have been successful because recent 2005 parasite prevalence showed that prevalence rates have been reduced from 80% to <20% in Mozambique, from 40% to <10% in South Africa and from 3.5%< 0% in Swaziland.
It should be mentioned that DDT has been introduced in the LSDI area (Mozambique) and significant reductions are expected.

5.2 Southern African Development Community.
The Kingdom of Swaziland is member of the SADC. In the SADC region malaria remains one of the major public health problems.

The SADC member states established a Sub Committee on malaria which is chaired by Swaziland. The objectives of the sub committee are to facilitate coordination and harmonization of control interventions in the region. The SADC region has developed a strategic framework for malaria.

The major areas of work includes strong components of vector more especially IRS, cross border initiatives, operational research and capacity building.

It should be noted that most of the countries in the region are implementing IRS. DDT is used in 6 (South Africa, Swaziland, Namibia, Zambia, Mozambique and Zimbabwe) SADC member states.

In a recent, November 2005 SADC health ministers meeting held in South Africa, it was resolved that member states should support IRS with

effective insecticides like DDT because it has been proven to be very effective.
The health ministers also indicated support of the establishment of cross border malaria control initiatives like the LSDI.

6. Lessons learnt

- Indoor residual house spraying with effective insecticide like DDT is very effective in reducing the burden of the disease but it requires proper organization and consistent allocation of resources .

- The Government commitment in resource allocation is very critical for the sustainability of the intervention. For example in Swaziland, in years when the resources for malaria control were reduced the country experienced significant increases in the incidence of the disease.
- The proper training of spray personnel in proper insecticide application is very critical for effective implementation of IRHS.
- Intensive community mobilization is also very important for effective implementation. Communities need to be educated on the importance of IRHS for them to cooperate with the spray teams and ensure high spray coverage. The country has over the years maintained spray coverage of above 90% because of investments in community mobilization.
- Collaboration with neighboring countries is very effective as indicated by the successes in the LSDI programme
- Use of effective drugs is very critical in reducing malaria morbidity and mortality
- Political commitment is important for sustainability of national malaria control programmes

6. Way forward.

In view of the successes the country has made in reducing malaria morbidity and mortality the program will continue implementing IRHS complimented by other interventions like ITNs.
The program will continue to closely monitor the effectiveness of IRHS to ensure the rational utilization of the scarce resources.

Testimony by Donald R. Roberts, PhD, Professor, Division of Tropical Public Health, Department of Preventive Medicine and Biometrics, Uniformed Services University of the Health Sciences, Bethesda, MD

Thank you Chairman Coburn and members of the Subcommittee on Federal Financial Management, Government Information, and International Security for the opportunity to present my views on malaria control and DDT use in public health programs.

I started my career of public health research in the 1960s and I have seen large reversals in the control of transmissible diseases like malaria, dengue, and leishmaniasis. The public health reversals are revealed by remarkable increases in malaria in countries that once had highly effective control programs. I want to emphasize that the cost of those reversals in lost health, lost lives, and lost economic vitality is enormous. One example of this enormous cost is the reemergence of dengue fever as a major public health problem in the Americas.

Aedes aegypti is the urban vector of dengue fever. Dengue fever disappeared from most countries of the Americas during many years when DDT was being used to eradicate *Aedes aegypti*. Today, in all countries from northern Mexico to northern Argentina, dengue and dengue hemorrhagic fevers are exacting horrific costs of human health and welfare. To large extent public health reversals in control of dengue, malaria and other diseases can be attributed to the unrelenting campaign of environmental activists against our public health insecticides, and DDT in particular.

To begin to fix our public health problems, we must first recognize that the large and complex system responsible for regulatory control over public health insecticides is severely broken and needs repair. The repair I speak of encompasses fundamental changes in regulatory authorities and responsibilities.

There are some special considerations in the practice of public health that should be mentioned in discussing the overall question of what needs to be done to protect registrations and uses of public health insecticides. First, there is no strong commercial interest in public health insecticides. This is certainly true for the older insecticides. In fact the insecticide industry might actually join with environmental activists in opposing use of the older and less profitable chemicals. Second, public health programs are almost entirely dependent on limited government funding. Third, there is great competition among public health programs for limited government funds. These factors should be considered because they help explain why the public health community can easily be silenced by political pressure or by threats of litigation. It also explains why the public health community often has no commercial allay in confrontations with well-funded environmental activists. For these reasons I think authority over public health insecticides should reside in agencies and organizations responsible for disease control. Decisions on use of public health insecticides should be made with priority on the most serious threats to the health of those at risk of disease and death. The decisions should be based entirely on the underlying science of what is required to protect human health, chemical efficacy, cost and chemical safety, not on fear of political pressure from environmental activists, fear of litigation, or on environmental ideology. Change is required at international and national levels, but the United States must get its own house in order before turning its attention to the international arena.

Within the United States we seldom hear about diseases like malaria, dengue, and leishmaniasis. Yet our current experience with West Nile fever is a gentle reminder that insect-borne diseases can strike even in the United States. Perhaps many believe that malaria, dengue and leishmaniasis have been defeated as major public health problems. The truth is that far from being defeated, these diseases are laying waste to countries and populations around the globe. The Democratic Republic of Congo reports an estimated 226,000 childhood deaths per year and malaria is the primary killer of those children.[1] So in many countries the diseases continue siphoning away lives, health, and economic

[1] http://web.worldbank.org/WBSITE/EXTERNAL/COUNTRIES/AFRICAEXT/CONGODEMOCRATICEXTN/0,,contentMDK:20634700~menuPK:349472~pagePK:141137~piPK:141127~theSitePK:349466,00.html

vitality as they always have, in others where the diseases were once controlled, the diseases are now returning to the devastating levels before the advent of DDT and effective disease control programs.

The 30 years of data from control programs of the Americas plotted in Figure 1 illustrate just how effective DDT was in preventing malaria. The period 1960s through 1979 displays a pattern of malaria controlled through house spraying. In 1979 the World Health Organization (WHO) changed its strategy for malaria control, switching emphasis from spraying houses to case detection and treatment. In other words, the WHO changed emphasis from malaria prevention to malaria treatment. Countries responded to WHO guidelines and pressures from bilateral and multilateral donors. Most countries dismantled their spray programs over the next several years. The line graph in Figure 1 illustrates the progress of the dismantling. As you can see, fewer and fewer houses were sprayed. The bar graph illustrates the cumulative increase in cases over the baseline of cases that occurred during years when adequate numbers of houses were being sprayed (1965-1979). As you can also see, as countries reduced numbers of houses sprayed, the number of malaria cases continually increased.

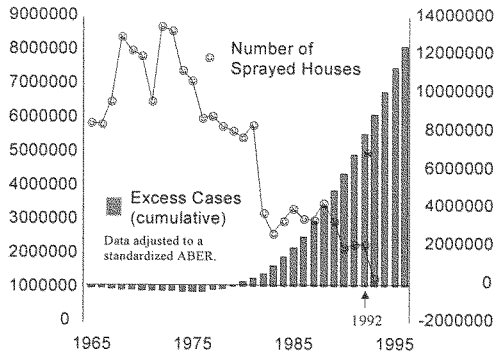


Figure 1. Impact of the World Health Organization's malaria control strategy in 1979 to de-emphasize indoor spraying of house walls and adoption of World Health Assembly resolution in 1985 to decentralize malaria control programs in the Americas. The x-axis is years and the y-axis is cumulative numbers of malaria cases above the baseline. Baseline is defined as the average number of malaria cases each year from 1965 to 1979.

In spite of quantitative proof that declining use of DDT has caused increasing disease, those who oppose use of DDT steadfastly deny that such a relationship exists.[2] A Wilkipedia internet site suggests that a claim of causation, in the case of DDT and malaria, amounts to Post hoc ergo propter hoc.[3] This is to say it is a logical fallacy to suggest that declining use of DDT, since it occurred before increasing malaria, was the cause of increasing disease. The Wilkipedia challenge goes on to admit that "temporal sequence is integral to causality — it is true that a cause always happens before its effect. The fallacy lies in coming to a conclusion based only on the order of events, which is not an accurate indicator.[4]" The Wilkipedia analysis is exceptional shallow and incomplete. It ignores issues of consistency, statistical coherence, and predictive performance.

A causal relationship would suggest that before DDT was used, disease rates were high. With use of DDT, disease rates declined, and without use of DDT, disease rates increased in proportion to decreased DDT usage. As a point of fact, this is precisely what has happened in many countries around the world. The exceptions are found in those countries that reduced disease and simultaneously went through an economic transition. In other words, increasing wealth can improve control over disease. Regardless the relationships described above have been documented for many countries.[5]

I am including in this testimony as annex 1 a model of the proportional dose-response relationships between DDT usage and malaria over a 34 year period in Ecuador.

---

[2] Matteson, P. C. (1999). "Malaria control in South America." Emerg Infect Dis 5(2): 309-11.

[3] http://en.wikipedia.org/wiki/DDT#Arguments_for_and_against_DDT
[4] http://en.wikipedia.org/wiki/Post_hoc%2C_ergo_propter_hoc
[5] Roberts DR, Laughlin LL, Hshieh P, Legters LJ. DDT, global strategies, and a malaria control crisis in South America. Emerg Inf Dis 1997; 3:295-302

This same analysis has been performed with data from other countries and the results have been consistent.[6] The powerful fit (statistically significant) of actual data to the model of increasing malaria with decreasing numbers of sprayed houses attest to the causal relationship between reduced use of DDT and re-emerging malaria. I propose that the link between declining use of DDT and increasing disease fulfills both the criterion of consistency and the criterion of a proportional dose-response relationship. This relationship also fulfills the criterion of predictive performance. When South Africa restarted its DDT spray program in 2001, malaria rates dropped precipitously. The same precipitous decline in disease rates has been documented for Madagascar, Eduador, Belize, and Mexico after the countries restarted or renewed DDT spray programs.

For reasons I will explain later, there is no insecticide recommended for malaria control that rivals, much less equals, DDT's unique actions to prevent malaria transmission inside houses. No other insecticide recommended for indoor spraying of houses exerts a powerful spatial repellent action, as does DDT, that stops mosquitoes from entering houses and biting during the night, or is as long-acting, as cheap, as easy to apply, as safe for human exposure, or as efficacious in the control of malaria. For all these reasons, the malaria endemic countries still need the freedom to use DDT in malaria control operations if they choose to do so. Yet, most indoor spray programs the world over have been stopped, and any and all uses of DDT have been discouraged. As stated before, to a very great extent control programs have been dismantled because of regulatory policies against public health insecticides in developed countries, and the enforcement of those policies by bilateral and multilateral donors. It should go without saying that the underlying regulatory policies have been developed as a result of pressures from environmental activists, often through environmental litigation.

In the United States, the Environmental Protection Agency has regulatory authority for all insecticides, to include those that are critical in preventing transmission of important diseases. Yet the agency has no responsibility at all for disease control.

---

[6] Roberts DR, Laughlin LL, Hshieh P, Legters LJ. DDT, global strategies, and a malaria control crisis in South America. Emerg Inf Dis 1997; 3:295-302

Actions against DDT illustrate how EPA has exerted regulatory authority on basis of political pressure. To appreciate the full dimension of EPA action against DDT, we need to reflect back to the beginning of a transition from effective disease control to the present conditions of reemerging diseases and stark failure of public health programs.

1969 was an important year of environmental activism against DDT. It was also the beginning of a move away from effective malaria control programs. In 1969 Sweden banned most uses of DDT.[7] In the United States there were hearings on DDT in the State of Washington[8] and in Madison, Wisconsin.[9,10] Hearings occurred just six years after the appearance of Rachel Carson's publishing phenomenon "Silent Spring." DDT was Carson's primary target, so hearings against DDT received considerable press coverage. Science magazine had made contributions against DDT in 1968 by publishing 10 articles and letters, mostly antagonistic to DDT. Four of the 10 Science articles were authored by Charles Wurster,[11] co-founder of the extremist anti-DDT Environmental Defense Fund. The 1968 articles portrayed DDT as an insidious and mortal threat to robins, the Bermuda Petrel, and our global oxygen supply. Those claims were false, but the papers gained credibility by appearing in our most prestigious science magazine.

Another fateful act in 1969 was a decision to stop the *Aedes aegypti* eradication program in the United States. The program was dependent on use of DDT. Termination of that program was entirely political. Ending eradication, which was successful in many other countries of the Americas, was vigorously opposed by leading tropical medicine

---

[7] http://www.chem.unep.ch/pops/POPs_Inc/proceedings/bangkok/WAHLS1.html

[8] In this year the global malaria eradication program ended and the U.S. *Aedes aegypti* eradication program was stopped. Both of these critical public health programs were entirely dependent on use of DDT.

[9] http://www.uwmc.uwc.edu/geography/350/DDT-hearing.htm

[10] http://fightingbob.com/article.cfm?articleID=462

[11] Wurster, C. F., Jr. (1968). "DDT and robins." Science **159**(822): 1413-4.

, Wurster, C. F., Jr. (1968). "DDT reduces photosynthesis by marine phytoplankton " Science **159**(822): 1474-5.

, Wurster, C. F., Jr. and D. B. Wingate (1968). "DDT residues and Bermuda petrels." Science **161**(839): 397.

, Wurster, C. F., Jr. and D. B. Wingate (1968). "DDT residues and declining reproduction in the Bermuda petrel." Science **159**(818): 979-81.

specialists of that time.[12] Unfortunately the decision fell within the authority of a political appointee who headed the CDC, Dr. David Sencer. He ended the program and end of eradication in the United States collapsed the programs that had eliminated threats of dengue fever and urban yellow fever from most countries of the Americas. Programs collapsed in other countries because program managers knew the U.S., as the major trading partner, would be a continual source of *Aedes aegypti* re-infestations—it would be a never ending problem. As those programs collapsed the countries were reinvaded by *Aedes aegypti.* To make a long story short, dengue fever is once again endemic, and often epidemic, in almost all countries of Central and South America.

In Sencer's justification for ending *Aedes aegypti* eradication he stated that it was not possible to eradicate in one country or region alone, if eradication were to be attempted, it would need to be global in scope.[13] Yet this argument was without merit because many countries had already eradicated the mosquito and had maintained their *Aedes aegypti*-free status for many years. All that was required to remain *Aedes aegypti*-free was vigilance and a willingness to mount a decisive response once an infestation was detected. So, why did Sencer abandon the eradication effort? As a political appointee, we can assume that politics flavored his decisions and the decision to end the program occurred during the peak of environmental activism against DDT. Thus it is no surprise that during the 11th Plenary Meeting of the World Health Assembly (WHA) in Geneva in May 1972, Sencer iterated a view that "the control of malaria and typhus were the only cases in which the use of DDT was justified." In other words, use of DDT to eradicate *Aedes aegypti* was not justified in his opinion.

The EPA prohibitions of DDT for agriculture were signed June 14, 1972. Yet, even before EPA prohibitions against the use of DDT in agriculture, environmental activism was reducing abilities of malaria endemic countries to acquire the insecticide. As stated in the 11th Plenary WHA meeting in May 1972, "Many countries were now

---

[12] Downs, W. G. (1969). "Health protection in a shrinking world." Am J Trop Med Hyg **18**(3): 482.
, Soper, F. L. (1969). "Health protection in a shrinking world." Am J Trop Med Hyg **18**(3): 482-4.

[13] hrinking world." Am J Trop Med Hyg **18**(3): 341-5.

facing difficulties because of the limited amounts of DDT on the world market, and because of the rise in price that had followed limitation of production." So, even before specific EPA action against DDT there was tremendous public health harm of environmental activism against DDT and that harm was known and widely discussed.

Court proceedings were seemingly required for EPA to act against the use of DDT in agriculture. For seven months the pros and cons of DDT were aired in court[14]. The hearing examiner, Edmund Sweeney concluded in April, 1972 that DDT was not a human carcinogen, and that approved uses of DDT were not a source of major environmental harm. Two months later the head of the newly formed Environmental Protection Agency, William Ruckelshaus, ignored the court findings and cancelled all agricultural uses of DDT. So, even when hearings were required, an entirely political decision was still used to override findings of the court. As one observer described it "DDT demonstrated the effect public pressure could have on EPA policy decisions."[15] Exemptions for DDT use were granted for public health use in control of vector borne diseases, USDA or military use for health quarantine, and use in prescription drugs for controlling body lice.[16] But in a follow-up action the EDF filed a suit in 1973 to prohibit all uses of DDT.[17] This action and others showed clearly that environmentalists had no interest at all in protecting human health or human welfare.

Science magazine lost interest in DDT after it was prohibited for agriculture use and published only 3 DDT papers in 1973, and fewer in subsequent years. Nature magazine acted similarly, publishing many DDT related publications (again, mostly antagonistic) from 1969 to 1971, and then losing interest after the EPA prohibition. Some DDT opponents published in both magazines, e.g., David Peakall, Robert Risebrough, and Joel Bitman. As described in a paper by Gordon Edwards entitled

---

[14]

[15] http://www.epa.gov/history/publications/formative6.htm

[16] http://www.cec.org/files/PDF/POLLUTANTS/HistoryDDTe_EN.PDF

[17] http://www.epa.gov/history/topics/ddt/02.htm

"DDT: A case study in scientific fraud,"[18] many frenzied anti-DDT reports were found wanting in scientific validity.

If we put aside tremendous harm of the EPA decision on use of DDT for disease control, the agriculture prohibition of DDT was still a striking example of a political decision overriding public health, or more to the point, occupational health. One factor in de-registering DDT was that the EPA could recommend an efficacious substitute, so agricultural productivity would theoretically not be harmed. The substitute chemical was parathion. All registered agricultural uses of DDT ended January 4, 1973. Even allowable use in public health required EPA approval after the new policy was implemented.

To understand the magnitude of the EPA's 1972 action against DDT, one needs to understand that no human death or human illness had been attributed to appropriate/approved uses of DDT (this statement is still true today). On the other hand, parathion is one of the most toxic insecticides in existence. So, the EPA stopped uses of a chemical that posed no proven risk to humans and substituted one widely known, even in 1972, to be dangerous. Of course EPA supposedly allowed time to prepare agriculture workers for use of a more dangerous chemical. The time allowed was from June 14, 1972 to 4 January 1973, when all uses of DDT were stopped. This token effort pales in comparison to the real danger of parathion. In a 1999 opinion, EPA stated "Methyl parathion is hazardous to workers - people who handle or apply the pesticide as part of their occupation, and people who work in fields to harvest treated crops. Protective clothing and equipment are not sufficient to reduce the risks to workers to acceptable levels.[19]" So, 27 years later we are told that even protective clothing and equipment were not sufficient to protect workers. If EPA's own assessment is correct, then there can be no doubt that for 27 years agricultural workers suffered illness and death from parathion. This illustrates the price EPA was willing to pay to get rid of DDT—the DDT prohibition was a political win paid for in human lives.

---

[18] http://www.jpands.org/vol9no3/edwards.pdf
[19] http://www.epa.gov/pesticides/factsheets/chemicals/mpfactsheet.htm

What I describe here is a broad exercise of regulatory authority without public health responsibility. As the DDT example illustrates, even EPA findings suggest the 1972 decision against DDT and the decision to substitute parathion for many agricultural uses had adverse impacts on occupational health of agriculture workers. The adverse impact of DDT prohibitions on insect borne disease control is a separate issue. The public health cost of eliminating DDT from malaria control programs alone can be measured in tens of millions of preventable deaths, and hundreds of millions of preventable malaria infections. If we look around the globe at increasing problems of malaria, dengue, and leishmaniasis, it seems to me that the sum of all benefits of EPA actions and of environmental activism against insecticides is meaningless compared to the enormous harm imposed on poor people in poor countries as a result of DDT prohibitions. For this reason I believe our system of authorities and responsibilities is seriously out of balance with the global need for public health insecticides.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to require EPA to conduct "a comprehensive review of older pesticides (those initially registered before November 1, 1984) to consider their health and environmental effects and to make decisions about their future use."[20] Shortly after the process of reregistration began, DDT was dropped from the list of insecticides registered for public health use in the United States. The reregistration process required a payment of fees. Additionally there may have been maintenance fees for keeping an insecticide on the approved list. Whether for failure to pay the former or latter, there was no payment of fees, so DDT was erased from the list of insecticides for public health uses.[21] Once DDT was de-listed for public health use, USAID was then able to claim it could not spend government funds for DDT in other countries if DDT could not be used in the United States.

Lack of balance in regulatory authority continues to characterize EPA actions, even

---

[20] http://www.epa.gov/oppfead1/trac/factshee.htm
[21] http://www.cec.org/files/PDF/POLLUTANTS/HistoryDDTe_EN.PDF

today. Attached is a paper entitled "Overcoming regulation based on innuendo and litigation."[22] This article describes a struggle of mosquito control organizations in Florida to protect the registration (or as current process dictates, reregistration) of Baytex (fenthion). This chemical was used in some mosquito control districts in Florida to control adult mosquitoes. Registration for use was voluntarily cancelled. I am also citing here the URL for the Notice of Intent to Sue for Violations of the Endangered Species Act, Migratory Bird Treaty Act, and Administrative Procedure Act Concerning Registration of the Pesticide Fenthion.[23] There is no balance visible in these documents, all emphasis is on potential environmental risk, with no emphasis on value of using fenthion to protect human health. The notice of intent to sue also shows the enormous legal protections for wildlife. Where are the laws that provide protections to human health and where are the activists who litigate to preserve the remaining few chemicals registered for use against vectors of human disease?

I think it is fair to say that environmental activist groups have abused litigation as a tool to force compliance with their views and ideologies. The price of environmental activist victories against DDT and other public health insecticides has been an ever increasing burden of death and disease for the world's poorest and most vulnerable populations. In my opinion, it is time to place constraints on litigation against registrations and uses of public health insecticides.

The U.S. deliberative position during the persistent organic pollutants negotiations for DDT elimination was that the U.S. government was to seek reasonable measures to lead to, optimally, a phase out of production and use [of DDT], and at a minimum, use only for vector control purposes. This seemingly reasonable position also stipulated a willingness of the U.S. government to work with WHO and others to identify alternatives to DDT.[24]

I stated earlier that I would explain why there is no insecticide presently

---

[22] Stivers, J. 2003. Overcoming regulation based on innuendo and litigation. Wing Beats. 14 (4):14-15.
[23] http://www.defenders.org/wildlife/birds/fenthion.pdf
[24] U.S. Approach for DDT. Draft 4: 6/18/98. Janice Jensen. EPA Office of Pesticide Programs.

recommended for disease control that equals DDT's unique actions to prevent malaria transmission inside houses. As a matter of historical correctness, EPA adopted legally binding prohibitions against DDT in 1972. But to my knowledge, EPA has not even defined criteria for a reasonable alternative to DDT. In my opinion, a reasonable alternative would be chemical that replicates DDT's unique actions of a powerful spatial repellent, a strong contact irritant, and a moderately toxic compound and be rapidly biodegraded (metabolized in a living system). The fact is, in all the years the EPA has exercised prohibitions on use of DDT, the agency has invested nothing to discover a alternative chemical. This is another damming expression of authority without responsibility. Our National Institutes of Health have invested almost nothing in searching for DDT alternatives. The USAID has invested almost nothing in comparative research to identify chemicals that improve on or mimic DDT actions to control malaria, and the same statement is true for the CDC.

The United States is the greatest and most powerful country in the world. The U.S. government, acting through USAID, EPA, and through the offices of the World Health Organization and the United Nations Environment Programme has had more influence eliminating DDT from malaria control operations than any other country or organization. So, how is it possible that until recent time, the U.S. has made no investment or contribution to finding a DDT alternative?

Regulatory authority has been used as a basis for creating a whole set of barriers and obstacles to use of public health insecticides. We see these barriers in requirements for environmental assessments (EAs) and environmental impact assessments (EIAs) for any public health uses of insecticides for spraying inside houses. The cost of these assessments should not drain away precious resources for control of malaria and other diseases. The cost of EAs and EIAs should be evaluated on the basis of cost versus benefit. What is the real benefit in lives saved or prevention of public health harm from EAs and EIAs? Beyond this, there are other costs that are going to be tacked onto uses of DDT, and perhaps other public health insecticides. The WHO is now stating that the Stockholm Convention recommends that a "centralized regulatory and administrative

authority should be set up" to supervise DDT procurement or importation and use.[25] In my opinion, all of these requirements do not accurately reflect requirements to protect public health and to prevent diseases that are draining away lives, health, and economic viability of many developing countries, especially those in Africa.

[25] http://www.who.int/malaria/docs/FAQonDDT.pdf

Annex A

The proportional dose-response relationship between use of DDT and malaria rates for Ecuador.

A proportional dose response relationship exists between numbers of houses sprayed with DDT and malaria cases.[26,27] A threshold level of effective spraying can be empirically defined by fitting house spray and malaria data to a logistic regression model[28]. The threshold value is the minimum effective house spray rate (MEHSR). When spraying is below the MEHSR, numbers of malaria cases will increase in roughly inverse proportion to the reduced number of houses sprayed. Alternatively, when spraying is above that threshold, numbers of cases will decline in roughly inverse proportion to the increase in number of sprayed houses.

I tested logistic regression models against 34 years of malaria control data[29] for Ecuador. For this model we used published methods to standardize annual parasite indexes (APIs), which express the yearly number of slide diagnosed malaria cases per 1000 population.[30] The logistic regression model was developed and tested with SAS software. A derived binary variable was the response variable and the house spray rate was the independent variable. A binary variable was developed by assigning a value of 0 if the standardized annual parasite index (API) increased during the following year and 1 if it declined. The API was standardized against the average annual blood examination rate (ABER) for years from 1965 to 1979. Significance was established at the 0.05 probability level.

---

[26] Roberts DR, Alecrim WD, Hshieh P, Grieco JP, Bangs M, Andre RG, Chareonviriyaphap T. A probability model of vector behavior: Effects of DDT repellency, irritancy, and toxicity in malaria control. J Vector Ecol 2000; **25(1)**,48-61.

[27] Grieco JP, Achee NL, Andre RG, Roberts DR. A comparison study of house entering and exiting behavior of *Anopheles vestitipennis* (Diptera: Culicidae) using experimental huts sprayed with DDT or deltamethrin in the southern district of Toledo, Belize, C.A. J. Vector Ecol 2000; 25(1):62-73.

[28] Roberts DR, Vanzie E, Bangs MJ, Grieco JP, Lenares H, Hshieh P, Rejmankova E, Manguin S, Andre RG, Polanco J. Role of residual spraying for malaria control in Belize. J Vector Ecol 2002; 27(1):63-69.

[29]"Status of Malaria Programs in the Americas. XLII Report." Washington, DC, Pan American health Organization (1994).

[30]Roberts DR, Laughlin LL, Hshieh P, Legters LJ. DDT, global strategies, and a malaria control crisis in South America. Emerg Inf Dis 1997; 3:295-302.

The logistic regression model is $\log\left(\frac{\rho}{1-\rho}\right)$; where p = probability of decreasing malaria. The probability that malaria will decrease in Ecuador with increasing house spray rate (HSR) is -1.0398 + 0.0178(HSR).

A statistically significant ($p<0.05$) fit of data to the model defined a MEHSR of 58.4 for Ecuador. Each house was sprayed twice each year so only 29 different houses were actually sprayed per 1000 population. This model illustrates the proportional dose-response relationship between malaria incidence and levels of indoor DDT spraying. Ecuador dropped below the MEHSR in 1980.[31] The years after 1980 up through 1993 were marked with almost continuous increases in standardized APIs. The only exception to progressive increases in malaria was the years in when Ecuador restarted its use of DDT and quickly dropped its malaria rates.[32]

[31] "Status of Malaria Programs in the Americas. XLII Report." Washington, DC, Pan American health Organization (1994).

[32] Roberts DR, Laughlin LL, Hshieh P, Legters LJ. DDT, global strategies, and a malaria control crisis in South America. Emerg Inf Dis 1997; 3:295-302

Testimony outline: Dr. Andy Arata

Thank you, Chairman Coburn and members of the subcommittee on Federal Financial Management, Government Information, and International Security for the opportunity to speak before you today and to present my perspective on malaria control and progress in malaria control programs.

I have spent over 35 years working in malaria and vector-borne disease control, working for a number of international organizations in over 30 countries. I began my career at the peak of the Malaria Eradication program, worked for WHO on new control methods in the 1970's, and have served as a consultant evaluating malaria control programs using indoor residual spraying (IRS) in Africa, Latin America and Asia for both USAID and the World Bank.

I am pleased to see that US foreign aid for malaria control is re-considering the use of indoor residual spraying and DDT. For a number of years I have felt that the almost sole approach to vector control through the employment of insecticide-treated nets (ITNs) was very short-sighted producing positive but limited, results.

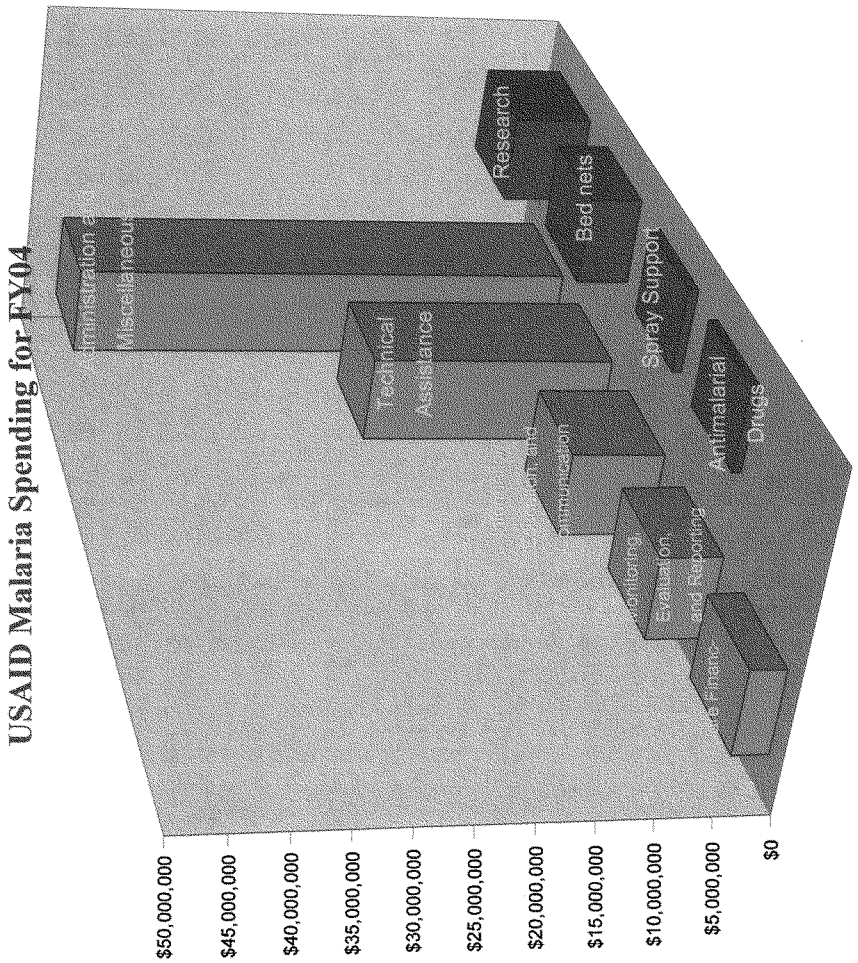
In general, I and many field oriented colleagues have proposed integrated control measures, employing more than one approach to vector control, depending on the ecology of the vectors in a specific area. This approach is employed not only for malaria control, but for the control of other vector-borne diseases, as well as nuisance insects. Integrated control is used extensively in agriculture. For malaria vectors this may include larval control (by chemical or biological insecticides), elimination of breeding sites, (especially man-made), housing improvements, ITNs, etc, depending on the characteristics and vector ecology in a given area.

Malaria is a very variable disease- 4 parasite species, numerous anopheline vectors, a range of transmission intensities (endemic, stable, unstable), variable biting patterns in terms of where and when the mosquitoes prefer to bite, resistance potential for both the parasites (to drugs) and the vectors (to insecticides), forest versus urban transmission, etc, etc. In other words, measures that work in southern Africa may not necessarily work in the Congo. The variety of circumstances facing the control program manager in the field is huge. On top of these factors, there are more complexities: differences in housing construction materials (wood, mud, etc) will modify the efficacy of any insecticide, so depending on only a single compound or method of application, is, in my opinion, a recipe for failure.

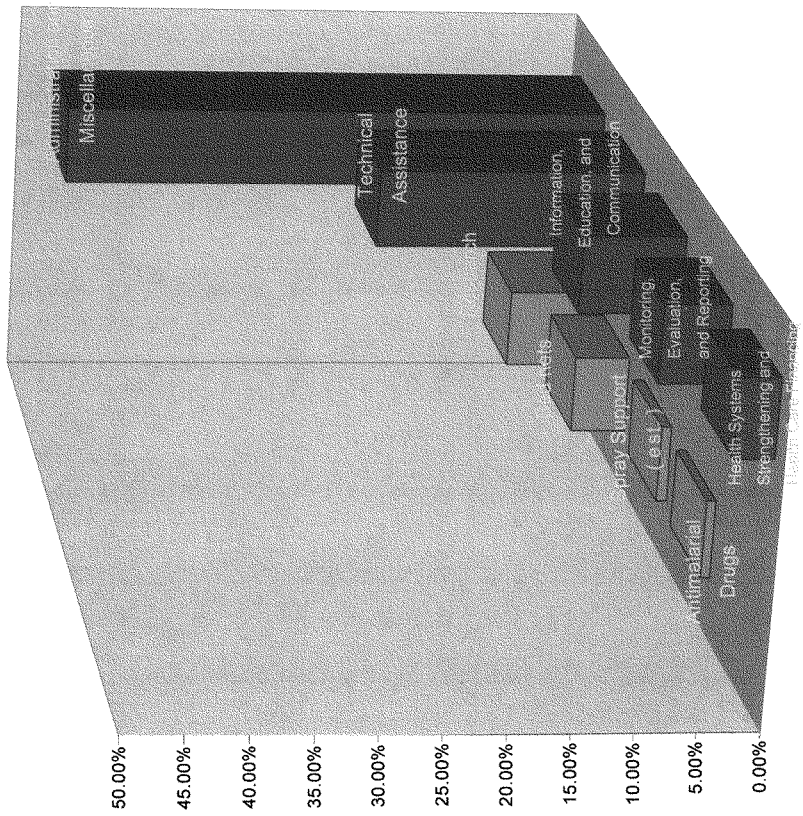
My career in malaria control has spanned from the Eradication era through to the re-emergence of IRS as a major control measure. To my mind, the over-riding lesson of the malaria eradication period was that there was no "magic bullet"- local variations mattered, and a flexible approach, what I've called "integrated control", was the most effective. Cookie-cutter approaches to malaria control were problematic. Sole reliance

on IRS with DDT did not work well. We now have more tools available to us than we did at that time. ITNs and the newer drugs for malaria treatment offer new opportunities for effective control programs using integrated approaches tailored to local circumstances and vector specific variables. Integrated control also implies development of infrastructure and management practices, as well as community participation, even diagnosis and treatment.

I hope that those charged with the development of new malaria control programs will see their way to employ DDT as they would any other insecticide, to be tested and evaluated for efficacy, safety and cost in each situation. I think DDT has a role to play in malaria vector control, if used as a component in integrated control systems.


USAID Malaria Spending for FY04
$50,000,000
$45,000,000
$40,000,000
$35,000,000
$30,000,000
$25,000,000
$20,000,000
$15,000,000
$10,000,000
$5,000,000
$0
Miscellaneous
Technical Assistance
Research
Bed nets
Spray Support
Antimalarial Drugs
Evaluation and Reporting

USAID Malaria Spending for FY04



Commentary

Overcoming Regulation Based on Innuendo and Litigation

by Dr. Jeff Stivers

The recent voluntary cancellation of Baytex (fenthion), the final result of the reregistration process, should serve as a wake-up call for our industry. A number of precedents were established during that Environmental Protection Agency (EPA) process which could spell trouble for the rest of our adulticide products.

Many in our industry did not become involved in the reregistration of Baytex because it was only used in Florida. That lack of involvement only played into the hands of the environmental groups attempting to have the Baytex registration cancelled. For those who were not involved, here are some of the highlights of the disappearance of Baytex.

The EPA held a series of public meetings with the people interested in the reregistration of Baytex. These meeting were attended by a number of people from the mosquito control industry, as well as individuals representing several environmental groups. As a result of these meetings it appeared that the EPA was prepared to reregister Baytex with relatively minor label changes and a requirement that Bayer supply some additional data. Then the U.S. Fish and Wildlife Service (USFWS) and a coalition of environmental groups, led by the American Bird Conservancy, entered the picture.

The USFWS provided the EPA with unpublished in-house data claiming to indicate that Baytex, applied by the Collier Mosquito Control District (CMCD), had been responsible for bird mortality on Marco Island, FL. As a result of this unreleased data the EPA took another look at Baytex.

The CMCD, and other mosquito control agencies, tried to get the USFWS data in order to study it and discuss it scientifically with the EPA. However, due to the ongoing investigation by the USFWS, the EPA was prohibited from releasing any of the data. Unfortunately, the data has never been released. The only thing ever released to the public was an internal EPA memo discussing the bird mortality in very general terms.

Nevertheless, the lack of good data did not deter the American Bird Conservancy and other environmental groups from mounting a media campaign designed to inundate the EPA, several mosquito control districts, and other state and national agencies with emails opposed to the reregistration. Truth and relevance to mosquito control operations played no part in this media campaign. The fact that the people sending the emails knew little, if anything, about the issue was of no importance, sheer numbers were the objective of the campaign.

As a result of the political pressure exerted by these environmental groups, and the lawsuit they filed against the EPA, the EPA proposed a new label with a number of ridiculous requirements. One of the major requirements was that any district wanting to use Baytex would have to annually develop, have approved by the EPA, and follow what the EPA called an Integrated Mosquito Management (IMM) plan.

The requirements of the IMM plan were, for the most part, bureaucratic in nature and would have done little to protect non-target organisms. Most of the requirements were for record keeping. The EPA wanted to know every detail of each application of Fenthion, down to the plumbing parts used on the application equipment. They also wanted to know what efforts the districts made to educate the public about Fenthion and mosquito control. While these would have been time consuming and, of little, if any, value as far as protecting the environment was concerned, the requirement for prescription treatment with a seven day limit on re-treatment intervals was particularly outrageous. For mosquito control operations in southwest Florida, this re-treatment interval was simply not practical-and it was based on litigation rather than science.

Toward the end of the Baytex reregistration process it became readily apparent that the litigants (environmental groups) were setting policy for the EPA. During discussions between several representatives of the mosquito control industry and EPA personnel, regarding requests for changes to the Baytex label and IMM plan the EPA made comments such as "...we'll have to run that by the litigants to see if they will accept it..." or "... we can't do that because the litigants will not accept that change."

So what happened to cause Baytex to be voluntarily cancelled? A variety of things, but lack of involvement by mosquito control districts around the country was definitely a contributing factor. While the AMCA was involved in the process, very few districts outside of Florida actively supported the reregistration of Baytex. This lack of support, combined with the media campaigns and litigation supported by environmental groups, allowed the EPA to make decisions that are not supported by science. Which of our mosquito control prod

ucts will be subjected to this same process next?

What can we do in the future to insure that other mosquito control products do not suffer a similar fate? **GET INVOLVED!** That means you, and the district, university, health department, or company that you represent. Without the active support of our entire industry, the EPA will continue to be guided be pressures from environmental activists, not sound science.

When the next mosquito control product comes up for re-registration, our industry must make a concerted effort to protect that product, regardless of whether it is used by an individual district or not. Any district that takes the stance that a particular product is not important, simply because the district does not use it, is gravely mistaken. All of our products are important to the industry, even those not used by a particular district.

Start collecting data on the products that you use now so that we have valid scientific data to present to the EPA. Without good data, the EPA resorts to computer models, designed for agricultural applications, to determine such things as drift and deposition. The information from these models is then used to determine the risk to humans and non-target organisms. The models used by EPA have never been validated for mosquito control applications, and probably do not accurately reflect the results of mosquito control operations. This is a classic case of garbage in, garbage out.

Data on ground deposition and drift of adulticide products would be extremely useful. We need to determine what information EPA uses in their models and collect that data when we make our applications. This way we will be able to present the EPA with valid data to verify the accuracy, or inaccuracy, of their models.

We also need to start developing field data on non-target impacts, or data indicative of this type of impact, for our products. Here, actual trials exposing non-targets would be wonderful to have. The degradation rate of our products after application would also be useful. Most non-target studies are performed in the laboratory with the specimens being exposed to fixed doses of chemical for long periods. We need to demonstrate that our products do not expose non-targets to a continuous high, dose of insecticide but to a rapidly reducing dose.

Most importantly we have to get organized and develop campaigns to get the public, our elected officials, and other mosquito control professionals involved. The EPA places great store on the shear numbers of comments it receives on a topic. We also need to be ready to counter the negative media campaigns run by the environmental groups. We need to be able to counter innuendo, misrepresentation, and outright lies with verifiable facts.

Part of this organizational effort should also be the development of a war chest to fund lawsuits against the EPA, environmental groups, or both to insure that the provisions of the Food Quality and Protection Act, which governs how the EPA regulates pesticides, are followed. The EPA is required to make all of its decisions based on sound science and we should stand ready to force the EPA to meet this legal requirement. If it takes a lawsuit to accomplish this, we must be ready to file such a suit.

Baytex is gone and we have lost one of our few weapons in the fight against mosquitoes and mosquito-borne diseases. Let's not lose any more weapons because of apathy or lack of foresight and preparation.

Dr. Jeff Stivers
Director of Research
Collier Mosquito Control District
Naples, FL

QUESTIONS FOR THE RECORD FROM SENATOR COBURN
FOR:
MICHAEL MILLER, DEPUTY ASSISTANT ADMINISTRATOR
FOR GLOBAL HEALTH,
U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

Question: At our hearing last May, you stated that less than 8% of USAID's budget went to commodities. While I am encouraged that USAID has taken bold steps to change their approach to fighting malaria, the public needs to know that its malaria monies are spent saving lives. You committed to a public website for contracts and progress on the fight against malaria. When will this be operational? Will this include money for the President's Malaria Initiative? If so, how?

Answer: USAID's public web site for the President's Malaria Initiative (www.Fightingmalaria.Gov) has been operational since October 2005. The web site allows the public to access the PMI's country-specific plans and reports, summary data on the Agency's program inputs, latest news, announcements, and press releases. In January, USAID posted detailed funding and program information on its obligations of FY 2004 malaria funds. On February 10, USAID posted the same information on its obligations of FY 2005 malaria funds. In addition, USAID will provide a complete list of FY 2006 obligations under the PMI and will post PMI contracts and grants on the web once they are awarded (after redactions by the awardees).

Questions for the Record Submitted to Michael Miller
Deputy Assistant Administrator for Global Health
U.S. Agency for International Development
January 19, 2006

Question: History and science both tell us that DDT is not only safe, it's the most effective and cheapest weapon that we have to fight malaria with Indoor Residual Spraying. I believe that what the United States says and funds matters. What are your plans to encourage the use of IRS and DDT in your programs?

Answer: Beginning this fiscal year, USAID increased significantly its support for IRS – including IRS with DDT. In FY 2006, USAID funding for IRS will increase to more than $20 million, and we will support IRS with DDT in at least three countries (Ethiopia, Mozambique, and Zambia), including direct purchase of the compound. All three countries selected for the first year of the President's Malaria Initiative (PMI) -- Angola, Tanzania, and Uganda -- include USAID-funded IRS activities. For example, in Angola, spraying of approximately 120,000 households (protecting 500,000 residents) began less than six months after President Bush's announcement of the PMI, and is scheduled to finish by the end of March, 2006. In these three cases the national control plans did not include the use of DDT this year for reasons of resistance and national laws, although one is likely to switch to DDT next year.

Because DDT is effective, relatively inexpensive, and often has a residual effect for longer than other insecticides, it is the insecticide of choice in much of Africa. Based on significant anecdotal evidence, interest in its

use appears to be growing among malaria control programs in the region. Still, the choice of which insecticide to use is dependent on many factors beyond those positive qualities of DDT, including the type of housing to be sprayed, insecticide resistance, other local factors, and even legal prohibitions in some cases. USAID is exploring with governments in other countries in which we work opportunities to employ DDT where it is efficacious, cost-effective, and approved for local use. In each case, USAID will seek to use the insecticide that is most effective and will ultimately save the most lives. In addition, as a way of focusing attention on the importance of IRS for malaria control in Africa, USAID has commissioned a review of the scientific literature with respect to IRS and insecticide-treated mosquito nets (ITNs) in Africa and will be funding a consultative meeting later in 2006 to discuss and disseminate the findings and make recommendations about the roles of IRS in malaria control. In addition, USAID will fund other studies about malaria prevention, including studies to further our knowledge about the repellent, irritant, and toxic effects of DDT on major African vectors of malaria.

Questions for the Record Submitted to Michael Miller
Deputy Assistant Administrator for Global Health
U.S. Agency for International Development
January 19, 2006

Question: You told my staff that this Programmatic Environmental Assessment would likely be completed in March, 2006. What actual date can I expect to see this completed?

Answer: The Programmatic Environmental Assessment (PEA) has been completed, and has been posted on USAID's website for comment. We will be hosting a public meeting on the PEA in early April.

1Questions for the Record Submitted to Michael Miller
Deputy Assistant Administrator for Global Health
U.S. Agency for International Development
January 19, 2006

Question: Can you please discuss the issue of technical assistance and Global Fund grants? Do you have any information about specific country examples where USAID is providing technical assistance to Global Fund grants or any summary of the number of countries or total dollar amounts provided?

Answer: Although Global Fund malaria grants are proceeding well in some places, bottlenecks still exist and have slowed implementation of activities in many countries. USAID has provided significant amounts of technical assistance to Global Fund grants in a variety of ways. In Ethiopia, Kenya, Madagascar, Rwanda, and Senegal, USAID helped develop malaria procurement and supply plans, which were required to release funds from Global Fund grants. In Cote d'Ivoire, the Democratic Republic of the Congo, and Niger, USAID provided assistance to develop Global Fund grant implementation plans. In Kenya and Angola, USAID and its technical partners helped change national malaria treatment policies to artemisinin-based combination therapies (ACTs) so those countries could receive their Global Fund grants. USAID has provided support to the World Health Organization (WHO) and various ministries of health in forecasting of ACT needs and ensuring adequate supplies of antimalarial drugs in country. In addition, USAID has provided support to Burundi, Cote d'Ivoire, Cameroon, DR Congo, Gambia, Ghana, Guinea-Bissau, Kenya, Liberia, Madagascar, Mali, Niger, and several sub-regional networks in developing Round 4 and Round 5 Global Fund proposals.

QUESTIONS FOR THE RECORD FROM SENATOR CARPER
FOR:
MICHAEL MILLER, DEPUTY ASSISTANT ADMINISTRATOR
FOR GLOBAL HEALTH,
U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

Question: How much money has been allocated for the President's Malaria Initiative? Given that USAID is implementing this program, is this new money or more or less what USAID has been getting to address malaria in Africa? Will this be enough to meet our goals of halving malaria deaths by 2010?

Answer: In FY 2006, $30 million is committed for the President's Malaria Initiative (PMI) for start-up in three countries. These funds come out of USAID's FY 2006 appropriation for malaria, which totaled $99 million (after rescission). The FY 2006 appropriation was a $10 million increase over the FY 2005 levels.

The President's announcement of the malaria initiative outlined the funding needs over the next five years to meet the target of reducing by 50 percent the number of malaria-related deaths in each target country. The plan included $30 million in FY 2006, $135 million in FY 2007, $300 million in FY 2008 and 2009, and $500 million in FY 2010. These amounts are in addition to USAID's planned baseline malaria funding. Based on the cost of implementing high-impact malaria interventions, this funding is sufficient to reduce malaria-related mortality in 15 African countries with a total population of about 175 million people.

Questions for the Record Submitted to Michael Miller
Deputy Assistant Administrator for Global Health
U.S. Agency for International Development
January 19, 2006

Question: In your opinion, what role should malaria experts and African governments be playing in defining where house spraying should be used? Is there any concern that legislating that a percentage of U.S. funding be for spraying taking both African governments who may better understand logistics in their particular country and experts who may best understand which sprays, nets, and other tools may work best, out of the equations?

Answer: The PMI and USAID's other malaria programs are directly focused on the successful implementation of a sound malaria control program in the host country. Decisions about what interventions to fund and when to utilize them are developed in full cooperation with the National Malaria Control Program – and often with other donors and international organizations as well. These national programs – including planning for IRS – always reflect the priorities of the host government's program and are largely a reflection of their expertise about their own country. The level of technical expertise within any given national program can vary greatly for many reasons, but ultimately, the focus of the PMI and of all our malaria programs is to build sustainable national capacity and expertise with the ultimate goal of a self-sustaining and self-funded national malaria control program.

Our recent experience in both PMI programs and other USAID malaria programs indicates a growing interest in the value and use of IRS among African malaria control programs. The belief of many African experts is that IRS is a highly-effective intervention that has been under-utilized in Africa to prevent malaria among at-risk populations.

Questions for the Record Submitted to Michael Miller
Deputy Assistant Administrator for Global Health
U.S. Agency for International Development
January 19, 2006

Question: What procedures has USAID instituted to ensure that the funding it provides contractors through its malaria program is spent effectively? How have the application and review processes a contractor must go through before receiving a grant changed to prevent abuses that have been reported in the past? What changes have been made to ensure that our programs are working more closely with African countries and organizations to combat malaria?

Answer: USAID has several procedures, checks, and reviews to ensure that funding provided to contractors is spent effectively. Except under exceptional circumstances, contracts and grants are bid competitively, and selection is made against a set of objective criteria as determined by a multi-member expert review panel. In addition, each contract or grant has a USAID project manager responsible for ensuring that resources and activities are effectively targeted. Every year, the contractor or grantee submits annual work plans and monitoring plans which USAID reviews and approves. Also, all contracts and grants are reviewed for overall performance annually by either USAID Mission or USAID Washington office management, including recipient-contracted financial audit by an approved outside auditing firm.

USAID also provides detailed information on malaria obligations by country and category, beginning with Fiscal Year 2004. Going a step further, USAID will provide copies of contracts and grant agreements (after redactions by the awardees) for all malaria activities in the PMI. We believe that this level of transparency and accountability to Congress and the public is essential for the support and success of the programs.

Questions for the Record Submitted to Michael Miller
Deputy Assistant Administrator for Global Health
U.S. Agency for International Development
January 19, 2006

Question: In your view, does the President's Malaria Initiative address calls to devote a higher percentage of U.S. malaria spending to the purchase of commodities? Based on the research you have seen, what percentage should be spent on commodities? What percentage should be spent on spraying and what types of spraying?

Answer: The goal of the PMI is to reduce malaria-related deaths by 50 percent in 15 countries by achieving 85 percent coverage of proven preventive and curative interventions, targeting children under five and pregnant women. Achieving these goals requires that a substantial portion of the U.S. malaria spending be devoted to the purchase of commodities. In each of the initial three PMI countries, the planning process involved considerable discussion with host country counterparts and other donor partners on the ground to identify commodity gaps for each country. Even with substantial resources from the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), significant commodity needs still exist.

The specific percentage of commodity purchases and spraying activities applied to any given country will depend on many factors, including other donor activity, strength of the existing health system infrastructure, national malaria control policies, and malaria transmission intensity. For example, many countries have existing Global Fund grants funding significant levels of artemisinin-based combination therapies, nets, and

other commodities. Likewise, the percentage of U.S. funding spent on IRS will depend on local conditions, the direction of the national malaria control plan, entomology, cost-effectiveness, and, in many cases, the host government's laws.

Because of the activities of other donors, the funding plans and calendars of Global Fund grants, and of the particulars of the malaria situation in a given country, the exact amount of commodities will vary from country to country and will change from year to year. In the first year of implementation, the percentage of funding for life-saving commodities in the three target countries has averaged around 50 percent; we expect that level to be typical in other countries, but may vary over the life of the programs.

QUESTIONS FOR THE RECORD FROM SENATOR COBURN
FOR:
DONALD R. ROBERTS,
DIVISION OF TROPICAL PUBLIC HEALTH,
DEPARTMENT OF PREVENTIVE MEDICINE AND BIOMETRICS,
UNIFORMED SERVICES UNIVERSITY OF HEALTH SCIENCES

ROBERTS QFRs:
Question 1: Dr. Anne Peterson, former director of USAID's malaria program, once told television journalist John Stossel, "I believe the strategies we are using are as effective as using DDT." (She was referring to bed-nets and technical assistance.) Would you agree with that assessment? Why or why not?

Answer: No I do not agree. There has been no use of bed nets that provides the same level of benefit as spraying houses with DDT. Benefit of spraying DDT is seen in the recent history of DDT use in South Africa and other countries. Insecticide treated nets (ITNs) should be an option for malaria control programs; but support for ITNs should not be exercised in an exclusionary manner. Unfortunately, in the past, USAID has supported ITNs and at the same time specifically excluded support for IRS and DDT. In fact, this exclusionary position is implied in Dr. Peterson's statement, e.g., "strategies we are using" versus the use of DDT.

DDT has a long history of successful application in control of malaria. It should continue to be an option for endemic countries and external funding should never be contingent on non-use of DDT or non-use of indoor residual spraying. The weakness of the ITN approach to malaria control is that use of ITNs requires user compliance. Additionally, protection against malaria-transmitting mosquitoes is limited to time people are under nets. Household members not under nets are not protected. In contrast, the strength of an IRS approach to malaria control is that all residents of a sprayed house are protected 24 hours a day. IRS with DDT often provides a very high level of control without user compliance issues.

Question: *Historically, how many times has a resistance been developed to DDT as a malaria control vector?*
Some populations of mosquito species that transmit malaria to humans have developed resistance to DDT. However, resistance is a localized phenomenon and there may be other populations of the same species entirely susceptible to DDT. The science question has been whether the resistance is a result of DDT use in agriculture or a result of DDT use in malaria control? The weight of evidence from field studies suggests that most cases of resistance are a result of DDT use in agriculture. This has been the conclusion of published WHO assessments and it has been the conclusion of individual researchers involved in the study of DDT resistance. I tend to believe that agricultural uses of DDT are the primary cause of resistance in malaria vector mosquitoes. Mosquitoes cannot avoid DDT when it is used in agriculture (agricultural use often involves wide area treatment of the environment). When broadcast widely in the environment DDT exerts pressure on mosquito populations to either die or become resistant. DDT on house walls acts mostly as a spatial repellent, stopping the mosquito from entering houses and biting people while they are sleeping. Thus, DDT on house walls does not constitute a big risk for mosquitoes and it does not exert pressure for resistance. The repellent action of DDT

on walls does provide considerable protection for people sleeping inside the sprayed house.

Question: *If DDT resistance were developed in an indigenous mosquito, would it still be effective in controlling malaria?*

Answer: Our research data suggest that resistance to DDT does not interfere with the spatial repellent action of DDT residues. The data I am referring to is with a malaria vector in Central America (*Anopheles albimanus*), and more recently with *Aedes aegypti* (a vector of dengue fever) in Thailand. Obviously, a pilot study or experimental hut study could be used to provide some determination whether resistance poses a problem for use of DDT in a malaria control program. A pilot study is an optimal solution because it would immediately show whether spraying DDT reduces disease rates.

Question: *How does DDT compare to other insecticides in terms of cost-effectivenesss*?

Answer: DDT continues to be our most cost-effective chemical for spraying inside houses. The purchase price of DDT is lower than other chemicals. Purchase price is low because there are no patent issues and it is easily manufactured. DDT has a long residual effect and it exerts a complex of protective actions (not just a killing action), characteristics which add to its overall cost-effectiveness. Even if purchase price of DDT were equal to more expensive chemicals, DDT would continue to be more cost effective in many settings simply because there would be a need for less frequent spraying of houses.

Question: *You have said that DDT IRS does not pose any measurable health or environmental risks. Even if it did, do you believe that DDT's benefits outweigh any potential health risks in terms of its impact on human lives?*

Answer: Yes, I believe the benefits of using DDT for control of malaria far outweigh any potential negative impact of DDT on the environment or on human health. I am confident of this because our experience with DDT now spans more than 60 years. There are no studies showing that DDT on house walls causes harm to the environment or to human health. I am being specific with this statement. I define harm as death and/or disease of humans or wildlife as a direct result of DDT. Finding DDT residues in soil, in living tissues, and other environmental samples does not equate to harm. In absence of proof of harm, all reasonable people should conclude that the benefits of DDT use far outweigh its potential harm.

QUESTIONS FOR THE RECORD FROM SENATOR CARPER
FOR:
DONALD R. ROBERTS,
DIVISION OF TROPICAL PUBLIC HEALTH,
DEPARTMENT OF PREVENTIVE MEDICINE AND BIOMETRICS,
UNIFORMED SERVICES UNIVERSITY OF HEALTH SCIENCES

Question: *What factors need to be examined when choosing the type of insecticide to use in indoor residual spray programs in Africa? What is your own experience in making these decisions in African programs?*

Answer: First Question--The main factor to consider is choosing a chemical for spraying in Africa is; which chemical works to reduce malaria rates. By this I mean which chemical will have the longest action and most impact against malaria transmission inside houses. The chemical should act to immediately begin reducing numbers of malaria cases. My list of the main factors to consider, not necessarily in order of importance, are: safety for spray applicators, safety for house residents, availability of chemical, cost of chemical, shelf life of chemical, levels of training needed for use of the chemical, requirements for safety equipment for spray operators, equipment needed for spraying, maintenance requirements for spray equipment, effectiveness of chemical in reducing disease and duration of chemical effectiveness.

In the process of selecting a chemical there seems to be a tendency to focus first on whether the vector mosquito shows resistance to a particular chemical. In reality, mode of chemical action should be defined before deciding that resistance is of utmost importance. DDT's first order action is spatial repellency and contact irritant action is its second order action. The pyrethroids appear to function as strong contact irritants. Thus the pyrethroid's irritant action might still reduce transmission inside houses even when the vector shows resistance to the chemical's toxic action. The same principles apply to use or non use of DDT.

Answer: Second Question--I have experience with malaria control programs during years when effective spray operations were being conducted. Also I have experience with country programs as spraying was deactivated because of external political and financial pressures. In the former, I saw year after year how malaria was maintained under very strict control. In the latter I saw how malaria rates spiraled upwards with fewer and fewer houses being sprayed. My country experiences have been confined to Central and South America, and some experience in Asia. My experiences and analyses of data from functional malaria control programs would be difficult to duplicate with African countries because most countries never had organized malaria control programs. A few African countries did have such programs. Observations from one such country were provided by testimony of Mr. Simon Kunene. Other experiences and perspectives can be provided by Drs. Clive Shiff (Johns Hopkins School of Public Health) or Brian Sharp (in South Africa). Both have had experience conducting malaria control programs in Africa.

Question: *I have heard that high coverage of households is critical to the success of house spraying programs. According to your calculations, how many houses would need to be sprayed and how often in sub-Saharan Africa for spraying to be successful? Is it feasible to spray every house in sub-Saharan Africa? What type of infrastructure and training would be necessary to make this happen especially in rural areas?*

Answer: The answers to these questions vary from location to location, vector species to vector species, and with variations in human behaviors, and with characteristics of the chemical selected for use. For these reasons I cannot give specific answers; but I can offer some generalizations from historical data, observations, and personal experiences.

Any approach to control should include a program of surveillance. Without surveillance you will never know program impact, you will not know where most of your malaria problems reside, and you will have no information for program modification as malaria rates decline. This requirement should be a priority whether one opts for ITNs, IRS, of just case detection and immediate treatment. You simply cannot know impact of whatever you are doing without a program of malaria surveillance. A program of surveillance means building public health infrastructure.

Any attempt to rapidly reduce numbers of malaria cases will require high coverage. This is true whether you are using ITNs, IRS, or even pharmaco-suppression through mass drug distribution. With surveillance and high coverage there will be opportunities for reducing coverage rates as malaria rates and distributions of malaria are reduced.

Dr. Shiff has stated that his program in Africa sprayed DDT in houses once a year. Other chemicals will require more frequent spraying. Additionally, in the beginning, as a program struggles to reduce high malaria transmission rates, there may be a need to even spray DDT more frequently than once a year. These are all on-site decisions and value judgments that should be based on surveillance data.

Many claims about coverage rates actually evolved during the eradication years. The goal during the eradication years was total interdiction of malaria. In other words, the goal was to completely stop malaria transmission, which is a very high standard. For that reason, you may read that DDT spraying failed in one place or another. The truth is that in some areas (refractory ecological settings) no method or approach will completely stop malaria transmission. However, some level of disease control should be possible even in highly refractory settings.

The modern goal for malaria control should be to achieve some reasonable level of reduction in disease. What is reasonable will be defined differently from area to area because the obstacles to control will vary greatly from area to area. However, an operational concept of distributing ITNs and not investing in infrastructure is flawed. This approach to control provides no meaningful measure of success and makes no long-lasting contribution to the health and welfare of the people or to the country. Large amounts of money can be spent with no measures of success, no apparent reductions in malaria, no measures of compliance, no building of infrastructure, and no training of people to detect, treat, and prevent disease.

I do not believe it is possible or desirable to spray every house in sub-Saharan Africa. I know of no country in the Americas where all houses, over time, were sprayed. It just never happened. Only a small proportion of houses were sprayed during most years in most countries. Once spray programs are launched, malaria first disappears from the bigger urban areas. Populations in many countries are, proportionately, largely urban. As malaria declines in urban areas spraying can be reduced in cities, towns and villages. As these changes occur, it will allow the control program to direct its limited resources with greater force to control malaria in rural areas. Malaria in rural areas must be controlled in order to reduce, as much as possible, introductions of malaria back into urban areas. What I am describing here is a program approach to control. Spraying must be responsive to changing epidemiological situations, and this requires surveillance and infrastructure. Spraying should be stratified according to malaria risk. If a village has not reported much malaria for a year or two, spraying should be reduced. Spraying should be focused only on houses and neighbors where cases occur. There will always be houses and collections of houses where cases never occur. With good disease surveillance, such houses and collections of houses can be identified and removed from the spray list.

Infrastructure and training for spraying or other approaches to control can take many forms. Governments can build public service infrastructure for conduct of all disease control activities. Training will be required for reading malaria slides, for spraying, for case treatment, for proper use of safety equipment and supplies, etc. An alternative approach would be for the government of contract out one or more of the disease control operations. Some countries in the Americas contract for spraying and use voluntary collaborators in villages and towns for taking blood smears and distributing drugs. There are many options for getting the work done—but it is all doable.

Questions For the Panel:

1. *What were the biggest challenges you faced when designing and implementing malaria programs on the ground in Africa: What was done to overcome those challenges?*

2. In your opinion, what is most greatly needed to address sub-Saharan Africa's malaria problem? Will the President's Malaria Initiative be enough to halve malaria deaths in 2010 or are increased efforts by the U.S. government and other donors needed?

Answer: I can offer views on the second question—I have no experience designing and implementing programs on the ground in Africa.
Second Question: I believe funding and additional resources are great needs for malaria control in Africa. However, I think the greatest need is to refocus malaria control efforts from case detection and treatment to an emphasis on malaria prevention. The state of the world should be used as an illustration that more cases can be produced than can be treated. We must begin preventing malaria, not just treating cases. To begin preventing malaria cases we must return to the use of insecticides, DDT in particular, and indoor residual spraying. It is really important that all the measures to stop uses of public health insecticides be eliminated.
The President's Malaria Initiative may not be sufficient to halve malaria deaths in Africa; but it is a wonderful start. I have no doubt that more funding and more resources will be needed.

USAID'S NEW POLICY REFORMS: MOVING PAST RHETORICAL COMMITMENTS TO REAL CHANGES

By Roger Bate[*] and Richard Tren[†]

TESTIMONY

Thank you Senator Coburn for the opportunity to submit written testimony for this important hearing on the subject "Bilateral Malaria Assistance: Progress and Prognosis.", 2pm Thursday 19th January 2006, Senate Committee on Homeland Security and Government Affairs Subcommittee on Federal Financial Management, Government Information and International Security (FFM).

This testimony is a follow-up report to a previous one: "The Blind Hydra-USAID Policy Fails to Control Malaria" to the FFM on May 12, 2005, submitted by Roger Bate.

SUMMARY

Recent news from the United States Agency for International Development (USAID) has lent new hope to the fight against malaria. On Wednesday December 14, 2005 USAID announced far-reaching reforms to its malaria control program, partly in response to pressure from legislators, malaria scientists and informed commentators.

USAID claims it will allocate nearly half of its budget to the purchase of commodities, such as insecticides and drugs. Fifteen million dollars has also been pledged to indoor residual spraying of insecticides, an extremely effective mechanism for reducing the burden of malaria. Additionally, the agency has promised to shut down all minor programs that spend less than $1.5 million annually; it will also restrict and consolidate malaria control planning strategies to Washington, rather than outsourcing this responsibility to its various missions around the world. Finally, and perhaps most important of all, the Agency has promised to disclose publicly details of contracts, budgets and outcomes of its malaria efforts on a website. USAID is right to have made this policy shift; it shows that the Agency is willing and capable of change in the face of increasing pressure from legislators and malaria experts.

Before the FFM Subcommittee eight months ago, Roger Bate voiced concerns on how USAID's policy at the time was failing to control malaria. In that testimony, Bate urged USAID to take many of the steps it has taken now to restructure its malaria control programs. However, there is still more room for improvement. The agency must move quickly to enact these changes as millions continue to die annually from this largely preventable and curable disease. For some years, USAID's malaria control strategies have often been plagued with ambiguous outcomes, and little to no measurable success in saving lives.

---

[*] Resident Fellow, American Enterprise Institute & Director, Africa Fighting Malaria
[†] Director, Africa Fighting Malaria

With USAID's vow to move toward "greater effectiveness," this committee must ensure that does not simply announce changes; it must implement them too.

As 2006 unfolds, promises of bringing life saving interventions against malaria must be kept and all funds pledged must be accounted for—the millions who suffer from this debilitating disease deserve no less.

THE STATE OF MALARIA IN THE WORLD

The United States successfully tackled and eradicated malaria in the 1950s through wealth creation, better nutrition, window screens and DDT insecticide spraying. However for many other malarial countries, the battle against malaria continued. The malaria scourge continues to kill over one million children every year, mostly in sub-Saharan Africa, and affects millions more in parts of Latin America and Asia.[1]

To date, the most effective proven methods of halting the spread of malaria have been a combination of primarily indoor residual spraying (IRS) of insecticides, and secondly insecticide treated nets (ITNs) for prevention as well as the use of effective drugs for treatment. Government and private entities in South Africa and Zambia have long employed these methods and have witnessed first hand startling reductions, as much as 70-90%, in their malaria rates.

In October 1998, USAID in partnership with the World Health Organization (WHO), the World Bank, UNICEF and other prominent international health groups launched the Roll Back Malaria (RBM) program. With millions allocated to its implementation, this multilateral initiative pledged to halve malaria deaths by 2010, but annual deaths from malaria worldwide are now higher than when the initiative began, possibly by about 10%.[2]

The primary culprits of RBM's failure are clearly its core players: USAID, WHO, UNICEF, World Bank among others. Their combined failure is typified in their perennial inability to employ, beyond a marginal scale, any of the most proven methods of malaria control. For instance, for many years, RBM failed to promote the use of IRS and the historically maligned but singularly effective insecticide, **d**ichloro-**d**iphenyl-**t**richloroethane (DDT). In addition, some donors, such as USAID, were reluctant and then sluggish to assist with the roll out of artemisinin-based combination therapy (ACT).[3]

Each year Congress earmarks a specific sum for USAID to spend on malaria. Reflecting greater concern with rising malaria mortality rates, that sum has increased from nearly $14 million in 1998 to $90 million in 2005. Yet, this commendable monetary commitment has not translated into any measurable results in lowering malaria rates on the ground. Unnecessary bureaucratic interference, data monitoring flaws, deficiencies in organization, accountability and transparency as well as poor intervention policies have long prevented this global health organization from being effective in malaria control.

"BLIND HYDRA" TESTIMONY BY ROGER BATE REVISITED: POLICY RECOMMENDATIONS

In April 2005, Senator Sam Brownback (R-Kansas) introduced the Eliminate Neglected Diseases (END) Act to Congress that mandates a minimum of fifty-five percent of program budgets for commodity purchasing. Senator Brownback found USAID's recurrent inability to reduce malaria rates appalling, especially as malaria is a curable and preventable disease. Subsequently, he made it clear that USAID's internal guidelines for malaria control undergo drastic reevaluation.

Both Roger Bate's May 12, 2005 testimony to this Subcommittee and his September 14, 2004 testimony to the House Committee on International Relations before that, echoed these very same sentiments. Bate stated explicitly then that if USAID failed to heed the call to restructure its malaria control program, it would have to bear the risk of Congress reallocating its malaria budget to another agency.

After a careful and comprehensive analysis of USAID's malaria program, four key areas in need of serious revision became immediately apparent: first, funding of life-saving commodities; second, consolidation of malaria control programs; third, improving transparency, accountability and measurement; and fourth, involvement of local institutions.

1. *Funding of life-saving interventions:* 5-7% of USAID's $80 million malaria funding was being used for the purchase of life-saving interventions such as mosquito netting, insecticides and drugs. By its own admission: "USAID typically does not purchase drugs other than in exceptional or emergency circumstances..."[4] Additionally, it was most troubling that USAID adhered to this statement: "IRS [Indoor Residual Spraying] is not a major focus of programs," despite the wealth of available scientific literature which proves the effectiveness of this method.[5]

   Disregarding sound scientific advice appeared to be an increasing characteristic of the Agency, and no case depicts this better than the Agency's refusal to use DDT, an extremely effective spatial repellent for vector control. Rather, USAID has continued to promote malaria control through bed net marketing. Bed net marketing and distribution has not succeeded in reducing malaria rates. This is primarily because it is unknown how many people will regularly sleep under the bed nets provided. Ubiquitous in Bate's testimony was the message that funding spraying programs, buying bed nets and purchasing effective drugs should be the Agency's first priority. Bate stated: "USAID should provide funding so health ministers that want to eradicate malaria from their districts with IRS can buy necessary chemicals and equipment, and USAID should stop using inaccurate environmental opposition to IRS to thwart these ministers. USAID must adopt, rather than shun, these common sense approaches to malaria funding, if Agency officials are serious about stemming the malaria pandemic."[6]

2. *Consolidation of its Malaria Programs*: Second, USAID was urged to desist from spreading its funds too thinly across numerous countries and programs. By operating malaria programs in over thirty countries in the developing world with insufficient funding (funds average less than $1.5 million per country), no one program is in a position to successfully tackle a problem as large as malaria. In recognition of this Bate acknowledged, "the fractured and confusing organization of USAID's malaria efforts constitutes a key obstacle to focused and effective programming. USAID manages resource constraints by diffusing funds thinly across numerous countries, which hampers efforts to make significant strides in any one place." To cure itself of this undesirable trait, the Agency must "...consolidate ...resources and expand the scope of its programs in fewer countries. That means prioritizing funding by both the extent of a country's malaria funding and the likelihood that programs will succeed. Countries lacking the political will and local institutions must be bypassed for ones that have the right structures but are simply lacking the resources."[7] Aside from the obvious advantage of improving overall effectiveness, consolidation of malaria programs and funds will ensure that "information is readily available through a centralized network and not scattered between central headquarters, country missions, private voluntary organizations (PVOs) and contractors."[8]

3. *Transparency, Accountability and Measurement:* Most of USAID's deficiencies in performance are in fact symptoms of a greater problem--that is, its lack of transparency. USAID has been singularly secretive with details of procurement operations, program budgets, performance evaluations and contracts. In previous testimony, Bate pointed out: "The Agency's transparency deficiency is evident not only in its refusal to release details of contracts it uses to allocate its $80 million malaria endowment, but also in the vague and ambiguous information it does provide." Bate's co-researcher Benjamin Schwab found it extremely difficult to secure any information on the organization's contracting and disbursement process. For example, the Yellow book, an online record available to the public, designed by USAID to provide a complete listing of the contracts and supplies of live-saving materials distributed during the course of the year has not been updated since 2001. Moreover, no evaluation reports or documents concerning USAID's malaria activities have been recorded on the publicly available database, also known as the Development Experience Clearinghouse. Notwithstanding, the limited information that was found revealed disturbing insights into USAID's malaria activities.

   From all indications, the vast majority of USAID malaria funding either never left the United States—used primarily for conferences and advice giving efforts— or funded the employment of US citizens. As Bate testified: "Although exact figures are unclear, USAID spends a significant percentage of international development funds on domestic goods and services. Data from USAID's Buy American Report, the best available assessment, indicates that over the last decade, between 70 and 80 percent of funding appropriations were directed to U.S sources."[9]

Furthermore, the Agency's malaria program has been built largely on flawed measurement systems. Data regarding its own projects and financial commitments are grossly inadequate both for designing effective projects based on past experiences and managing existing ones. To upgrade organization and data management, USAID was asked to publish a website similar to that of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), which would hold all technical information: contracts, grants and cooperative agreements, budget and implementation plans. Such an action will in one swoop put an end to many of the criticisms leveled against the Agency for conducting its development operations under the table.

4. *Involvement of Local Institutions*: For years USAID has funneled money towards U.S contractors to build capacity in other countries. Since local institutions must comply with Washington based decisions to maintain funding, the danger is that they may simply adopt US determined strategies so as not to lose funding. This system undermines subsequently the concept of project ownership. Not surprising, these programs are rarely sustainable and once US funding is withdrawn, the project soon collapses. Clearly, a long-term solution cannot be achieved when only a quick fix is being provided. To promote sustainability, USAID must lessen its support for U.S contractors in favor of empowering indigenous organizations to build capacity in their own countries. By increasing direct grants to these groups, capacity building efforts in the health sector have a much greater chance of succeeding, and staying successful.[10]

USAID: NEW REFORMS FOR MALARIA CONTROL PROGRAMS

USAID's new policy reforms this December appear to have closely followed the recommendations issued in the "Blind Hydra" testimony and those offered by most concerned malaria experts. According to a USAID press release issued on December 14, 2005, the new reforms "will effectively combine all USAID malaria activities into a single, strategic effort."[11] Specifically:

- ***Lifesaving Drugs and Supplies***: Beginning in fiscal year 2006, 40 percent of USAID's budget will be directed to the purchase of life-saving drugs and supplies - insecticides and equipment for spraying, insecticide-treated bed nets, artemisinin-combination therapies (ACT) and diagnostics, drugs for intermittent preventive treatment of pregnant women, and drugs for severe malaria.
- ***Indoor Residual Spraying (IRS)***: 25 percent (or $15 million) of the malaria budget will pledged in fiscal year 2006 towards indoor residual spraying in malaria-affected countries.
- ***Country Program Funding***: To promote effectiveness, minor programs operating at levels insufficient to achieve measurable results will be terminated in favor of sponsoring programs which can make a greater impact on saving lives. Beginning in fiscal year 2006, no developing country malaria program will be

funded at less than $1.5 million; minimum funding for country programs will rise to at least $2.5 million in 2007.

- ***Malaria Program Transparency*:** Rigorous measures to promote transparency will be undertaken. Information on program budgets, inputs, outputs, and outcomes will now be posted on a publicly-accessible USAID website.

FUTHER POLICY RECOMMENDATIONS AND CONCLUSION

In response to the announcements from USAID, Senator Brownback publicly applauded the policy change. He is hopeful that these new policy guidelines, especially the emphasis on providing the necessary live-saving supplies, would significantly help the fight against malaria. Such a policy would diminish the rate of mortality, and eventually lead to the eradication of malaria in Africa[12].

In addition, Africa Fighting Malaria (AFM) openly welcomed the policy changes and acknowledged the importance of allocating more funds towards Indoor Residual Spraying. AFM noted that the new system of providing data and monitoring the results would allow for a better method to judge the progress.

The "Kill Malarial Mosquitoes Now! (KMMN) coalition which presented USAID in October with an international declaration calling for two thirds of the agency's budget to be used to buy life-saving commodities also joined in the praise.

The euphoria generated from USAID's announcements is expected, even desirable; however, only time will tell if it is justified. Careful scrutiny and monitoring of USAID activities by legislators and malaria experts must continue. This will ensure that USAID's stated changes are actually enacted. Skepticism stems from a disquieting sense of *déjà vu*. Not since the testimony of Anne Peterson in September 2004, then Assistant Administrator for Global Health, has the USAID provided additional statistics or program evaluation. In the ensuing months after Peterson's testimony, little or no actual action was taken. It has been another eight months since the hearing in May, and USAID shows only rhetorical commitments as progress. This begs the question of how long it will take USAID to activate its own recent policy changes. Legislators should remain vigilant and ensure that the agency follows through on its promises swiftly.

It is unclear from the proposed reforms if USAID will take appropriate measures to upgrade its organizational systems and diminish its reliance on US contractors. The struggle against malaria requires successful collaboration with external experts and the indigenous communities we seek to help. USAID should put more emphasis on cooperating with other agencies that have a successful record with fighting malaria, and with the indigenous communities. By doing so, USAID will be fulfilling its mission to help locals sustain programs in their own country.

Finally, USAID must better define its role in the health arena both at the country level and at the global level. As a provider of health funds and programs to national

governments, USAID has a unique role in helping countries with practical health-sector development and disease-specific programs. As one of the largest financiers of health care in developing countries, USAID must stay involved in the global health agenda, and must never undermine that process with a lack of transparency and a lack of appreciation for the full scope of the disease it sets out to tackle.

Thank you.

AEI Research Assistant Kathryn Boateng provided significant help in researching this written testimony.

---

[1] Bate R. and Schwab B. 2005. "The Blind Hydra: USAID Policy Falls to Control Malaria" *AEI Working Paper* May 2005. Paper also presented as government testimony before the Senate Committee on Homeland Security and Government Affairs Subcommittee on Federal Financial Management, Government Information and International Security, May 12, 2005, Washington. Copy of Testimony available at: http://www.aei.org/publications/filter.all,pubID.22508/pub_detail.asp, accessed 10/12/2

[2] Attaran, A. 2004. "Where Did It All Go Wrong" *Nature* 430: 932-3

[3] Bate, R. 2006. "Fighting Malaria-The Right Way" *The Examiner*, January 9

[4] Bate R. and Schwab B. 2005. "The Blind Hydra: USAID Policy Falls to Control Malaria"

[5] *Ibid.*

[6] *Ibid*

[7] *Ibid*

[8] *Ibid*

[9] *Ibid*

[10] *Ibid*

[11] "USAID Reforms Agency Malaria Programs for Greater Effectiveness" USAID Press release, December 14, 2005. Available at: http://www.usaid.gov/press/factsheets/2005/fs051214.html, accessed 01/010/2006.

[12] "Brownback applauds USAID Policy Change: Agency improves management of funds dedicated to fighting malaria", Wednesday, December 14, 2005, Senator Brownback Press Release. Available at: http://brownback.senate.gov/pressapp/record.cfm?id=249754

○