

**MEETING THE GLOBAL CHALLENGE OF AIDS,
TB AND MALARIA**

HEARING
OF THE
**COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS**
UNITED STATES SENATE
ONE HUNDRED TENTH CONGRESS

FIRST SESSION

ON

EXAMINING THE GLOBAL CHALLENGE OF HIV/AIDS, TUBERCULOSIS,
AND MALARIA, FOCUSING ON THE PRESIDENT'S EMERGENCY PLAN
FOR AIDS RELIEF (PEPFAR)

DECEMBER 11, 2007

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(II)

C O N T E N T S

STATEMENTS

TUESDAY, DECEMBER 11, 2007

	Page
Kennedy, Hon. Edward M., Chairman, Committee on Health, Education, Labor, and Pensions, opening statement	1
Enzi, Hon. Michael B., a U.S. Senator from the State of Wyoming, opening statement	3
Prepared statement	5
Dybul, Mark, Ambassador, U.S. Global AIDS Coordinator, Washington, DC. ...	7
Prepared statement	10
Gerberding, Julie, Director, Centers for Disease Control and Prevention, Washington, DC.	18
Prepared statement	21
Zulu, Princess Kasune, HIV/AIDS Educator, World Vision, Federal Way, Washington, DC.	43
Prepared statement	44
Hearst, Norman, Professor, University of California San Francisco, San Fran- cisco, CA	44
Prepared statement	45
Smits, Helen, Vice Chair, IOM Evaluation Committee, Washington, DC.	46
Piot, Peter, Executive Director, UNAIDS, Switzerland	47
Prepared statement	48

ADDITIONAL MATERIAL

Statements, articles, publications, letters, etc.:	
Edward C. Green, Harvard University	59
Response to questions of Senators Kennedy, Enzi, Dodd, Clinton, Brown, and Coburn by Mark Dybul	62
Response to questions of Senator Kennedy by Princess Zulu	79
Response to questions of Senators Kennedy, Enzi, Dodd, and Brown by Helen Smits	79
Response to questions of Senators Kennedy, Enzi, and Dodd by Peter Piot	84

(III)

MEETING THE GLOBAL CHALLENGE OF AIDS, TB AND MALARIA

TUESDAY, DECEMBER 11, 2007

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 10:00 a.m., in Room SR-325, Russell Senate Office Building, Hon. Edward M. Kennedy, chairman of the committee, presiding.

Present: Senator Kennedy, Brown, Enzi, Isakson, Allard, and Coburn.

OPENING STATEMENT OF SENATOR KENNEDY

The CHAIRMAN. We'll come to order. The hearing this morning is on the reauthorization of the President's Emergency Plan for AIDS Relief, PEPFAR. And I thank all of our witnesses and our colleagues on the committee for joining us at a busy time.

There are many issues before us that have wide ranging affects on vast numbers of people. But few are as consequential as our response to the global HIV/AIDS epidemic where entire societies are at risk. Sometimes history is changed by great leaders, by wars, by scientific breakthroughs and sometimes history is transformed by something as tiny as a virus.

We have seen the devastating effects of HIV/AIDS on our own shores with our own citizens. The fight against HIV/AIDS here at home continues as we are reminded that our responsibilities here at home are far from over. But we also know that in recent years the HIV virus has affected the lives of millions of people across the globe. It's destroyed families, even whole villages. It threatens the well being of entire nations.

At times this disease has brought out the worst in mankind. Children orphaned by AIDS have been deprived of their rights. Women and girls have been shamefully exploited. And millions of people living with HIV/AIDS have faced stigma, fear and discrimination.

But we've also seen the best in mankind. Nation after nation has pledged to help. Scientists have devoted their lives to finding better ways to prevent and treat AIDS. Doctors, nurses and other health professionals that work tirelessly in cities and towns and villages across the world to give hope and help to persons living with AIDS.

But the true heroes of this global challenges are those that struggle with the epidemic everyday. The parents who fight to provide a better life for their children, the grandparents who take on the

unexpected responsibility of caring for children whose parents have been lost, the millions of people who face their extraordinary challenges with quiet dignity and unshakeable determination. We're here to help these heroes win their battle for a better, healthier life for themselves and for their children.

We must set ourselves the goal that within our lifetimes we will be able to say no child was left an orphan by AIDS today. No life was cut short by this dread disease. Our Nation has stepped forward and applied our resources and expertise, not only to combat HIV in our country, but for people around the world. And I commend President Bush for launching the PEPFAR Global AIDS Initiative to help meet these challenges and for joining Democrats and Republicans in calling for its renewal.

PEPFAR and our contributions to the Global Fund have made a real difference in the lives of millions of people. PEPFAR currently supports treatment with life saving antiretroviral drugs for nearly 1½ million people. The program supported services to prevent mother-to-child transmissions of HIV for over 10 million pregnancies and has provided help for 2.7 million orphans and vulnerable children.

We must build on these successes and examine where the program needs improvement. With our colleagues on the Foreign Relations Committee we have a special responsibility in this task since so many of the key elements of PEPFAR are within our scope.

We're honored today by Julie Gerberding, the leader of the CDC, with us today to help provide her insight and recommendations. And we are also honored to join with the U.S. Global AIDS Coordinator, Dr. Mark Dybul. We are joined today by an extraordinary panel of witnesses who bring important perspectives to inform our discussion.

Our work in evaluating this program has been assisted by the thoughtful analysis of expert bodies such as the Institute of Medicine that have examined the PEPFAR program and made recommendations for improvement. One major conclusion from all these reviews is that the rigid funding allocations included in the original legislation hamper the flexibility that is essential in a program that spans the globe. We must examine how generic medicines become eligible for funding under PEPFAR. At the time of the original legislation, Senator McCain and I offered an amendment to require PEPFAR to adopt the same standards that other major donors use. Our amendment was rejected but the PEPFAR program has since acted to improve the use of generic drugs and our committee must determine whether this process is working effectively to bring safe and low-cost medicines to the people who need them.

Finally, the challenge in renewing PEPFAR is to make the transition from short-term emergency response to a long-term sustainable initiative. This means many things including investing in effective prevention efforts and finding ways to assist other nations in strengthening their health systems. The President has called for \$30 billion for PEPFAR in the years to come. Many experts believe that this is insufficient to meet the need.

Nations around the world are calling on us to act and act quickly to renew the promise of PEPFAR. We are answering that call. Our

hearing is part of an extensive process of consultation that our committee has undertaken to prepare for the reauthorization. Our colleagues on the Foreign Relations committee have been just as diligent.

It's our intention to take action on this important responsibility as soon as possible in the New Year. Reauthorization will be a bipartisan inclusive process. Senator Enzi has a strong commitment to renewing and improving PEPFAR and the same commitment is shared by the members of the committee on both sides of the aisle.

We also look forward to working with Senator Biden, Senator Lugar and all our colleagues from the Foreign Relations committee. Most of all we look forward to learning from the real experts, those who work everyday to improve the lives of persons with HIV/AIDS. To facilitate our discussion, we're convening in a roundtable format.

After Senator Enzi makes his comments we'll hear from the testimony of our two Administration witnesses, Julie Gerberding and Mark Dybul and we will then have a period of questions for these witnesses. On conclusion of that period I'd like to invite our extraordinary panel of outside witnesses to join our roundtable, make brief comments, introduce themselves to the committee. And I hope that our Administration witnesses will join us in this discussion which will be informative with their comments.

I'll close with my thanks to all our witnesses many of whom have changed plans to travel great distances to be with us today. Their commitment is the most eloquent testimony to the importance of the task before us. Thank you all for joining us today. We look forward to your recommendations.

Senator Enzi.

OPENING STATEMENT OF SENATOR ENZI

Senator ENZI. Thank you Mr. Chairman. And I thank you for holding this hearing. The global challenge of AIDS, tuberculosis and malaria quite properly reaffirms our commitment in Congress for a global response to these terrible diseases. Anything less would not get the job done.

I would ask that my full statement be a part of the record.

The CHAIRMAN. It will be a part of the record.

Senator ENZI. I remember when the President shocked all of us at a State of the Union speech when he suggested that we ought to put \$15 billion into AIDS. I'm sure the Democrats and the Republicans were both shocked for a different reason, but we were both shocked.

[Laughter.]

And that was a lot of money. And so it drew a lot of interest in Congress and there were a lot of people working on it. In May 2003, the Senate passed the President's Emergency Plan for AIDS Relief and it was a breakthrough piece of legislation that underscored our commitment to bring relief to the nations fighting the high infection rate of diseases. And I don't think we really had any idea at that time how infectious or how universal or how distressing the whole problem could be.

After we passed the bill there were a number of us that were sent to Africa to take a look at the problem. That's often how Con-

gress does things. Solve it and then we go look at it. And I've got to tell you that it was terribly shocking to me. I found out that the two fastest growing businesses in Africa were funeral parlors and coffin makers. In some of the countries they didn't have enough wood to go around so they were saving newspapers to make paper maché coffins and re-using the coffins.

I don't know how anyone could see these things and not feel changed. We came back pleased that we were doing something and fortunately we were able to take that action and make a difference. But we struggled with how to provide additional funding and how to take care of things.

When we were in South Africa, we met with the Health Minister who thinks that it's an American plot to eliminate Africans. And she suggests that lemon juice and garlic are a solution for the pill that she personally sells. We talked to traditional healers and they had learned some things about AIDS. They found out that they shouldn't bleed two people with the same knife.

We learned about the mother-to-child transmission of the disease and found that there is a cure for that but it has a lot of requirements with it. And one is that the mother have the tablet at the time she goes into labor and then the child being able to get a liquid dose at the time that the baby is born. We in the United States anticipate that most babies are born in a hospital. In Africa, the difficult cases are all deliveries in hospitals. As soon as the baby is born, they leave.

So we found some different methods for getting that to them, but there's a previous problem that exists with it and that's testing for HIV/AIDS in the first place. And it is important to keep a faith-based concept as a part of HIV/AIDS. They were the ones providing solutions at that time.

We visited an orphanage that the Salvation Army was running and there were 32 beds around the room. I asked how many kids were being treated for AIDS, they said five. I asked how many should be treated for AIDS. They kind of danced around the answer. Later the doctor caught up with me and he said you realize that any child that's not being treated for AIDS will die before they're 5 years old? So out of those 32 the Salvation Army has had to select the five that are going to get to live. And that's the kind of thing that we can change with this legislation.

We also found that most countries don't have the sexual harassment laws that we have in the United States and that it leads to more problems with AIDS. And when the husband finds out that there's a problem the woman is beaten up and thrown out of the house. Consequently people in other countries don't test for AIDS so it's difficult to know who needs the AIDS drugs.

There's a lot of stigma that's involved with it. Uganda has solved the problem best. But that's because the leaders of that country took an active role. They got the test, publicly and eliminated a lot of the stigma. One bad thing that we learned on the trip was that the NGOs from the United States were hiring up the providers in these other countries as fast as they could, even before the legislation went into effect, which caused a shortage of providers that had been taking care of AIDS in those countries.

I want to add a final note about Bill Gates and a hospital that he had over there that was just jammed packed with people. Other places that we visited hardly had any patients and we wondered what the difference was. The difference was transportation.

They bought a bunch of Suburbans. The Suburbans have been remodeled. There were benches down the two sides and a double bench down the center. And the driver got up each morning and drove 50 to 100 kilometers picking people up and taking them to this hospital. They put them in one end of these double wide trailer houses and later in the day after they had received their prescription, picked them up on the other end and deliver them back to their house. And every day he drove a different route over a 2-week period.

Transportation. We take that for granted in this country. But in the countries with these kinds of problems, you can't take that for granted.

I'll have a lot more comments as we go on through this, but as we work to re-examine the legislative framework that has been successful we have to maintain a high level of accountability for the results. While some have stated that there needs to be more flexibility in the program, any additional flexibility must come with corresponding accountability to make sure our tax dollars are being spent wisely and efficiently because that's the only way we'll be encouraged to put more into the program. And make our fight against global HIV/AIDS successful.

I look forward to hearing from the witnesses today. And I hope this hearing will provide a strong start to our efforts to re-examine these key programs. And I thank the Chairman for this roundtable format. It brings us a lot more information sometimes than we get from just a regular hearing. Thank you, Mr. Chairman.

[The prepared statement of Senator Enzi follows:]

PREPARED STATEMENT OF SENATOR ENZI

Today's hearing about the global challenge of AIDS, tuberculosis and malaria quite properly reaffirms our commitment in Congress for a global response to these terrible diseases. Anything less just would not get the job done.

It wasn't all that long ago, May 16, 2003, when the Senate passed the President's Emergency Plan for AIDS Relief. At the time, it was a breakthrough piece of legislation that underscored our commitment to bring relief to those nations fighting a high infection rate of these diseases. AIDS, tuberculosis, and malaria threatened to claim unthinkable numbers of people.

When this legislation was passed, there was still some uncertainty as to how well it would work. Some thought that the treatment it would provide would not be enough. Others thought that the stigma that comes along with being identified as an AIDS patient would doom efforts to fail. Still others were certain that prevention and education wouldn't make a difference in those countries and would fail to increase awareness among the population.

It has been nearly 5 years since Congress took that vital first step to address the global epidemic facing far too many nations of the world. Now we have a legislative framework from which we can build and improve upon those early efforts. We have a program in

place that has been successful in supporting community outreach activities to educate nearly 61.5 million people and make them aware of the importance of preventing the transmission of these diseases and teach them how to keep themselves safe and infection-free. It has provided antiretroviral prophylaxis for HIV-positive women to deal with over 500,000 pregnancies, which has helped to avert more than 100,000 infant HIV infections. It has also funded life-saving antiretroviral treatment for nearly 1½ million men, women and children.

In the years since we passed that landmark legislation I have had a chance to visit Africa and see firsthand how efforts are progressing to deal with that disease throughout the continent.

I will never forget the people I spoke to and the concerns and comments they made to me about their fear of these diseases. As you can imagine, they are worried about things like losing their insurance if they are diagnosed with AIDS. Apparently that is common in high incidence AIDS countries.

In addition, we found that the two fastest growing businesses are funeral parlors and coffin makers. Namibia doesn't have enough wood to go around, so people save their newspapers so coffins can be made of paper mache.

How could anyone see things like these and not feel changed? We all came back wanting to do something. Fortunately, we were able to take action several years ago that has begun to make a difference.

Today, the hope of the people of those countries is again centered on us, and their belief that we will renew our commitment to fight HIV/AIDS. We must increase our assistance to them so that their children and their children's children might be safe from these terrible diseases.

Initially, I struggled with how quickly we could provide additional funding so we could scale up new programs to address the need that grows larger every day. Now, we are moving from that quick scale up to a more sustained response. In that sustained response, we must better share information among those who are providing HIV prevention, care and treatment. For instance, we need better linkages between the Department of Labor's work with employers to de-stigmatize the disease and help them stay connected to testing and treatment possibilities.

We must also increase the connections between the various HIV programs and other key developmental programs that are designed to provide food, clean water, safe roads and transportation, among other programs. The global AIDS programs cannot be responsible for general development activities. Rather, it must retain its focus on providing HIV prevention, care, and treatment. However, it will be most successful if it links to those other key development programs.

Finally, as we work to re-examine the legislative framework that has been so successful, we must maintain a high level of accountability for results. While some have stated that there needs to be more flexibility in the program, any additional flexibility must come with corresponding accountability to make sure our tax dollars are being spent wisely and efficiently, and our fight against global HIV/AIDS is successful.

I look forward to hearing from the witnesses today. I hope this hearing will provide a strong start to our efforts to re-examine these key programs.

The CHAIRMAN. Thank you. We call the roundtable the Enzi format. This is really developed by Senator Enzi. And we look forward to our witnesses. I see my friend, Mike Kiscowitz, who's in the back who remembers that the first HELP AIDS funding was \$5 million that we offered in 1987, I think. So we've made progress in terms of resources, still a ways to go. Listening to Mike Enzi reminds us of the challenges that are out there and we look forward to our witnesses we have this morning.

They're well known, but I'm going to include the brief comment of both, that they certainly deserve the recognition. Ambassador Dybul serves as the U.S. Global AIDS Coordinator. Before coming to the Coordinator's office, Ambassador Dybul served on the Planning Task Force for the Emergency Plan. He continues to be the staff clinician in the laboratory in NIAID-NIH, maintains an active role as the principle investigator for clinical and basic research for U.S. international protocols, emphasis on HIV therapy.

Dr. Julie Gerberding has been the Acting Director of CDC since 2002. Before becoming CDC Director, Dr. Gerberding was Acting Deputy Director of the NIH National Center for Infectious Disease. She played a major role in leading CDC's response to the Anthrax bioterrorism events of 2001.

Prior to coming to CDC, Dr. Gerberding was a faculty member at the University of California, San Francisco, directed the Prevention Epicenter in a multidisciplinary research, training, and clinical service program that focused on preventing infections in patients and their healthcare providers. She's been a great public servant. And has been of enormous value and help to our committee on a wide range of health measures.

So we're delighted to have a very distinguished panel. And we'll ask if you'd be ready to proceed, Ambassador?

STATEMENT OF AMBASSADOR MARK DYBUL, U.S. GLOBAL AIDS COORDINATOR, WASHINGTON, DC.

Ambassador DYBUL. Thank you very much, Mr. Chairman, Senator Enzi, members of the committee. It's a great pleasure for me to be here my first time before this committee. We greatly appreciate the long standing effort of this committee and its members and staff in support of HIV/AIDS, in particular for this committee hearing, Global HIV/AIDS.

It's a great pleasure to be on a panel with Dr. Gerberding who represents the Department of Health and Human Services. The Secretaries, both Secretary Leavitt and Thompson—I've been privileged to travel with them to Africa. I have a deep commitment to HIV/AIDS. And HHS joins a strong interagency program with USAID, with the Department of Defense, the Peace Corps, Department of Labor, bringing the full expertise of the U.S. government together in an interagency way to combat global HIV/AIDS.

And through this strong interagency effort and actually outside commentators have called it one of the best, if not the best, interagency efforts our government has engaged in right now. By bringing all this expertise together we are tackling HIV/AIDS in around

120 countries around the world through bilateral programs which is part of the Emergency Plan, but specifically in 15 focus countries. And those 15 focus countries, 12 in Sub-Saharan Africa, Vietnam, Haiti and Guyana represent half the disease in the world. It's rather remarkable that 15 countries have 50 percent of the disease. And so we're particularly focused there.

But this strong bilateral program is not just a bilateral program. This interagency approach also supports the Global Fund to fight AIDS, tuberculosis and malaria, a multilateral effort where the largest contributors, by 30 percent of the Global Fund resources come from the American people as part of PEPFAR. But we also support in terms of administrative and secretarial and making the program work. We have a very strong interagency team that does that. So PEPFAR is both multilateral and bilateral.

Now in the history of public health I think PEPFAR will be remembered for two principle things: its scope and its size. In terms of size, Senator—Mr. Chairman, you mentioned where we were not too long ago. Now the \$15 billion is the largest international health initiative in history ever for a single disease. I'm told it's the largest development initiative today anywhere in the world for anything. So the size is extraordinary.

But Senator Enzi as you pointed out, it's not just about money. It's also about results. And so it came tagged with specific goals to support treatment for 2 million, to support prevention of 7 million new infections and to support care for 10 million people including orphans and vulnerable children. And to put that size of effort in perspective, when the President announced this only 50,000 people in Sub-Saharan Africa were receiving treatment. That 7 million infections is a 60 percent reduction in projected new infections. So it's a very ambitious effort in terms of size and really an extraordinary effort going forward. And we're on track, as you pointed out Mr. Chairman, to achieve those goals with great success so far.

The second main thing PEPFAR will be remembered for is its scope. And I think this is critically important and it touches on some of the issues the Chairman and ranking member mentioned in their opening comments. The first issue of scope is integrated prevention, treatment and care. This is the first time we came together and said you can't just do one? You need to do prevention, treatment and care.

And I think we've all seen pendulum swings. I think this committee has, between treatment and prevention, now back to prevention a bit. Sadly, care always gets lost. Care for orphans and vulnerable children, care for people living with HIV/AIDS.

The President and Congress got it right the first time. And a bipartisan, bicameral Congress has been so important to the success of this program. We have to have integrated prevention, treatment and care, not one or the other.

People won't get tested for HIV if they don't have treatment available. We know this. If people don't get tested they can't get treated. If people don't get tested we can't target our prevention programs more effectively and so we need an integrated approach. Without care the orphans aren't taken care of and so an entire society and social fabric begins to break apart.

But importantly, prevention has got to be at the heart of what we do because ultimately the way to care for an orphan or to treat someone for HIV is for someone not to get infected to begin with. And the sad fact is that we will probably not be able to keep pace with the treatment demand if we don't tackle new infections. And so integrated prevention, treatment and care is essential. Prevention is the bedrock, but it's a shaky foundation without care and treatment.

Now the Emergency Plan has probably the most balanced, comprehensive approach to prevention in the world. It includes prevention of mother-to-child transmission. It includes safe blood and as was talked about not re-using needles, particularly in kids. Now blood programs and those re-use of needles don't contribute a lot to infection in Sub-Saharan Africa in particular, but it's important that we do it.

But as I mentioned we're heavily targeted in Sub-Saharan Africa and there in generalized epidemics, it's mostly a sexually transmitted disease. About 90 percent of new infections are from heterosexual transmission. And so much of our prevention program targets sexual transmission.

I'd like to talk a little bit about that. Our approach is founded in something that was created in Africa. The ABCs: Abstain, Be faithful, and Correct and Consistent Condom Use.

But I think it's important to talk about what that means on the ground. What it means is prevention is a chronic activity. You have to start with very young children and walk with that person through the rest of their lives. And the messages change as you grow older.

And so you begin with programs, they're called life skills now for the most part, where you get to very young children and teach them to respect themselves and to respect others. And if you do that it has consequences including better personal responsibility in your sexual activity. It also means young boys shouldn't abuse young girls and so a lot of gender activity is built into this. It also means older men should not prey on younger girls which is contributing to infection.

So a lot of gender equality issues are built into Abstaining, Be faithful and Correct and Consistent Condom Use. It must be because it's part of this overall effort. And the data are there. What we've seen in Sub-Saharan Africa is that these three components are critical in turning the tide against HIV. But we also have to incorporate new approaches including male circumcision.

Now the second major part of scope and I think this is very important is this is the first time in the history of development the United States or anyone else is tackling a chronic disease. We've tended to do immunizations or things that are one offs, ins and outs. This is a chronic disease and it's chronic for prevention, treatment and care.

Care and treatment, of course, is chronic, but so is prevention. It's not one off. Prevention is beginning with a 10-year-old and staying with that person until they're beyond risk, which is well into their fifties and sixties if the person is still alive.

And that means building health systems. So a fundamental aspect of what we do to achieve prevention, care and treatment re-

sults is building health systems because you have to do that for chronic care. And that means national systems. And that's why we have focus countries to support the expansion of the health workforce, to build systems like logistic systems and communication systems, things that aren't too sexy but are essential if we're going to tackle a chronic disease. And so the chronic nature of this disease requires us to build those health systems and be more heavily dedicated to it in resources and commitment.

Now I would just like to end by talking briefly about reauthorization because it came up. The bipartisan, bicameral approach the last time is something we strongly support and want to be as heavily engaged in it as possible as the President said. The President has called for a doubling of the original commitment, what was already the largest international health initiative.

The first law was a very good law. It wasn't a perfect law, but I believe as you say often Mr. Chairman, "let's not let the perfect be the enemy of the good" and in this case, the very, very good. Now there are some things that need to be changed, but in general, as you can see from the success of the program so far, not a lot needs to be changed, just a couple of things.

And the Institute of Medicine actually called PEPFAR a learning organization. It's an organization that looks at itself. That is very self aware of what needs to be changed and we're constantly changing and progressing in the areas that need to be changed. And the current law allows us, for the most part, the flexibility to do that. So we look forward to working with your committee and the entire Congress to develop a bipartisan, bicameral bill that can have that strong support that we've had going forward.

I wanted to end with a piece of why we think this is important. Not only because of what we're doing on a humanitarian basis because it's also good for the American people. It's good in two ways.

One, it gives people of the world a new window into our hearts. People know what we stand for, when we stand with them. And I can tell you there are a couple of anecdotes in my written testimony about how people view the United States with these humanitarian efforts.

I happened to be with the Ambassador from Rwanda to the United States last night. He used to be governor of a province in Rwanda. He told me that he was just home recently and every one in the province was talking about what the American people are doing on HIV/AIDS through PEPFAR, everyone in his province. And that's what we see over and over again. People know who we are and what we stand for through these programs. And also as President Bush said, this is good for our national character, our national soul, our national conscience.

So we look forward to working with you to continue in this important work for humanitarian purposes but also because it's also both a noble work and an ennobling work. Thank you for your time. Thank you for your interest.

[The prepared statement of Ambassador Dybul follows:]

PREPARED STATEMENT OF AMBASSADOR MARK DYBUL

Mr. Chairman, Senator Enzi, members of the committee and staff: let me begin by thanking you for your leadership and commitment on global HIV/AIDS, for your actions in 2003 to pass the authorizing legislation for the President's Emergency

Plan for AIDS Relief (PEPFAR), and for your actions leading to today's hearing on reauthorization of this historic legislation and program.

Just 5 years ago, many wondered whether prevention, treatment and care could ever successfully be provided in resource-limited settings where HIV was a death sentence. Only 50,000 people living with HIV in all of Sub-Saharan Africa were receiving antiretroviral treatment.

President Bush and a bipartisan, bicameral Congress reflected the compassion and generosity of the American people as together you led our Nation to lead the world in restoring hope by combating this devastating pandemic. You recognized that HIV/AIDS was and is a global health emergency requiring emergency action. But to respond in an effective way, it has been necessary to build systems and sustainable programs as care is rapidly provided, creating the foundation for further expansion of care to those in need. The success of PEPFAR is firmly rooted in these partnerships, in the American people supporting the people of the countries in which we are privileged to serve—including governments, non-governmental organizations including faith- and community-based organizations and the private sector—to build their systems and to empower individuals, communities and nations to tackle HIV/AIDS. And in just 3½ years, it is working.

RESULTS

In rolling out the largest international public health initiative in history, we have acted quickly. We have obligated 94 percent of the funds appropriated to PEPFAR so far, and outlayed or expended 67 percent of them. But success is not measured in dollars spent: it is measured in services provided and lives saved.

PEPFAR is well on the way to achieving its ambitious 5-year targets of supporting treatment for 2 million people, prevention of 7 million new infections, and care for 10 million people infected and affected by HIV/AIDS, including orphans and vulnerable children.

PEPFAR-supported programs have reached tens of millions of people with prevention messages. Since 2004 the U.S. Government has supplied 1.8 billion condoms worldwide—as Dr. Piot of UNAIDS has said, more than all other developed countries combined. PEPFAR has supported antiretroviral prophylaxis during approximately 800,000 pregnancies, preventing an estimated 152,000 infant HIV infections. In fact, five of the focus countries have greater than 50 percent coverage of pregnant women—the goal of the President's International Mother and Child Prevention Initiative (which preceded the Emergency Plan)—and Botswana has achieved a 4 percent national mother-to-child transmission rate, which approximates that of the United States and Europe. With Emergency Plan support, focus countries have scaled up their safe blood programs, and 13 of them can now meet two-thirds of their national demand for safe blood—up from just 45 percent when PEPFAR started. PEPFAR has supported HIV testing and counseling for 30 million people, and supported care for nearly 6.7 million, including more than 2.7 million orphans and vulnerable children infected and affected by HIV. And through September 2007, PEPFAR supported antiretroviral treatment for approximately 1.45 million men, women, and children worldwide. Of these, approximately 1.36 million are in the focus countries, and more than 1.33 million are in Sub-Saharan Africa.

SUCCESS REQUIRES A COMPREHENSIVE STRATEGY

When the history of public health is written, the global HIV/AIDS action of the American people will be remembered for its size, but also for its scope: the insistence that prevention, treatment and care—all three components, with goals for each—are all required to turn the tide against HIV/AIDS.

Within the past decade, the pendulum of preferred interventions has swung from prevention to treatment and back to prevention. By the way, care always, and tragically, seems to get lost. Using these pendulum swings to determine policy and programs can be dangerous—and even deadly.

The President and a bipartisan Congress got it right the first time, because a comprehensive program that includes prevention, treatment and care reflects basic public health realities:

- Without treatment, people are not motivated to be tested and learn their HIV status.
- Without testing, we cannot identify HIV-positive persons and so we cannot teach them safe behavior, and they cannot protect others.
- Without care and treatment programs, we do not have regular access to HIV-positive persons to constantly reinforce safe behaviors—a key component of prevention.

- Without testing and treatment, we cannot “medicalize” the disease, which is essential to reducing stigma and discrimination—which, in turn, is essential for effective prevention and compassionate care for those infected and affected by HIV.

- Without testing and treatment, we have no hope of identifying discordant couples, and women have no possibility of getting their partners tested so that they can protect themselves.

- And, of course, without prevention, we cannot keep up with the ever-growing pool of people who need care and treatment.

Currently, we’re spending 46 percent of our programmatic funds on treatment. When you include counseling and testing as a prevention intervention, as most of our international partners do, we’re spending 29 percent of our funds on prevention. The rest is going to care.

Will that be the right mix going forward? It’s impossible to know, because there is no way to know what the HIV/AIDS landscape will look like in 3 to 7 years. This is why, as we’ve discussed reauthorization with many of you and your staff, we’ve supported an approach to reauthorization that doesn’t include specific directives for the allocation among those three broad categories.

Part of the reasoning behind this is that we are one piece—albeit a very large piece—of a complex puzzle of partners engaged in combating HIV/AIDS. The other pieces include: the contributions of the countries themselves, including remarkable efforts by people living with HIV, families, communities, and national leaders, and which can include substantial financial contributions in countries such as South Africa, Botswana, Namibia and others; the Global Fund to Fight AIDS, Tuberculosis and Malaria—for which the American people provide 30 percent of its budget and which is an important piece of our overall global strategy—and other multilateral organizations; other nations’ bilateral programs; private foundations; and many others. We constantly adapt the shape of our bilateral programming piece to fill its place in this puzzle, so flexibility is needed.

PREVENTION IS THE BEDROCK OF PEPFAR

That being said, prevention is the bedrock of an effective global response to HIV/AIDS. In PEPFAR’s Five-Year Strategy, in each Annual Report, in nearly every public document or statement, including those before Congress, we have been clear that we cannot treat our way out of this pandemic, and that prevention is the most important piece for success.

Prevention is also the greatest challenge in the fight against HIV/AIDS. Globally, and certainly in the hardest-hit countries, which are in Africa, the vast majority of HIV is transmitted through sexual contact. Changing human behavior is very difficult—far more difficult than determining the right prescription of antiretroviral drugs, building a health system or creating a better life for orphans and vulnerable children.

Not only is effective behavior change and, therefore, prevention, more difficult than care and treatment, measuring success is also far more complicated. While it is possible to rapidly and regularly report on numbers of people receiving care and treatment, prevention is evaluated every few years, with metrics and mathematical methods that are constantly being refined. We must currently rely on estimating prevalence—or the percent of HIV-positive persons in a population—rather than evaluating directly the rate of new infections, which would be a far better indicator of success of interventions. In addition, as treatment programs are scaled up, fewer people die and prevalence may actually go up despite successful prevention efforts. Therefore, we cannot provide updates on success in prevention in the same way we do for care and treatment.

But that does not mean that prevention has failed—as some seem to want to say. A recent UNAIDS report stated that:

“In most of sub-Saharan Africa, national HIV prevalence has either stabilized or is showing signs of a decline. Cote d’Ivoire, Kenya and Zimbabwe have all seen declines in national prevalence, continuing earlier trends.”

The report further states that:

“Global HIV incidence likely peaked in the late 1990s at over 3 million new infections per year, and was estimated to be 2.5 million new infections in 2007 . . . This reduction in HIV incidence likely reflects natural trends in the epidemic as well as the result of prevention programmes resulting in behavioural change in different contexts.”

I do not mean to minimize the seriousness of disturbing increases that we’re seeing in certain places, nor the fact that there is an urgent need for greater progress in every country and region. But I highlight these successes because the data make

something very clear. Our best hope for generalized epidemics—the most common type of epidemic in Africa, which is home to more than 60 percent of the global epidemic and where our efforts are highly concentrated—is ABC behavior change: Abstain, Be faithful, and correct and consistent use of Condoms. Of course, bringing about these behaviors, as Uganda did during the 1990s, is a far more complex task than the simple letters suggest, because the roots of human behavior are so complex.

ABC requires significant cultural changes. We have to reach children at an early age if they are to delay sexual debut and limit their number of partners. We must partner with children's parents and caregivers, supporting their efforts to teach children to respect themselves and each other—the only way to truly change unhealthy gender dynamics. We are rapidly expanding life skills programs for kids because of the generational impact they can have—changing a 10-year-old's behavior is far easier than changing a 25-year-old's. Behavior changes due to programs for children may not immediately be apparent, because you're working to change their future behavior rather than their immediate behavior. Yet we must be patient and persistent—we are only 3½ years into PEPFAR's generational approach to prevention.

For older adolescents and adults who are sexually active, ABC includes reducing casual and multiple concurrent partnerships, which can rapidly spread HIV infection through broad networks of people. We must also identify discordant couples, in which one partner is HIV-positive and the other is HIV-negative—especially in countries like Uganda where they represent a significant contribution to the epidemic—and focus prevention efforts on them.

We also need to teach correct and consistent condom use for those who are sexually active, and ensure a supply of condoms—and we are doing just that.

ABC also includes changing gender norms. As young people are taught to respect themselves and respect others, they learn about gender equality. Through teaching delayed sexual debut, secondary abstinence, fidelity to a single partner, partner reduction and correct and consistent condom use to boys and men, ABC contributes to changing unhealthy cultural gender norms.

And, of course, we need to reduce stigma against people with HIV—and also reduce stigma against those who choose healthy lifestyles. On the other hand, we must identify and stigmatize transgenerational sex and the phenomenon of older men preying on young girls, and we must also prevent sexual violence. Again, life skills education—a part of ABC—is key.

TAKING PREVENTION TO THE NEXT LEVEL

While PEPFAR is aggressively pursuing prevention as the bedrock of our efforts, it is also true that we need to improve what we are doing—in every area of our work. We need to take prevention to the next level. I'd like to share with you some of our lessons learned in prevention and give a glimpse of some new directions.

Know Your Epidemic

First, you must know your epidemic and tailor your prevention strategy accordingly. While ABC behavior change must undeniably be at the core of prevention programs, we also recognize that one-size-does-not-fit-all.

This is why we take different approaches depending on whether a country has a generalized and/or a concentrated epidemic. It's surprising how little this is understood. The existing congressional directive that 33 percent of prevention funding be spent on abstinence and faithfulness programs is applied across the focus countries collectively, not on a country-by-country basis—and certainly not to countries with concentrated epidemics.

Even speaking of the epidemic at a country level can be misleading, in fact, because a country can have both a concentrated epidemic and a generalized one. Even in generalized epidemics, we must identify vulnerable groups with especially high prevalence rates, such as people engaged in prostitution, and tailor prevention approaches to reach them. On recent trips, I've seen great examples of this sort of program in Haiti, Cote d'Ivoire and Ghana.

Moreover, epidemics can shift over time. In Uganda, for example, ABC behavior change had such a significant impact that we now see the highest infection risk in discordant couples.

Combination Prevention

While much progress has been made in effective prevention, often we are still using prevention techniques developed 20 years ago. It is important for prevention activities to enter the 21st Century, to use techniques and modalities that have been developed to change human behavior, especially those developed in the private sector for commercial marketing.

We also need a focused and concentrated effort that mirrors progress in treatment. As we need combination therapy for treatment, we need combination prevention. Combination prevention includes using many different modalities to affect behavior change, but it also includes geographic concentration of those different modalities and adding existing and new clinical interventions as they become available. PEPFAR is supporting many extraordinary prevention programs, but they are not always concentrated in the same geographic area. We need to make sure that, wherever people are, we are there to meet them at every turn with appropriate knowledge and skills. For example, many youth listen to faith leaders, while others don't. Many youth hear prevention messages in church or in school, but then hang out with their friends and hear conflicting messages. Many have no access to either school or church. We need to make sure that we blanket geographic areas with varied prevention modalities, so that all the youth hear the messages and can change their behavior accordingly.

We also need to create effective approaches to older populations, including discordant couples, and have them in the same geographic concentration as the youth programs. Effectively reaching these populations demands work that is outside the traditional realm of public health, such as gender, education and income-generation programs, for example.

We have made great strides to provide both linkages and direct interventions in these areas under the expansive existing authorities of the Leadership Act. But we also need to evaluate these combination programs with real science to know how best to do them. Some things might be good for general development, but if they don't prevent infections in a significant way, they are the purview of USAID and Millennium Challenge Corporation (MCC) development programs, not those of PEPFAR.

As part of the effort to implement innovative prevention programs, while evaluating their impact, we are developing several exciting and future-leaning public-private partnerships for combination prevention. Part of this effort includes "modularizing" successful prevention programs so that the components found to be most effective and easy to transfer to other geographic areas can be rapidly scaled up.

Integrating Scientific Advances

Part of combination prevention is to rapidly incorporate the latest scientific, clinical advances to expand the effectiveness of behavior change programs. As you know, recent studies have shown that medical male circumcision can significantly reduce the risk of HIV transmission for men. PEPFAR, working closely with the Gates Foundation, has been the most aggressive of any international partner in pursuing implementation. We have to be clear that this is not a silver bullet, but rather one part of a broad prevention arsenal that must and will be used. We also need to ensure that programs demonstrate cultural sensitivity and incorporate ABC behavior change education.

We need to manage rollout carefully, beginning in areas of high HIV prevalence and with those at greatest risk of becoming infected. For example, male circumcision could be very important in discordant couples in which the woman is HIV-positive.

As for other promising biomedical prevention approaches, we are also hoping for more scientific evidence on the effectiveness of pre-exposure prophylaxis to prevent infection, which could be another valuable tool for most-at-risk populations. Microbicides and vaccines still appear to be a long way off. Yet thanks to our wide network of care and treatment sites, we will be able to implement these methods rapidly whenever they become available—demonstrating again the value of integrated programs.

Along with these prevention interventions, we are also incorporating the latest scientific advances in evaluation. We hope to have markers for incidence—new infections—available in the field soon: they have been validated, and we are now awaiting calibration. These will make evaluation of prevention programs and our overall impact much easier, leading to program improvement and perhaps cushioning against pendulum swings.

Confronting Gender Realities

Addressing the distinctive needs of women and girls is critical to effective prevention, as well as to treatment and care. Taken as a whole, the Leadership Act specifies five high-priority gender strategies: increasing gender equity in HIV/AIDS activities and services; reducing violence and coercion; addressing male norms and behaviors; increasing women's legal protection; and increasing women's access to income and productive resources. In fiscal year 2007, a total of \$906 million is dedicated to 1,091 interventions which include one or more of these gender strategies.

For example, PEPFAR supports the Kenya Federation of Women Lawyers, which provides legal advice to people living with HIV/AIDS concerning rape, sexual assault, and property and inheritance rights. In Namibia, PEPFAR supports the Village Health Fund Project, a micro-credit program that provides vulnerable populations, such as widows and grandmothers who care for orphaned grandchildren, with start-up capital for income-generating projects. In South Africa, PEPFAR supports the Men as Partners project, which tailors behavior change interventions to define masculinity and strength in terms of men taking responsible actions to prevent HIV infection and gender-based violence.

PEPFAR has been a leader in addressing gender issues and has incorporated gender across its prevention, treatment and care programs. The Emergency Plan was the first international HIV/AIDS program to disaggregate results data by sex. Sex-disaggregated data is critical to understanding the extent to which women and men are reached by life-saving interventions, and helps implementers to better understand whether programs are achieving gender equity. For example, an estimated 62 percent of those receiving antiretroviral treatment through downstream U.S. Government support in fiscal year 2007 were women. Girls represent 50 percent of OVCs who receive care.

BUILDING HEALTH SYSTEMS

While HIV/AIDS remains a global emergency, which we are responding to as such, we are also focused on building capacity for a sustainable response. As President Bush has said, the people of host nations are the leaders in this fight, and our role is to support them. Eighty-five percent of our partners are local organizations.

An important part of that effort is the construction and strengthening of health systems. Like the pendulum swing between prevention and treatment, discussions here sometimes reflect misconceptions and unsubstantiated opinions on the effect of HIV/AIDS programs on the capacity of health systems. Some wonder whether by putting money into HIV/AIDS, we're having a negative impact on other areas of health systems.

Yet all the data suggest just the opposite. A peer-reviewed paper from Haiti showed that HIV resources are building health systems, not siphoning resources from them. A study in Rwanda showed that the addition of basic HIV care into primary health centers contributed to an increase in utilization of maternal and reproductive health, prenatal, pediatric and general health care. It found statistically significant increases in delivery of non-HIV services in 17 out of 22 indicators. Effects included a 24 percent increase in outpatient consultations, and a rise in syphilis screenings of pregnant women from one test in the 6 months prior to the introduction of HIV care to 79 tests after HIV services began. Large jumps were also seen in utilization of non-HIV-related lab testing, antenatal care and family planning. In Botswana, infant mortality rose and life expectancy dropped by one-third because of HIV/AIDS despite significant increases in resources for child and basic health by the Government of Botswana. Now, because President Mogae has led an all-out battle against HIV/AIDS, infant mortality is declining and life expectancy is increasing.

The reasons for these improvements make sense. For one thing, PEPFAR works within the general health sector. When we improve a laboratory to provide more reliable HIV testing or train a nurse in clinical diagnosis of opportunistic infections of AIDS patients, that doesn't just benefit people with HIV—it benefits everyone else who comes in contact with that clinic or nurse, too. Through September 30, 2006, PEPFAR had provided nearly \$200 million to support 1.7 million training and retraining encounters for health care workers.

A recent study of PEPFAR-supported treatment sites in four countries found that PEPFAR supported a median of 92 percent of the investments in health infrastructure to provide comprehensive HIV treatment and associated care, including building construction and renovation, lab and other equipment, and training—and the support was higher in the public sector than the non-governmental sector. In fact, many of our NGO partners are working in the public sector. In Namibia, the salaries of nearly all clinical staff doing treatment work and nearly all of those doing counseling and testing in the public sector are supported by PEPFAR. In Ethiopia, PEPFAR supports the Government's program to train 30,000 health extension workers in order to place two of these community health workers in every rural village; 16,000 have already been trained. So it is clear where those broader improvements are coming from. We estimate that nearly \$640 million of fiscal year 2007 funding were directed toward systems-strengthening activities, including pre-service and in-service training of health workers. In Rwanda, for example, these systems-strengthening efforts have enabled us to begin using performance-based contracts that resemble the block grants used in our domestic treatment programs. In areas where

that capacity has not yet been created, however, such an approach is not currently possible, and so PEPFAR supports the provision of treatment through other means.

Another key fact is that in the hardest-hit countries, an estimated 50 percent of hospital admissions are due to HIV/AIDS. As effective HIV programs are implemented, hospital admissions plummet, easing the burden on health care staff throughout the system. In the Rwanda study I just mentioned, the average number of new hospitalizations dropped by 21 percent at 7 sites that had been offering antiretroviral treatment for more than 2 months.

As the Chair of the Institute of Medicine panel that reviewed PEPFAR's implementation put it, "[O]verall, PEPFAR is contributing to make health systems stronger, not weakening them."

We know that building health systems and workforce is fundamental to our work, and PEPFAR will remain focused on it. We are working to improve our interagency coordination on construction, and we recently tripled the amount of resources available for pre-service training of health workers. We've already trained or retrained 1.7 million health care workers, and we need to continue to expand that number in order to keep scaling up our programs.

"CONNECTING THE DOTS" OF DEVELOPMENT

At this point, I want to step back and offer a look at a larger picture: the role of PEPFAR in "connecting the dots" of development. PEPFAR is an important part of the President's expansive development agenda, with strong bipartisan support from Congress. Together, we have doubled support for development, quadrupled resources for Africa, supported innovative programs like the MCC, President's Malaria Initiative (PMI), Women's Empowerment and Justice Initiative (WEJI) and African Education Initiative (AEI), as well as more than doubling trade with Africa and providing 100 percent debt relief to the poorest countries.

In Haiti, for example, the Emergency Plan works with partner organizations to meet the food and nutrition needs of orphans and vulnerable children (OVCs) using a community-based approach. The kids participate in a school nutrition program using USAID–Title II resources. This program is also committed to developing sustainable sources of food, and so the staff has aggressively supported community gardens primarily for OVC consumption, and also to generate revenue through the marketing of vegetables.

In education, we have developed a strong partnership with the President's African Education Initiative, implemented through USAID. In Zambia, PEPFAR and AEI fund a scholarship program that helps to keep in school nearly 4,000 orphans in grades 10 to 12 who have lost one or both parents to AIDS or who are HIV-positive, in addition to pre-school programs and support for orphans in primary school. Similar partnerships exist in Rwanda, where PEPFAR and AEI are working together to strengthen life-skills and prevention curricula in schools. This program, with \$2 million in funding in fiscal year 2007, targeted 4 million children and 5,000 teachers.

We are also working with the President's Malaria Initiative and the Millennium Challenge Corporation to coordinate our activities in countries where there are common programs. In Zambia, by using PEPFAR's distribution infrastructure, known as RAPIDS, PMI delivered nearly 500,000 bed nets between May and November of this year at a 75 percent savings—and the U.S. Government saved half the remaining cost of nets through a public-private partnership led by the Global Business Coalition on HIV/AIDS, Tuberculosis and Malaria. In Lesotho, PEPFAR is co-locating our staff with that of MCC to ensure that we are jointly supporting the expansion of health and HIV/AIDS services.

Broadly speaking, PEPFAR is contributing to general development in the following ways:

- (1) leveraging an infrastructure developed for HIV/AIDS for general health and development, as demonstrated by the data from Rwanda, the Zambia malaria initiative and other examples;

- (2) supporting aspects of general development activities with a direct and significant impact on HIV/AIDS, as demonstrated by OVC education programs, and in aspects of general prevention such as gender equality and income generation if scientific evaluations show that they impact significantly on HIV/AIDS; and

- (3) providing a piece of a larger approach, for example by supporting the HIV/AIDS component of Ethiopia's community health worker project.

When President Bush called for reauthorization of the Leadership Act, he emphasized the need to better connect the dots of development. The Leadership Act provides us with expansive authorities for such work, and we are constantly trying to improve our efforts.

But let me candidly make clear our view of the appropriate limits of PEPFAR's role. While we want to connect dots, PEPFAR cannot and should not become USAID, MCC, PMI, or any of its sister initiatives or agencies. Nearly every person affected by HIV/AIDS could certainly benefit from additional food support, greater access to education, economic opportunities and clean water, but so could the broader communities in which they live. We must integrate with other development programs, but we cannot, and should not, become them. PEPFAR is part of a larger whole. Congress got this right in the original legislation, and that is the right position going forward.

IMPROVING INDICATORS AND REPORTING

As we improve the linkages between our programs and other related areas of development, we also need to do a better job of measuring the impact and outcomes of our programs. We need to know not just the number of people that we support on treatment, but also what impact that is having on morbidity and mortality. We need to know not only how many infections we're averting, but also how we're doing at changing societal norms such as the age at sexual debut, the number of multiple concurrent partnerships, or the status of women. To do this, we have instructed our technical working groups to develop a new series of impact indicators, in consultation with implementers and other interested groups. These new indicators should be completed by early next year, and we will then incorporate them into our planning and reporting systems.

Of course, not all of the new indicators will be reported up to headquarters—we don't need all that information, and we don't want to burden our staff in the field with more reporting requirements. But we believe they will be useful to the country teams as they plan and evaluate their own programs, giving them a better idea of the impact they're having and where improvements can be made.

We believe that kind of information can improve the overall quality of programs and potentially reduce the demands on one of our most valuable assets—our U.S. Government staff in the field, both American citizens and Locally Employed Staff. Our Staffing for Results initiative also seeks to ensure that we have the right people in the right place in each country so that we can avoid unnecessary duplication of work and make the best use of our extraordinary human resources.

REAUTHORIZATION OF PEPFAR

I think the understanding that PEPFAR is essentially in the position it needs to be in going forward is critical in the conversation about reauthorization. We could spend a lot of time debating new authorities and new earmarks on everything from the amount of money we spend on operations research to the number of community health workers we train. Yet the bottom line is that the Leadership Act already has the authorities we need, and provides the right amount of flexibility to put them into use. None of the issues being discussed truly require significant changes in the law. The Institute of Medicine called PEPFAR a learning organization. We have used the flexibilities of the original legislation to learn, and to constantly change our approach based on the lessons learned.

Congress enacted a good law the first time. It's not perfect, but it's very good—that is clear from its results. While there are some modifications that are needed, rather than letting the perfect be the enemy of the good, it should be possible to take the time that is needed to develop a thoughtful, solid, bipartisan bill. And the President has made clear the Administration's desire to do just that. It is in no one's interest to be hasty—global HIV/AIDS is too important. But with a solid foundation in the first, good law, it is possible to move expeditiously.

And thoughtful but rapid action is important. In Haiti, a few weeks ago the Minister of Health expressed the same concern as every other country I have been to—“Will this continue? Can we scale up now or should we wait to see what happens?” A recent letter from the Health Ministers of our focus countries conveyed this same urgency. While U.S.-based or local organizations experienced in the workings of the U.S. Government might have less concern, the policymakers who set standards and must decide the level of scale-up to allow in their countries are asking for rapid action. They need to be convinced that it is prudent to attempt the significant expansion in prevention, and especially care and treatment services, that is needed in 2008, to achieve our original goals and to save the maximum number of lives.

Because of this reality, President Bush has called for early, bipartisan, bicameral action. He has announced the Administration's commitment to double the initial commitment to \$30 billion, along with setting new goals—increasing prevention from 7 to 12 million, treatment from 2 to 2.5 million and care from 10 to 12 million, including—for the first time—an OVC goal of 5 million. These goals reflect the need

for increased focus on prevention within our comprehensive program—that's why our prevention goal would nearly double while care and treatment would see smaller increases. President Bush challenged the G-8 leaders to respond to the U.S. commitment, and in June the G-8 committed \$60 billion to support HIV/AIDS, tuberculosis and malaria programs over the next few years. For the first time, the other leaders also agreed to join us in supporting country-owned, national programs to meet specific, numerical goals. President Bush has also called for enhanced effort on connecting the dots of development and strengthening partnerships for greater efficacy and increased sustainability.

A NOBLE AND ENNOBLING WORK

Mr. Chairman, Senator Enzi and members of the committee, through PEPFAR and our broader development agenda, the American people have engaged in one of the great humanitarian efforts in history. Through this partnership, people of distant lands have a new window into the hearts of Americans. They know what we stand for when we stand with them.

One year ago, I was in rural east Africa. With the power lines hidden in the mist of daybreak, the town seemed to be set hundreds of years ago—streams of people, robed in white, riding or walking their camels and donkeys to market or morning prayers. We visited a clinic there, where the American people are supporting life-giving care and treatment. The head of the clinic, who was also one of the four town elders, mentioned "PEPFAR" a few times. Acronyms are not as common in rural Africa as Washington so I asked him what PEPFAR meant—expecting him to say "the President's Emergency Plan for AIDS Relief". He said, "PEPFAR means the American people care about us"—the American people care about us. In rural Namibia, a brilliant young doctor ended a detailed and clinically impressive presentation on the scale-up of prevention, treatment and care they had accomplished with PEPFAR support with a slide that read "God bless America."

In the new era of development, we too have a new window into the hearts, cultures and abilities of our global brothers and sisters. The time is long past to discard notions of "donors" and "recipients," notions that we are coming to help poor, uneducated people, notions that chronic health care is not possible in resource-poor settings. While poor in resources, these distant lands are rich in some of the most talented, dedicated and compassionate people in the world. Those whom we think have nothing, give everything they have and everything of themselves for others. We are partners with many thousands of heroes, and even a few saints.

Finally, as President Bush has said, the new era of development is good for our national character, our national soul. When we base our policies and politics in the dignity and worth of every human life and dedicate ourselves to the service of others, we are dignified and have a great dignity of purpose.

We are, together, embarked on great works of goodness. This noble and ennobling work has only just begun. Working together through the power of partnerships, everything is possible.

The CHAIRMAN. Thank you very much. Excellent statement.
Dr. Gerberding.

STATEMENT OF DR. JULIE GERBERDING, DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, WASHINGTON, DC.

Dr. GERBERDING. Good morning. And thank you so much for including me as a representative of CDC and the Department here on this very important panel. I really appreciate the opportunity to provide a witness. I appreciate the committee's interest.

I'm a very privileged CDC Director and part of that privilege is having the chance to go into the field and see our work first hand. Many of the people who do this work have joined me here today from CDC. We have distinguished scientists, but also some very passionate public health workers who really have provided some of the boots on the ground workforce to help make the success evolve and evolve so quickly in the 15 focus countries as well as many other places around the world.

I've put a picture up here that shows the 15 focus countries and gives you a little bit of impression of the scope of the problem that we're dealing with and if you just turn to the next graphic where the numbers are put in more concrete terms. This lists the 15 countries and the prevalence of HIV. What this means is that basically in some of these countries, one in every four persons has HIV. Imagine a country where 25 percent of the adults in that country are infected with this virus. That is a big challenge and PEPFAR is the first scaled investment that anyone has made on a scope large enough to really have an impact on those kinds of figures.

The CHAIRMAN. Those indicate that they're more in the southern part of Africa. I mean if you look at the percentages. You've got Zambia and South Africa and Botswana. It seems to—

Dr. GERBERDING. Go back.

The CHAIRMAN [continuing]. Indicate that these are the places where it's primarily focused.

Dr. GERBERDING. If you look in the color coding—

The CHAIRMAN. The color probably reflects that.

Dr. GERBERDING. The redder the country the higher the prevalence.

The CHAIRMAN. Ok.

Dr. GERBERDING. I think that's shown very nicely here on this map.

The CHAIRMAN. Alright, thank you.

Dr. GERBERDING. So, it's a big challenge. It's 33 million people who have this virus around the world. We have tackled big problems before but as the Ambassador said, not necessarily chronic disease verses the ability—

The CHAIRMAN. Can I ask Dr. Gerberding, in—I don't want to interrupt until the questions, but if you could also talk about the countries as you're moving on through. I think the Ambassador had indicated what countries we're doing. Well, we can get into the specific kind of questions, where you've got the greatest concentration are you finding the best programming or are there trends that you can identify where there's smaller concentrations, countries able to handle it, large concentrations, not. I'd just be interested as you're going through the survey here, any observations you can make on it.

Dr. GERBERDING. What I can tell you in shorthand is that one of the important lessons we have learned is that we have to develop plans that make sense from the country's point of view. And it's different in every country.

The CHAIRMAN. Ok.

Dr. GERBERDING. The kind of problem, the kind of transmission, the people at risk aren't the same everywhere so we have to be able to have the flexibility and adopt our programs to adjust to whatever the issue is in the specific environment. But that is a very important point.

When you have a big challenge like this you try to look around and figure out what are the ways to address it. And I agree that PEPFAR is a very, very, very good program. It has three characteristics that are the hallmarks of successful solutions to very difficult health problems.

One of those is commitment to a set of goals. And in PEPFAR, our government committed to accomplish certain things over a certain period of time with a certain level of investment and we are on track to achieve those commitments. And I think that's very, very important to make that visible and to hold ourselves accountable to it.

The second ingredient is building capacity. There are two kinds of capacity at stake here. One is technical capacity and I think on the next couple of slides, I've illustrated some of the key components of technical capacity.

First is the capacity to diagnose the disease. New innovations have helped a lot: rapid tests where people don't have to wait a long time to get their test result or it can be tested with saliva or blood on the spot. These really help speed up people's ability to know they're infected and we know that knowing your status is one of the single most important things you can do to prevent transmission because when people know they take steps to protect others.

Another very important component of capacity is illustrated on the next graphic which is the importance of building the laboratory. As Ambassador Dybul said, we are investing in the health system because by solving the laboratory dilemmas we have with HIV, we're also creating the technical capability to look at malaria and TB and many of the other problems that this same set of people have. We've been able to develop training laboratories, a very large reference training laboratory in South Africa, so that we can train Africans to be able to work in their own laboratories and sustain that effort as it goes forward.

On the next graphic I've illustrated a very, very important component of capacity that really brings all of these things together, the prevention of maternal child transmission, as well as early diagnosis of infants. These require the technical capability to identify the women at risk, get them rapidly tested, intervene with antiviral drugs if they're infected. But also the ability to test their infants after birth to know whether or not that child is infected. And for complicated medical reasons it's difficult to tell early on whether a child is truly infected or is passively carrying its mother's antibodies. So we've been able to develop new tests and new technology that are based on finding the DNA of the virus in the baby to help us make that diagnosis much earlier.

And on the next graphic mention the importance of care and treatment and the technical support for doing that in a sustainable, long-term way, but I think it also brings up the other dimension of capacity which is the social capacity. We can do a lot with our technology and that's one of the ways that the Department is contributing. But social capacity is much harder.

And social capacity are the things that we've referenced already, the laws that protect the safety of women, the laws that allow women to inherit property, the support for jobs and micro economies to keep people employed, the social, cultural changes necessary to make it inappropriate for older men to prey on younger women or for rape and assault to be part of a common pattern of behavior in certain communities in certain areas. So, we are work-

ing on the social capacity which is a much harder challenge than some of the technical capacities that we've addressed.

The third component of a successful program is connectivity. It's building the network of people who need to come together to be successful. And I'm proud today to represent the connectivity within the Department of Health and Human Services where HRSA and FDA and SAMHSA and all of our agencies are working together as well as the relationship that we have with the Department of State and other government cabinets. You referenced the connectivity between the Republicans and the Democrats and the Administration and the Congress and the coming together to work collaboratively on such an important project.

But that connectivity goes way beyond us or our government. It extends to governments everywhere in the developed and the developing world. It extends to international organizations like the World Health Organization and the U.N. It extends to faith-based and community-based organizations. And I think most importantly, it includes the American people and our people to people, health diplomacy that is really at the heart and soul of our ability to spend the tax payers dollars for this kind of a program.

So I've talked about commitment, capacity and connectivity and I guess the fourth C that I would end with is probably the most important of all and that's the compassion. It takes a lot of compassion to look at people in a country where 25 percent of the people are infected and not feel it in your heart.

[The prepared statement of Dr. Gerberding follows:]

PREPARED STATEMENT OF JULIE L. GERBERDING, M.D., MPH

Mr. Chairman and members of the committee, I am pleased to be here to discuss with you the role of the U.S. Department of Health and Human Services (HHS) in the implementation of the President's Emergency Plan for AIDS Relief. I will cover a number of our Department's recent accomplishments under the Emergency Plan, as well as provide some considerations for the future. We, at HHS, are proud to be one of the main implementing agencies of the Emergency Plan, under the leadership of Ambassador Mark Dybul, M.D., and I am pleased to join him to represent the Department and Secretary Mike Leavitt at this hearing today. I had the privilege of traveling with Secretary Leavitt and Ambassador Dybul in August of this year to four Emergency Plan focus countries in Africa, and saw first-hand the programs' results and challenges.

HHS has a long history in global health, and all of us appreciate this committee's bipartisan support for our international work. The Department, through the Centers for Disease Control and Prevention (CDC), played a leadership role in the eradication of smallpox, and is currently working to eradicate polio and guinea worm, and eliminate measles. Over the years, the scope of HHS' global efforts has expanded to strengthen the capacity of other countries to conduct critical public-health activities. Today, we have made global health a central part of our mission, and HHS continues to be on the frontlines of international disease eradication, health promotion and, increasingly in the 21st century, global health preparedness—focused on protecting the United States and the world from emerging, and re-emerging, worldwide threats.

HHS has been proud to play a seminal role in the early development of The Emergency Plan and its precursors. A number of our Operating and Staff Divisions have been involved in the design and scale-up of the U.S. Government's expanded battle against HIV/AIDS since the beginning of the Administration, and indeed, since the early days of the HIV/AIDS pandemic. Work at HHS also led to the ideas the President endorsed when he called in 2001 for the creation of what became the Global Fund to Fight AIDS, Tuberculosis and Malaria and made the founding contribution to the Fund. We, at the Department, have stayed closely involved in the governance structure of the Fund, and in the creation and implementation of many of its projects around the world.

The Department received a total of more than \$1 billion in fiscal year 2007 to carry out activities under the Emergency Plan in the treatment, care and prevention of HIV/AIDS, and we are active in more than 30 countries, and support an additional 30 countries through regional programs and headquarters. Everything we do on behalf of the Emergency Plan is part of a well-coordinated, cross-Government team, both here in Washington and Atlanta, and in the field. We believe in a "One U.S. Government" approach. We participate in the inter-agency technical working groups that oversee the implementation of the Emergency Plan, provide scientific counsel to Ambassador Dybul, review proposals for public-health evaluations or operational research on aspects of the Plan's work, and provide a network of technical staff of medical and public-health experts who do the day-to-day work of the Plan on the ground. HHS staff scientists, medical officers and public-health experts serve on nearly all the Technical Working Groups and inter-agency committees that give policy advice to Ambassador Dybul and review the yearly Country Operational Plans that U.S. Embassies around the world develop with local partners. Finally, the Department has detailed staff members to the Office of the Global AIDS Coordinator in leadership and expert advisory roles since the inception of the program.

In the same way each Federal partner brings a well-defined contribution to our bilateral programs in global health, under the Emergency Plan, each HHS agency contributes its expertise to tackle the many facets of the HIV/AIDS pandemic. As of May 2007, HHS has approximately 120 direct-hire staff assigned to 26 countries around the world to work on the Emergency Plan, part of a total complement of nearly 270 staff overseas, who represent a range of scientific expertise in environmental health, infectious disease, chronic disease, and injury prevention and control. The vast majority of these personnel come from HHS/CDC. The Department also employs approximately 1,400 local staff in host countries to support its global programs, and has approximately 40 U.S. experts detailed to work with international organizations, especially the World Health Organization (WHO) and the United Nations Children's Fund. Supporting these in-country staff are teams in Atlanta and at other HHS Operating Divisions, who facilitate the sharing of best practices, provide technical assistance, and who, in addition to being renowned experts in their own right, draw on the capacities of the Department's domestic efforts.

HHS's main role in the Emergency Plan is to provide scientific and technical expertise to build the capacity of host-country health-care institutions to respond to HIV/AIDS. We work in collaboration with the U.S. Agency for International Development (USAID), the U.S. Department of State, and other Federal Departments and agencies; national Ministries of Health (MOH) and their sub-components; and international partners such as the WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS). HHS provides the scientific and medical evidence base for implementing treatment, care, and laboratory support within the Emergency Plan, and plays a critical role in gathering strategic information, including through disease surveillance, epidemiology, evaluation, research, and health informatics. I would like to highlight a few areas that demonstrate our Department's critical and substantial contributions.

Prevention of New HIV Infections

The prevention of new infections represents the only long-term, sustainable means to stem the global HIV/AIDS pandemic. As Ambassador Dybul has said, we cannot defeat the HIV/AIDS pandemic through treatment alone. To support the Emergency Plan's prevention activities, HHS/CDC assists with the development of comprehensive, evidence-based programs to prevent the spread of HIV/AIDS through sexual and non-sexual transmission. In addition, in collaboration with the HHS National Institutes of Health (NIH), HHS/CDC supports research internationally to identify new prevention interventions, such as microbicides, vaccines, and the prophylactic use of anti-retroviral (ARV) medications. HHS/CDC also collaborates with the WHO Secretariat and UNAIDS to develop guidelines, protocols, and training curricula to support nations in their efforts to prevent new HIV infections. The following are some of the Department's recent activities and accomplishments in support of prevention under the President's Emergency Plan:

- *Prevention with HIV-positive individuals:* "Prevention with positives" (PwP) involves working with HIV-positive individuals and their partners to prevent further HIV transmission. HHS/CDC spearheaded a new, provider-initiated intervention for HIV-infected individuals in Kenya, and we are now implementing it in countries throughout Africa under the guidance of the Office of the U.S. Global AIDS Coordinator. This technique gives providers the tools and skills to deliver tailored prevention messages to HIV-infected persons at the end of every routine clinic visit. Mes-

sages focus on the disclosure of HIV status, partner testing, the reduction of transmission to others, and the prevention of other sexually transmitted infections.

- *Addressing drug and alcohol abuse as drivers of the epidemic:* The Substance Abuse and Mental Health Services Administration (SAMHSA) within HHS is engaging with U.S. Government Emergency Plan country teams to address the role abuse of alcohol and injectable drugs are playing to spread HIV in focus countries. As part of this work, under the Emergency Plan HHS/SAMHSA has assigned an expert to work in the field overseas for the first time, to help design HIV-prevention and drug-treatment programs in Viet Nam, which has a concentrated epidemic driven in many places by heroin abuse.

- *Provider-initiated voluntary testing and counseling:* Assuring access to quality HIV testing is a necessary step in preventing transmission and treating HIV-infected persons. HHS/CDC is taking a lead role to help make provider-initiated voluntary testing and counseling routine in medical facilities in Emergency Plan focus countries through training, the development of curricula, and pediatric counseling and testing. HHS/CDC is also collaborating with the WHO Secretariat in the development of normative guidance on provider-initiated testing and counseling, to encourage host Governments in high-prevalence countries to assure everyone has an opportunity to get an HIV test during all medical encounters. This summer, Secretary Leavitt and I saw the power of testing in action as he participated in “know-your-status” events in several countries, but we will never reach the number of people we need to unless more individuals have a chance to receive an HIV test every time they come in contact with the health-care system.

- *Preventing HIV infection in children:* Through the Emergency Plan, HHS supports a wide range of activities, including support to countries in the rapid scale-up of the prevention of mother-to-child transmission (PMTCT), such as counseling and testing and ART for pregnant women, and the expansion of polymerase chain reaction (PCR) testing for early infant diagnosis. In addition to the prevention of pediatric HIV/AIDS, HHS is committed to building national capacity and policy regarding formulations for and access to appropriate long-term combination antiretrovirals for HIV-infected children. HHS also supports the international scale-up of comprehensive, quality PMTCT and pediatric programs by providing leadership and technical expertise for country programs, Emergency Plan Technical Working Groups (TWGs) and public-health evaluation (PHE) teams, U.S. Government partners, and international organizations.

- *Male circumcision:* As a result of research funded by the HHS National Institutes of Health (NIH), evidence from several African countries has now shown medically provided adult male circumcision can decrease the rate of heterosexual HIV acquisition in men. Under the guidance of the Office of the Global AIDS Coordinator and local legislation, HHS is providing support and technical assistance to many Ministries of Health, including the South Africa National Department of Health, to formulate policies and guidelines in this area. In fiscal year 2008, the Emergency Plan’s specific activities will include working with local health officials on the development and dissemination of policies related to safe male circumcision, working with traditional healers regarding safe circumcision, and incorporating HIV-prevention messaging into circumcision activities.

Clinical and Behavioral Research, Public-Health Evaluation, and Disease Surveillance

Research conducted over the past 26 years with funding from the HHS/NIH National Institute of Allergy and Infectious Diseases and other HHS/NIH Institutes and Centers, and to a lesser extent HHS/CDC, has provided the scientific and clinical tools to allow the Emergency Plan to provide HIV/AIDS care to millions. HHS/NIH’s role in the Emergency Plan has been a specific and defined one in providing expertise to the Office of the Global AIDS Coordinator to assure it reviews and implements service-provision programs that are in keeping with the most current scientific findings. Grantees funded by HHS/NIH in the United States and elsewhere have the opportunity to seek financial support from the Emergency Plan for partnerships that can help improve individual survival and quality of life, while also helping to strengthen the Plan’s programs. Also, by studying populations served by the Emergency Plan, researchers can address key questions important to the countries most severely affected by HIV/AIDS, tuberculosis (TB) and associated co-infections.

Through CDC and NIH, HHS provides critical support to public-health evaluations (PHE) under the Emergency Plan, which ensures all interventions are scientifically sound and delivered as effectively and efficiently as possible. PHEs are necessary to understand the outcomes and effects of Emergency Plan activities, to inform the design of current and future programs, as well as to optimize allocation

of human and financial resources. HHS also contributes to the Emergency Plan a wide range of scientific and technical resources that inform practice in the field, such as scientific and operational research, technical guidelines, standard operating procedures for laboratories, curricula and other training materials. A partial list of PHE activities supported by HHS in support of the Emergency Plan includes the following:

- *Anti-retroviral costing studies:* Efficient scale-up of ARV treatment requires an accurate estimation of resource needs and an understanding of how these needs change over time as a result of changes in the epidemic. HHS/CDC is providing technical support on ARV costing/budgeting in five countries—Nigeria, Uganda, Ethiopia, Botswana and Viet Nam. Preliminary analysis of data indicates treatment costs vary widely across facilities, and that the composition of spending changes markedly as programs mature. This ongoing study will strengthen knowledge about the costs of comprehensive HIV treatment to inform efficient and cost-effective policy and planning.

- *Evaluating barriers to care and treatment:* HHS/NIH is helping enable the Office of the Global AIDS Coordinator to investigate the biological and behavioral predictors of adult and pediatric treatment compliance and success, while HHS/CDC is supporting studies in Mozambique and Tanzania to evaluate the key enabling factors and barriers within the community and the health system that affect children's access to and use of HIV care and treatment. This evaluation will include examining the beliefs, attitudes and experiences of clients, health-care providers and community members associated with providing or seeking access to care and treatment for children. Identifying reasons for the poor access to and use of HIV care and treatment will help to identify policies and specific interventions that can improve the identification of more effective strategies and best practices. It will also help reduce loss to follow up of HIV-exposed and infected children, and thus improve their survival.

- *Disease surveillance:* HHS/CDC is at the forefront in developing new surveillance and reporting tools to help track and fight the global HIV/AIDS epidemic. Working with Ministries of Health and international partners, HHS/CDC is helping to build capacity in focus countries to design and implement HIV/AIDS surveillance systems and surveys, and to monitor and evaluate the process, outcomes, and impact of HIV programs. The recent estimates of the scale of the HIV/AIDS epidemic released by the WHO Secretariat and UNAIDS are, in part, the fruits of this investment.

Capacity-Building

A good public-health laboratory network is a cornerstone of a strong response to HIV/AIDS in any country. Without laboratory support, it is difficult to diagnose HIV infection and provide high-quality care and treatment for people who are living with HIV/AIDS. Under the Emergency Plan, HHS/CDC is building capacity for high-quality laboratory services to assist with the rapid expansion of HIV treatment, and the accompanying need for HIV diagnosis and associated care. This year, HHS/CDC's Global AIDS Program (GAP) laboratory in Atlanta received the internationally recognized accreditation of the College of American Pathologists (CAP), and provides critical, external quality-control and quality-assurance programs for partner laboratories that are helping to implement the Emergency Plan throughout the world.

Similarly, health-care workers who have participated in training and research-capacity programs funded by HHS/NIH have used the expertise gained through this training to become the core personnel who are helping to implement in-country treatment programs under the Emergency Plan, and are also serving as trainers of other health-care providers. As part of HHS/NIH-funded research training supported by the Fogarty International Center and other HHS/NIH Institutes/Centers, scores of clinicians have learned how to optimally treat HIV/AIDS by using anti-retroviral therapy, and how best to manage co-infections. In addition, these scientists have learned how to evaluate and analyze health outcomes in clinical settings, and to incorporate these new findings into the design of prevention and treatment programs.

In an innovative partnership through a "Twinning Center" managed by the American International Health Alliance, the HHS Health Resources and Services Administration (HRSA) is helping to match U.S. institutions with indigenous groups in Emergency Plan focus countries to transfer skills and train local professionals. These peer-to-peer, collaborative relationships between American universities and other organizations with partners in seven of the Emergency Plan focus countries are proving an effective way to share best practices and create sustainability.

HHS/HRSA supports the International AIDS Education and Training Center (I-TECH), the American International Health Alliance, the Georgetown Nursing

School and numerous other partners to provide training to HIV professionals and paraprofessionals in nine African countries, as well as in India, the Caribbean, and Viet Nam. This multiple-agency effort was responsible for training 8,783 health-care workers across 25 countries during fiscal year 2007.

Care and Treatment

As President Bush announced on November 30, 2007, the Emergency Plan is supporting anti-retroviral (ARV) treatment to more than 1,445,500 individuals throughout the world, approximately 1,358,500 of whom are men, women and children in the 15 focus countries in Sub-Saharan Africa, Asia and the Caribbean. Complementing the work of USAID and in conjunction with local partners, HHS has made strong contributions to the success of the Emergency Plan in this area. We supervise treatment grants at the field level in the focus countries, and manage four, large, multi-country grants through HHS/CDC and HHS/HRSA that deliver anti-retroviral treatment to 300,000 people among the total above. We also provide direct technical assistance to help host countries integrate HIV prevention, care and treatment with TB care; help teach medical professionals to prevent, diagnose, and treat opportunistic infections, including TB; and support the prevention of mother-to-child transmission (PMTCT) of HIV. HHS also works with the Ministry of Health in each Emergency Plan focus country to develop guidelines for HIV care and treatment that address first- and second-line drug regimens, as well as how to apply WHO guidelines for beginning treatment and changing regimens. Recent examples of successes by HHS in care and treatment in support of the Emergency Plan include the following:

- *Basic Care Package:* HHS/CDC led groundbreaking research conducted in rural Uganda and elsewhere that used an integrated package of interventions to minimize the susceptibility of HIV-positive persons to common opportunistic infections and illnesses spread by unsanitary water. This research demonstrated the Basic Care Package is a low-cost, evidence-based way to reduce deaths, hospital visits, and illnesses, including malaria and diarrhea, among HIV-positive people and their families. The package includes insecticide-treated mosquito nets; a safe-water vessel, filter cloth, and bleach solution to disinfect water; information on how to obtain HIV family counseling, HIV testing; and cotrimoxazole—an antibiotic that reduces opportunistic infections among HIV-positive persons. Armed with the evidence we gathered in Uganda, the Emergency Plan is now rolling out the Basic Care Package in a number of focus countries.

- *Quality improvement:* To answer the need for the systematic measurement of quality improvement and to promote consistent quality standards for care and treatment in Emergency Plan programs, HHS/HRSA works in partnership with the International HIV and AIDS Quality Center to support the expansion of the New York AIDS Institute's HIVQUAL initiative, which has already implemented quality-management programs in Thailand, Uganda, and Mozambique, and this year initiated programs in Namibia and Nigeria.

- *The review and use of safe and effective anti-retroviral drugs:* Since 2004, the HHS Food and Drug Administration (FDA) has ensured the availability of safe and effective anti-retrovirals to meet the President's treatment goals through (1) an intensive process to help generic manufacturers from developing countries that are not familiar with HHS/FDA procedures to prepare high-quality applications and prepare for inspections; (2) an expedited review of generic ARVs, including combination products and pediatric formulations; and, (3) tentative approval for generic ARVs that meet U.S. safety and efficacy standards, but for which existing patents and/or market exclusivity prevent their immediate approval for marketing in this country. Through this fast-track process, HHS/FDA has approved or tentatively approved 56 low-cost, high-quality, generic anti-retroviral therapies since December 2004, and, in August 2007, tentatively approved the first fixed-dose anti-HIV product designed to treat children under the age of 12 years. All of these products are now available for purchase by the Emergency Plan. Also, through a confidentiality arrangement with the Quality Assurance and Safety Medicines Unit of the WHO that allows the exchange of sensitive data, HHS/FDA tentatively approved products move quickly onto the WHO pre-qualification list that many Governments use as the basis for their national drug-registration and procurement decisions. More than 90 percent of ARV purchases under the Emergency Plan are now generic products given approval or tentative approval by HHS/FDA, which is saving lives while also reducing the cost of treatment by millions of dollars.

- *HIV/TB integration:* TB is the leading cause of death among HIV-infected individuals, and one of their most common opportunistic infections. The prevalence of HIV infection among patients in TB clinical settings is high—up to 80 percent in some countries. In many countries, including Botswana, Ethiopia, Kenya, Rwanda

and Tanzania, HHS has worked with partners to support the expansion of provider-initiated testing and counseling among TB patients, and collaborated with international partners to develop and disseminate protocols, training and policy to improve the integration of HIV and TB service care.

- *HIV/Malaria integration:* In Sub-Saharan Africa, co-infection with malaria and HIV is common. The President's Malaria Initiative (PMI) presents us with a perfect opportunity for collaboration to reduce the dual burden of HIV/AIDS and malaria and to create synergies between two major international initiatives in the eight focus countries they share. Examples of successful collaborations between PMI and the Emergency Plan in the field include the following: (1) distributing long-lasting, insecticide-treated mosquito bed nets through a home-based-care network funded by the Emergency Plan in Zambia; (2) streamlining supply-chain coordination for malaria and HIV/AIDS commodities under one manager in Mozambique; and (3) integrating Emergency Plan PMTCT program activities, such as testing, counseling and treatment, with general maternal and child health care, and including malaria prevention in these activities by providing bed nets to expectant and new mothers.

THE ROAD AHEAD

HHS is proud of our role in helping to design and implement the President's Emergency Plan, and we look forward to our continued participation in this important initiative. Mr. Chairman, I would like to share with you and your colleagues some observations for the road ahead, based on my recent travels in Emergency Plan focus countries.

Preventing New Infections is Key

Prevention of HIV is the single most critical factor for turning the tide against the global HIV/AIDS epidemic. We must work intensively with Governments and the private and not-for-profit sectors to ensure they put HIV prevention at the top of their agendas. In the coming years, the Emergency Plan should place additional emphasis on the following approaches: (1) carefully defining current and emerging risk groups who are contributing to new infections so our field teams and partners can appropriately target prevention interventions; (2) intensively rolling out prevention for discordant couples and concurrent partners; (3) assuring maximum coverage of proven prevention interventions—including male circumcision, consonant with local laws and regulations—and ensuring prevention of HIV transmission for all infants; (4) exploring the potential of pre-exposure prophylaxis; (5) maximizing behavior-change interventions with all infected persons to decrease the rate of HIV transmission, such as the evidenced-based, balanced “ABC” approach—abstinence, being faithful, and correct and consistent use of condoms; and (6) making provider-initiated testing routine in all health-care settings.

Infrastructure and Human Capacity

Another key challenge for the Emergency Plan is sustainability, which will largely depend on strengthening indigenous infrastructure and local human capacity. Additional laboratory infrastructure is necessary to provide adequate geographic coverage across Africa and Asia. In addition to continuing to provide focus countries the technical expertise to establish regional training and reference laboratories, we also need to make sure we can leverage our investments in labs through other programs, such as pandemic-influenza preparedness and HHS/NIH grants, and avoid duplication.

In the area of human resources, the Emergency Plan should continue to increase our efforts to train local health-care workers and public-health specialists; the so-called “task-shifting” Secretary Leavitt and I saw in Africa that has increased the use and skills of community health workers is one answer. To the greatest extent possible, we should increasingly rely on local service providers to assure sustainability and to lower per-person costs.

We should also expand appropriate training programs by HHS/CDC and HHS/NIH to help produce more skilled health professionals who can investigate disease outbreaks, strengthen surveillance and laboratory systems, conduct cutting-edge research studies and serve as mentors for future public-health officers in their countries.

Better Data

The increased scale-up of HIV/AIDS prevention, care, and treatment activities has increased the demand for accurate, sophisticated data on the epidemic. The Emergency Plan has successfully supported Ministries of Health to implement innovative surveillance and data-collection systems. The result has been better, more informed

programming. Still, many countries have collected data that sit unused, and we need to help our partners analyze and use these data for decisionmaking.

Public Health Research and Translation

Increased focus on Public Health Research and Translation is also critical to our success in fighting the HIV/AIDS epidemic through the Emergency Plan. As we move from emergency responses to sustainable strategies, and from individual-, project- or activity-focused effectiveness to community or population-wide impact, we need to be asking ourselves questions such as: (1) Is what we thought would work—based on best evidence and principles—actually working?; (2) How do we best move beyond the basics, to enhancing quality and complexity of interventions?; and (3) What needs to be done to expand prevention, care, and treatment to more difficult-to-reach populations? HHS-supported research and translation is critical for the scale-up and sustainability of Emergency Plan programs. Research should be undertaken strategically to answer questions critical to improving the quality, scope, effectiveness, and impact of our programs. When effective interventions are identified, HHS should support the translation into practice, as well as the scale-up and roll out of these interventions by HHS and other U.S. Government agencies.

Integration of the Emergency Plan With Other Programs

While the Emergency Plan is the largest investment the American people are making in health in the developing world, it is not the only one. An important emphasis for the coming years should be cross-program collaboration on key global initiatives, such as pandemic influenza, global disease detection, neglected tropical diseases, and the President's Malaria Initiative. Increasingly, HIV and malaria programs are conducting joint planning and program execution. Linking our HIV and TB investments will bring more care and treatment to the large numbers of co-infected people. Comprehensive and integrated service delivery is key to the sustainability of the Emergency Plan, and can increase its impact and reach. To ensure our own U.S. Government complement of experts in our focus countries has the right mix of skills, we should expand the "Staffing for Results" exercise that Ambassador Dybul has begun, so we can place the right experts in the right places, regardless of their home-agency affiliation.

Better Branding of Our Assistance

Finally, we should work to maximize the public-diplomacy impact of our investments under the Emergency Plan. Secretary Leavitt and I toured more than a dozen sites funded by the Emergency Plan in four countries, from rural clinics to urban hospitals to schools and universities. We noticed that we need to pay even more attention to assuring that the generosity of the American people is evident where we are working in partnership with health-care providers around the world. To this end, HHS will enhance our efforts to assure the programs implemented with Emergency Plan support make the commitment of the American people more evident. Furthermore, we will continue to work with our colleagues in other U.S. Government agencies to promote a "One-U.S. Government" approach to branding and communicating about the Emergency Plan, so both Americans and the people we are serving overseas have a clearer understanding of what we are doing together to fight this pandemic.

CONCLUSION

HHS has contributed significantly to the Emergency Plan's remarkable achievements in HIV prevention, care, treatment and training of local health professionals. We look forward to continued collaboration with our sister Federal Departments and agencies to implement the President's vision for this life-saving program. Secretary Leavitt and I, and our colleagues across HHS, greatly appreciate the committee's interest in these important issues, and I am happy to answer questions from you on their behalf.

I would be happy to answer any questions.

The CHAIRMAN. Ok. Thank you very much. Excellent comments, enormously helpful to us.

Let me get both of your reactions then. There was no question that in the early years there was some general reluctance in a number of the countries to move forward in the comprehensive ways which you've each described. You know whether it's prevention, the treatment, the caring, the prescription drugs, other kinds of things.

What can you tell us now in terms of the region? Have all of the countries basically been willing to understand that we need a science-based solution to this issue? Maybe you can just describe briefly the transition that's taken place. Is there still work to do? What needs to be done? How is that best done? Maybe each of you could comment on that?

Ambassador DYBUL. It's a very important question and I think it's a mix of all the above. You know, actually a lot of the countries were ready to go. What they didn't have were the resources. So countries like Uganda, for example, had a national plan. Rwanda had a national plan. They just didn't have the resources.

So some countries are ready to go and those are the countries that are achieving extraordinary coverage and prevention, treatment and care. Other countries were a little bit behind both in capacity and planning. They've all caught up. And even in countries where some of the governments have made statements that some might have difficulty with, they still have good programs going on.

And what we see is that all the countries are on the same basic trajectory which is very common in public health. You start very slowly and then you uptake rapidly. And we're seeing that exact pattern in all of the countries in prevention, treatment and care. It's rather extraordinary. It's the exact same pattern when you put them all together, but also individually. Some countries started at different points at that trajectory.

But there's work to be done. And both the Chair and the Ranking Member mentioned some of them. We have to work on gender equality. We have to work on workforce policies. We have to work on more comprehensive prevention programs.

We don't always have the same geographic coverage. You know, children and youth aren't very single dimensional. They have many different parts of their life and we're not addressing each aspect of their life all the time. So there's a lot of work to be done. We can improve everything we're doing.

But the trajectory is right. And the commitment is there. And I think one thing we should recognize is we really should get away from terms like help and aid in this. It's not us. It's really the most extraordinary people you'll ever meet like Princess Zulu and others on the ground from every walk of life, from the private sector, from faith- and community-based organizations, the government who are giving everything they have. People who often have very little giving everything they have in the service of others.

So we're really supporting this extraordinary ground swell from every sector and country. And it's extraordinary to see.

The CHAIRMAN. Let me just move on, just because my time is limited too.

Ambassador, the IOM recommended in their recommendations, that some of the rigid budget allocations currently in the PEPFAR be eliminated to allow countries to adapt their work, fit their needs of their country. What's your view on the budget allocations?

Ambassador DYBUL. Our view is that we don't need a number of the current allocations. So, the allocations that we think are important in going forward are the 10 percent for orphan and vulnerable children and a directive that has a comprehensive prevention ap-

proach. And so, for example, the language that Senator Lugar has proposed is language that we think gets us there.

And the reason for that is when we started this program we needed to do more in treatment, for example. So it was appropriate to have that type of directive. The purpose of directives from our standpoint is to make sure we're doing things that we might not otherwise do or the government has not traditionally done.

We're still pretty far behind in orphan care. We're not doing well enough in orphan care. So we think there needs to be a continuing directive there.

We also don't think we're quite where we need to be in prevention. That a comprehensive approach that includes all the components could get lost in the next 5 years unless we continue to have a directive that ensures we have all three of those pieces, A, B and C in the complex and comprehensive way I discussed.

So those are the two directives we think we need going forward. Otherwise, we think we're ok without them.

The CHAIRMAN. I've got just a short time left. I can come back to this. But with regards to the GAO and the IOM recommendations on the budget—the elimination of the earmarks, do you support the 33 percent earmark for the abstinence-only prevention? And what's your reaction to those recommendations of the GAO and IOM on that?

Ambassador DYBUL. Well, we want to pursue an evidenced-based approach and evidenced-based requires that we do effectively the A, B, C approach. The data from generalized epidemics in Sub-Saharan Africa indicate that reductions in HIV rates require all three of those activities. As I mentioned, I don't think we're quite in the position to ensure that the government would have that without a directive of some type.

Now in terms of the current 33 percent, we tend to support something more like Senator Lugar's language which is a little bit different than the 33 percent, but still ensures that we have a directive going forward.

The CHAIRMAN. Alright. Just finally, Dr. Gerberding, you mentioned the work in the maternal to child transmission. Can you just mention about how this works? Have you got it coordinated with the other prevention, treatment works and PEPFAR?

Dr. GERBERDING. Yes, I think—

The CHAIRMAN. And how does the women's access to the other women's health services factor into this?

Dr. GERBERDING. I don't want to underestimate the challenge. Cultural practice and birthing practices and where women have access to treatment and care when they're pregnant is very variable and requires a great deal of surround in connecting the dots so to speak. But I think the maternal-child program is extremely successful. We've had life-saving interventions in community after community.

The biggest barrier is finding women early in their pregnancy and getting them tested. And overcoming the barriers to testing is still something that we're working on. But I think it is one of the areas of the PEPFAR Program where we can take the most pride in documenting our prevention impact.

The CHAIRMAN. Senator Enzi.

Senator ENZI. Thank you, Mr. Chairman. Following up on that last answer that you gave, Dr. Gerberding, in Namibia we were visiting one of the hospitals there and we asked the question of what percentage of the women were tested for HIV to see what the transmission rate was and again it was a faith-based operation. The rather tall, German, catholic nurse put her hands on her hips and said, 100 percent. And I'm pretty sure nobody would have told her no to being tested.

What do you find to be the biggest similarities and differences between the prevention strategies with those countries with the high percentage of individuals and the low percentage with HIV? Are there some similarities and differences there?

Dr. GERBERDING. I think we got into the countries when the pattern of the epidemic was largely already set. And so it's not necessarily a correlation of a success or failure of the PEPFAR prevention programs as much as it was—what was the situation that we found when we got started. And as you know we selected PEPFAR countries for many reasons including having a high burden or a high potential burden.

So I'm not sure there's a correlation between low prevalence and success of the prevention program per se as much as there is a correlation between the change in who's got it and how frequently it's been transmitted once the program was started. Am I answering your question?

Senator ENZI. Yes, but would you anticipate that there are tensions between the government and the non-government grantees or what are some of the problems that are caused, you know, with the process of actually giving the treatment, the prevention, the connectivity out there that you mentioned.

Dr. GERBERDING. One of the things that I didn't mention in my list of success factors and Mark, the Ambassador, has alluded to indirectly is the importance of country leadership. And we do see much higher rates of uptake and initiation and, I think, penetration in countries where the leaders are visibly and vocally involved and committed in supporting the program and the changes that are necessary.

So it is important that the country and the country leaders, not just the government leaders, but the health leaders and the health ministry are fully behind these programs and supporting their introduction and development. It also has a very major role to play in developing capacity to imagine sustainability over long periods of time.

Senator ENZI. Thank you. Mr. Ambassador is there any relationship then between the leadership and the people in the countries and allocation of funding? Are there some more efficient ways that we could be allocating the funding? And the same question to you, the tensions between government and nongovernment entities.

Ambassador DYBUL. There can be tensions. And I do think we need to talk about leadership at every level. There's governmental leadership, but really you need to get down to the community level and that involves tribal leaders. It involves local leaders. It involves faith and community leaders. Often you'll go to a village and the only thing there is a church, so you need to work with the faith

leaders if you're going to affect an epidemic there. So it's leadership at every level.

We have not, to this point tagged resources in the first part of the emergency plan to leadership as a prerequisite, for example. And the reason for that is half the disease was in these 15 countries. And so we needed to just go in and work with the countries to make it happen. And that's happening.

But for the second phase the President has called for \$30 billion and goals, but hasn't said necessarily where the money ought to go. What he said was let's work on partnership compacts. Work with countries that want to tackle their epidemics, that will contribute their own resources, both in terms of financial resources, if they can, but also in terms of leadership and policy changes that will effect outcome like gender equality, like orphan protection, like, for example, the use of opt-out testing which we know is a critical piece of prevention of mother-to-child transmission.

You'll go from 50 percent coverage to 95 percent coverage if you have opt-out testing. So why do you put a lot of money in that country that doesn't want to do opt-out testing when the tax payer dollar could go further in a country that does. So this is the approach that we're trying to take—going forward to say, “let's work with countries that want to work on their epidemic at multiple levels in the next phase of the Emergency Plan.”

Senator ENZI. In the early days there were some problems with warehouses full of the pharmaceuticals that were expiring on the shelf and also a problem with companies that were donating pharmaceuticals being charged a tariff for the value of the pharmaceuticals even though they weren't receiving anything. Have those problems pretty well been overcome?

Ambassador DYBUL. They have and this is one of the advantages of the interagency approach. The Foreign Assistance Act which is where most of the resources to the Department of Health and Human Services come from, the vast majority, actually has a penalty of 200-fold for any taxation. So we actually are free from those taxations for drugs and for commodities and actually any services that are provided for the Emergency Plan. It's one of the advantages of doing this under the Foreign Assistance Act.

In terms of products and warehouses, that's actually not a problem anymore. We've actually supported a developmental supply chain management system. There was no supply system in most of these countries before. And now that we have a supply system built, it's not just for HIV/AIDS products. They're putting their malaria, TB and all their other products through this system as well.

We're negotiating lower prices. We now get the lowest price in the world, \$89 a year for the three-in-one combination through the system because we do bulk procurement. We have regional warehouses developed for the first time in Africa to avoid stock out. Stock out is actually more of a problem now because the programs are moving so rapidly. And now with this regional warehouse system we've avoided stock out, not only for us but also for multilaterals like the Global Fund.

It's really extraordinary. It's extraordinary what's happening in this way. So the progress at every level has been extraordinary, but we still have a lot to do. We've got a lot more to do. We've got a

lot to work on. But the progress here has been rather extraordinary.

Senator ENZI. Thank you. My time's expired.

The CHAIRMAN. Senator Brown.

Senator BROWN. Thank you, Mr. Chairman. Dr. Gerberding and Ambassador Dybul, thank you for all your work and all you do on international health issues and your infectious enthusiasm too, thank you for that.

I want to follow on Senator Enzi and Senator Kennedy's comments and questions about pregnant women. And the numbers that I have seen is that about one-sixth of new infections occur in children and yet children get significantly less antiretrovirals. Could you talk, either of you, talk that through what we need to do to make sure that in—and my understanding is in three-quarters of those children after being infected die likely at a very young age. But how do we address that, either of you?

Dr. GERBERDING. I'll start by just talking about again some important progress that's been made. They're acknowledging that we've got a lot of work to do to get children treatment options as good as they are for adults. Overall the FDA has tentatively approved or made available through our approval process 56 drugs.

And in August a combination pediatric drug tablet was approved, making it much easier to treat children.

Senator BROWN. Is this a different antiretroviral or just a low dosage?

Dr. GERBERDING. Two-in-one pill to make compliance and tablet taking—

Senator BROWN. Easier with the child.

Dr. GERBERDING. Much easier with the children.

Senator BROWN. But the same antiretroviral in a lower dosage but combining two-in-one.

Dr. GERBERDING. Exactly. Exactly. So we are all aware that's it's a tremendous need and in an area where we need to do more than we're doing right now. But we have made a lot of progress in some real tangible improvements in the ability to treat children. It's actually a problem in developing countries as well. It's just a little bit slower and takes a little bit longer to get the pediatric drug pipeline as robust as it is for the adults.

Ambassador DYBUL. I think there are multiple components here. We should also point out there's been success. I mean just in the past 6 months we've seen a 77 percent increase in the number of children we're supporting for treatment. So there is growth there.

But there are a couple of issues. One is the availability of drugs that are easy to use. The second is people who are trained. Adult doctors are generally, like myself, scared to death of children. And it takes a while to teach them to take care of children and to teach them how to do pediatric care and treatment because it's a little bit more complicated.

But one of the most important things is diagnosing the children. We don't have DNA testing yet available in many laboratories or RNA testing, looking for the virus itself. We look for the antibody that the human body creates to the virus. And that actually continues in the child for months after they're born if the mother was

infected. So it's very difficult to tell if a child is actually HIV positive without this testing.

But one of the things CDC is——

Senator BROWN. The child has the antibody whether or not he or she is——

Ambassador DYBUL. Could have, whether or not——

Senator BROWN [continuing]. Has positive HIV.

Ambassador DYBUL. But CDC—and we're supporting this national scale up in Namibia and Botswana and a number of countries to actually do the test that allows us to identify whether or not a child is positive. One of the things CDC is doing by building this laboratory capacity to do that. So we'll be able to identify the kids appropriately so that we can treat them.

But it's part of a cascade. On the other hand, we know it will succeed. There are hospitals for example in northern Kenya where 20 percent of the treatment is going for children in excess of the international goal of 15 percent. So we know it can be done we just need to do it.

But there are these steps and bottlenecks we need to overcome and it's one of the things we want to work on going forward.

Dr. GERBERDING. There's one other issue here that I neglected to mention that has to do with the nutritional status of children. Because when you're taking antiretroviral drugs it's very important that you have a decent level of nutrition. And so, the program does support, for people who meet criteria for malnourishment, to also provide food supplementation to help assure that when they take drugs, they're effective and the side effects are as low as possible.

Senator BROWN. Is it at all common that children infected with HIV at in vitro and then you treat, that they are carrying the tuberculosis bacteria too? Is that very common?

Dr. GERBERDING. It's very common for babies to acquire tuberculosis after birth.

Senator BROWN. After birth.

Dr. GERBERDING. After birth generally because they're held close to somebody who's coughing with tuberculosis and they're in the breathing zone of the people who are infectious and transmitting the bacteria. So it's almost impossible for a child in that situation not to catch tuberculosis if someone else in the home is infectious. Of course with HIV infection, if the parent has HIV they're much more likely to activate their tuberculosis and serve as a source of infection.

So it is a very important——

Senator BROWN. So many of these babies or small children are being treated for tuberculosis also at the same time?

Ambassador DYBUL. That is the goal and what is being worked on. It's not just for tuberculosis but for a number of other diseases as well. Malaria is a part of our program as well because young HIV positive children and mothers are actually—more for pregnant women—are more prone to malaria so we're working on combining malaria as well.

Malnutrition is an issue for the children. Also pneumocystis, one—some of the lung infections could be common in the young children. So that's why care is important, not just antiretrovirals.

Dr. GERBERDING. I don't want to take your time so, but there is just a vignette that I think illustrates what you're talking about so powerfully in my mind. I visited a hut out in Western Uganda where we were delivering drugs on motorcycles to people. You can't get it there any other way because there were no roads.

And in this household a woman was near death from HIV. And the first thing the CDC team gave her was a clean water vessel so that the family had decent drinking water. And then they diagnosed and treated her tuberculosis. And when you talk to her she says that that's the intervention that was the most life saving for her and helped her feel healthier so that she could go back to feeding her family.

Then she eventually got started on AIDS treatment. The family got bed nets. The children gained weight. The whole household benefited from our care and treatment intervention.

So we just don't treat the mother with the HIV. We're treating the whole family. Creating an environment where the whole family is healthier.

Senator BROWN. Could I just ask one more brief question, Mr. Chairman? I apologize.

As you talk about nutrition, you talk about HIV, you talk about TB with children, are you satisfied with the progress that the Global Health community is making on leaving a public health infrastructure behind as you do this? I mean, it seems you are doing a more comprehensive treatment than just taking care of their HIV. Are you making good progress that way?

Ambassador DYBUL. We're making good progress, but to be honest, if we're ever satisfied then I'm going to be worried. We can improve everything we're doing. And we need to improve this as well.

But I do think, and this is why I emphasize the fact that we're treating a chronic disease. Systems that never existed before are being built. Health systems are being created and they will last as long as we continue to support them. And so I wouldn't say we're satisfied, but we see a lot of progress and a lot of success. And that we need to build on.

Senator BROWN. Thank you. Thank you, Mr. Chairman.

Senator ISAKSON. Well, first of all being a Georgian, I just want to reiterate our great pride in being the home of CDC and our great pride in the work that Dr. Gerberding does. Thank you very much for what you do.

I had the privilege of being in Ethiopia in 2002 and ran into by accident in the back country of Owasa, Ethiopia, a CDC team. They were working in the early process of identifying what we could do and the work these people do when I heard you talk about delivering on motorcycle. If the average American could only see what might describe this testimony in terms of what a challenge you have in Africa. I commend you and your staff at CDC for all that you do, all of you over there.

Mr. Dybul, Ambassador Dybul, in your written—and I had to go for an interview so I missed part of the testimony. I apologize. But in your written testimony you say right now you're deploying about 46 percent into treatment and 29 percent of your funds into prevention. And then on the next page you say, "prevention is the bed-

rock of getting our arms around the epidemic.” And you talk about flexibility in funding.

Would you elaborate on that for me?

Ambassador DYBUL. Prevention, ultimately, is how we can tackle this epidemic right now. Unfortunately we don't have a vaccine or even a microbicide on the horizon. And while compassionate care and treatment is essential, ultimately we want to avoid new orphans. We want to avoid people that require care and treatment, both for humanitarian reason, but also for a cost reason.

Constantly keeping up with people or a new infection in care and treatment is something in terms of cost, but also in a health system. That's going to be very difficult to sustain. So we need to prevent infections. But you have to do it all together. And that's why I think it's so important. What this initiative did to integrate prevention, treatment and care was so critical. Because before, everyone was just talking about treatment or just talking about prevention, but care no one was talking about and still unfortunately are not. You got to do them all together.

And you won't have as good a prevention program if you don't have treatment. And you won't have as good a care program. And you won't have as good a prevention program. You've got to put it all together. That's public health. That's public health, you can't do it independently.

And so our budgetary allocations are determined largely by the countries with congressional guidance in terms of where we should be. That 29 percent includes counseling and testing. If you take counseling and testing out it's about 22 percent for our prevention activities.

You can't look at dollar amounts and say, “that's the priority.” You know, it's only 29 percent for prevention therefore prevention is less of a priority. The fact of the matter is that treatment is more expensive than most prevention interventions. Another reason it's important to focus on prevention.

So you can't look at the budgetary allocations and say, “there's your priority.” The priority is to have an integrated balance prevention, care and treatment program because that's good public health.

Senator ISAKSON. And I know this is going to be a hard question to answer, but this is just really an opinion but take before the program started, and take now, what percentage of those potentially infected, people who could potentially be infected, do you think we're now reaching with prevention programs and actually stopping from becoming infected. Is it 10 percent over what it was? Is it 20? What do you think?

Ambassador DYBUL. It's hard to say and it's different by country. We can say with treatment and we can say with prevention of mother-to-child transmission. We know that we've reached 61, more than 61 million people with prevention messages, but whether or not that led to behavior changes, something that we're just beginning to see.

Part of the problem—outside of prevention of mother-to-child transmission—as Dr. Gerberding mentioned, it's very difficult to track in the way we can report to you, in the last 6 months, the number of people received treatment because it's based on demographic health surveys which occur twice or three times over the

life of the emergency plan. But we are starting to see some tremendous signs of improvement.

Dr. Piot will be on the next panel and UNAIDS just reported on behavior changes that we're seeing in countries. In some countries that behavior change correlating with changes in infection rates. And those behaviors are delaying sexual debut, reducing your partner or abstinence, also secondary abstinence, people who were sexually active refraining from sexual activity. There's great data in Kenya for that. Reduction in numbers of partners, 50 percent of young men reducing casual partnerships. Some increase in condom use, but that doesn't mean the condoms don't work.

What it means is that we focused so much on that before—you know, what we're getting in terms of new people using them is less than some of the other behavior changes. So we're starting to see the behavior change that correlate with change. And so we're very optimistic. But we've got a lot of work to do.

Senator ISAKSON. My time's running out. But Dr. Gerberding, one quick question on the tuberculosis. Within the United States is there an increase in the incidents of tuberculosis in this country?

Dr. GERBERDING. There's not an increase in active tuberculosis in the country. In fact we have the lowest rate of tuberculosis ever, so that's very good news. What there is an increase in is the proportion of those cases that are drug resistant. And that's a very worrisome marker.

There's also an increase in the proportion of our cases in tuberculosis that were the result of people being infected elsewhere in the world and coming into the country. And that's a very, very important focus for us in terms of international tuberculosis control because we're beginning to see that drug resistance emerging in more and more parts of the world, not just in the AIDS areas, but in other parts of the world as well.

Senator ISAKSON. Thank you. My time is up.

The CHAIRMAN. Senator Allard.

Senator ALLARD. Mr. Chairman, thank you. I want to thank the witnesses for their testimony. And we also share some CDC facilities in Colorado.

Senator ISAKSON. That's right.

[Laughter.]

Senator ALLARD. And we're very proud of it. Vector-Borne Diseases and we're very proud of the workforce and the great job that they do there. We also recognize that the CDC lab, generally does a very good job and very much appreciate the work that you're doing.

I guess I want to look at this as little more than an epidemiological aspect. In those countries where there is an epidemic, what sort of risk do they pose to domestic populations in the United States or any country out there in the modern world, or currently how are they affecting it? And, in the future how could they have an impact on our populations, if any?

Dr. GERBERDING. Well, first of all AIDS or any other virus and bacteria doesn't appreciate borders and there's not a wall that will keep them out. I can guarantee that. And so we have to recognize that whatever promotes transmission within someone's country is

also capable of promoting transmission across that country and in ours.

In the case of HIV the major vector of transmission is sex. So any opportunity for people from different parts of the world to socialize and engage in risk behavior is an opportunity for the virus to be transmitted. We know that this is a global pandemic. And it got there because people move and the virus moves with them. And it can spread very quickly in populations that have high risk.

So I think the frame for CDC's work and you know as a veterinarian, our interest in zoonotic diseases, but the frame for this is a very good metaphor for the whole arena of infectious diseases today. It's a flat world. And it's very flat for viruses and bacteria that can spread far faster and quicker than we can develop vaccines or drugs to combat them.

Senator ALLARD. I've noticed in your budget—I was looking at some of the budget figures that we have there on the CDC lab. The question that comes to my mind is what proportion of your budget goes into testing?

Dr. GERBERDING. From a domestic perspective or the international?

Senator ALLARD. Well, let's talk about both perspectives, but I'm mainly—I mean this hearing is about the international perspective. So I'm particularly interested in the international perspective.

Dr. GERBERDING. You want to answer that for the international?

Ambassador DYBUL. You can start. You do a lot on that.

Dr. GERBERDING. The prevention budget is 33 percent and of that about 80 percent of that or so is for counseling and testing, for voluntary counseling and testing programs.

Senator ALLARD. So whenever you have a counseling session you automatically do a test?

Dr. GERBERDING. Well, that's—

Senator ALLARD. It's kind of hard to break. I'm trying to break this out a little better than which you did. Yeah.

Dr. GERBERDING. Yeah. First of all I am going to make sure that we make the point about testing, because the traditional model you had, to go in and have a very comprehensive, educational session and get informed consent and so forth before anyone could do a test, is not the only approach to getting people tested anymore. We thankfully—

Senator ALLARD. You're talking about in the United States now, domestic.

Dr. GERBERDING. Internationally as well.

Senator ALLARD. Oh, internationally, have the informed consent?

Dr. GERBERDING. Yeah, the CDC developed a pilot program in Kenya on provider initiated testing so that anytime someone comes in and has contact with the health care environment they're automatically encouraged to get a HIV test. And in some cases it's really an opt-out mechanism where it's done unless the person says, "no," I don't want to have the test done which is exactly what we're trying to do here in the United States. And the States are slowly changing their laws so that we can accomplish that.

So the Ambassador talks about A, B, C, but I like to talk about A, B, C, D because I think D, the diagnostic testing is absolutely

critical to solving this problem anywhere in the world, including in the United States. And we need to be doing a lot more of that.

Ambassador DYBUL. Over the last several years many of the countries have adopted these opt-out approaches. They're not always implemented to the full extent. But where they are implemented is tremendously successful.

Some Presidents and leaders are really coming to this. Mrs. Bush proposed an international testing day which was adopted by the United Nations on this topic. President Kikwete in Tanzania has been publicly tested. Ethiopia is reporting a quintupling of numbers of people being tested.

So these opt-out approaches are being widespread—being moved in a wide way and it's having a very important impact. The reason for it is likely because treatment is available. As in this country 20 years ago, people won't go in to get tested if it's a death sentence and there's nothing they can do about it. The availability of treatment, the Lazarus Effect that people talk about—

Senator ALLARD. That leads to my next question. Push on because my time's running out here.

How much of your budget goes toward research? I mean it seems like there's a real research need. I'm trying to get a handle on how much research is done in the private sector companies and everything that might be developing products, how much you would be doing in the communal disease center on understanding vaccines and how they act with maybe some particular types of medications that wouldn't be effective on treatment.

Dr. GERBERDING. Let me really emphasize the point that in my opinion not enough of the learn-as-you-go kind of research is being done. But many of the things that have led to success in this program occurred because we were able to do field work to evaluate them and then disseminate those innovations to the other program countries. But we are not doing enough so that we've got a lot of questions about practical on the ground things that we're doing that we need answers to.

There's also an investment in the NIH in some of the more basic research. That's not part of the PEPFAR program dollars. That money is separate and it needs to be separate in my opinion because it really provides the foundation that leads to the development of drugs and vaccines. And that's going on in a very robust way. Of course Dr. Fauci is the best person to describe that work.

And then we do have the flexibility within the PEPFAR program to do some evaluation of our success and to try to understand why is it working here and why isn't it working there. But we need to continue to have that flexibility because the worst possible outcome is that we would make a macro investment in a set of interventions and never know for sure which of them was the most powerful or the most important or which of the ones weren't really contributing at all. So we've got to have that learn-as-you-go research capability.

Ambassador DYBUL. About 3 percent of our current budget goes for that activity, but to be honest we're not doing a good job. And we've created a new approach called Public Health Evaluation to have an integrated approach that asks those important questions. What is it we need to know to affect our programs? And it's just begun. We've actually detailed someone from CDC and NIH to our

office to help put this together. But I think it will be a very important approach going forward.

Senator ALLARD. Thank you. Thank you, Mr. Chairman.

Senator COBURN. Thank you, Mr. Chairman. And I want to personally thank each of you for your dedication and service to our country. Tough jobs.

I'm excited to hear about what we're doing on infrastructure and how the CDC is helping guide that because we can offer treatments, but if we don't have infrastructure to do it we'll never get there. I'm also extremely appreciative of you, Ambassador Dybul, for your balanced approach and how you look at it. I think you're a great representative for us in terms of how the world views you, your plain spokenness comes across with compassion combined with it and I think you're a great representative for our Nation and what we're trying to do.

I have some real concerns, as we reauthorize this, that we make sure prevention is our key. We've decided to treat, but even if we're highly successful with treatment, if we don't markedly slow down new cases then we won't have the finances and neither will the world to actually make a difference in so many Africans lives. And it really is too early to know, you know, what the effect of delayed sexual debut is going to be and truly abstinence and secondary abstinence. We don't know that yet because it's too early in the program.

And you testified that we need all three of the components and I would really agree with you. My worry is the Lugar bill doesn't have any minimum requirement in it. You know, it's not solid. There's no requirement for an abstinence portion or a secondary abstinence or delayed sexual debuts.

And my concern is where we were versus where we go and I don't want to see us go back the other way. And we're not the only ones that are participating in this spot. We are, though, very significantly the leaders in terms of trying to prevent through sexual delay, debut, as well as abstinence, as well as secondary abstinence and fidelity with that.

And so my concern comes is if we take away these minimums, not just on abstinence but also on a percentage of the amount of money that actually has to go for treatment. And I know this is a changing picture for you. What kind of assurance can you give me that we're not going to fall back to the same thing where we're advertising condoms only and this is the solution? Where, in fact, that's not the solution, it's a part of the solution. Can you give me some reassurance on that?

Ambassador DYBUL. Yes and we actually would strongly favor a minimum standard in terms of resource allocation and for a comprehensive approach. You know the language Senator Lugar's proposing again. You know this needs to be a bipartisan, bicameral approach. But there actually is a percent there. It's at least 50 percent of resources dedicated to sexual transmission need to go for the A B component. So it is to ensure it's comprehensive, and A, B, and C is the mechanism we discussed.

And the 33 percent currently needs to be applied to prevention of mother-to-child transmission and safe blood activities because

it's 33 percent of all prevention and that didn't seem to make a great—

Senator COBURN. Yes, I agree with you.

Ambassador DYBUL. So now it is applied only to those resources dedicated to sexual transmission, but it does have a minimum requirement there of at least 50 percent and we do believe that's necessary. I'm not sure in 5 more years it will be necessary because so much progress has been made. There are so many data out there on the effectiveness of these approaches in generalized epidemics.

But for the moment we do think we need to maintain that to ensure that we do have a comprehensive program going forward.

Senator COBURN. Yeah, my staff tells me there's no absolute requirement on allocations in the Lugar bill. So I'll be happy to help you with it and we'll work on that and I'll work with Senator Lugar on that.

Dr. Gerberding, working to increase voluntary testing and counseling in the focus countries, do we know what the rate of return is on clients who get tested and then come back to find out the results?

Dr. GERBERDING. Well.

Senator COBURN. Or are we using all rapid testing now?

Dr. GERBERDING. We are trying to move in the direction of rapid testing for exactly the reason that you've described and that is just get instant results back.

Senator COBURN. We don't know the data on that though right now where we're not using rapid testing? Do we know that, Ambassador Dybul?

Ambassador DYBUL. We do and this is in our annual report. Most countries now have adopted a rapid test approach on paper. It's just implementing it. And many have moved toward it but not effectively.

One of the things we're seeing is people are doing rapid tests but then they're drawing blood for the rapid test and they're sending it to the lab technician. So they're using technically on paper our rapid test, but they're not actually implementing a rapid test. Elizabeth Marum from CDC actually says that's like using a mobile phone but keeping it plugged into the wall.

I mean, so you need to actually move toward implementing the rapid test where you're doing a finger stick rather than drawing blood and you're allowing a lay counselor to do it. Also nurses are still doing a lot. Nurses don't need to be doing this. We could increase health care capacity tomorrow by allowing lay counselors to do this.

Now I don't want to get too severe there because we also want a comprehensive approach. Sometimes they draw blood so they can do syphilis testing and other testing as well. So you have to be balanced in it and I don't want to get too far one way. But countries are moving there. We need to keep pushing them to move there.

And that's why for these partnerships compacts this is one thing we want to work on the countries with. This is something we need to be doing.

Senator COBURN. Yes. Ok, right.

Dr. Gerberding, you're here on behalf of all HHS efforts and not just CDC. This question really is for you. The Global Fund shares

administrative links with the World Health Organization which is part of the United Nations system. The U.N. system is un-transparent at best and one of the things we'd like to see is transparency because we know that leads to accountability. And at worst it's corrupt.

The U.N.'s own auditors found that 40 percent of all U.N. procurement is tainted by fraud and corruption. That's \$4 out of every \$10. Given this record I think it's important that our efforts through the Global Fund establish administrative and financial independence from the U.N. Is there any plan to sever that link with the U.N. so that we don't have the potential, and I'm not saying we're actually doing that, but have the potential to have 40 percent of what we're doing through the Global Fund defrauded or corrupted?

Ambassador DYBUL. I can probably answer that. I happen to be the Chair of the Finance and Audit Committee of the Global Fund Board.

[Laughter.]

Senator COBURN. Oh, great.

Ambassador DYBUL. Yes. And this is an area the United States has cared about deeply. And, in fact, at the last board meeting, strongly from U.S. efforts, we have an agreement that the administrative services agreement with the World Health Organization will end by December 31 of next year. And there's a process that this committee is following to have that occur. So that's a decision that the board took and the full separation will be complete by the end of next year.

Senator COBURN. In terms of the nations where the primary recipient, the principle recipient ends up being a government agency, where do we see the transparency with that versus others?

Ambassador DYBUL. Well, this is an issue and has been in development for quite a while and one of the other things that is being worked on is enhancing those transparency and accountability measures. Currently the Global Fund has local funding agents that monitor flow of resources. Another thing the board has decided to do is to beef up those local fund agents and go deeper with them.

We also just hired an inspector general who will be in charge and with a fully staffed office that will be charged with looking at these. Unfortunately it's not just governmental agencies that sometimes have problems, sometimes it's nongovernmental agencies too. So we need to keep a watchful eye. The American people need to know their tax dollars, both for bilateral and multilateral, are going to good use.

Senator COBURN. Mr. Chairman, could I have the privilege of just asking one short question? Would you think that it would be prudent that the money that the Federal Government, our government, gives to the Global Fund be conditioned on the fact that the purchasing and contracting be transparent within that fund?

Ambassador DYBUL. Well there's no question that all purchasing needs to be transparent. And it would depend on how that is developed, but I think we do need to have transparency and accountability for everything, not just purchasing but for everything, grant making, everything. And we need to do it in our own program.

Senator COBURN. So you would be supportive of the funds being conditioned on the fact that we have transparency that will lead to accountability? This year, as a matter of fact this week, we're going to announce all the transparency for this government. It's actually coming online, on time, and when we require that of our funds that we spend within our government here, it's actually by law, mandated, that the Global Fund will do that too, to be in compliance with the Federal Financial Accountability and Transparency Act.

We should have that and how we do it. I think we can do it in a manner that does not disrupt but at the same time gives transparency that leads to accountability. And I'd be very hopeful that you'd support those efforts. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you. Thanks very much. On the transparency, I think all of us are mindful that we haven't had that as much and certainly at the Defense Department area over the period of recent years that we're all very mindful of. So it is something the American people want and need and deserve.

You've been a terrific, a great panel. And I think all of us have additional kinds of questions—but we have some other witnesses as well. But I would like to ask you, if you can, to remain. We have four other witnesses and we want to try and get some interchange here. I know you've got schedules to do but this has been enormously helpful. And if you can remain with us we'd be grateful. I don't know whether you feel that you have to depart.

Ambassador DYBUL. Unfortunately, I think we probably do. But thank you for the kind offer. You have a wonderful panel. We wouldn't want to interfere with their—

The CHAIRMAN. Well you leave that up to us. If you have to depart, you can depart. But we make our judgments on that.

We'll submit some other questions to you.

Ambassador DYBUL. Thank you.

The CHAIRMAN. Thank you very much.

We'll ask Princess Zulu, Kasune Zulu is it, if she would come forward, if the witnesses come forward as we mention them, is a native of Zambia, has been a HIV/AIDS advocate and educator for World Vision HIV and AIDS Hope Initiative since 2001. After losing both parents to AIDS by the time she was 17, Zulu herself tested positive in 1997. In 2003 Zulu was part of a delegation to the White House Oval Office that met with President Bush, former Secretary of State Colin Powell convincing the U.S. government to commit \$15 billion to the AIDS epidemic in Sub-Saharan Africa.

Norman Hearst, Dr. Hearst is a professor of family community medicine, epidemiology and biostatistics at University of California San Francisco, School of Medicine. Dr. Hearst has worked extensively on HIV, epidemiology and prevention in the developing world especially Latin America. His other areas of international health experience include health sector reform and research capacity development.

Dr. Helen Smits, Vice Chair of the Institute of Medicine's Evaluation Implementation Phase of PEPFAR released in March of this year. Prior to this, Dr. Smits taught a Master's of Public Health program in Mozambique, during her 3 years in Mozambique she also served as a volunteer at the Clinton Foundation HIV/AIDS Initiative, and participated in the first AIDS treatment plan. In the

United States, Dr. Smits held the position of Deputy Administrator Chief Medical Officer of the Health Care Financing Administration, known as CMS, during President Clinton's term.

And then Dr. Piot, Executive Director of UNAIDS and since its creation in 1995 and under Secretary General of the United Nations, Dr. Piot has challenged world leaders to view AIDS in the context of social economic development as well as security. Collaborative effort, Dr. Piot launched in Zaire in the 1980s was the first international project on AIDS in Africa, widely acknowledged as having provided the foundation of understanding of HIV/AIDS infection in Africa.

So this is a very distinguished group. We'll start off with Princess Zulu. And then go to Dr. Hearst and then Helen Smits and then Peter Piot. Go in that order, please.

**STATEMENT OF PRINCESS KASUNE ZULU, HIV/AIDS
EDUCATOR, WORLD VISION, FEDERAL WAY, WASHINGTON, DC.**

Ms. ZULU. Good morning. My name is Princess Kasune Zulu and I work with World Vision as a child advocate. World Vision is nearly 100 countries in the world and it is a Christian humanitarian organization.

The CHAIRMAN. Princess Zulu, the acoustics in here, I was trying to listen carefully to our other—the echoing and all the rest, so I want to make sure we hear. I'm trying to listen carefully to every word on our last panel. So would you just speak just a tiny bit slower so—

Ms. ZULU. Ok.

The CHAIRMAN. At least I'll be able to hear? There's a lot of echo. This is a magnificent room, but once in a while we miss an important panel. And we look forward to hearing from you. Thank you.

Ms. ZULU. Thank you, Mr. Chair. Like I said my name is Princess Kasune Zulu and I'm excited to be here. I'm a child advocate for World Vision. And World Vision is a Christian humanitarian organization working in nearly 100 countries in the world. Thank you, Mr. Chair for holding this hearing today. And thank you to all that the U.S. government is doing in fighting the global AIDS.

HIV and AIDS is very personal to me. At the age of 17 I had already lost both of my parents to HIV and AIDS, as well as two siblings. I was then left to care for eight other children in Zambia, three of them being my siblings, three being my cousins as well as two of my nephews.

I then tested HIV positive in Zambia in 1997. I decided to go public about my HIV status as to break the silence, the stigma and the discrimination attached to people living with HIV and AIDS. But I also knew that it was important to raise the awareness so I went to schools, churches and other businesses.

Global AIDS has a major impact on children everyday. Thousands of children lose a parent due to HIV and AIDS. Worldwide 15 million children have been orphaned due to HIV and AIDS. Either they have lost one parent or both due to AIDS.

It is for this reason that World Vision strongly supports the reauthorization of the Global bill as well as continued provision of 10 percent of the resources be allocated directly to the care of orphans

and vulnerable children. Thank you for having me and I look forward to our discussion this morning. Thank you.

[The prepared statement of Ms. Zulu follows:]

PREPARED STATEMENT OF PRINCESS KASUNE ZULU

Good morning. It is a pleasure to be with you today. My name is Princess Kasune Zulu and I work with World Vision as an advocate for children. World Vision is a Christian humanitarian organization dedicated to working with children, families and their communities worldwide to reach their full potential by tackling the causes of poverty and injustice. World Vision has programs in nearly 100 countries with 5 million donors, supporters, and volunteers in the United States. Today, World Vision runs AIDS prevention and care programs in more than 60 countries.

First, I want to say thank you to the Senators on this important committee, the full U.S. Congress, and President Bush for your leadership on Global AIDS. The President's Emergency Plan for AIDS Relief is saving lives. It is a holistic approach focusing on treatment, prevention and care. However, more needs to be done to fight the AIDS pandemic.

Global AIDS is very real to me. By the time I was 17, I had lost both of my parents and a baby sister to AIDS-related illnesses. I was left alone in Zambia to care for nine children—four younger siblings, three of my cousins and two nephews. I tested positive for HIV infection in 1997. At that time in Zambia, AIDS was rarely discussed and it carried a heavy stigma, yet I went public with my diagnosis. I launched a campaign to educate other Zambians about AIDS. I spoke to truckers, gave seminars to businesses and worked with churches and schools. I even hosted my own national radio show in Zambia to educate people about the dangers of AIDS. It was called "Positive Living" and received an award from the U.S. Embassy in Zambia for excellence in broadcasting on HIV and AIDS.

Global AIDS is having a major impact on children. Every day thousands of children lose a parent to AIDS. Worldwide, more than 15 million children have lost one or both parents to AIDS. World Vision supports continuing the requirement which was included in Public Law 108-25, "The United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003," to require that 10 percent of all resources in this act are directed to the care of orphans and vulnerable children. World Vision strongly supports the reauthorization of the Global AIDS, TB and Malaria bill. Congress must act on this legislation quickly to ensure continuation of the life-saving global AIDS programs. Congress must also ensure that adequate resources are provided so the United States can hold up its end of the promise all G8 leaders made in 2005 to provide universal access to AIDS treatment, prevention and care by 2010.

I will be glad to elaborate more with the committee during the question and answer session on the real-life challenges that exist in Africa for children, women and families responding to the devastation of AIDS. I look forward to our discussion.

The CHAIRMAN. Alright.

Dr. Hearst.

**STATEMENT OF DR. NORMAN HEARST, PROFESSOR,
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, CALIFORNIA**

Dr. HEARST. Thank you, Mr. Chairman. PEPFAR II is all about sustainability and that has to mean prevention despite all the progress we're making and the tremendous efforts being made, people continue to get infected in Africa much more quickly than we can get them onto treatment. We cannot treat our way out of this epidemic.

Like many people, I used to believe that condoms would be the key to prevention in the generalized AIDS epidemic that ravaged many African countries, but experience has proven otherwise. Unfortunately, the condoms first approach used for so many years simply hasn't worked. What has worked in Africa, first in Uganda and now elsewhere is when people change their sexual behavior.

I'm here today to encourage you to make sure that PEPFAR II maintains and strengthens its focus on promoting healthy sexual

behavior. We must avoid the easy trap that so many AIDS programs fall into of putting all of their money into the same old strategies that haven't worked in Africa. Similarly we can't be distracted by those who in the name of A, B, C-plus would siphon off AIDS prevention dollars to whatever other good cause they're promoting. I go into more detail about this in my written testimony and I look forward to our discussion.

[The prepared statement of Dr. Hearst follows:]

PREPARED STATEMENT OF NORMAN HEARST, M.D., MPH

We're here today to talk about making PEPFAR sustainable, and the key to sustainability must be prevention. We cannot treat our way out of this epidemic. Even now, five people are being infected with HIV in Africa for every one starting treatment. And treatment or not, these people will die of AIDS.

For prevention, it's fundamental to distinguish between "concentrated" and "generalized" HIV epidemics. These are different situations that require very different strategies. In most countries, HIV is mainly transmitted in high risk settings and groups, including men who have sex with men, injecting drug users, and commercial sex, so that's where you need to do prevention.

But in generalized epidemics, transmission is widespread in the heterosexual population, so you can't focus only on high risk groups. Just a few countries in eastern and southern Africa have this pattern. But these countries, because of their very high infection rates, account for most of the world's HIV infections. Most PEPFAR priority countries have generalized epidemics.

Five years ago, I was commissioned by UNAIDS to conduct a technical review of how well condoms have worked for AIDS prevention in the developing world. My associates and I collected mountains of data, and here's what we found.

First, condoms are 85–90 percent effective for preventing HIV transmission when used consistently. We then looked at whether condom promotion has been successful as a *public health* strategy—something very different from *individual* effectiveness. Here we found good evidence for effectiveness in concentrated epidemics. For example, condoms made an important contribution to controlling HIV among gay men in places like San Francisco and epidemics driven by commercial sex in places like Thailand.

We then looked for evidence of a public health impact for condoms in generalized epidemics. To our surprise, we couldn't find any. No generalized HIV epidemic has ever been rolled back by a prevention strategy based primarily on condoms. Instead, the few successes in turning around generalized HIV epidemics, such as in Uganda, were achieved not through condoms but by getting people to change their sexual behavior.

UNAIDS did not publish the results of our review, but we did ourselves. I would like to have the following article entered into the record: Hearst N, Chen S. Condoms for AIDS Prevention in the Developing World: Is It Working? *Studies in Family Planning* 2004;35:39–47 (see <http://www.usp.br/nepaids/condom.pdf>).

These are not just our conclusions. A recent consensus statement in *The Lancet* was endorsed by 150 AIDS experts, including Nobel laureates, the president of Uganda, and officials of most international AIDS organizations. This statement endorses the ABC approach to AIDS prevention: Abstinence, *Be* faithful, and Condoms. It goes further. It says that in generalized epidemics, the priority for adults should be B (limiting one's number of partners). The priority for young people should be A (not starting sexual activity too soon). C (condoms) should be the main emphasis only in settings of concentrated transmission, like commercial sex. I also ask that this article be entered into the record: Halperin DT, Steiner MJ, Cassell MM, Green EC, Hearst N, Kirby D, Gayle HD, Cates W. The time has come for common ground on preventing sexual transmission of HIV. *Lancet* 2004; 364: 1913–1915 (see <http://www.thelancet.com/journals/lancet/article/PIIS0140673604174874/fulltext>).

PEPFAR follows this ABC approach. Last year, I was on a team reviewing PEPFAR's prevention activities in three African countries for the Office of the Global AIDS Coordinator. We found a strong portfolio of prevention activities that mixed A, B, and C (though, in my opinion, probably not enough B). This contrasted with other funders that often officially endorse ABC but in practice continue to put their money into the same old strategies that have been so unsuccessful in Africa for the past 15 years: condoms, HIV testing, and treating other sexually transmitted infections.

One might ask why they continue to do this despite all the evidence. It's difficult to convey the tremendous inertia for doing the same old things. First, they're relatively easy to do. Second, many of the implementing organizations and individuals have backgrounds in family planning. They're good at distributing condoms and providing clinical services but may have no idea how to get people to change sexual behavior. Third, decisions are often made by expatriates and westernized locals trained in rich countries who have internalized prevention models from concentrated epidemics. Finally, if you try to do everything, expensive clinical services quickly eat up budgets, leaving little for the critical A and B of ABC.

Let me close with a warning regarding talk about "ABC-plus" or "moving beyond ABC" and diverting AIDS prevention funding to whatever other good cause people are promoting. Always ask, "Where is the evidence?" For example, I'm all in favor of poverty alleviation. But in most countries with generalized epidemics, the rich have higher HIV infection rates than the poor. I ask that the following article which documents this be entered into the record: Mishra V, Assche SB, Greener R, et al. HIV infection does not disproportionately affect the poorer in sub-Saharan Africa. *AIDS* 2007; 21 (suppl 7): S17-S28 (see <http://www.ncbi.nlm.nih.gov/pubmed/18040161>).

Similarly, for gender equity, many of the African countries with the best records in this regard (like Botswana) have the highest rates of HIV infection. The question here is not whether poverty alleviation, treating STI's, and improving the status of women are important. Of course they are. The question is whether they are where we should put our limited AIDS prevention dollars. This decision needs to be based on evidence of effectiveness, not facile sociologic arguments. Are there credible scientific studies showing proof that poverty alleviation programs reduce HIV transmission? There are none. Are there specific examples of programs to improve the status of women that resulted in reduced rates of HIV? There are none. Are there randomized controlled trials showing that treating STI's reduces HIV transmission? There is one, but there are five others that showed no such effect.

PEPFAR must instead put its money into strategies that have been proven to be effective. The most notable of these was the home-grown Ugandan "Zero Grazing" approach. When Ugandans decided to tackle their AIDS problem head on in the late 1980s, they did not say, "We must alleviate poverty before we can control AIDS," or "We must improve the status of women before we can fight AIDS." Instead, they took a common sense approach based on the knowledge that HIV is sexually transmitted. They mobilized all sectors of society to get people to change their sexual behavior, and they succeeded with little outside help and very limited funding.

PEPFAR has been a leader among international AIDS prevention programs by truly putting its money into ABC and not just giving it lip service while spending most of its prevention budget on other things. It would be foolish to change this without clear evidence that other approaches are more effective, not just emotional arguments that would divert energy and funding in unproven directions. Anything that dilutes the focus of AIDS prevention in Africa from changing sexual behavior may do more harm than good.

The CHAIRMAN. Very fine.
Dr. Smits.

**STATEMENT OF DR. HELEN SMITS, VICE CHAIR, IOM
EVALUATION COMMITTEE, WASHINGTON, DC.**

Dr. SMITS. I'm Dr. Helen Smits. I served as Vice Chair to the Institute of Medicine Committee. I'd like to start by thanking the large multinational committee that I worked with for all their efforts, as well as the staff at the Institute of Medicine. This was a big report and people worked very hard on it.

We visited 13 of the 15 focus countries and did extensive telephone interviews with the other two. Those were remarkable visits for me. I told people I was evaluating, but people thanked me. It was amazing. People sang. They danced. They gave us presents. Sometimes we had to give them back.

There is enormous appreciation and I would like to bring that appreciation back to the members of this committee. People really see what we've done. And they thank us for it.

I was also very impressed to meet some of the African leaders who are devoting their lives to fighting this epidemic. They're ready to do a good job. And we have given them resources to help them.

The Institute of Medicine came up with a series of recommendations about a future PEPFAR, that is integrated, that's sustainable, that's highly flexible to be able to respond to the differences across the countries and also to the differences in inside countries over time. I heard a very interesting speech by the head—at the implementers meeting by the head of Uganda's AIDS effort and we should talk about that later in terms of what he now sees as what he needs in prevention.

Our recommendation to the Congress is to support that sustainability and flexibility by eliminating all earmarks but substituting accountability. We are not suggesting you just hand off the money, but rather that you work with the agencies to set goals for areas that you're particularly concerned about such as the children.

So, thank you for the chance to be here. I've always enjoyed talking about this work. And I'm looking forward to the discussion.*

The CHAIRMAN. Fine.

Dr. Piot.

**STATEMENT OF DR. PETER PIOT, EXECUTIVE DIRECTOR,
UNAIDS, SWITZERLAND**

Dr. PIOT. Thank you, Mr. Chairman. I'm Peter Piot and I'm heading UNAIDS which is coordinating the AIDS efforts of the U.N. system from the World Bank, UNICEF to the World Health Organization and thereby also spearheading U.N. reform and maximizing our effectiveness.

We're supporting country's efforts on AIDS. We've got staff on the ground in 81 countries. And our mantra is making the money work for people. All the money that is there for AIDS, to make sure it is getting there where it is making a difference.

I would like really to thank you for U.S. leadership. It can't be said enough that PEPFAR has really changed completely the landscape and the response to AIDS in the world and it is making a measureable difference. And we're starting to see a return on the investment, meaning we're entering a new phase.

And PEPFAR reauthorization is an opportunity to keep the momentum, not only for the United States, but also for other countries. Because what you will decide here will set a trend for other countries. Other western countries as PEPFAR I has done because other dominations have followed that trend.

Finally let me mention three things for your consideration when reauthorizing PEPFAR. The first one is to build on PEPFAR's success. Along the same lines, increase the resources, commensurate with the magnitude of the challenge and in keeping with strong U.S. leadership.

Second as mentioned by many others, add a sustainability strategy to the current emergency, the E in PEPFAR. But there's still a crisis. Let's not forget the 5,800 people dying every single day.

*The prepared statement submitted by Dr. Smits regarding "PEPFAR Implementation: Progress and Promise" can be viewed on the following Web site: <http://www.nap.edu/catalog/11905.html>.

But it means also a better balance between prevention and treatment and more investments to strengthen health care systems, and human resources for community-based organizations.

And third, to maximize our collective effectiveness of these investments through increased partnership and coordination. Thank you, Mr. Chair.

[The prepared statement of Dr. Piot follows:]

PREPARED STATEMENT OF PETER PIOT, M.D., PH.D.

My name is Peter Piot and I am executive director of UNAIDS. Thank you for inviting me to testify today before the Senate Health, Education, Labor, and Pensions Committee about the HIV/AIDS epidemic, the work of UNAIDS to address this epidemic, and the critical difference that PEPFAR has made in the global fight against HIV/AIDS.

A quarter of a century into this epidemic, we are at a critical juncture. It is a turning point that beckons us to not only manage the urgent and daily emergencies presented by the epidemic—but also forces us to take a long-term view and to establish a sustainable response.

According to our most recent UNAIDS figures, there are an estimated 33.2 million people living with HIV. Each day, there are more than 6,800 new infections and over 5,700 people die of AIDS.

The encouraging news is that HIV prevalence has been leveling off, and is declining in Sub-Saharan Africa. That's a real tribute to the significant investment that the G-8 countries, led by the extraordinary commitment of the United States, have made in prevention, care and treatment.

Yet, while the prevalence is leveling off, the sheer number of people in the world living with HIV continues to increase. Moreover, AIDS is still a leading global cause of mortality, and remains the primary cause of death in Sub-Saharan Africa.

Prevention and treatment efforts that save lives still remain available to only a small percentage of those who need it. Both new infections and early deaths are preventable if the global community continues its commitment to scaling up essential prevention, treatment, care and support efforts worldwide. Even the most conservative resource need estimates demonstrate that the global need far outpaces the global response to it.

It's important to take a moment and note a few trends of the epidemic. First, the epidemic is still expanding. In fact, it is globalizing. This disease, a disease that was not even known 26 years ago, is now the fourth cause of death in the world; the fourth cause after heart disease, stroke, and respiratory illness. This is clearly not a marginal phenomenon.

Second, there is the feminization of the epidemic. In every single region in the world, including here in the United States, the proportion of women among those who are becoming infected with HIV is increasing. Half of those living with HIV today are women. Globally, 15.4 million women are currently living with HIV. In Sub-Saharan Africa, approximately 61 percent of people living with HIV are women. In the United States, AIDS is now the leading cause of death for African-American women ages 25-34. In hard hit areas, AIDS is undoing any development gains for women and girls.

Third, we're seeing a tremendous human and social capital loss in the worse affected countries as a result of this epidemic. I refer to it as reverse development or un-development. We estimate that by 2010 the five most affected countries in Africa will have lost about one in five workers due to AIDS. Some sectors that drive national economies are really reaching the crisis point. For example, the mining industry in Botswana loses more than 8 percent of its profits every year because of costs related to HIV. And in the tourism industry in Zambia, which is one of the future assets of the country, HIV-related costs total nearly 11 percent every year.

And there is also the absolutely devastating human toll. The numbers of orphans, of vulnerable children in Africa and elsewhere, remains unacceptable. For example, 19 million orphans and vulnerable children will need our help by 2010.

When we look at these trends, it is fair to say that we have a good understanding of the biological drivers—the virology of the disease. However, the societal drivers, which are basically the reason that we have this epidemic, have not been studied that well. And unlike what is often said, AIDS is not just a disease of poverty; AIDS is a disease of inequality, gender inequality being the most striking. When you look at HIV infection rates by income, it's the highest income in most African countries that have had the highest HIV rates. That is very unlike any other health problem.

When you look at maternal mortality, child mortality and similar global health challenges, there's a direct link with low income and poverty, but that's simply less true for AIDS.

Economic inequality, social inequality, marginalization of groups because of sexual orientation or drug use or other factors; immigrants, gender inequality, lack of access to service—all of this has created a perfect storm. A perfect storm that sets AIDS apart from other health issues. A perfect storm that forces us to design strategies that directly meet the challenges of this epidemic.

And the AIDS community has worked hard to design and implement country-driven, country-specific strategies. That's why I feel that we are at a real turning point—a real time for hope. And it's evidence-based or evidence-informed hope; it's not just something that we wish will happen, or had happened. It's supported by facts. An estimated 2.5 million people are on antiretroviral therapy today in the developing world. Just 6 years ago, when the United Nations held an historic special session in the General Assembly on AIDS, only about 100,000 men and women were receiving antiretroviral therapy in the developing world. Most of these individuals receiving treatment were men living in Brazil because it was the first country in the developing world to offer treatment at state expense.

We're also starting to see the impressive results of prevention efforts. Prevalence is leveling off. In Uganda, we are beginning to witness a reversal in some communities, just as we are seeing it in gay communities in Western Europe. This is the first time in the history of this epidemic that we're seeing these kinds of real results on such a large scale.

A less well known, but equally important development is that investments in the fight against AIDS are having a measurable impact beyond AIDS. A recent study done by FHI in Rwanda shows that primary health care centers where basic AIDS activities were introduced, have seen a much higher coverage and uptake of services beyond AIDS—particularly maternal and child health services and family planning services.

We're also seeing for the first time that there are investments in programs on violence, particularly sexual violence, against women. This issue predates by far the AIDS epidemic, but had received very little attention with the exception of small microfinance programs. So in many cases, it's the first time that longstanding issues have been given some serious investments, and in that sense, work on AIDS is opening many doors for development.

All of this is positive news, but also reminds us that we cannot become complacent in our early successes. All of the lives saved are the direct result of the significant increase in the world's commitment to fighting AIDS. When UNAIDS began its work in 1996, about \$250 million was spent on AIDS in developing countries. This year, we estimate that the global investment in this effort will be about \$10 billion total in the world.

There is no doubt that the most significant infusion of leadership, commitment, and resources has come from the United States, through PEPFAR. U.S. leadership has truly transformed the global response to AIDS and the course of the epidemic. It has enabled all of us to make a qualitative and quantum leap forward.

At the 2005 G8 summit at Gleneagles, the leaders of the most powerful economies of the world made a commitment that was incredibly bold, to come as close as possible, as the text said, to universal access to HIV prevention, treatment, care and support. And that was affirmed later by the General Assembly of the U.N., and is really our ultimate goal. We cannot rest until the last person living with HIV has access to treatment. We cannot rest until we're reaching everybody with prevention activities, and transmission is stopped.

This needs to be our mission, but we have a lot of work to do if we are to truly achieve this mission. At the current pace, there will be fewer than 5 million people on treatment by 2010; just over half of the people who will need it. And when you look at coverage of mother-to-child transmission prevention programs, they are extremely low in many countries with the exception of Botswana which is, thankfully, doing remarkably well.

So, what does this all mean for PEPFAR? Simply put, just as we are at a turning point in the fight against AIDS, we are also at a turning point in the world's response to AIDS. We are at a point where we must acknowledge that AIDS is not just a short-term emergency, but also a long-term crisis that will require serious commitment and serious resources for decades, not years, to come.

We have reached the point where we must ensure that everything we do contributes to an effective response that can be sustained over the longer term. This means taking a cold hard look at what we are doing, dropping what doesn't work and consolidating and scaling up what does.

And it also means that we must continue to make needed investments. It is not an understatement to say that we wouldn't be where we are today without the commitment and leadership of the United States.

Reauthorizing PEPFAR is critical because PEPFAR is making a real difference. In looking ahead to reauthorization, UNAIDS offers three overarching recommendations:

- **Promote a truly global effort supported by bold new investments.** This means building on PEPFAR I successes, increasing resources commensurate with the magnitude of the challenge and ensuring the strong leadership of the United States. It means continuing support to "focus countries" and expanding support in other parts of the world where significant and high yield opportunities exist.

- **Move from an Emergency to a Sustainability Strategy.** We must support a country-driven and flexible approach that allows for an enhanced focus on *prevention* while also strengthening health care delivery systems, human resource capacity, and local community-based service organizations. We must also break down implementation barriers and bottlenecks to getting the job done by supporting reform of legal and regulatory processes and policies, as well as research and development to accelerate access to affordable and high quality commodities, medicines, and diagnostics.

- **Maximize effectiveness of investments through partnership and coordination.** At UNAIDS, we call this "Make the Money Work."

Our recommendations are largely based on some extensive surveys that we had with our field operations. On the first point of supporting bold new investments, let's look at where we are. This year, approximately \$10 billion will be spent. While that's a considerable investment, it's only slightly more than half of the global need. If we are going to achieve universal access to HIV prevention, treatment, care, we will need a major increase in funds.

In terms of PEPFAR Reauthorization, President Bush has requested \$30 billion. That is definitely a very generous proposed investment. But given that the United States will likely contribute more than \$5.5 billion this year, quite frankly, greater increases will be needed to keep the global momentum growing. The good news is that U.S. leadership leverages action by both partner governments and other donor countries.

With that in mind, I urge Congress and the President to go further, to continue on the same upward trajectory that Congress and the Administration have been following during the first 5 years of this landmark legislation. Substantial progress has been achieved in bringing essential HIV services to those in need in the low- and middle-income countries where 95 percent of all people living with HIV reside. The number of people receiving antiretrovirals in these countries increased five-fold between 2003 and 2006, and declines in HIV prevention have been reported in several countries following the implementation of strong HIV measures.

According to the September 2007 UNAIDS "Financial Resources Required to Achieve Universal Access to HIV Prevention, Treatment, Care and Support" Report, available financial resources must more than quadruple by 2010 compared to 2007—up to \$42 billion.

We simply cannot afford to slow down now. Just consider five points. First, the most obvious one is that failure to increase efforts will not keep pace with increased needs, and will result in far more deaths.

Second, what we have learned in the fight against AIDS is that it's either act now or pay later. If we had acted 10 or 20 years ago with the same resources, determination and political will that we have today, the AIDS bill would have been much cheaper. So if we delay increased investments now, 5 years from now the bill will be even greater, particularly if we continue to fall short on HIV prevention. As the UNAIDS Report states,

"Had the world made prudent investments 10–20 years ago—in prevention, in strengthening health systems in low- and middle-income countries, in preserving and building essential human resources, in addressing the corrosive effects of gender inequities and other drivers of the epidemic—much smaller amounts would be required today."

The same principle holds true today—we cannot afford the costs of inaction. A comprehensive, scaled-up HIV prevention response would avert more than half of all new infections that are projected to occur between 2005 and 2015. Unless we can prevent new infections, future treatment costs will continue to mount.

Third, putting resources into combating AIDS is also key to improving health systems, if only because in many countries 50 percent of hospital beds are occupied due to AIDS. And if we can't reduce that burden through antiretroviral therapy, it's only going to get worse.

Fourth, because of the work we have done, we are now set to be more efficient in the future. A great deal of energy and time has been invested in setting up systems—supply chain management, procurement, community activities—which will provide us with greater economies of scale in the future.

And, finally, earlier investments that have been made will be lost if we do not continue to trend upward. And as a European, I can also say that putting more money into PEPFAR will compel the rest of the world to do the same.

We saw that when President Bush announced in his State of the Union in 2003 that this country would put \$15 billion on the table in the fight against AIDS. And the Congress has actually appropriated more than the \$15 billion pledged. This global leadership was followed by others—first the UK and, then others. This has happened time and again and demonstrates the true power of American leadership.

In addition to increasing investments, we must maximize the effectiveness of our investments through partnerships and better coordination. We must make the money work more for people on the ground by spending it more efficiently. At UNAIDS, “Making the money work” is our mantra. That is what every staff member knows, that is what we are working for in countries in partnership with national governments and NGOs, PEPFAR and the Global Fund. It means maximizing our effectiveness by improving coordination among donors, government implementers, and everyone in the global fight against AIDS.

It is no surprise that working in partnership produces significant results. In Rwanda, where governments are full partners, and the U.S. effort is fully integrated with national strategies, progress has been measurable. All this may sound a bit bureaucratic, but it means the difference between fighting AIDS effectively or losing ground.

And finally, UNAIDS believes strongly that now is the time to add a long-term view, and sustainable strategies to the emergency response, the “E” in PEPFAR. This shift has a number of implications. First, it means supporting a country-driven and flexible response that allows for an enhanced focus on prevention. For every person who is put on antiretroviral therapy, six become infected with HIV. To get ahead of this epidemic, greater investments in prevention are absolutely essential. Furthermore, strategies must be designed and implemented that respond to the epidemic in that country, and the cultural and social context. It also means minimizing programmatic setasides to foster an appropriate balance among prevention, treatment, care and support in each country. We must increase support for solutions that work best for the particular country.

When it comes to addressing AIDS, anything that has the word “only” in it doesn’t work—whether it’s treatment only, prevention only, condoms only, abstinence only, male circumcision only. The fact is that we need it all to reach our goals. And, more importantly, we need to be smart and effective in our investments. We can benefit from lessons learned. And we have the added benefit that learning from our lessons will save lives.

In conclusion, there is no doubt that, in large part due to U.S. leadership, we have made major progress in the fight against AIDS worldwide. As we prepare for the years to come, and as we make our budgets and formalize our plans, we must commit ourselves to not simply continuing our efforts, but intensifying them and adapting them to the new reality on the ground. We must adapt them to the new and encouraging reality that we’ve all created through U.S. and global investments and efforts.

I am a big believer in the fact that while we cannot predict the future, we can create it. We have a road map for the fight against AIDS. We have the evidence to know what works. We have reached a turning point where even turning back slightly is a slippery slope that will jeopardize progress for years to come. We must continue the trajectory upward. And that will require your continued leadership and unwavering support.

This committee, under the extraordinary leadership of Senator Kennedy, has been a true catalyst for progress and for saving lives—for fighting AIDS and building sustainable health systems. I am confident that in the context of PEPFAR Reauthorization, this longstanding tradition will continue.

UNAIDS stands ready to support this bipartisan effort in any way we can. To that end, I have included a host of recent UNAIDS publications that I hope you will find useful in your effort.

Thank you very much.

The CHAIRMAN. Thank you. Thank you very much. There’s just three of us here so if it’s alright with Senator Enzi, we might just take 7 minutes. Five minutes goes by quickly.

Dr. Zulu, how do you keep your sense of passion about this issue? What continues to motivate you? You've had an extraordinary career, faced incredible tragedy. Obviously had a very important impact in terms of altering and changing national, international policy. What sort of keeps you going?

Ms. ZULU. Well, I think my story can be echoed by many children, as well as women in particular, in Africa. And that is why it's important to continue to ask for 10 percent to be allocated to the direct support of orphans and vulnerable children. And also the story that I bring here was once orphaned being the head of the house which many people have already spoken to, that we need to continue to support those African mothers, where community workers are helping child-headed household and grandparent-headed household as well because we, the children, have been orphaned by HIV.

We are growing. Today I'm a 31-year-old woman. And we are not just victims. But we want to be part of making the difference. And that is what it's all about.

The CHAIRMAN. Are you basically more hopeful and optimistic given all of the focus and attention and both not just what you've heard today, but what you've seen over your extraordinary life about the concern and actions that have been taken?

Ms. ZULU. Yes, absolutely. I think what the U.S. government has done through the Global bill is very important and the PEPFAR. But we also need to continue raising awareness in terms of the nutritional needs for people living with HIV and AIDS because when people are HIV positive, they have a higher request for nutrition. And if they do not have those things that drives them to involve themselves in risky behaviors and that also leads to a lot of children dropping out of school to work for food. So I think we need to work on that as well as gender equality issues.

The CHAIRMAN. Well thank you very much. You're an inspiration to all of us.

Dr. Hearst, I thank you for your focus and attention on the areas of prevention. You're familiar with the Institute of Medicine. They're passed the comments of even those that want to get the earmarking of percentages here. That they feel that there is a very, very important role for prevention, but there's also recognition that with the progress that's been made in recent times that there ought to be more flexibility that will permit these countries and these societies and these communities to develop their own kinds of programs, in their own kind of way with a tight kind of accountability. What's really wrong with that?

Dr. HEARST. Well, I agree that in an ideal world there would be no need for these earmarks, but we have to be realistic when we talk about countries developing their own plans. I'm just back from Uganda, for example which is where A, B, C got started and was putting together their new 5-year plan. Really these plans get largely put together by a group of foreign consultants, westernized, local experts, who have absorbed the western model of dealing with concentrated epidemics where, for example the condom approach has been much more effective than it has been in Africa.

And when you say let local people decide it ends up being this small circle that decides. The new Uganda report, for example, a

nearly final version had almost removed all mention of A and B and it wasn't included in the numerical targets at all. That got, fortunately, improved.

But I think the earmarks in PEPFAR I, in my opinion, have certainly done more good than harm. And I personally don't believe that we are ready to remove them. I don't think that would be a good idea.

I'm not saying they couldn't be re-changed, recast, but we must keep our eye on the prize. Even this Uganda report with its improvements, 96 percent of the budget is being spent on things other than changing sexual behavior which is the thing that worked so spectacularly in Uganda.

The CHAIRMAN. Dr. Smits, this is Dr. Hearst. He says they're there for the prevention aspects and that the countries aren't quite ready to make that kind of a judgment yet. And that this is a program that does work.

You mentioned even in your very brief opening that Uganda has a prevention program. You've also indicated that you didn't need the earmarks and wanted accountability but what about the fact that in too many of these countries or many of these countries these programs are being drafted by people that are not of the people so to speak. Would you?

Dr. SMITS. I don't think that's entirely fair. I have only been to Uganda through the airport. So I really can't speak personally about the country.

I did hear an outstanding speech at the implementers meeting by the leader of their AIDS program, who said, "the way to fight this disease"—and he's in a country that's had great success—"to fight this disease in a prevention sense, is to identify the cause of the last thousand cases and focus on them." He went on to say, that in his country discouraged couples, people who are faithful to one another where one is positive and one is not are one of the biggest risk factors, if not the biggest risk factor.

That means you need a new kind of counseling. You need to ensure partner testing for every time you identify one person, you have to find out the other. And you do need a different emphasis on condoms. This is not a country that is—that I perceived as rejecting the abstinence message.

The CHAIRMAN. But just quickly, because my time's going to run out and I have one question for Dr. Piot. Just generally, without getting into one particular country, can you make the evaluation about all of these nations that are developing these different programs? We did know that there was initially a lot of reluctance in terms of moving. Some countries move much more rapidly than others.

Dr. SMITS. I found—

The CHAIRMAN. But now we've made a very important and significant progress as we've heard from the earlier panel.

Dr. SMITS [continuing]. I find many, the countries that I do know well, have a lot of natural sympathy with the abstinence message and use it very effectively. But there are other prevention things that are needed and strict earmarks get in your way. You need to spend quite a bit of money for a few years to catch up with the demand for male circumcision, for example in some settings.

If your real problem is discouraged couples then you need to focus on educating them and on providing condoms. So that you need to know where your epidemic is right now and put your fight there.

The CHAIRMAN. Ok.

Dr. SMITS. But let me just remind you, we have recommended an elimination of all earmarks, not just the abstinence one.

The CHAIRMAN. Ok.

Dr. SMITS. We think the segregation into prevention, treatment and care is more of a problem in the field than Ambassador Dybul suggested simply because the funding streams force it.

The CHAIRMAN. We might come back to that. Let me just ask in the final moment I have here, Dr. Piot. Your testimony highlights new estimates in declining of the prevalence of the disease. Can you describe how your organization tamed the latest HIV data estimates and how the data represents the current state of the epidemic?

Dr. PIOT. Yes, a few weeks ago, we announced a new estimate and one of the byproducts of the greater investments in AIDS is that we have much better information. Better information, I'll just give you one example. In India, 5 years ago, there were 100 sites where HIV prevalence in pregnant women was followed. Today there are about 1,300. Of course, it is still for a country of one billion population.

In addition there have been demographic and health surveys particularly starting in 2004, 2005, 2006. The results become available. And that led us to much better estimates.

One of the key messages is that we're going into a far more complex picture of AIDS in the world. There are countries who will see a real decline in new infections. Take Kenya, as a result of among others the PEPFAR program, with a spectacular decline. They are now at the same level as Uganda because of prevention efforts. And that's true for most East African countries.

We see a decline in mortality for the first time the last 3 years. And that's probably due to treatment programs. And it comes much earlier than we thought. On the other hand we see countries like Mozambique where infections are going up and particularly in Eastern Europe, 150 percent increase in people with HIV over the last 5 years. And we see also an increase in East Asia.

So the picture is becoming more and more complex but the good news is we're seeing results. We're seeing measureable results for all of our efforts.

The CHAIRMAN. Senator Enzi.

Senator ENZI. Thank you, Mr. Chairman. Dr. Smits, I thank you for the time that you spent with the Minister of Health in Mozambique. So far that's the poorest country that I've ever visited and I was just astounded by some of their challenges there.

One of the challenges is languages. Virtually every tribe has a different language which prevents a lot of communication, particularly on AIDS, but other things as well. I asked the President of the country what his No. 1 goal was and it was to have everybody within 5 miles to have clean water. That's quite a shock to an American. You know, we just turn on the tap and we expect it to be cleaner than clean.

And I also found out during the course of that trip that if the cattle drank out of that, it was contaminated and people did their laundry in it and bathed in it. It was within 5 miles. It met the country goal. And so there are a lot of challenges there and in the other countries.

In your IOM recommendations you said that Congress should remove budget allocations and replace them with appropriate mechanisms to ensure accountability for results. Could you further discuss what those other appropriate accountability measures would be? That's one of the keys, I think.

Dr. SMITS. Well we could have days of seminar on that, but just a few examples. In treatment you want to have both the raw numbers. You have adherence of how people are taking the treatment, how long people stay on treatment and crucially do they return to a healthy and productive life.

And you can measure do the children stay in school? Do the adults go back to work? Very important issues and if the program can bring those numbers to you, you should be comforted that they're doing what they should.

In prevention you want to look very carefully at some of the surveys that Dr. Piot has mentioned, particularly behavior change surveys, delaying sexual initiation, different patterns of relationships. Some of these countries have, what I as an American, regard as problems with polygamy so that there are some issues there. Some of that's changing, but it's changing slowly.

So that you can ask to see what's changing, what's been accomplished with the money rather than specifying percentages. That way if a country suddenly discovers it has a big problem with needle sharing where it hadn't been seen as a big problem before, they can focus all their prevention efforts, all their new prevention efforts there for a year and try to stamp it out.

So that my sense is we understand the epidemic better, the local leaders understand it very well. And there are ways to target. And I have a lot of Mozambiquean friends who are really concerned about the new numbers. I need to talk to Dr. Piot about it afterwards.

Senator ENZI. Well I'll follow up with some written questions on that.

Dr. SMITS. Yes, we'd be happy to respond to written questions.

Senator ENZI. As the only accountant in the Senate, I love this accounting stuff, so—

[Laughter.]

I don't know if they'd be any good. Princess Zulu, from your experience what's been the best method to educate the at-risk communities? What method draws the most positive attention to the pandemic? What would you suggest is the best way to educate without alienating?

Ms. ZULU. I think it's critical that all methods are included. Abstinence and being faithful is very important to the approach, but it's just part of the whole approach of A, B, and C because we live in the real world and people are going to make different decisions. And so I think we have to be inclusive to everyone else.

And again, I continue to go back to children are the faces of HIV and AIDS today. And they need to be taken into consideration. And

direct care for them is critical and their voices need to be heard as well.

Senator ENZI. Thank you.

Dr. SMITS. Could I just add briefly that advocates like Princess Zulu are incredibly important. I've met many of them, people under treatment who have become the message of prevention. I think that's one of the big changes I saw when going on the official visit.

So I thank her. But I thank all the thousands of women like her.

Senator ENZI. Yes. Thank you. Dr. Hearst, from a social standpoint there are a lot of challenges to educating individuals about HIV/AIDS. What programs have worked in relation to prevention and resulted in behavioral changes or shown signs of social stigma lessening, particularly the social stigma lessening?

Dr. HEARST. Well, I think if we want to look at examples of success in changing behavior, certainly the earliest and perhaps still the best example is what happened in Uganda in the late 1980s and early 1990s when with very little international help—and probably if they'd had international help they wouldn't have done such a good job, frankly. Uganda decided to confront their AIDS epidemic and their approach was what we now call A, B, C. They really didn't call it that then. The emphasis was on zero grazing which means don't let your cow graze outside the family compound. In other words, don't go outside the home for sex.

And you know we tend to get into this polarizing debate between A, abstinence and C, condoms, but really the main thing was B, the fidelity, reducing the number of partners. We have very good data on that—in fact, there were dramatic changes in sexual behavior. No, not everyone changed, but the proportion of people with multiple partners went way, way down.

Also there was some increase in the age of sexual debut. And condoms were part of the message but the message was not, "here use condoms, do whatever you want, now it's ok." The message was, "stick to your partner, but don't start sexual activity at too young an age" and as the President himself often put it, and if you're going to do something really stupid anyway, at least use a condom. And rates went way down. Prevalence went down by two-thirds. Incidents went down. New infections went down even more than that.

We're seeing now in many other African countries rates of infection, new infections going down. In almost every one of those countries that is preceded by changes in sexual behavior. Reductions in how many people have multiple partners. Seems that multiple concurrent partners, in other words, two or more ongoing relationships at once are particularly dangerous for how the virus spreads.

We are not necessarily seeing in these countries differences in condom use. So as far as stigma goes, Uganda was a leader in reducing stigma. Reducing stigma can be part of prevention. It isn't necessarily prevention. You can reduce stigma without doing prevention. Reducing stigma is a good thing in and of itself.

Similarly testing, testing is a great thing for treatment and very important for prevention of mother-to-child transmission that I think people have an exaggerated idea that getting everyone tested will immediately get them to change their behavior. In fact, the latest evidence from Africa is that in a randomized control trial in

Zimbabwe, testing in fact, tend to make behavior worse. People who test negative think, oh, I'm ok. I don't have to worry anymore.

We really have to keep our eye on the prize which is reducing multiple sexual partnerships which is how the virus spreads in a generalized epidemic.

Senator ENZI. I think this has been one of the most shocking things to me mostly due to my lack of knowledge on it. I've been learning a little bit about it, but I was surprised at the lack of sex education, the taboo in fact. We've been talking about it. A father couldn't talk to a son. A mother couldn't talk to a daughter. And of course a father couldn't talk to a daughter or a mother to a son. And that's where a lot of that information could come from.

But I found that there are some unique ways of conveying that information, but very difficult ways. One country was using the commercial sex workers to carry the message. So thank you for your answers. I have more that I will follow up with in writing. Thank you.

The CHAIRMAN. Thank you.

Senator Coburn.

Senator COBURN. Thank you, Mr. Chairman. You know one of the things that strikes me both with our last panel and this panel is the assumption that our policy on prevention in terms of abstinence and fidelity and then condoms is not needed because we're there. We're the only country that has any emphasis on true prevention. All the rest of the world is spending their money on treatment and condoms. And so for us to discuss this in a vacuum saying we no longer need it when we're the only ones that are actually funding that message strikes me as unaware of what's actually happening.

What I'm fearful of is like it was, early in 2005, when we looked at USAID's malaria program in Africa, where less than 4 percent of the money was actually going to treatment. We funded a lot of technical assistance programs and a lot of conferences and a lot of other things, but we didn't make any difference in anybody's lives in Africa. And I'm happy to say over 90 percent of the money now is actually going for treatment of malaria through the USAID program.

And so this worry about having a mandate or an earmark for abstinence and for prevention, I think is critical because we're the only ones sending the message with our dollars. We're not the only ones sending the message, but we're the only ones saying a certain percentage of dollars.

Dr. Hearst, thank you for coming all the way here. Your collaboration with Dr. Helene Gayle who was at the forefront of the knowledge as this epidemic was coming about and is not a conservative by any means and your study. Would you take just a minute to summarize the findings of your study because I think they're very instructional for us in terms of where we go?

Dr. HEARST. I think you're referring to the study that was a few years ago, that was funded by UNAIDS to do a review of the evidence for how well condoms are working for AIDS prevention. And we pulled together a lot of information. I would say when I went into this I was pretty much your standard middle of the road per-

son in AIDS who was doing research on how to get people in Africa to use condoms.

And we found that condoms are about 85 to 90 percent effective when they're used consistently and correctly. And that they have had a public health impact in concentrated epidemics, situations like, gay men in my hometown, San Francisco, or in Thailand where the epidemic was concentrated in commercial sex. But try as we might we could not find any good evidence that they have had any impact in generalized epidemics like most of the PEPFAR countries are.

This was a surprise to me. I think it was a surprise to UNAIDS when I turned in the report. I think it's becoming a little bit more accepted now that certainly the condom-only approach is not the right approach. And apply the condom-first approach isn't the right approach either.

I support the A, B, C approach which includes the C. I'm in no way opposed to condoms but I think there are a lot of reasons why condoms haven't worked as well in generalized epidemics. And I could go on about why I think that is, but the bottom line isn't for me to prove I know why they haven't worked. The bottom line is that they haven't. Thank you.

Senator COBURN. Thank you. Dr. Smits, in your report in terms of your recommendations, were African leaders asking you or did we have complaints as you looked at this, that we should not be spending money on abstinence? Was there an African nation in PEPFAR that came to you and said, "this is crazy?" We shouldn't be doing this. We don't think this is a valid method as you bring it and make an agreement that somehow we're going to treat this epidemic.

Dr. SMITS. No, no. I don't believe. Everyone that we met with, well not everyone, but most of the people that we met with at the leadership level and that's the African leadership level, had very strong commitment to the abstinence message. They simply wanted more flexibility in terms of being able to pinpoint the sort of danger zones in the epidemic in their country.

Since our visits, that pinpointing issue has become—a lot of that is male circumcision. As a physician, I'm sure you realize that's not an economical or easy intervention to undertake. It will cost a fair amount of money for several years in areas where there is demand—you can't force it, where men are now not circumcised. But it will have a big impact if we can get it done.

So it's more the flexibility—it's not so much I don't approve of abstinence. It's I would like to focus on some other things.

Senator COBURN. Is there any trend and I probably should have asked this of Ambassador Dybul or Dr. Gerberding, is there any trend in male circumcision at birth of the male children? Are we starting to see that? We know the lesser effective transmission with circumcision but is there now a trend in terms of public health strategy for male circumcision at birth?

Dr. SMITS. Dr. Piot could probably answer that better than I can. That news is very new.

Senator COBURN. Yes.

Dr. SMITS. I mean there haven't been a whole lot of babies born since it. The tradition or circumcising or not circumcising in in-

fancy has very profound cultural implications. So I wouldn't expect to see it change rapidly.

Senator COBURN. Ok.

Dr. Piot.

Dr. PIOT. Dr. Coburn, I would say that we've been working with a number of countries particularly Swaziland, Mozambique where I met with the President a few months ago and who announced that they would launch now a program for circumcision both to offer it to adolescent and adult men, which is one quite complicated issue as you know very well, but then also starting it now with neonates, which I think is the best option in the long-term.

So we're starting to see that translation of research into policy.

Senator COBURN. I'd like the unanimous consent to introduce into the record from Dr. Edward Green from Harvard his PEPFAR and the IOM report and his analysis of that, if I may?

The CHAIRMAN. Yes, it will be so included.

[The information previously referred to follows:]

PREPARED STATEMENT OF EDWARD C. GREEN, HARVARD UNIVERSITY

In anticipation of funding a 5-year extension of PEPFAR, the Institute of Medicine (IOM) was asked to carry out a general evaluation of what PEPFAR has accomplished to date. In spite of the long and impressive list of scientists who were consulted on this, or who are authors of the IOM report, there seems to be an underlying assumption that abstinence or even abstinence—fidelity/partner reduction together are only distractions from better interventions, such as condoms. In the parts of the report where the Uganda ABC approach is mentioned, it is often either mischaracterized or shown in a rather negative light. For example, "It is important to understand that ABC represents neither a program nor a strategy, but a goal of changing key behaviors." Allocation of funds for AB programs would therefore be without merit if neither A nor B are programs or strategies, but just well-meaning but unachievable ideas or ideals.

The report also sets up the usual straw man, abstinence-only, and then knocks it down, e.g., "The committee has been unable to find evidence for the position that abstinence can stand alone or that 33 percent is the appropriate allocation for such activities even within integrated programs." Who required that it stand alone? Abstinence should be part of a balanced, comprehensive program of prevention, relevant mostly for young people, especially if they have not yet become sexually active. It is regrettable that the language of the congressional earmark gave the impression that "abstinence-only" was the new policy, as if this were a stand-alone and time-unlimited intervention for all youth (many females in Africa marry while in their teens).

There are some other weaknesses in the IOM report, in fact outright errors. It states: "The epidemiologic facts are clear . . . the rate of new HIV infections continues to grow."

Of course this is not the case. UNAIDS has finally posted the data on its Web site that HIV incidence has been declining worldwide for about a decade. IOM must know the data, because even HIV *prevalence* (which occurs later than changes in incidence) has been declining globally for several years, with a few exceptions. It is now increasingly acknowledged that HIV *incidence* peaked globally in the mid- or late-1990s. To suggest otherwise reflects the **advocacy** (rather than scientific) posture of UNAIDS and other activist groups who continuously ask for more funds, yet no amount is ever enough.

After the above comment, the report urges that we "put the accent on preventive measures of proven efficacy on a much larger scale." "Proven efficacy does not seem to refer to A or B programs, even though we always see significant declines in the proportion of men and women reporting more than one sex partner in the past year in the 7–8 African countries where prevalence decline has been established (literature the IOM seems unfamiliar with.)

A related oddity: the AIDS prevention component of PEPFAR is meant to demonstrate that by concentrating resources on the 14 original focus countries, programs can have an impact on HIV prevalence. As it happens, prevalence is declining in at least half of the focus countries, yet nowhere is this acknowledged. This is truly a baffling oversight that demands some explanation. One might only refrain

from mention of impact if there had been none, but this was not the case. This is not to say PEPFAR can necessarily claim credit for the improvements in HIV infection rates, but these improvements should be mentioned along with monitoring and impact evaluation strategies to determine any links between interventions and biological outcomes. There have been positive behavioral outcomes as well.

The U.S. taxpayer deserves to know the impact of a \$15 billion expenditure.

As a recent member of the Presidential Advisory Council on HIV/AIDS, International Committee, I helped write an internal document, a White Paper on PEPFAR, that we hope will influence the design of PEPFAR II. It is more evidence-based than the IOM report, which seems more a political consensus document.

Senator COBURN. I just want to make one last point. And I want to show the poster of an ad. This ad tells the problem. Not everybody is so focused on a balanced approach and the fears that I have.

I believe we need to change somehow some of the mix. But Botswana was essentially offended by this ad and you can understand why. It is that we're now endorsing through the use of a condom, the opposite of abstinence, the opposite of fidelity. And this is done with international dollars to make a point.

But the fact is, that's the wrong message. And so you can see. You can take that down. You can see—I'll read it to you if you want.

Here's what she says, Ke le, "I'm 14 and I'm going out with an older man who adds flavor to my life. And one thing I do is have protected sex using lovers-plus condoms every time." Well this is a 14-year-old girl—that we're now encouraging the rest of the 14-year-old girls that you don't have to make a difference.

The fact is, that's not the message. And the problem is, will we get back to that again? I was in Cote D'Ivoire in 2001 and I saw the condom promotion, but that was all it was. There wasn't anything else there. And Cote D'Ivoire has a fairly high, you know, I think it's a 7 or 8 percent prevalence rate. And yet probably that prevalence right there is because it's seen in light of just that.

You know, I've delivered 4,000 babies. I've done all sorts of things in this country. And I always tell all of my patients if you're going to do the other thing always use a condom.

I believe there's another thing that we're not talking about and I know you're aware of it. And I know Dr. Hearst is aware of it. Is that we have an epidemic cervical cancer in Africa. And a condom doesn't do anything to prevent that.

But fidelity, sexual delay and marked decrease in the number of partners are directly correlated with a woman not dying from cervical cancer. They don't usually die in this country because we have a wonderful health care system where women get PAPs and it's identified very early and treated before it can harm.

But I guess the point I would make is we're going to have to have some strong discussions as we do this, as we modulate this. And I think it's very important and I hope that all would agree that we need to look at the dollars going into condoms and treatment and prevention in total. But we can't ignore the fact that we're the only ones talking about international dollars on A and B.

We're the only ones who are mandating that money needs to be spent there. And in light of the total dollars it's not something we should walk away from if we really want to have a long-term impact on this epidemic. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you and thank the panel. We're going to submit some additional questions.

I think we all understand, certainly from this morning's testimony of all of our panelists that the years of evidence demonstrate that comprehensive prevention for HIV works. And we're now using the comprehensive prevention methods: abstinence, partnership reduction and consistent and corrective use of condoms. And Dr. Gerberding testified, Ambassador Dybul, the IOM, GAO will support a comprehensive support. And I believe that's what we should support as well.

I want to thank all of our panelist. Very, very helpful. We'll be submitting some additional questions to you. We didn't get into the issues of prescription drugs and the differences that we have in terms of the FDA and other kind in the World Health Organization. There's other kinds of issues as well that I'd like to try to get into. So we'll be inquiring of you on a number of different kinds of matters that we'll be interested in, our committee's interested in as well. But this has been very, very valuable and we're grateful to all of you. The committee will stand in recess.

[Additional material follows.]

ADDITIONAL MATERIAL

RESPONSE TO QUESTIONS OF SENATORS KENNEDY, ENZI, DODD, CLINTON, BROWN,
AND COBURN BY MARK DYBUL

QUESTIONS OF SENATOR KENNEDY

Question 1. The IOM PEPFAR evaluation recommends that you study the WHO Pre-qualification Process and determine what it would take for that process to provide sufficient assurance of the quality of generic ARVs for purchase by PEPFAR so that we can transition to using that globally-accepted process as soon as feasible.

How are you responding to this recommendation? Could you please explain precisely how FDA is regulating drugs in the focus countries? Do you see this as being a workable approach in the long-term, especially given the goals of harmonization and supporting countries to develop the capacity to sustain their own programs?

Answer 1. The President's Emergency Plan for AIDS Relief (PEPFAR/Emergency Plan) and the World Health Organization (WHO) are working together to make essential antiretroviral drugs (ARVs) more rapidly available in countries where they are most urgently needed. The U.S. Department of Health and Human Services (HHS)/Food and Drug Administration (FDA) and the WHO Pre-qualification Program have established a confidentiality agreement by which, with company permission, the two organizations share dossier information regarding reviews and inspections. As a result, generic ARVs which have been HHS/FDA-approved or tentatively approved can be added rapidly to the WHO pre-qualification list. The rapid WHO pre-qualification of these medications hastens in-country drug regulatory review and, consequently, the availability of lower-cost, high-quality ARVs in-country.

The WHO pre-qualification program with generic drug manufacturers provides a valuable framework to assist countries in their procurement of medicines. The WHO pre-qualification program does not serve as a drug authority/agency but serves as a mechanism to evaluate and help ensure minimum drug quality. As drugs are reviewed and approved for addition to the "pre-qualified" list, this greatly aids developing countries as they seek to ensure quality when purchasing pharmaceuticals using resources from the Global Fund, other international partners, or country governments.

In regard to regulating drugs in the focus countries, HHS/FDA does not regulate the approval or marketing of drugs in the focus countries of the Emergency Plan, or in any other countries outside of the United States. Each country maintains its own drug-regulatory system.

However, approval or tentative approval from HHS/FDA of a drug (including a generic antiretroviral) is necessary for U.S. Government country teams and grantees to purchase that drug under the Emergency Plan. In May 2004, former HHS Secretary Tommy H. Thompson and former U.S. Global AIDS Coordinator Randall L. Tobias announced an expedited process through which HHS/FDA would review applications from generic manufacturers of antiretroviral medications for use under the Emergency Plan. That program has successfully given approval or tentative approval to 62 generic antiretroviral formulations. (If a product still has marketing protection in the United States, HHS/FDA issues a "tentative approval" rather than a "full" approval. The "tentative" approval signifies that a product meets all safety, efficacy, and manufacturing-quality standards for marketing in the United States, but existing patents and/or exclusivity prevent its full approval for marketing in the United States.)

At the same time, HHS/FDA has worked to strengthen the knowledge and training of national drug-regulatory authorities in the Emergency Plan focus countries, alone and in collaboration with each other, so they can better ensure the quality of the medical products available to their citizens. Since 2005, FDA has held five drug-regulatory fora for international regulatory authorities. Representatives of 14 of the 15 focus countries attended the first forum, and some countries have been able to send experts to subsequent fora in an attempt to train multiple members of their regulatory staffs.

Question 2. Ambassador Dybul, the FDA has a program to tentatively approve generic HIV drugs, which can then be purchased with PEPFAR funds. This program supposedly provides for fast FDA reviews, of only several weeks. I understand, however, that in at least one instance, FDA's review of a generic HIV drug, the triple combination anti-retroviral drug, took 3 years. Such a delay would delay PEPFAR access to the cheaper generic version of a drug, and in this case would have required patients to take several pills several times a day, instead of just one pill in the morning and one pill at night.

Could you send me information on the FDA review time for each drug that has been given tentative approval for purchase by PEPFAR?

Answer 2. *With respect to the drug referenced in the question*, the 3-year figure includes the time it took for the company in question to conduct studies against the U.S.-reference standard for the underlying, branded drugs in the fixed-dose combination, and to submit the results to HHS/FDA. Once the company submitted its full and complete application, HHS/FDA approved the generic HIV drug in less than 6 months. We should note that the approval of this product marked the first time this particular triple-combination anti-retroviral therapy had met the standards of a stringent drug-regulatory authority.

Since December 2004, HHS/FDA has approved or tentatively approved 62 antiretroviral formulations under the expedited review program associated with PEPFAR. Timeframes vary for the review process for each product, which includes the time it takes for the companies to respond to requests for information. These products appear on the HHS/FDA Web site at <http://www.fda.gov/oia/pepfar.htm>, and on the Web site <http://www.globalhealth.gov>. Antiretroviral formulations that receive approval or tentative approval from HHS/FDA also become eligible for procurement by grantees of the Global Fund to Fight AIDS, Tuberculosis and Malaria, and, through a special information-sharing arrangement, quickly appear on the pre-qualification list maintained by the Secretariat of the World Health Organization (WHO). The HHS/FDA expedited review process today facilitates the purchase by the Emergency Plan of approximately 90 percent of its antiretroviral drugs from generic manufacturers, many in the developing world, and has greatly expanded the global marketplace for these companies because of our arrangements with the Global Fund and the WHO.

The time for review by HHS/FDA for each drug given approval or tentative approval can vary, but, in large part, depends on the timeliness and completeness of the applications submitted by the companies. HHS/FDA reviews the marketing applications by using its normal standards for approval. If a product still has marketing protection in the United States, HHS/FDA issues a “tentative approval” rather than a “full” approval. The “tentative” approval signifies that the product meets all safety, efficacy, and manufacturing-quality standards for marketing in the United States, but existing patents and/or exclusivity prevent it from being approved for marketing in the United States. Once any existing patents or exclusivities have expired, tentatively approved products can receive a full approval, which allows them to be marketed in the United States. Since the expedited review process began, HHS/FDA has fully approved seven drugs in this way.

Under the expedited review process associated with the Emergency Plan, HHS/FDA works intensively with manufacturers that have not interacted with the agency previously to help them prepare an HHS/FDA application and to prepare for the requisite HHS/FDA inspections of their clinical trials and manufacturing facilities. Because of the significant public health impact of these products on the individual and population levels, HHS/FDA prioritizes the review of these marketing submissions. The review process can take a longer time when companies submit incomplete applications, or when follow up is required.

Question 3. According to many experts, operations research is the best method of evaluating HIV/AIDS programs and service delivery and maximizing PEPFAR’s financial investment and lifesaving impact—is this a priority for OGAC?

Can you describe what OGAC has done in this regard? What are your recommendations for us to address operations research in PEPFAR Reauthorization?

Answer 3. PEPFAR dedicated approximately \$46.4 million to operations research and evaluation in fiscal year 2007, including spending for public health evaluations funded through PEPFAR’s Country Operational Plan (COP), process, public health evaluations funded centrally by PEPFAR, and other operations research activities. Of this, \$26.4 million was directed toward operations research in priority prevention activities, including those associated with gender-based violence, male circumcision, prevention with positives, adolescent and young girls, and men as partners. PEPFAR further spends over \$135 million on strategic information in all countries, including monitoring and evaluation activities that may include operational research. Some monitoring and evaluation activities are budgeted by countries under prevention, care, and treatment categories.

Operations research and evaluation, including public health evaluations, are integral to guiding program implementation and improvement under PEPFAR, and significant resources are dedicated to this area. Guidance to country teams in PEPFAR focus countries suggests 1 to 4 percent as a reasonable spending range to support public health evaluations in the COP planning process. This level of spending is ap-

propriate and compares to that provided under the Ryan White Care Act, which provides a useful domestic benchmark for the PEPFAR program.

Another vitally important component of PEPFAR's program and its continued success is monitoring and evaluation (M&E). Indeed, PEPFAR's intensive focus on measuring progress, establishing evidence, and adapting to experience prompted the Institute of Medicine to label it a "learning organization" in its congressionally mandated assessment in 2006. PEPFAR guidance for country operational plans states that PEPFAR country teams should spend approximately 7 percent of their budget on strategic information, including M&E. M&E projects can be found throughout Country Operational Plans in every intervention area.

One of the most useful ways to improve the impact of monitoring and evaluation in the next phase of PEPFAR is through an initiative to improve the quality of PEPFAR program indicators. PEPFAR is developing outcome-based indicators for programs in addition to its existing output indicators, which have centered on the number of people trained or served. These second generation indicators will help improve reporting on whether programs are having a positive or negative impact on the outcomes, such as risk behavior in youth, and also help strengthen monitoring at the individual, clinic/facility and program level. Monitoring and evaluation, therefore, will have a continued strategic role in assessing program effectiveness. Each PEPFAR technical working group (TWG) will develop a set of these indicators in consultation with country teams and international experts.

Additionally, in 2007, PEPFAR developed the Public Health Evaluation (PHE) Framework to provide strategic coordination of evaluation activities. This framework monitors and supports country evaluation activities to help reduce redundancy and to share information across programs. More importantly, this framework supports broader strategic operations research that measures the effectiveness of programmatic interventions across populations and even countries, aiming to answer some of the most critical programmatic questions PEPFAR faces. All PHE activities are guided by interagency committees of strategic information experts, and successful evaluation activities are shared at the annual HIV/AIDS Implementers' Meeting to disseminate program results and thereby strengthen PEPFAR (and other) programs. The PHE framework will increase the impact, use, and dissemination of evaluation studies conducted in PEPFAR countries throughout the next phase. In fiscal year 2008, the PEPFAR interagency PHE Subcommittee and Scientific Steering Committee directed that PHE emphasize applied research efforts that: (1) address high-priority public health questions to inform and improve how services are delivered; (2) PEPFAR programs and partners are uniquely poised to address; and, (3) take advantage of central coordination of multi-country efforts to ensure sufficient scale and rigor. PEPFAR has moved aggressively toward implementing this heightened focus on coordinated multi-country PHE activities, in order to ensure that PHE studies might provide PEPFAR with definitive, scientifically informed operations research to guide the design and implementation of PEPFAR programmatic activities.

Last, the role of monitoring and evaluation will be undertaken consistent with PEPFAR's continued support for the UNAIDS "Three Ones" principles: *one* agreed HIV/AIDS Action Framework that provides the basis for coordinating the work of all partners; *one* National AIDS Coordinating Authority, with a broad-based multi-sectoral mandate; and *one* agreed country-level M&E System. This commitment means that PEPFAR coordinates at a national level to support patient monitoring, program evaluation, and quality assurance activities, among others. PEPFAR has been a leader in building national capacity in the Ministries of Health and important civil society partners to manage the M&E portfolio. These efforts have included building surveillance and patient monitoring systems and training staff in the analysis and use of data for programmatic decisionmaking. In these efforts, PEPFAR is not the sole M&E provider but part of a team, working in coordination with other partners to ensure sustained country ownership, the continued support of other international partners, and ultimately, the sustainability of the national M&E program. PEPFAR investments in operations research are quite extensive under the current authorities of the Leadership Act and we look forward to working with you to develop further guidance and oversight.

Question 4. What is the role of other agencies in the planning and reviewing of the yearly country operational plans? Is the time and level of feedback appropriate and most reflective of the knowledge on-the-ground?

Answer 4. PEPFAR is built upon a model of interagency coordination to achieve shared HIV prevention, care, and treatment goals. Collaboration among agencies occurs at the planning, implementation, and evaluation stages of HIV activities, as well as at the decisionmaking level.

In each country that receives PEPFAR support, a PEPFAR country team including representatives from USG agencies in-country (e.g. USAID, CDC, Peace Corps, and Department of Defense) works together to plan HIV/AIDS activities, in coordination with the host government and civil society. This process requires agencies to consider comparative strengths, avoid duplication, and provide technical coordination and support to one another to deliver one HIV/AIDS program with a shared set of targets at the country level. An ongoing "staffing for results" effort has further strengthened the concept of one interagency country team to achieve common targets, by profiling the expertise and function of each agency staff member and making sure she or he fits efficiently into one USG country team, without unnecessary overlaps between agencies. After planning, these USG country teams continue to work closely together to make sure that they achieve their shared targets. This includes regular technical and operational meetings, site monitoring, and evaluation visits.

The Country Operational Plans (COPs) and results of each country program are assessed through a rigorous series of technical and programmatic reviews, which are conducted by working groups with participation from USAID, Department of State, Department of Health and Human Services (including National Institutes of Health, Health Resources and Services Administration, and Centers for Disease Control and Prevention), Department of Labor, Department of Commerce, Peace Corps, and Department of Defense. These interagency COP reviews are a complex and labor-intensive process that takes approximately 3 months. Further, PEPFAR's principals and deputy principals committees are interagency bodies that provide senior policy and implementation leadership. These committees meet regularly to make collaborative decisions on operational, technical, and policy issues.

Collaborations with other agencies/offices of the USG also occur continuously to integrate HIV/AIDS activities with other development programs. PEPFAR's Public-Private Partnership section works closely with USAID's Global Development Alliance (GDA) to further integrate public-private partnerships in these and other areas.

At the headquarters level, PEPFAR collaborates with other agencies through technical bodies such as the "HIV/Food and nutrition working group," comprised of USAID Food for Peace and PEPFAR technical advisors that coordinate integrated HIV/food and nutrition activities. Further integration takes place through joint programming in-country, where country teams "wrap around" HIV prevention, care, and treatment activities with non-HIV activities. Every year, countries show increasing investment in these models of service integration.

PEPFAR welcomes further dialogue and coordination at the headquarters level to share information, develop improved field guidance, and plan special initiatives. At the same time, decisions on the delivery of integrated and wrap-around programs will continue to take place at the country level, to make sure that interventions are appropriate to local needs. For this reason, PEPFAR reaches out on a continual basis to other agencies and offices so they can strengthen wrap-around programs by supporting PEPFAR field teams—such as through site visits and technical assistance during the COP planning season. Rather than making recommendations at headquarters during COP review, ongoing contact between programs in each country throughout the planning cycle is essential for wrap-around partners to have their input fully reflected in the COP document.

QUESTION OF SENATOR ENZI

Question 1. In relation to my question regarding barriers created by tariffs and duties, have you noticed any obstacles with tariffs and duties on goods, such as drugs, water, food, supplies, etc., that are donated by organizations outside of PEPFAR? Is this a concern we should focus on during reauthorization?

Answer 1. The President's Emergency Plan for AIDS Relief (PEPFAR/Emergency Plan) does not allow tariffs on commodities procured with its resources. U.S. Government bilateral Agreements, in particular agreements negotiated by the U.S. Agency for International Development (USAID) and the U.S. Department of Health and Human Services (HHS), provide exemption from tariffs and duties on goods.

Standard terms for the USAID Agreements have evolved over the years, and in some cases agreements implementing arrangements with host-country Governments supplement the Agreements. However, the USAID Agreements all provide exemption from tariffs and customs duties (in addition to other tax exemptions), and generally extend these benefits to implementing partners and their employees. To avoid having such costs added to contracts, USAID staff negotiate these Agreements to stipulate the host government will allow implementing partners to import materials and equipment required under their contract free of customs duties and tariffs.

Under a business model to pursue an interagency approach across the U.S. government, HHS, as one of PEPFAR's main implementing agencies, has used the USAID Agreements to leverage host Governments to provide exemption from customs duties and taxes for its agencies and implementing partners.

Challenges remain to the tax- or customs-free delivery of goods and services in the name of humanitarian aid. USAID bilateral Agreements signed at the national level do not always translate down to operational levels, which can require ongoing efforts to ensure proper implementation. Donor organizations that are working independently in a country can still face multiple obstacles in negotiating with Government officials to import products duty-free. For pharmaceuticals, an added issue is registration for local use of the donated product, as well as the expiration date; any donated pharmaceutical product must be able to be fully incorporated into the existing health-care regimens.

These Arrangements to implement assistance under PEPFAR on the ground generally function well for U.S. Government Departments and agencies and their implementing partners. However, taxes, fees, and customs duties are still a reality for several independent donors. The U.S. Government is working through multilateral channels to raise awareness of the barrier that taxes, fees, and customs duties place on assistance, and to the scaling-up of HIV/AIDS prevention, treatment and care programs to provide universal access. This ongoing, multilateral approach is the most effective means to advocate that host-country Governments adopt appropriate policies to exempt foreign assistance from such charges.

QUESTIONS OF SENATOR DODD

Sustainability

Question 1. When Congress passed PEPFAR in 2003, it was widely recognized that the HIV/AIDS pandemic in developing countries had reached crisis proportions and required an emergency response. During the next phase of PEPFAR this sense of urgency should be maintained—the global pandemic clearly demands it. At the same time, country capacity must be dramatically expanded, to meet the current and future challenges of the pandemic and to achieve success and sustainability.

The Institute of Medicine's 2007 report on PEPFAR implementation states,

“The continuing challenge for PEPFAR is to simultaneously maintain the urgency and intensity that have allowed it to support a substantial expansion of HIV/AIDS services in a relatively short period of time while also placing greater emphasis on long-term strategic planning and increasing the attention and resources directed to capacity building for sustainability”

While there is a general consensus around the importance of moving toward sustainability, there is a need for clarity and definition to guide this transition. How would you define the term sustainability? How do you believe it should be put into practice in the field in this next phase of PEPFAR?

Answer 1. There are three major areas where sustainability is a critical concern and a focus of Emergency Plan/PEPFAR programming: sustainability of services, organizational sustainability and financial sustainability. Achieving increased levels of sustainability through the greater assumption of responsibility over programming and management by host country nationals, as well as support for developing the capacity of local indigenous organizations, are key considerations in developing Emergency Plan Country Operational Plans (COP).

The increase in PEPFAR funding coupled with changes in host nation policies has led, in many cases, to large increases in patient load and demand for treatment, counseling and testing, care and prevention programs. Host nation human resource capacity is being stretched to its limit. Since the government is one of the most sustainable organizations implementing HIV/AIDS programs in many countries, technical assistance is provided to human resource units of ministries of health to help facilities conduct workforce analyses to provide HIV/AIDS services without compromising the budget or manpower for other health services. U.S. Government (USG) implementing partners working with nongovernmental organizations (NGOs) providing HIV/AIDS services are encouraged to harmonize local compensation practices with the ministries of health compensation for health workers with the understanding that they do not have to match government salaries but, in general, should not exceed them.

The organizing structure, management, coordination and leadership provided by host governments and local NGOs are essential to an effective, efficient and sustainable HIV/AIDS response. Strengthening the institutional capacity of host governments and national systems is a fundamental strategy of the Emergency Plan. Activities are designed to increase the number of indigenous partners to help expand and diversify the country's base of partners and support a sustainable response.

In addition to efforts to support governmental and non-governmental capacity-building, other important activities for sustainability include: enhancing the capacity of health systems and health care workers; strengthening quality assurance; improving financial management and accounting systems; building health infrastructure; and improving commodity distribution and control. Where feasible, national information systems and supply chain management systems that serve an array of governmental and non-governmental partners are supported as opposed to separate costly systems for each partner.

Country estimates of the number of health workers and other health managers that PEPFAR supports remain important as we maintain our longstanding emphasis on sustainable programs and scaling up country activities. In the fiscal year 2008 COP we requested that countries provide estimates of the numbers of staff who will receive full or partial salary support in the following three categories: clinical services staff; community services staff; and managerial and support staff. Staff in these three categories totaled 111,300 health care workers in the 15 focus countries plus India, Malawi, and Cambodia.

While PEPFAR does not generally support salaries for government employees, there are many areas where PEPFAR is supporting staff in ministries and government facilities through technical advisors, recruiting agencies, and others.

At present, host nations' ability to finance HIV/AIDS and other health efforts on the scale required varies widely. Many deeply-impooverished nations are years from being able to mount comprehensive programs with their own resources alone, yet it is essential that these countries appropriately prioritize HIV/AIDS and do what they can to fight the disease with locally-available resources, including financial resources. A growing number are doing so. Many other nations do have significant resources, and are in a position to finance much of their own HIV/AIDS responses. Some countries are making progress, and a growing number of nations are investing in fighting HIV/AIDS on a scale commensurate with their financial capacity. In some cases, for example, host nations are procuring all or a portion of their own antiretroviral drugs (ARVs), while PEPFAR provides support for other aspects of quality treatment. These developments within hard-hit nations build sustainability in each country's fight against HIV/AIDS.

With support from PEPFAR, host countries are developing and expanding a culture of accountability that is rooted in country, community, and individual ownership of and participation in the response to HIV/AIDS. PEPFAR is collaborating with host nations, UNAIDS and the World Bank to estimate the cost of national HIV/AIDS plans, a key step toward accountability. Businesses are increasingly eager to collaborate with the Emergency Plan, and public-private partnerships are fostering joint prevention, treatment, and care programs.

While HIV/AIDS is unmistakably the focus of PEPFAR, the initiative's support for technical and organizational capacity-building for local organizations has important spill-over effects that support nations' broader efforts for sustainable development. Organizations whose capacity is expanded in order to meet fiduciary accountability requirements are also in an improved position to apply for funding for other activities or from other sources. Expanded health system capacity improves responses for diseases other than HIV/AIDS. Capacity-building in supply chain management improves procurement for general health commodities. Improving the capacity to report on results fosters quality/systems improvement, and the resulting accountability helps to develop good governance and democracy.

HEALTHCARE WORKER CAPACITY

Question 2. How is PEPFAR building health care worker capacity in the countries in which it operates?

Answer 2. PEPFAR focuses on areas that most directly impact HIV/AIDS programs: HIV/AIDS training for existing clinical staff such as physicians, nurses, pharmacists, lab technicians; management and leadership development for health care workers; and building new cadres of health workers. This support of local efforts to build a trained and effective workforce has provided the foundation for the rapid scale-up of prevention, treatment, and care that national programs are achieving, and provides a solid platform on which other health programs can build.

Recognizing the continued importance of human capacity development, for fiscal year 2008 PEPFAR country teams were asked to estimate the amount of training they planned to support. They reported that they plan to support nearly 2.7 million training and re-training encounters in fiscal year 2008 alone, more than the cumulative total in the preceding 4 years.

Pre-service training: It is clear that the expansion of care and treatment requires an expansion in the workforce to provide these services. In fiscal year 2008 the

amount of PEPFAR funds each country team could use to support long-term pre-service training of health professionals was increased threefold, to \$3 million. Unfortunately, few country teams took advantage of this opportunity, and long-term pre-service training will be a focus for the coming year. Namibia is one country that took advantage of this new allowance. There are no schools of medicine and pharmacy in Namibia, so in fiscal year 2008, there are plans to scale up an existing scholarship program for students in these disciplines to attend training institutions in South Africa, with a requirement to return. In Kenya, an HIV fellowship program has been developed to train senior HIV program managers. In Vietnam, PEPFAR is working with the Hanoi School of Public Health to increase the number of health professionals receiving advanced degrees in public health and management. There has also been a significant increase in support for expanding HIV curricula in pre-service training programs. These efforts reflect the increase in resources dedicated to training of new doctors, nurses, clinical officers, laboratory technicians, and pharmacists in HIV/AIDS.

Support for salaries: Along with support for training, supporting new highly trained health professionals and task-shifting, PEPFAR supports the growing number of personnel necessary to provide HIV/AIDS services. To capture this support more comprehensively, in the fiscal year 2008 Country Operational Plans (COPs) PEPFAR country teams estimated the number of health care workers whose salaries PEPFAR is supporting. They reported support for over 111,000 workers, illustrating PEPFAR's commitment. PEPFAR has worked to ensure that these positions are sustainable for the long term. In Kenya, for example, PEPFAR has reached an agreement with the Ministry of Health to incrementally absorb these personnel into the public health system, providing long-term sustainability while also allowing for rapid hiring and deployment.

Question 3. What is PEPFAR doing to help support “task-shifting,” the process of delegation whereby tasks are moved, when appropriate, to less specialized health workers?

Answer 3. While building cadres of new highly trained professionals is a long-term objective of PEPFAR and other development initiatives, that takes years and we do not have years to wait. As experts from PEPFAR and the World Health Organization (WHO) argued in an article published in the *New England Journal of Medicine*, policy change to allow task-shifting from more specialized to less-specialized health workers is the one strategy that will have the most significant and immediate effect on increasing the pool of health workers in resource-limited settings. Changing national and local policies to support task-shifting can foster dramatic progress in expanding access to HIV prevention, treatment, and care, as well as other health programs. The Emergency Plan supported WHO's efforts to develop the first-ever set of task-shifting guidelines, released in January 2008. This continues and expands PEPFAR's support for the leadership of its host country partners in broadening national policies to allow trained members of the community—including people living with HIV/AIDS—to become part of clinical teams as community health workers.

Question 4. What is PEPFAR doing to specifically address the need for providers trained to address the special needs of children with HIV/AIDS? What are the unique challenges for providers of pediatric and family-centered care?

Answer 4. A number of challenges remain to scaling up services to meet the unique needs of children.

Challenge 1: HIV Diagnostic Testing

Most pediatric HIV infections worldwide are attributable to mother-to-child transmission, with transmission occurring during pregnancy, around the time of birth, or through breast feeding. Barriers to testing infants and children for HIV infection lead to a delay in diagnosis, and many infants and young children die before HIV is diagnosed or treatment can be given. It is estimated that 50 percent of HIV-positive children will die before the age of 2 years if they are not treated.

For adults and children older than 18 months, diagnosis of HIV infection is made by identification of antibodies to HIV in serum. However, because of the transfer of maternal HIV antibodies to the infant, newborn infants and children younger than 18 months will often test positive for the presence of anti-HIV antibodies even in the absence of true infection. Therefore, definitive diagnosis of HIV infection among infants and children younger than 18 months often requires the use of special infant diagnostic tests (i.e., HIV-specific RNA or DNA) to detect the virus itself, instead of the inexpensive and readily available antibody tests that can be used in adults and children older than 18 months. These special tests are more complex to

perform and more expensive, and are not available in many resource-constrained areas of the world in which the risk of HIV infection in infancy is highest.

PEPFAR's existing authorities have allowed it to respond to this challenge. PEPFAR supported the development of the innovative dried blood spot polymerase chain reaction (PCR) test, for HIV-specific RNA or DNA, improving the rate of accurate and timely HIV diagnosis in infants under 18 months. PEPFAR is now supporting a significant scale-up of this new testing technology in Botswana, Rwanda, South Africa, Uganda, Namibia, Zambia, Kenya, Mozambique, Ethiopia, Cote d'Ivoire, Nigeria, Malawi and China, through the establishment of national guidelines, training of personnel, and implementation support. This effort will help to identify more quickly HIV-positive infants under 18 months and to link them to care and treatment programs.

PEPFAR also helped develop guidelines for the use of HIV rapid tests that have been disseminated to PEPFAR countries to support a systematic scale-up of rapid HIV counseling and testing for children, adolescents, and adults. PEPFAR is further supporting policy development and program implementation to hire thousands of lay counselors to implement quality HIV counseling and rapid testing throughout PEPFAR focus countries, including among infants and children over 18 months. A priority for such counseling and testing activities is to establish adequate linkages for infants and children to care and treatment services.

An important component of the scale-up of infant diagnosis will be the expansion of sites where infants at risk of HIV can be identified and tested. Prevention of mother-to-child HIV transmission (PMTCT) programs at antenatal care sites provide excellent access to infants at risk of HIV. PEPFAR is substantially increasing its support for the national scale-up of PMTCT programs through the development of national PMTCT policies, strategies and program plans; provision of training, infrastructure support, and assistance for monitoring and evaluation activities; development of key reference PMTCT tools for program implementation and country adaptation; and collaboration with multilateral partners, including WHO and UNICEF.

A foundational component of PEPFAR's scale-up of infant diagnosis is PEPFAR's continued strengthening of national, tiered laboratory networks that have the capacity for accurate and timely infant diagnostics. This includes training and mentoring laboratory personnel, establishing standard laboratory operating procedures for HIV and TB diagnostics, providing a reliable supply of test kits and laboratory reagents, renovating and constructing laboratories, and developing quality assurance mechanisms, among other activities. In fiscal year 2007, PEPFAR invested over \$160 million in strengthening laboratory systems.

Scaling up infant diagnostic testing, rapid HIV testing, laboratory strengthening, and linkages from testing to infant and child care and treatment will continue to be priorities for PEPFAR in the next phase.

Challenge 2: Clinicians to Provide Care for Children With HIV

Even where appropriate HIV diagnostic testing is available and drugs for treatment of HIV infection and prophylaxis for HIV-associated infections are accessible, lack of personnel trained in treatment of children with HIV severely limits access to treatment for large numbers of children. In many areas of the world, medical care is provided by physicians, nurses, and other clinicians with training and experience in the management of adult, but not pediatric, patients. Additional efforts are needed to expand the availability of clinicians who are skilled in pediatric HIV care in resource-limited areas of the world.

PEPFAR has made sizeable investments in building the health workforce capacity in PEPFAR countries to provide pediatric care and treatment, and will continue to do so. First, PEPFAR provides partial and full salary support for physicians, clinical officers, and nurses providing HIV care and treatment for infants and children across national HIV/AIDS programs.

Second, PEPFAR strengthens pre-service training institutions, such as schools of medicine, nursing, and pharmacy, to produce graduates qualified to work in pediatric HIV care and treatment. Activities include developing curricula, hiring and training faculty, and providing scholarships for students to attend school within or outside their countries. In the case of Namibia, no schools of medicine or pharmacy exist, so an ongoing scholarship program supported by PEPFAR has successfully subsidized students to study in South Africa, with the agreement to serve in the public health system for 2 years upon completion of their degree.

Third, PEPFAR has supported the on-going training and mentorship of thousands of medical providers, nurses, and pharmacists in pediatric care and treatment services. Notably, PEPFAR has been promoting and supporting a standardized model of pediatric care and treatment in the focus countries. This 10-Point Package for Com-

prehensive Care of an exposed/infected child includes: (1) Early infant diagnosis; (2) Growth and development monitoring; (3) Routine health maintenance; (4) Prophylaxis for opportunistic infections (5) Early diagnosis and treatment of infections; (6) Nutrition counseling; (7) HIV disease staging; (8) ART for eligible children; (9) Psychosocial support to the child and family; and (10) Referral for additional care. Providing a standardized model of care helps ensure PEPFAR countries are providing quality care for infants and children in a systematic manner.

Fourth, PEPFAR has further supported the development of “centers of pediatric treatment excellence,” which establish best practices and facilitate training and skills-building among pediatric providers in multiple PEPFAR countries. PEPFAR will continue to leverage the current rapid expansion of care and treatment services for people living with HIV/AIDS to expand pediatric access beyond centers of excellence to community-based health facilities. In Zambia, for example, with support from PEPFAR and the Global Fund, the government expanded antiretroviral treatment to children at primary health care centers, using a model led by nurses and clinical officers. The program resulted in strong health outcomes, providing further evidence for the PEPFAR-supported model of “task-shifting,” or the shifting of care responsibilities from more specialized providers to less specialized.

Last, a WHO-PEPFAR collaboration on task-shifting in seven countries mapped the provision of care and treatment services by all levels of providers, including providers of care to children. WHO normative guidelines on task-shifting for HIV prevention, care, and treatment were developed and are now available on the WHO Web site. These guidelines will help countries scale up pediatric and adult care and treatment more rapidly, by making strategic use of their existing health workforce.

Challenge 3: ARV Formulations

Assuming that appropriate HIV diagnostic testing is available, and the necessary clinical personnel are available to provide care and treatment to HIV-infected children, appropriate formulations of antiretroviral drug (ARV) agents for children are also necessary. However, pediatric formulations may cost up to four times as much as adult formulations, and the regimens can be complex and difficult to follow. Lack of availability of appropriate ARV formulations that are inexpensive and easily usable is a major impediment to access for children with HIV.

PEPFAR’s existing authorities have allowed it to respond to this challenge. Most notably, PEPFAR has announced an unprecedented public-private partnership to promote scientific and technical solutions for pediatric HIV treatment, formulations, and access. This partnership seeks to capitalize on the current strengths and resources of: innovator pharmaceutical companies in developing, producing and distributing new and improved pediatric ARV preparations; generic pharmaceutical companies that manufacture pediatric ARVs or have pediatric drug development programs; the U.S. Government in expediting regulatory review of new pediatric ARV preparations and supporting programs to address structural barriers to delivering ART to children; and civil society/multilateral organizations to provide their expertise to support the success of the partnership.

The partners are working to identify scientific obstacles to treatment for children that the cooperative relationship could address. They are also sharing best practices on the scientific issues surrounding dosing of ARVs for pediatric applications. Finally, the partners are developing systems for clinical and technical support to facilitate rapid regulatory review, approval, manufacturing and availability of pediatric ARV formulations. An upcoming meeting of the pediatric public-private partnership will highlight the group’s progress to date.

Challenge 4: Appropriate Dosing of ARVs in Children

Even when appropriate formulations of ARV agents are available for children, pharmacokinetic data may be insufficient to appropriately guide drug dosing, especially in the youngest children (who metabolize these drugs differently) but also in adolescents, who may need higher than the “maximum adult dose” for adequate drug exposure. Earlier evaluation of ARV safety and pharmacokinetics in children is needed so that when new ARV formulations are approved for use in adults, there are also preparations available for children; enough information about drug pharmacokinetics in children is available to allow rational dosing recommendations. Appropriate dosing of drugs in pediatric patients requires measurement of weight and height and the complex calculation of body surface area. The requirement for different doses according to age, weight, and body surface area may put accurate prescribing and safe dispensing of ARVs and other drugs to pediatric patients beyond the reach of many of the front-line health care professionals who treat children with HIV.

Under existing authorities, PEPFAR has supported the development and implementation of WHO-simplified dosing guides, which are readily available to clinicians who care for children and adolescents with HIV infection in resource-limited settings (available at www.who.int/hiv/paediatric/en/index.html). These guides will increase the accuracy of dosing and dispensing ARV medications to children. The PEPFAR pediatric technical working group has also assisted in the development of the "Handbook for Pediatric AIDS in Africa," which provides instructions and job aids on simplified dosing and quality services in pediatric care and treatment.

Moreover, through a fast-track approval process developed under PEPFAR, HHS/FDA recently approved the first-ever fixed-dose pediatric formulation, which simplifies dosing of, and adherence to, a triple combination of pediatric ARV innovator drugs for use in children under 12 years old. This formulation is one of 51 HIV/AIDS drugs approved or tentatively approved for purchase under PEPFAR by HHS/FDA. Further, through an existing agreement with WHO, this HHS/FDA-approved formulation is added automatically to the WHO prequalification list, which will expedite the regulatory processing of this formulation at the national level across PEPFAR countries.

Lastly, concerning family-centered care, this type of care offers members of a single household access to HIV testing, treatment, prevention services such as bed nets for malaria, and other care services in one encounter with the healthcare system, whether in the home or in a facility. It represents a public health approach that recognizes the link between the family environment and health and leverages the availability of the healthcare worker to provide consistent care and prevention messages to an entire family. Although widely accepted as a model of delivering care, family-centered care requires healthcare providers to provide care to both adults and to children, and in some cases may raise issues around confidentiality within families. Both of these challenges are routinely overcome through healthcare worker training, and the use of a public health model of delivering care and services.

Prevention of Mother-to-Child Transmission (PMTCT)

Question 5. Every day more than 1,100 children across the globe are infected with HIV, the vast majority through mother-to-child transmission. What is most tragic is that research has shown that these infections are largely preventable. The simple reason that the infection rate among children remains so high is that pregnant mothers and their babies are not getting the life-saving care they need. Less than 10 percent of pregnant women with HIV in resource-poor countries have access to prevention of mother-to-child transmission services.

What do you think have been the specific barriers to reaching more mothers and babies?

Answer 5. Mother-to-child transmission remains the leading source of child HIV infections, and prevention of mother-to-child transmission (PMTCT) remains an essential challenge. According to UNAIDS, the global number of children who became infected with HIV has dropped slightly, from 460,000 in 2001 to 420,000 in 2007.

Access to vital antenatal clinic (ANC) interventions varies across the focus countries. As a key element of its support for comprehensive programs, the Emergency Plan supports host governments' and other partners' efforts to provide PMTCT interventions, including HIV counseling and testing, for all women who attend ANCs. Key obstacles to successful scale-up of PMTCT programs that PEPFAR is working to address include: (1) failure to adopt and fully implement "opt-out" provider-initiated counseling and testing; (2) lack of integration of PMTCT as a basic part of maternal and child health care; (3) difficulties extending coverage to peripheral and rural sites; and (4) challenges in developing effective linkages with HIV care and treatment services.

Despite significant resources from PEPFAR, levels of PMTCT coverage continue to vary dramatically from country to country. While all PEPFAR focus countries have scaled up services significantly in recent years, the results in some countries remain disappointing. Yet, nations that have adopted and implemented opt-out testing have dramatically increased the rate of uptake among pregnant women, from low levels to around 90 percent at many sites.

Barriers currently limiting the scale-up of pediatric treatment and care services for children infected through maternal transmission include a lack of providers equipped with the necessary skills to address the special needs of HIV-positive children, the relatively high cost of pediatric ARV formulations, regulatory barriers to registering pediatric ARV formulations, weak linkages between PMTCT and treatment services, and limited information about pediatric doses of medicines at different ages and weights.

Question 6. Where is PEPFAR succeeding in overcoming these barriers and where is it falling short?

Answer 6. To address these barriers, PEPFAR has supported host nations' efforts to provide PMTCT services, including HIV counseling and testing, for all women who attend antenatal clinics (ANCs), and sharply increased its PMTCT resources in fiscal year 2007. PEPFAR has supported PMTCT services for women during approximately 10 million pregnancies to date, providing antiretroviral prophylaxis for over 827,000 women who were determined to be HIV-positive, preventing an estimated 157,000 infections of newborns.

Some countries, such as Botswana and South Africa, had already started their PMTCT programs before the U.S. Government's Mother and Child HIV Prevention Initiative was launched in 2002. Many nations have made very significant progress in reaching pregnant women with PMTCT interventions with PEPFAR support in the last 4 years. In other countries, progress has been slower, and the Emergency Plan is supporting these nations in redoubling efforts to close the gap. When comparing results from the first year of PEPFAR in fiscal year 2004 to fiscal year 2007, all countries have scaled up, and most have dramatically improved availability of PMTCT services to pregnant women.

Under the highly successful national program in Botswana, where approximately 13,000 HIV-infected women give birth annually, the country has increased the proportion of pregnant women being tested for HIV from 58 percent in fiscal year 2004 to 92 percent in fiscal year 2007. The percentage of infants born infected has declined to approximately 4 percent, compared to about 35 percent without a PMTCT program. This type of change can be seen in other countries as well. It reflects a combination of political leadership, adoption of opt-out testing policies, and the introduction of rapid testing. Increased integration of maternal and pediatric care services is another critical piece of successful programs, and is another component of the technical guidance provided to countries as they prepare their PEPFAR country operational plans. Without effective implementation of the policies, success similar to that achieved by Botswana is unlikely to occur.

PEPFAR has also expanded access to treatment for children, with the number of children receiving antiretroviral treatment through downstream PEPFAR support increasing 77 percent from fiscal year 2006 to fiscal year 2007. PEPFAR dedicated nearly \$191.5 million to pediatric treatment in fiscal year 2006 and 2007 combined, reaching approximately 85,900 children with downstream support in fiscal year 2007, compared with only 4,800 in fiscal year 2004.

In the same way that successful maternal health programs have supported human resource development and training and use of lower level providers such as nurse midwives where appropriate, PEPFAR supports training programs for healthcare workers in HIV prevention, care and treatment and task-shifting to make the best use of the available health workforce. In fiscal year 2008 Country Operational Plans (COPs), PEPFAR country teams estimated that PEPFAR is supporting the salaries for over 111,000 workers and is working with governments to ensure the sustainability of these positions. Additionally, it is estimated that PEPFAR supported training or re-training of 109,826 individuals in the prevention of mother-to-child transmission between fiscal year 2004 and fiscal year 2007. This high level of support of human resource development, along with increasing support of maternal and pediatric antiretroviral treatment, is further evidence of PEPFAR's commitment to reducing transmission of HIV to children and supporting those children infected and affected by HIV/AIDS.

Question 7. In 2001 the United Nations set a goal to cut the number of pediatric infections by half in 2010. To reach this goal, it is estimated that 80 percent of pregnant women must have access to PMTCT services. As you may know, I recently introduced the "Global Pediatric HIV/AIDS Prevention and Treatment Act," along with Senator Gordon Smith, which would set a target that within 5 years (by 2013), in those countries most affected, 80 percent of pregnant women receive HIV counseling and testing, with all those testing positive receiving antiretroviral medications for the prevention of mother-to-child transmission.

Can you provide your thoughts on such a target?

Answer 7. Prevention of mother-to-child transmission (PMTCT) is a key element of the prevention strategies of host nations, and PEPFAR is supporting their efforts. Across focus countries, the Emergency Plan has increased the estimated coverage of pregnant women receiving HIV counseling and testing from 6 percent in fiscal year 2004 to 23 percent in fiscal year 2007. As noted in the answer to Question #2, the Emergency Plan's goal is to replicate the results of the highly successful national program in Botswana, where approximately 13,000 HIV-infected women give birth annually, the country has increased the proportion of pregnant women being

tested for HIV from 58 percent in fiscal year 2004 to 92 percent in fiscal year 2007. The percentage of infants born infected has declined to approximately 4 percent, compared to about 35 percent without PMTCT interventions. This type of change can be seen in other countries as well. It reflects a combination of political leadership, and implementation of opt-out and rapid testing. Without these changes of policy—and effective implementation of the policies—success similar to that achieved by Botswana is unlikely to occur.

Nations have sought to ensure that all women receive the option of an HIV test through pre-test counseling during pregnancy (or at or after delivery, if they do not seek care before delivery). By promoting the routine, voluntary offer of HIV testing—so that women receive testing unless they opt-out—host nations have increased the rate of uptake among pregnant women from low levels to around 90 percent at many sites. Adoption and effective implementation of opt-out testing, rapid testing, and other essential policy changes, is essential for success and providing pregnant women with as much access to PMTCT interventions as possible.

Question 8. How is PEPFAR currently integrating PMTCT services with continuum of care services for mothers and families? How can PEPFAR improve the integration of PMTCT services with other prevention, care and treatment programs?

Answer 8. Mother-to-child transmission remains the leading source of child HIV infections, and prevention of mother-to-child transmission (PMTCT) remains an essential challenge. As a result, PEPFAR programs are increasingly linked to other important programs in prevention, treatment, and care—including those of other USG agencies and other international partners—that meet the needs of people infected or affected by HIV/AIDS in such areas as nutrition, education, and gender.

For example, in Uganda, PEPFAR and the President's Malaria Initiative (PMI) are providing joint funding of a nationwide health facility survey. Several PEPFAR partners have gained access to free insecticide-treated nets (ITN) through PMI support, and PEPFAR and PMI are providing joint support for antenatal clinic (ANC) interventions for malaria and HIV/AIDS (e.g., distribution of ITNs through ANCs, and integrated training linking PMTCT and malaria prevention to maternal and child health curriculums).

Question 9. Do you agree that voluntary family planning services are an essential component of comprehensive PMTCT?

Answer 9. No. HIV prevention and voluntary family planning are two distinct activities with distinct purposes, and are supported through distinct U.S. programs. PEPFAR does, however, support linkages between HIV/AIDS and voluntary family planning programs, including those supported through USAID's Office of Population and Reproductive Health (PRH). PEPFAR works to link family planning clients with HIV prevention, treatment and care, particularly in areas with high HIV prevalence and strong voluntary family planning systems. Voluntary family planning programs provide a key venue in which to reach women who may be at high risk for HIV infection. PEPFAR supports the provision of confidential HIV counseling and testing within family planning sites, as well as linkages with HIV care and treatment for women who test HIV-positive. Ensuring that family planning clients have an opportunity to learn their HIV status also facilitates early up-take and access to PMTCT services for those women who test HIV-positive. PEPFAR's efforts remain focused on HIV/AIDS prevention, treatment and care, complementing the efforts of USAID/PRH programs and other partners.

QUESTIONS OF SENATOR CLINTON

Question 1. In your testimony, you note that the U.S. government has provided treatment for more than 1 million individuals worldwide. How many women are currently receiving treatment through the President's Emergency Plan for AIDS Relief (PEPFAR)? How many of them are pregnant women enrolled in programs to prevent mother-to-child transmission of HIV, and how many of them are non-pregnant women? How many children are enrolled in U.S.-funded treatment programs?

Answer 1. Globally, the President's Emergency Plan for AIDS Relief (PEPFAR/Emergency Plan) supported life-saving antiretroviral treatment for approximately 1,445,500 men, women and children through September 30, 2007. Of the 1 million people receiving antiretroviral treatment through direct U.S. Government (USG) support in the focus countries, nearly 86,000, or 9 percent, are children age 14 and under. This represents a 77 percent increase over the number of children on PEPFAR-supported treatment in fiscal year 2006. In the focus countries, 62 percent, or approximately 620,000, of the 1 million individuals on antiretroviral treatment as a result of direct PEPFAR support are women and girls.

In addition, the Emergency Plan has supported through September 30, 2007 in PEPFAR's 15 focus countries: prevention of mother-to-child HIV transmission services for women during more than 10 million pregnancies; antiretroviral prophylaxis for women in 827,000 pregnancies; prevention of an estimated 157,000 infant infections; care for more than 6.6 million people, including care for more than 2.7 million orphans and vulnerable children; and over 33 million counseling and testing sessions for men, women and children.

Question 2. According to the Government Accountability Office (GAO), your office has mandated that 66 percent of sexual prevention funding be spent on "AB" activities—activities that focus on abstinence and being faithful. However, more than 40 percent of women in Africa are married before their 18th birthday, and may have little control or influence over the sexual activities of their partners. Given these factors, how does your office justify the 66 percent spending requirement? How are you working to protect women who need information beyond what is provided through "AB" activities?

Answer 2. Millions of women and girls do not have the power to make sexual decisions. Abstinence, like condom use, is not an option when you lack the power to choose or are faced with sexual coercion or rape. Therefore, girls' education and women's empowerment are critical in the fight against AIDS. PEPFAR strongly supports addressing gender dynamics in all aspects of programming. Young girls who are married must receive a comprehensive Abstain, Be faithful, correct and consistent use of Condoms (ABC) prevention intervention. While ABC programs must be comprehensive to be effective, they also must be tailored to the contours of the epidemic in its specific time and place. ABC behavior change must undeniably be at the core of prevention programs, but one-size-does-not-fit-all. This is why PEPFAR takes different approaches, depending on whether a country has a generalized and/or a concentrated epidemic. The existing directive that 33 percent of prevention funding be spent on abstinence and faithfulness programs is applied across the focus countries collectively, not on a country-by-country basis—and certainly not to countries with concentrated epidemics.

In countries with concentrated epidemics where, for example, 90 percent of infections are among persons in prostitution and their clients, the epidemiology dictates a response more heavily focused on B and C interventions. For this reason, PEPFAR changed its fiscal year 2008 guidance to waive the directive that abstinence and faithfulness programs receive at least one-third of prevention resources for countries with concentrated epidemics—defined as a prevalence rate below 1 percent. (It was possible to do this because compliance with the directive is assessed for PEPFAR as a whole.) In countries with prevalence above 1 percent where PEPFAR teams believe meeting the abstinence and faithfulness directive would not make epidemiological sense, programs may also submit a justification explaining why they have chosen not to meet the requirement. PEPFAR has never rejected such a justification, and the number submitted by the focus countries has grown from 8 in fiscal year 2006 to 11 each in fiscal years 2007 and 2008.

Moreover, PEPFAR fully integrates gender considerations into all its prevention, care, and treatment programs, recognizing the critical need to address the inequalities between women and men that influence sexual behavior and put women at higher risk of infection—as well as those that create barriers to men's and women's access to HIV/AIDS services.

Additionally, the Emergency Plan supports five key cross-cutting gender strategies that are critical to curbing the HIV/AIDS epidemic, ensuring access to quality services, and mitigating the consequences of the epidemic: increasing gender equity in HIV/AIDS activities and services; reducing violence and coercion; addressing male norms and behaviors; increasing women's legal protection; and increasing women's access to income and productive resources. Activities in support of these focus areas are monitored annually during the Country Operational Plan (COP) review process. In fiscal year 2007, a total of \$906 million was dedicated to 1,091 activities that included interventions to address one or more of these gender focus areas; in fiscal year 2008, the total is expected to rise to approximately \$1.03 billion.

In 2007, three special gender initiatives were launched in nine countries to intensify program efforts in three of these focus areas: scaling up evidence-based programs to address male norms and behaviors; strengthening interventions for victims of sexual violence, including antiretroviral post-exposure prophylaxis (PEP) to prevent HIV infection; and reducing inequities that fuel girls' vulnerability to HIV/AIDS.

Gender issues are central to many HIV prevention programs, particularly those focused on youth. As young people are taught through the ABC approach to respect themselves and respect others, they learn about gender equity. While gender equity

does not directly reduce HIV transmission, the ABC approach is particularly important for the protection of women and girls, particularly when men successfully change their behaviors. By supporting delayed sexual debut, secondary abstinence, fidelity to a single partner, partner reduction, and correct and consistent condom use, ABC interventions can address unhealthy cultural gender norms among boys, girls, men, and women.

Question 3. In your testimony, I appreciate your mention of incorporating new biomedical prevention approaches, but also believe we can and should be devoting additional resources to identifying and replicating effective behavioral interventions. How much funding is the Office of the Global AIDS Coordinator devoting to operations research, not counting routine monitoring and evaluation activities that are carried out in the focus countries?

Answer 3. PEPFAR dedicated approximately \$46.4 million to operations research and evaluation in fiscal year 2007, including spending for public health evaluations funded through PEPFAR's Country Operational Plan (COP), process, public health evaluations funded centrally by PEPFAR, and other operations research activities. Of this, \$26.4 million was directed toward operations research in priority prevention activities, including those associated with gender-based violence, male circumcision, prevention with positives, adolescent and young girls, and men as partners. PEPFAR further spends over \$135 million on strategic information in all countries, including monitoring and evaluation activities that may include operational research. Some monitoring and evaluation activities are budgeted by countries under prevention, care, and treatment categories.

QUESTION OF SENATOR BROWN

Question 1. The Administration has shown impressive leadership in HIV/AIDS, TB, and malaria. However, the investment in funding for TB control and research could be stronger. As you know, TB is a preventable and curable disease and no region of the world is unaffected. Without access to antiretrovirals and proper TB treatment, most people living with HIV who are co-infected with TB will die quickly, sometimes in a matter of weeks. We cannot seriously talk about addressing HIV/AIDS without a massive increase in our investment into TB control and new tools research. The Stop TB Partnership's Global Plan to Stop TB sets 2015 targets so that at least 85 percent of TB patients should be counseled and tested for HIV and 57 percent of HIV+ TB patients should be initiated on ART.

How close are we to achieving these goals? Should addressing the crossover between TB and HIV services be a greater focus in PEPFAR reauthorization?

Answer 1. The co-infection of TB and HIV is a serious threat to the public health progress of many countries supported by the President's Emergency Plan for AIDS Relief (PEPFAR/Emergency Plan) and addressing the crossover between the two diseases will remain a priority in the next phase of the Emergency Plan. The Emergency Plan has invested significant resources in combating the co-infection of TB and HIV, leading a unified U.S. Government (USG) response to fully integrate HIV prevention, treatment, and care with TB services at the country level in Emergency Plan countries. PEPFAR is the largest bilateral supporter of TB programs in the world, investing resources in three primary ways.

First, PEPFAR increased its funding for HIV/TB five-fold, from \$26 million in fiscal year 2005 to \$131 million in fiscal year 2007, and a planned level of \$150 million for fiscal year 2008. Funding supports providing HIV testing for people with TB and TB screening and diagnosis for people living with HIV; ensuring eligible TB patients receive HIV/AIDS prevention, treatment and care; implementing the WHO-recommended TB treatment protocol, Directly Observed Therapy-Short Course (DOTS); bolstering surveillance and infection control activities; strengthening laboratory capacity and supply chain management; and working with the U.S. Federal TB Task Force to coordinate the USG response.

Second, the USG is the largest contributor to our most significant partner in the prevention and control of TB—the Global Fund to Fight AIDS, Tuberculosis, and Malaria. The U.S. Government, through PEPFAR, has contributed roughly 30 percent of the Global Fund's contributions from all sources, as well as technical assistance to the Global Fund country coordinating mechanisms to strengthen the planning, implementation, and evaluation of TB grant activities. With these resources, the Global Fund has committed roughly 17 percent of its funding to national TB programs around the world. PEPFAR is also involved in the oversight and management of the Global Fund, with high-level representation on the Board and several Global Fund committees, to ensure effective program delivery.

Third, the Emergency Plan invests additional resources for TB globally through strategic partnerships with the World Health Organization, and the STOP TB Part-

nership. The Emergency Plan worked closely with WHO to implement a 2-year collaborative effort to support scale-up of TB/HIV services in Rwanda, Kenya and Ethiopia. Lessons learned in this process are being replicated in other countries' TB/HIV scale-up plans. With the STOP TB Partnership, the Emergency Plan provides technical assistance for the Advocacy, Communication and Social Mobilization (ACSM) components of Global Fund TB grant programs to stimulate demand for TB services.

Through these three major mechanisms for reducing TB globally—(1) direct funding for PEPFAR TB/HIV activities, (2) financial and technical support for the Global Fund TB activities, and (3) financial and technical support for other major international TB partnerships—PEPFAR is a leader in global contributions to international TB efforts. The Emergency Plan will continue its efforts to control the spread of TB/HIV in the next phase.

PEPFAR plans to continue investing significantly in the integration and coordination of HIV/AIDS and TB programs in clinical and laboratory facilities, as well as at the level of policy, surveillance, and monitoring and evaluation systems. PEPFAR support for HIV care and treatment provides an extensive platform for intensified TB case finding. This includes routine screening for signs and symptoms of TB disease and rapid initiation of appropriate treatment. This effort also has the important effect of interrupting transmission of TB among susceptible individuals—including people living with HIV—and the community at large.

As country capacity and programming expands, PEPFAR will continue to focus on the TB/HIV nexus in its bilateral programs and in its collaboration with other USG TB efforts, the Global Fund, and host nations.

QUESTIONS OF SENATOR COBURN

Question 1. You testify that 46 percent of PEPFAR funding goes to treatment. The law requires 55 percent at minimum. What are the reasons for the disparity? Given that the President's targets were not required by law, though they were encouraged in the Leadership Act, but the 55 percent allocation to treatment was required by the law, if you were able to meet the targets spending less than 55 percent, wouldn't you agree that you are still required by the law to treat more people than the President's minimum?

Answer 1. The treatment funding directive was set before there was solid information on the cost of treatment in developing nations, such as those in Africa. Costs of treatment have fallen dramatically since 2003—largely because costs of antiretroviral drugs (ARVs) have plummeted, now accounting for only 20–30 percent of total cost of treatment. With treatment becoming so much cheaper, to spend 55 percent of program funds on treatment (and 75 percent of that amount on ARVs) would unnecessarily have starved programs for prevention (including behavior change, such as abstinence and faithfulness) and care (including care for orphans and vulnerable children as well as people living with HIV/AIDS)—programs that can prevent people from ever needing treatment. It was not possible to meet these directives while also meeting the prevention and care goals established by Congress. We have notified Congress of this situation each year.

Question 2a. Your testimony rightly acknowledges that the United States was not supporting treatment prior to the implementation of PEPFAR, only a few years ago. Today, as you testify, 46 percent of billions of dollars are spent on treatment. Also prior to the implementation of PEPFAR, very little if any was being spent by any donor on delayed sexual debut and partner reduction. Today, a third of billions of dollars of prevention money is spent on those critical interventions.

Would you agree that the allocations are largely responsible for creating this sea-change in priorities?

Answer 2a. As mentioned previously, our experience over the last several years has shown that while ARV prices vary (affecting the overall percentage of resources devoted to treatment in a given year), having a concrete goal of 2 million people receiving treatment has been a far more important benchmark and driver both in the field and in a broader international context. Because it is relatively easy to measure regularly the number of people on treatment, a results-based goal (rather than a funding-based one) has had the greatest impact in this area.

In the case of prevention, in contrast, the overall goal of 7 million infections averted does not by itself require a specified level of spending on abstinence and faithfulness activities. In this area, the abstinence and faithfulness directive has played a helpful role in re-orienting the U.S. Government's prevention portfolio. Moreover, because it is harder to measure the results of prevention programs quickly enough to adjust programmatic budgets on a yearly basis, an inputs-based requirement has

helped to ensure balanced prevention programs that maximize our impact in preventing new infections.

Question 2b. Isn't it true that most of the USAID staff are still the same as they were several years ago? And although we have brought in lots of new partners as grantees under PEPFAR, aren't we also still funding the same ones we used to be before PEPFAR?

Answer 2b. While many new USAID personnel have begun service since 2003, it is also true that many staff have been serving since before that date. Implementing partners are a mix of pre-existing and new partners, and PEPFAR has sought to increase the number of the latter category. An important part of systems-strengthening is PEPFAR's support for local organizations, including host government institutions, organizations of HIV-positive people and faith- and community-based organizations. Review of annual PEPFAR Country Operational Plans (COPs) includes evaluation of efforts to increase the number of indigenous organizations partnering with the Emergency Plan. In fiscal year 2007, PEPFAR partnered with 2,217 local organizations—up from 1,588 in fiscal year 2004—and 87 percent of partners were local. Reliance on such local organizations, while sometimes challenging, is essential for PEPFAR to fulfill its promise to partner with host nations to develop sustainable responses.

As another step in the direction of sustainability, PEPFAR country programs may devote no more than a maximum of 8 percent of funding to a single partner (with exceptions made for host government partners, commodity procurement, and “umbrella contractors” for smaller organizations). This requirement is helping to expand and diversify PEPFAR's base of partners, and to facilitate efforts to reach out to new partners, particularly local partners—a key to sustainability. The exception for umbrella contracts is based on a desire to support large organizations in mentoring smaller local organizations, supporting capacity-building in challenging areas such as management and reporting. PEPFAR has also worked with its international implementing partners to ensure that they have strategies to hand over programs to local organizations as those groups develop the capacity to work directly with the USG.

President Bush launched the New Partners Initiative (NPI), part of PEPFAR's broader effort to increase the number of local organizations, including faith- and community-based organizations (FBOs and CBOs), that work with the Emergency Plan. Through NPI, PEPFAR is enhancing the technical and organizational capacity of local partners, and is working to ensure sustainable, high-quality HIV/AIDS programs by building community ownership. NPI supports organizations that have previously worked as PEPFAR subpartners' receiving PEPFAR funds through larger organizations—in graduating to prime partner status. Each grantee receives comprehensive technical and organizational support through NPI, including support for financial and reporting capacity, enabling them to compete not only for PEPFAR prevention and care resources but also for grants and contracts from other sources of funding.

Question 2c. You, Ambassador Dybul, might be committed to the current mix of funding even if you weren't required to be by law. But when you're gone in a year, what assurance can you give that, without the allocations for treatment and for delayed sexual debut and partner reduction, the USAID staff and old implementing partners won't go right back to the interventions they were promoting before the law required them to change?

Answer 2c. The budget allocations expire with fiscal year 2008 (and the abstinence/be faithful directive, was removed even for fiscal year 2008 by appropriations action). Of course this Administration cannot offer any assurances about what will follow, but the reauthorization process provides a vehicle to address the issue of sustainability of the new directions this initiative has begun. It will be important for Members of Congress to review the successes we have had over the first 4½ years of implementation and evaluate an appropriate balance of flexibility and encouragement when determining the appropriate goals and mix of funding.

Question 3. Your testimony says: “In Rwanda, for example, these systems-strengthening efforts have enabled us to begin using performance-based contracts that resemble the block grants used in our domestic treatment programs.” Can you elaborate on this?

Answer 3. Performance-based financing (PBF) is an approach to health financing that emphasizes outputs in health services. In an important test of this approach, Rwanda's Ministry of Health and PEPFAR are working together to roll out national performance-based financing for the prevention, care and treatment of HIV/AIDS and a basic and complementary package of health services. PBF offers financial in-

centives to health facilities to increase the quantity and improve the quality of health services provided. In Rwanda, PBF is operational in health facilities in 23 of the country's 30 districts. With U.S. support, the Government of Rwanda created a detailed system to track and monitor the number of individuals who receive health services and the overall quality of each health facility. Each facility is responsible for tracking the quantity of services provided, and the overall quality of the facility is assessed by independent and external evaluations conducted by district health professionals with assistance from technical assistants from the Ministry of Health, international partners and implementing partners. The Government of Rwanda pays for the provision of basic health services, while PEPFAR funds HIV/AIDS services, which includes voluntary counseling and testing, prevention of mother-to-child transmission and treatment for those who are HIV-positive.

Health facilities enrolled in the performance-based financing initiative use the additional funding due to improved performance to address whatever needs the managers have identified. PBF has given health facilities the ability to increase staff support and improve infrastructure, and it has provided communities with greater access to health services.

Early results are promising. Across four health centers in Gicumbi District over a 12-month period that began in October 2006, the number of people receiving voluntary counseling and testing for HIV increased by 246 percent, from 417 to 1,443 tests per month.

In another early example, clinic staff at the Rwesero Health Center in Gicumbi District have made their services available to a greater number of people, with the number of clients who received voluntary HIV tests increasing 294 percent in just over a year. The Rwesero Health Center now has the means to regularly offer cotrimoxazole (CTX), an essential antibiotic that is used to help prevent opportunistic infections in those who are HIV-positive. Prior to PBF it was difficult for the health center to apply this national treatment guideline. However, under PBF, the number of such people receiving CTX in Rwesero each month has increased from 0 to 66.

While Rwanda's situation is unique and many countries are not yet in a position to implement PBF as Rwanda is doing, PEPFAR is closely examining this experience to assess its replicability in other venues.

Question 4. For years, CDC has been asking this committee to grant construction authority so that CDC can support its programs properly with the clinics and labs that rural Africa needs. Now, I'm not suggesting that CDC should run wild building buildings all over the world, especially buildings that are named after Senators. However, when the agency keeps asking again and again and makes the case that the backlogs at the State Department bureaucracy won't allow them to build what they need to build in order to run effective programs, I have to wonder if maybe they might have a real need for independent construction authority.

Why is the State Department continuing to thwart HHS efforts to meet this public health need, either through outright prohibition or bureaucratic obstruction? When will State back off and let CDC do what's necessary to effectively run PEPFAR programs in rural areas where there are no buildings to renovate and new buildings need to be built?

Answer 4. PEPFAR is working through a policy process to finalize Administration guidance on construction authority provided in law under PEPFAR; the process is intended to clarify legal interpretation of this current authority and therefore the use of funding. This process should be complete in the near future and will reduce future impediments to using PEPFAR funding for the construction needs of PEPFAR.

The Department of Health and Human Services/Centers for Disease Control and Prevention (HHS/CDC) is currently able to procure overseas construction projects through the State Department's Regional Procurement Support Offices (RPSO) in Ft. Lauderdale, Florida, and Frankfurt, Germany. The increase in PEPFAR-funded construction and renovation projects, especially in Africa, over the last 2 years has taxed the existing capacity at RPSO/Frankfurt, and we have been working with RPSO and its parent bureau in Washington to increase its capacity to manage the increased number of PEPFAR projects. Pending the guidance described above, we also are working to educate our field teams on how to engage RPSO in the most effective manner.

Question 5. There is no question that HIV/AIDS has a significant impact on the overall development of countries in which the pandemic is prevalent. I understand that a number of members and interest groups are advocating that PEPFAR funds increasingly be diverted away from purely HIV/AIDS programming to related programs such as education, nutrition, and family planning, that aren't necessarily the

primary focus of PEPFAR. I am concerned about this “mission creep” and PEPFAR losing its focus. Should PEPFAR be replacing USAID, Millennium Challenge and other programs?

Answer 5. The Emergency Plan is central to U.S. efforts to “connect the dots” of international development. PEPFAR programs are increasingly linked to other important programs—including those of other U.S. Government agencies and other international partners—that meet the needs of people infected or affected by HIV/AIDS in such areas as nutrition, education and gender.

But while PEPFAR is an important part of connecting the development dots, it does not—and could not—replace USAID, MCC, PMI, or any of its sister initiatives or agencies. Nearly every person affected by HIV/AIDS can benefit from additional food support, greater access to education, economic opportunities and clean water, but so could the broader communities in which they live. In order to respond effectively to the many interrelated causes and effects of the epidemic, PEPFAR must integrate with other development programs, as part of a larger whole.

RESPONSE TO QUESTIONS OF SENATOR KENNEDY BY PRINCESS ZULU

Question 1. We have heard from many experts and program implementers about the particular impact of gender inequalities for women and children affected by HIV.

Can you share with the Committee your knowledge of this issue as an HIV/AIDS educator?

Answer 1. Based on my own personal experience and observations in communities across Africa, gender inequality is a very real and compelling problem. Gender inequality leaves a lot of women and girls underpowered, and often results in the denial of their basic rights, including inheritance rights. Lack of financial independence or education can exacerbate these inequities. In some cases, women are unable to protect themselves and say no to sex or may be forced to engage in risky sexual behavior in order to provide basic necessities for their families such as food, shelter and school fees. Their children are also likely to drop out of school to work for food and other basic needs and, tragically, may be left orphaned if one or more of their parents succumbs to AIDS.

Combating the gender inequalities that influence HIV/AIDS among women and children requires the collaboration of governments, civil society groups and family units. In my experience, success can begin at the community level, where men and women, boys and girls, are empowered and provided with preventive information that positively influences their behavior.

Question 2. According to UNAIDS and WHO, young people are at greater risk for HIV infection, especially since many young people do not have access to HIV information and prevention services and do not believe that HIV is a threat to them and do not know how to protect themselves.

Answer 2. Evidence suggests young people who are uninformed about how to prevent transmission of HIV are more likely to be infected with the virus. As such, every effort must be made to fully inform young people about HIV and AIDS and empower youth to make positive decisions about their sexual behavior. With sexual transmission comprising a vast majority of new HIV infections in Africa, equipping young people with the information they need to make more informed decisions about abstinence, delaying sexual debut and being faithful to one partner and proper condom use is an absolute necessity.

Adequate funding for programs that promote abstinence, being faithful and consistent and correct use of condoms should be a top priority for HIV and AIDS programs funded by the United States. In my experience, young people are capable of making informed decisions about sexual activity when they are empowered, aware of the options before them and provided support in changing their behavioral patterns. If we hope to have an impact on the spread of HIV among young people, particularly in sub-Saharan Africa, we have to be investing in the activities that most effectively prevent spread of the virus through a change in sexual attitudes and behaviors. I urge Congress to include provisions for these types of prevention programs in the reauthorization of the Global AIDS bill.

RESPONSE TO QUESTIONS OF SENATORS KENNEDY, ENZI, DODD, AND BROWN
BY HELEN SMITS

QUESTIONS OF SENATOR KENNEDY

Question 1. There are some who believe that attention to the “legal, economic, educational and social” status of women is beyond the scope of a health program.

Why is PEPFAR working in this area and why has the IOM recommended greater attention to this area?

Answer 1. PEPFAR is working in this area because the U.S. Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (the Leadership Act) requires it to do so—see Chapter 8 of the IOM report (page 249).

The IOM Committee found that the Leadership Act's emphasis on women and girls was warranted—see Chapter 2 of the IOM report which discusses the increasing burden of HIV/AIDS on women and girls, pages 52–54 (emphasis added):

“As of 2006, almost half of all people living worldwide with HIV/AIDS were women (UNAIDS, 2006). In sub-Saharan Africa, however, women now represent 59 percent of all people living with HIV/AIDS, and the proportion is growing (UNAIDS, 2006). Today's statistics are the product of a trend toward increasing rates of infection among women, given that the pandemic started in men. **The reasons underlying this trend include the inferior social and economic status of women in many countries, which affects their chances of gaining access to either means for prevention of or treatment for HIV/AIDS and related complications; violence against women and girls, including domestic, sexual, and war-related violence; and biological factors that increase the susceptibility of women to infection.** UNAIDS has expressed concern about gender-based inequalities in access to treatment, with some evidence of women paying more for services and being hospitalized less frequently when clinically appropriate (UNAIDS, 2004b).

Teens and young adults (aged 15 to 24) continue to be at the center of the epidemic with heavy concentrations among those newly infected, accounting for more than 40 percent of new adult HIV infections in 2000. In sub-Saharan Africa, three young women are infected for every young man in this age group. The situation is similar in the Caribbean, where young women are about twice as likely as men their age to be infected with HIV (UNAIDS, 2006).

Biological characteristics place women at greater risk than men of contracting the virus from engaging in unprotected sex, **but gender disparities and inequity are probably more responsible for rising infection rates in women.”**

The IOM committee also found that PEPFAR was supporting numerous programs and services directed at reducing the risks faced by women and girls, but was unable to determine either the individual or collective impact of these activities on the status of and risks to women and girls (see Chapter 8, pages 249–252). The IOM committee recommends that the U.S. Global AIDS Initiative continue to increase its focus on the factors that put women at greater risk of HIV/AIDS and to support improvements in the legal, economic, educational, and social status of women and girls. The IOM committee believes such improvements are necessary to create conditions that will facilitate the access of women and girls to HIV/AIDS services; support them in changing behaviors that put them at risk for HIV transmission; allow them to better care for themselves, their families, and their communities; and enhance their ability to lead and be part of their country's response to its HIV/AIDS epidemic.

Specifically, the IOM committee was encouraged by OGAC's formation of the Technical Working Group on Gender and the focus that it could bring on the needs of women and girls and approaches to meet them. The IOM Committee also urges The Global AIDS Coordinator to keep his commitment to implement expeditiously the recommendations developed as a result of the June 2006 “Gender Consultation” hosted by PEPFAR.

In fighting this epidemic, we need to take the steps that work. The consensus opinion, both of the experts on the committee and of those with whom we consulted, is that increased economic empowerment for women is a critical step in allowing them to protect themselves from infection.

The problem can be seen very clearly in the prevalence rates of HIV by age and gender, which are remarkably consistent across African countries. Girls contract AIDS much earlier than boys, largely as the result of transactional sex with older men. Parents, we were told, are often complicit in such an arrangement because any additional resources help the family to survive. A girl who knows she can continue her education and who sees a clear path to a better economic future is more likely to resist the temptation of a cell phone and a nice dinner now; a mother who can comfortably feed the family is more likely to tell her daughter to resist.

Question 2. Your report states that to succeed in building long term sustainability PEPFAR must strengthen national health systems and the healthcare workforce. And you specifically recommend an increase in support to expand workforce capacity for the education of new health care workers.

Many other stakeholders believe task shifting is a sufficient strategy to deal with health worker shortages—do you agree with this statement?

Answer 2. The IOM committee found that while task shifting is an important component of a strategy to deal with health worker shortages, it is not by itself sufficient (see Chapter 8, pages 255–259). The IOM Committee also observed that while PEPFAR provides support for virtually all aspects of workforce capacity-building, it provides little to no support for training new health workers, even when it is a key component of a country's strategy.

The numbers that we saw regarding health professionals made clear to us that no degree of task shifting would, by itself, solve the problem. We should note that some of the countries that have done particularly well with task shifting have also increased the number of health workers in order to ensure that the nurses and clinical officers now involved in AIDS treatment do not leave a vulnerable health system even more vulnerable.

I would like to stress that in recommending an increase in support for the training of new health workers, we also emphasized that “such support should be planned in conjunction with other donors to ensure that comparative advantages are maximized and be provided in the context of national human resource strategies that include relevant stakeholders.”

QUESTIONS OF SENATOR ENZI

Question 1. In reference to your response regarding accountability measures, could you elaborate on the suggestions you gave during your testimony? Are any of these recommendations referenced in the IOM report?

Answer 1. Although the IOM committee did not develop specific accountability measures, it outlined the general types and foci of measures that should be developed to allow Congress to better understand PEPFAR's accomplishments.

Generally, the IOM committee argues for the following shifts in the foci and types of measures:

- From measures of spending (inputs) to measures of results (outputs and beyond);
- From “counts” of programs funded or people receiving services to measures of the effectiveness of the programs funded and effects on the people being served;
- From measures that promote rigid categorization to ones that promote comprehensive, integrated, and tailored programming and implementation; and
- From HIV/AIDS-specific measures exclusively to measures that include effects on population health and systems generally.

The IOM report also emphasizes the need for accountability measures to be harmonized with those of partner countries, coordinated with other donors, and sensitive to the burdens that can be created when specific attribution is demanded. The IOM report also underscores the need to support the monitoring and evaluation (accountability) enterprises of the partner countries as a critical component of capacity building.

More specifically, the section on Targets in Chapter 3 (see pages 101–102) recognizes that the measures PEPFAR has been reporting are reasonable for the short-term and acknowledges that the program has plans to measure more meaningful mid- and long-term results. In this section, the IOM committee makes two suggestions about setting future targets:

“PEPFAR would do well to consider a step taken by some other large donors: evaluating Country Teams on how well they cooperate with the partner government and the donor group as a whole and how effective they are at leveraging a successful package of services.

Finally, targets that are defined in terms of whether programs meet the full spectrum of needs of an individual person across his or her lifespan, of all members of the family or household, and of communities as a whole would create improved incentives for programming that is comprehensive, integrated, and accountable to those being served.”

Most specifically, the IOM committee recommends that a distinct target be set for orphans and other vulnerable children (see page 13 of the Summary)—currently, they are included within the Care target. Such a target will be especially critical when the budget allocations are removed, because currently the allocation for orphans and other vulnerable children is the only accountability measure for this population.

Also, in Chapter 8, the IOM Committee outlines a long list of questions that need to be asked and answered (see pages 261–267) and emphasizes the need to “measure what really matters” (see page 267), including:

- reductions in disability, disease, and death from HIV/AIDS;
- increases in the capacity of partner countries to sustain and expand HIV/AIDS programs without setbacks in other aspects of their public health systems; and
- improvements in the lives of the people living in these countries.

To understand whether countries are achieving these ultimate goals and what contributions the U.S. Global AIDS Initiative is making to their achievement, the initiative will need to study national trends, such as:

- rates of new HIV and other infections;
- rates of survival from HIV/AIDS and other diseases;
- child survival, development, and well-being; and
- general health status of the population and key subpopulations.

In addition, the last part of the committee's work was a workshop to discuss evaluation of the impact of PEPFAR. All of the materials from this workshop are available on the project webpage—www.iom.edu/pepfar—or, more specifically, at the following link: <http://www.iom.edu/CMS/3783/24770/42120.aspx>. A summary of this workshop is forthcoming and we will transmit it to you as soon as it is available.

Question 2. As the IOM reviewed the situation of women and girls, you noted that there was no evidence that women and girls were unable to access treatment. In fact, you noted that women comprised 70 percent of the individuals receiving care under the global AIDS program. What more should we do to emphasize family-centered care?

Answer 2. See response above re: developing targets that then drive program planning and implementation. To enable and promote family-centered care, the targets should be defined in terms of whether programs meet the full spectrum of needs of an individual person across his or her lifespan, of all members of the family or household, and of communities as a whole.

The IOM report discusses at length the benefits of community-based, family-centered care and suggests successful approaches to this important area (see especially Chapters 6 and 7). We note, for example, that “interventions at the community level involving the active engagement and participation of the community have the greatest likelihood of success.”

The IOM Committee observed that conceptualizing programs in terms of the needs of families and communities—rather than categorically in terms of prevention, treatment, and care—better promotes comprehensive, integrated care.

“During its visits to the focus countries, the committee observed several positive examples of integration among PEPFAR-supported programs—of systems for referral from counseling and testing programs to ART programs, of linkages between ART services and home-based care services, and of integration of HIV and tuberculosis testing and treatment. But the committee also observed many missed opportunities for improving the comprehensiveness and effectiveness of services through better integration—for example, between programs aimed at prevention of mother-to-child transmission and infant feeding programs; between counseling and testing services and further counseling services, ART, and other treatment; between counseling and testing and clinics addressing sexually transmitted infections and reproductive health; between HIV and tuberculosis testing and treatment services; among multisectoral services for orphans and other vulnerable children; and between HIV/AIDS and food aid programs.”

QUESTIONS OF SENATOR DODD

Prevention of Mother-to-Child Transmission (PMTCT)

Question 1. Every day more than 1,100 children across the globe are infected with HIV, the vast majority through mother-to-child transmission. What is most tragic is that research has shown that these infections are largely preventable. The simple reason that the infection rate among children remains so high is that pregnant mothers and their babies are not getting the life-saving care they need. Less than 10 percent of pregnant women with HIV in resource-poor countries have access to prevention of mother-to-child transmission services.

What do you think have been the specific barriers to reaching more mothers and babies?

Where is PEPFAR succeeding in overcoming these barriers and where is it falling short?

In 2001 the United Nations set a goal to cut the number of pediatric infections by half in 2010. To reach this goal, it is estimated that 80 percent of pregnant women must have access to PMTCT services. As you may know, I recently introduced the “Global Pediatric HIV/AIDS Prevention and Treatment Act,” along with Senator Gordon Smith, which would set a target that within 5 years (by 2013), in

those countries most affected, 80 percent of pregnant women receive HIV counseling and testing, with all those testing positive receiving antiretroviral medications for the prevention of mother-to-child transmission.

Are you supportive of such a target?

Answer 1. Prevention of mother to child transmission has continued to be one of the challenging aspects of the PEPFAR program. In order to be successful, a program must ensure that each mother-infant pair participates in a cascade of events that begins with HIV testing and continues through post delivery follow-up and testing (see pages 125–126). The report notes that “declines in participation have been found at each one of these steps as the result of a variety of factors, including denial of HIV infection, opposition from male partners, women’s fear of disclosure of HIV status to their partner and fear of being ‘found out’ if they are taking drugs or not breastfeeding, concern about taking drugs in pregnancy, failure to return for check-ups in the month before delivery, home delivery and premature delivery before treatment can be given.”

Evaluating individual programs was beyond the scope of the IOM committee. Consultation with PEPFAR’s PMTCT Technical Working Group may be useful for you in answering this question. In addition, a number of best practices were also reported at the Implementers’ Meeting last July and at previous meetings.

In principal, the IOM report is strongly supportive of setting meaningful targets and of expanding and improving PMTCT services. We did not, however, evaluate this specific target and thus cannot comment on it.

Pediatric Treatment

Question 2. Despite the recent expansion in HIV/AIDS care and treatment around the world, children continue to lag behind adults in access to lifesaving medicines. Of the 2.5 million-plus new HIV infections in 2007, more than 420,000 were in children. But while children account for almost 16 percent of all new HIV infections, they make up only 9 percent of those on treatment under PEPFAR. Without proper care and treatment, half of these newly-infected children will die before their second birthday, and 75 percent will die before their fifth.

What steps do you believe should be taken in PEPFAR reauthorization to level the playing field for children, so that they are accessing treatment at the same rate as adults?

The legislation I introduced with Senator Smith sets a target that within 5 years (by 2013), 15 percent of those receiving treatment under PEPFAR be children, to keep pace with the infection rate.

Are you supportive of such a target?

Answer 2. The IOM report both acknowledges the difficulties inherent in treating children and commends PEPFAR for the creation, in 2006, of a public-private partnership devoted to the scientific and technical discussion of solutions for the challenges of pediatric treatment, formulations and access. As the report notes, the scientific problems of dosing are among the most difficult barriers to overcome.

On a personal note, I was pleased to hear, at the Implementers’ Meeting, a number of reports of best practice in this area. Many PEPFAR participants are very concerned about the treatment of children; my impression is that progress is being made.

In principal, the IOM report is strongly supportive of setting meaningful targets and of expanding and improving services for children. The IOM committee recommended setting a distinct and meaningful target for orphans and other vulnerable children because none currently exists. We did not, however, evaluate this specific target and thus cannot comment on it.

QUESTION OF SENATOR BROWN

Question 1. What progress have we made in implementing the recommendations of the IOM PEPFAR evaluation report? What are the challenges to fully implementing these recommendations?

Answer 1. The response of PEPFAR staff to the report has been largely appreciative and supportive. We are unable to answer questions about what PEPFAR is doing to implement the IOM recommendations because they have not issued a recommendation-by-recommendation response to our report. I am sure that Ambassador Dybul will be pleased to describe for you how PEPFAR is responding.

QUESTIONS OF SENATOR KENNEDY

Question 1. Numerous stakeholder reports and discussions with implementing partners and agencies have shed light on the need to better communicate and coordinate across all management levels to ensure enhanced coordination of fiscal management, policy guidance, and planning and reporting. Based on your work, can you speak to the special challenges of central, intra-agency, field team and donor coordination? Please comment on ways of improving upon coordination and communication between implementing agencies, donors, and teams to help us plan for transitioning from an emergency effort toward a sustainable long-term strategy?

Answer 1. At UNAIDS, “making the money work” is paramount, a principal question through which we critically evaluate the relative strength of HIV programming. We aim to strengthen coordination for countries in partnerships with national governments and non-governmental organizations, the U.S. Global AIDS Initiative, and the Global Fund. It means maximizing our effectiveness by improving coordination among donors, government implementers, and everyone in the global response to AIDS. Partnering where possible produces significant coordination and significant results. In Rwanda, where governments are full partners, and the U.S. Global AIDS Initiative effort is fully integrated with national strategies, progress has been measurable, meaning the difference between fighting AIDS effectively and losing ground. Until recently, AIDS advocacy focused largely on (1) fostering leadership and commitment and (2) mobilizing the financial resources required to mount an effective response to AIDS, globally and within countries. More leadership and more money are still urgently needed, and thus these two areas of focus remain essential, but now there is widespread recognition that a third focus is also vital: making the money work more effectively.

In Washington, DC., April 25, 2004, UNAIDS, the governments of the United States and the United Kingdom, and the World Bank brought together representatives from governments, donors, international organizations and civil society who considered and endorsed the “Three Ones” principles for concerted action against AIDS at country level as follows:

- One agreed AIDS action framework that provides the basis for coordinating the work of all partners;
- One national AIDS coordinating authority, with a broad-based multisectoral mandate; and
- One agreed country-level monitoring and evaluation system.

All donors pledged to support implementation of these principles and UNAIDS was called on to help facilitate this process.

In London on March 9, 2005, UNAIDS, the governments of the United States, the United Kingdom, and France, as well as other key stakeholders again gathered and stated: “We affirm our commitment to promoting and supporting the application of the ‘Three Ones’ principles, recognizing that their application will result in adaptations appropriate to each country and the situations and institutions concerned. We affirm that the development and adaptation of the ‘Three Ones’ is intended to be a consultative and iterative process between donors, multilateral and country-level partners. We note the leading role of national governments in ensuring the full implementation of the ‘Three Ones’ principles.” With that in mind, all participants agreed to review their individual practices and to work closely with partners at country level to accelerate the effective implementation of the “Three Ones.”

To examine and assist in this implementation effort, UNAIDS and the United States President’s Emergency Plan for AIDS Relief held a bilateral meeting in Washington, DC. on April 27 and 28, 2005.

What follows are key points of agreement that arose from these discussions. While the actions delineated below were discussed and agreed to as part of a UNAIDS-U.S. Office of the Global AIDS Coordinator bilateral partnership, participants noted that they are best executed, not as bilateral actions, but in the context of nationally-led processes that involve all key stakeholders—as envisioned by the “Three Ones.”

A. The “Three Ones”

One National AIDS Action Framework

1. Support national government leadership in a broadly participatory process for developing and regularly updating the national AIDS action framework, including the development of a costed and results-based annual operational plan.

2. Support the national AIDS action framework and operational plan, by basing individual programming and assistance within these national guiding documents.

3. In an effort to maximize coordination and complementarity, make every effort to harmonize support with that of others, through ongoing dialogue with government and other key stakeholders about priorities, geographic and service mix, and division of labor, recognizing that each partner works within the specific parameters of its own mandates and rules (including procurement).

4. Work together to harmonize key programmatic tools (i.e. reviews of national response, technical working groups, activities database), and promote and participate in joint action in these areas. The formation of joint working groups on the key crosscutting issues of procurement, gender, and human resources were suggested. Avoid the establishment of parallel tools, groups and systems whenever possible.

5. Promote and participate in “partnership forums” to share information and coordinate implementation.

One National AIDS Coordinating Authority

1. Within the context of the Three Ones, urge each country to conduct a government-led *joint* assessment of the national coordinating authority leading to clear recommendations for strengthening its effectiveness including attention to areas such as: human capacity requirements, financial resource requirements, infrastructure needs, streamlining of operations, performance-based monitoring systems.

2. Provide support (financial and technical) to the national coordinating authority based on these recommendations. Some donors may consider performance-based incentive mechanisms in the provision of their support.

3. Strengthen political leadership and government commitment to a multisectoral national coordinating authority through diplomatic engagement at the highest levels.

4. Implement programming and assistance within the overall framework of the national coordinating authority and, to the greatest extent possible, within an agreed to division of labor.

One Monitoring and Evaluation System

1. Build local monitoring and evaluation capacity, participate regularly in national monitoring and evaluation activities, and support the development and operationalization of one national monitoring and evaluation system for the national AIDS response with a set of standardized and multisectoral indicators.

2. Support the development of a set of best practices for monitoring and evaluation for broad dissemination of lessons learned for replication.

3. Develop mechanisms for data and report sharing as well as data utilization for evidence-based program planning.

4. To the fullest extent possible, seek to synchronize the timing of surveys and reporting cycles among partners and the government in an effort to maximize harmonization opportunities.

5. Participate in joint monitoring and evaluation team visits by donors and multi-lateral partners to assess and support further progress on the above described monitoring and evaluation actions, to avoid duplication of effort, and to decrease the burden of individual agency missions on the national coordinating authority and other local stakeholders.

B. Other Key Issues

Central to the effective implementation of the “Three Ones” at country level are issues related to policy development and the coordination of technical assistance. Therefore key points of agreement have been put forward in these areas as well.

Policy

AIDS policy dialogue and development should actively involve all partners—government, donors, multilaterals, and non-governmental stakeholders such as non-governmental organizations, faith-based organizations, civil society, persons living with HIV, and the private sector.

Engage in consensus-building processes to:

- support the capacity of national authorities to develop and monitor policies; and
- seek policy agreement to the fullest extent possible and, in areas where differing policy approaches exist, seek to maximize complementarity, recognizing the conditionality of some sources of funding.

Technical Support

Technical support needs are best identified at the country level, and the development of in-country capacity is essential to an effective national AIDS response. To the fullest extent possible, technical support should be provided by local expertise.

Work within the national AIDS action framework to develop and implement a joint technical support plan which:

- recognizes and responds to the specific country context;
- identifies technical support needs;
- identifies core expertise and comparative advantages of individual partners to meet those needs; and
- provides for the sharing of terms of reference, results, and reports.

Continuum of Coordination & Collaboration

It is envisioned that collaboration will evolve along a continuum ranging from the current levels of engagement, whatever they are, toward the goal of full and complete implementation of the “Three Ones.” Obviously, current placement along this continuum varies from country to country as does the timing and support needed to effectively move toward the ideal collaboration embodied in the “Three Ones.” The chart below seeks to provide an illustration of how progress along this continuum plays out in the context of the each of the “Three Ones.”

Three Ones Principle	Minimal Engagement	Coordination and Collaboration Around Specific Issues	Ideal Collaboration
One National AIDS Action Framework.	Sharing information on individual programs.	Participate in periodic reviews and updates of National Strategic Frameworks.	Joint planning and shared division of labor on implementation of overall response.
One National AIDS Coordinating Authority.	Attending meetings of the National AIDS Authority.	Jointly identify country needs in specific areas (i.e., TA needs), and jointly respond.	Provide ongoing coordinated support to the National AIDS Authority.
One Monitoring and Evaluation System.	Sharing program indicators.	Harmonizing program indicators.	Support the establishment of, and utilize, one national monitoring and evaluation system.

As these programs and services are in place, they need reliable information to monitor their outputs (e.g. the number of people provided with preventive education) and outcomes (e.g. changes in the number of people using condoms) and longer-term impacts (e.g. changes in HIV prevalence). The third “One,” an agreed country-level monitoring and evaluation system, points to the most efficient and effective way of gathering, analyzing, and reporting this information.

The U.S. Global AIDS Initiative and other external partners’ efforts have had their greatest successes (i.e. Rwanda) where governments are full partners and the United States’ response is fully integrated into national strategies.

To that end, United States’ efforts can empower “country-driven” efforts to increase access by:

- Actively engaging in national planning, costing and joint evaluation/review processes and sharing information it gathers to support and improve national program implementation;
- Aligning U.S. Global AIDS Initiative investments with national AIDS strategies, priorities, plans, and targets and synchronizing the timing of U.S. Global AIDS Initiative planning and reporting cycles with those of the national AIDS authority to the fullest extent possible;
- Expanding access to technical assistance through support for the development of national technical assistance plans, quality assurance, coordination of technical assistance provision and follow up, (including utilizing innovative mechanisms such as the UNAIDS technical support facilities and technical assistance funds.)

As highlighted by the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, a key feature of United States’ leadership is commitment to coordination at all levels.

At the global level, it is essential for the United States to continue to work closely with UNAIDS, the Global Fund, and other multilateral and bilateral donors to ensure that the comparative strengths of each are maximized and have a positive, synergistic impact on countries, rather than a duplicative, inefficient, and empowering one.

Question 2. There has been much talk lately about the need to strengthen health systems in developing countries. How can PEPFAR help to improve the health systems in developing countries and address health worker shortages? Have we consid-

ered how to use our technological prowess to address the challenge of the health care brain drain?

Answer 2. The world is now paying the price, in the context of the AIDS crisis, for decades of inadequate investment in the developing world's public and private services to promote education and health. Lack of human capacity is the single biggest obstacle to an effective response to AIDS in many developing countries. Poor surveillance, planning and administration; bottlenecks in the distribution of funds; failures in the implementation, monitoring, and evaluation of activities; and inadequate provision of services are all largely due to systems of too few people with too few skills. According to the WHO World Health Report 2006, there is currently an estimated shortage of almost 4.3 million doctors, midwives, nurses, and support workers worldwide. The shortage of trained health-care workers is due in part to the ongoing "brain drain" of health-care providers from Africa and other heavily affected areas. A recent study estimated that, to cope effectively with AIDS and other health emergencies, sub-Saharan Africa will need to find 620,000 new nurses over the next few years (Chaguturu and Vallabhaneni, 2005).

- Curbing this exodus of professional people calls for action at both ends. Measures to improve working conditions and remuneration and other incentives to keep trained people at home are essential, as are formal agreements between countries and recruitment practices.

- National governments and international donors should take measures, where needed, to retain and motivate health workers, educators and community workers, and to increase financing for training and accreditation centers in countries facing severe human resource shortages.

- Speeding recruitment and training of health workers at all levels is also urgent. Countries should identify opportunities for drawing in new players from populations or sectors that are not yet fully engaged with the response, and should consider innovative ways of educating and training people.

- Where needed, countries should adopt alternative and simplified delivery models to strengthen the community-level provision of HIV prevention, treatment, care and support, including measures to enable "task shifting."

- National governments should also greatly expand their capacity to deliver comprehensive AIDS programs in ways that strengthen existing health and social systems, including by integrating AIDS interventions into programs for primary health care, mother and child health, sexual and reproductive health, and diagnosis and treatment of tuberculosis, malaria, and sexually transmitted infections.

- Education and other systems must be simultaneously strengthened. Most HIV prevention takes place outside the health-care delivery system, making the private and voluntary sectors particularly important.

A principal UNAIDS recommendation for reauthorization of the U.S. Global AIDS Initiative is to prioritize the strengthening of health care delivery systems, human resource capacity, and local community-based service organizations. Specifically, we recommend that the U.S. Global AIDS Initiative:

- Maximize current capacity by task-shifting, in-service and pre-service training/retraining, and increasing incentives for retention;

- Build greater indigenous national and local capacity "from doctors to nurses to community health workers and persons living with HIV" through training, accreditation, and adequate support and supervision;

- Target HIV training to education and social services sectors as well; and

- Support strategies that help countries operate their national AIDS program over the long term and avoid creating parallel U.S. systems and structures.

Many country teams have previously expressed concern that they were not allowed to fund activities unless they were specifically part of the AIDS response and thus could not support, for example, the training of new clinical officers, who in some countries are the mainstay of the treatment effort. UNAIDS maintains that the successful creation and sustainability of an HIV care delivery system should be fashioned in a manner that enhances the larger health care workforce/public health infrastructure rather than detracts from it.

UNAIDS supports Recommendation 8-3 of the recent Institute of Medicine (IOM) report which addressed the implementation of the U.S. Global AIDS Initiative: "To meet existing targets for prevention, treatment, and care, the U.S. Global AIDS Initiative should increase the support available to expand workforce capacity in heavily affected countries. These efforts should include education of new health care workers in addition to AIDS-related training for existing health care workers. Such support should be planned in conjunction with other donors to ensure that comparative advantages are maximized and be provided in the context of national human resource strategies that include relevant stakeholders, such as the ministries of

health, labor, and education; other ministries; employers; regulatory bodies; professional associations; training institutions; and consumers.”

QUESTION OF SENATOR ENZI

Question 1. With the AIDS epidemic in the United States we were able to curtail the spread of the disease by closing bath houses in San Francisco. This direct threat to one of the cities social norms was effective, yet controversial. What prevailing social norms are assisting in the spread of HIV/AIDS in PEPFAR countries? What is the best and most appropriate way to stop them from occurring and educate individuals on this danger?

Answer 1. As I said on September 20, 2007 to the Woodrow Wilson International Center for Scholars, “anything that has the word ‘only’ in it doesn’t work for AIDS, whether it is treatment only, prevention only, condoms only, abstinence only, male-circumcision only . . . we need it all.”

Risk behaviors and vulnerabilities are linked to economic, legal, political, cultural and social norms that must be analyzed and addressed at the policy and program levels. Therefore, comprehensive programming is necessary for the effective prevention of this disease. Effective HIV prevention programming focuses on the critical relationships between the epidemiology of HIV infection, the risk behaviors that transmit HIV and the social and cultural factors that aid or impede peoples’ abilities to access and use HIV information and services, and can thus make them more or less vulnerable to HIV infection. The term “driver” relates to the structural and social factors, such as poverty, gender inequality and human rights issues that are not easily measured that increase people’s vulnerability to HIV infection.

The prevailing social norm driving the epidemic worldwide is inequality. In the UNAIDS *Practical guidelines for intensifying HIV prevention*, there is clear recognition of the importance of tackling the social drivers of the epidemic. Three specific social drivers (all examples of inequality) are repeatedly cited as being central:

- **Human rights,**
- **HIV-related stigma and discrimination,**
- **Gender inequality.**

These may express themselves in dozens of different ways including: child marriage; transgenerational sex; the sexual exploitation of girls; violence against women; multiple partners inside and outside of marriage; the taboo of condom use; the disenfranchisement of high-impacted populations such as men who have sex with men, injecting drug users, sex workers, and others (which drives the epidemic further underground); and so forth.

Recognizing that each country is different, UNAIDS’ *Practical Guidelines* are designed to provide policymakers and planners with practical guidance to tailor their national HIV prevention response so that they respond to the epidemic dynamics and social context of the country and populations who remain most vulnerable to and at risk of HIV infection.

Reforming laws and policies that are based in deeply-rooted social attitudes and norms such as gender inequality requires multisectoral collaboration. Civil society, including organizations of people living with HIV, international organizations, and donors, have a critically important role to play. The protection of human rights, both of those vulnerable to infection and those already infected, is not only right, but also produces positive public health results against HIV.

QUESTIONS OF SENATOR DODD

Prevention of Mother-to-Child Transmission (PMTCT)

Question 1. Every day more than 1,100 children across the globe are infected with HIV, the vast majority through mother-to-child transmission. What is most tragic is that research has shown that these infections are largely preventable. The simple reason that the infection rate among children remains so high is that pregnant mothers and their babies are not getting the life-saving care they need. Less than 10 percent of pregnant women with HIV in resource-poor countries have access to prevention of mother-to-child transmission services.

What do you think have been the specific barriers to reaching more mothers and babies?

Where is PEPFAR succeeding in overcoming these barriers and where is it falling short?

In 2001 the United Nations set a goal to cut the number of pediatric infections by half in 2010. To reach this goal, it is estimated that 80 percent of pregnant women must have access to PMTCT services. As you may know, I recently intro-

duced the “Global Pediatric HIV/AIDS Prevention and Treatment Act,” along with Senator Gordon Smith, which would set a target that within 5 years (by 2013), in those countries most affected, 80 percent of pregnant women receive HIV counseling and testing, with all those testing positive receiving antiretroviral medications for the prevention of mother-to-child transmission.

Are you supportive of such a target?

Answer 1. UNAIDS agrees that prevention of mother-to-child transmission (PMTCT) is a critical priority for the use of prevention dollars through the U.S. Global AIDS Initiative. A comprehensive set of activities—including counseling and testing, prophylactic antiretroviral therapy in late pregnancy and delivery, as well as for the newborn; safe delivery practices; and use of breast milk substitutes when safe water is available—has been found to be effective in preventing transmission of HIV to infants.

We agree that to be fully successful in the prevention of HIV transmission to newborns that multiple interventions throughout pregnancy and nursing are required including: HIV counseling and testing of pregnant women; the provision of antiretroviral prophylaxis; counseling of behavior modification around breast-feeding; follow-up with mother and child post-delivery; and HIV testing and assessment for the infant at 18 months. In addition, interventions should also include primary HIV prevention for women (including integration of HIV prevention into reproductive and sexual health services), prevention of unintended pregnancies in HIV-positive women, and broader access to antenatal care.

There are a number of factors that impede the full prevention of HIV testing from mother to child in PEPFAR-focus countries including: denial of HIV infection among pregnant women, opposition from male partners, women’s fear of disclosure of HIV status to their partner and fear of being “found out” if they are taking drugs or not breastfeeding, concern about taking drugs during pregnancy, failure to return for checkups in the month before delivery, home delivery, and premature delivery before treatment can be given.

Though there have been significant successes in mother-to-child prevention through the U.S. Global AIDS Initiative. At the national level, the initiative provides technical assistance to host governments in the development and adoption of guidelines and policies aimed at improving the standardization and quality of such efforts. In addition, by helping to strengthen commodity management systems, partners of the U.S. Global AIDS Initiative increase the availability of many commodities essential to these prevention efforts including medications and test kits.

According to the United States Office of the Global AIDS Coordinator in 2007, approximately 6 million women in the focus countries have received PEPFAR-supported services to prevent mother-to-child transmission. The proportion of eligible pregnant women receiving services such as counseling and testing has increased from 7 to 16 percent, and the proportion of HIV-positive pregnant women receiving antiretroviral prophylaxis has increased from 9 to 21 percent.

UNAIDS is supportive of an aggressive target as high as 80 percent of pregnant women having access to prevention of mother-to-child transmission services as we have been since 2001.

Pediatric Treatment

Question 2. Despite the recent expansion in HIV/AIDS care and treatment around the world, children continue to lag behind adults in access to lifesaving medicines. Of the 2.5 million-plus new HIV infections in 2007, more than 420,000 were in children. But while children account for almost 16 percent of all new HIV infections, they make up only 9 percent of those on treatment under PEPFAR. Without proper care and treatment, half of these newly-infected children will die before their second birthday, and 75 percent will die before their fifth.

What steps do you believe should be taken in PEPFAR reauthorization to level the playing field for children, so that they are accessing treatment at the same rate as adults?

The legislation I introduced with Senator Smith sets a target that within 5 years (by 2013), 15 percent of those receiving treatment under PEPFAR be children, to keep pace with the infection rate.

Are you supportive of such a target?

Answer 2. UNAIDS recognizes the disappointing statistics regarding the number of HIV-infected children who are not antiretroviral therapies that could delay or prevent the life-threatening illnesses of untreated HIV disease. We agree with the following statement from the recent Institute of Medicine report addressing PEPFAR implementation: “The reasons for this are multiple and most are being addressed by PEPFAR. Diagnosis of HIV-related disease in children has been limited in part because most counseling and testing programs in the focus countries have

targeted primarily young adults. The general lack of linkage of prevention of mother-to-child-transmission to infants and small children has lessened the likelihood of identifying those who are HIV-positive at that level. Many children who are found to be HIV-positive are orphans or living with orphan heads of households, further complicating adherence to treatment regimens and follow-up clinical visits.”

With over 600,000 children contracting HIV infection each year, mostly through mother-to-child-transmission, access to affordable HIV diagnostics and treatment responses represents an urgent global health priority. In 2005, UNAIDS and UNICEF issued a global call to action that challenges the world to ensure that antiretroviral therapy and prophylaxis with the antibiotic cotrimoxazole reach 80 percent of children in need by 2010. The U.S. Global AIDS Initiative is vital towards achieving that goal.

Accurate diagnosis of HIV infection in children can be difficult in resource-limited settings. Because of the persistence of maternal antibodies up to 18 months after birth, highly sensitive tests such as polymerase chain reaction or viral load testing are typically needed to render a definitive diagnosis in infants. While such tests have long been regarded as not feasible in low-resource settings (because of their high cost and the difficulty of collecting blood from newborn infants), more recent technical developments using dried blood spots show promise, enabling earlier diagnosis and avoiding the need to take blood from a vein.

Formulations of antiretrovirals suitable for use in children remain rare and tend to be more expensive than adult regimens. Most pediatric antiretroviral formulations are syrups that taste unpleasant to many children, potentially complicating adherence. Some must be diluted with drinking water or refrigerated, which may be unpractical in certain settings. In many places, dosages of adult medications are simply reduced for children, risking under-treatment (which can lead to drug resistance) or over-treatment (which can produce side-effects because of the drugs' toxicity). Recently, some manufacturers have piloted the production of mini-pills, which are particularly suitable for young children. However, all new products need to be properly tested, pre-qualified and licensed to use.

Access to cotrimoxazole is critical, especially in settings where antiretrovirals are not yet accessible. The antibiotic, which provides protection against life-threatening opportunistic infections and can delay the need to initiate antiretroviral therapy, has been shown to reduce the risk of death in children living with HIV by more than 40 percent (Chintu, et al., 2004). However, even though cotrimoxazole costs as little as 3 cents a day, an estimated 4 million children who need the drug are currently unable to obtain it (WHO and UNAIDS, 2005).

Because HIV-positive children are vulnerable to severe infections, timely and proper immunization is especially important. Routine vaccinations are generally safe to administer to HIV-infected children, but additional research is needed to find ways to ensure the effectiveness of routine immunization in children living with HIV and to enable clinicians to make more informed treatment decisions (Obaro et al., 2004).

There are still no available FDA-approved combination preparations in dosages appropriate for small children and infants. This problem is exacerbated by the fact that several focus countries have few, if any, pediatricians and general practitioners are often reluctant to assume responsibility for treatment of small children with HIV-related disease.

UNAIDS believes that all of the above issues and strategies should be addressed in the upcoming reauthorization of the U.S. Global AIDS Initiative. Moreover, UNAIDS supports the prioritization of basic and clinical research within the NIH and other prominent research facilities to assess the pharmacokinetics for the safe and effective development of antiretroviral therapies for infants and children. We recognize the limited options available to be a significant barrier to the effective delivery of treatment to HIV-infected children around the world.

UNAIDS supports aggressive targets for aligning the percentages of those on antiretroviral treatment to mirror percentages by age of those who are infected.

[Whereupon, at 11:59 a.m., the hearing was adjourned.]

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