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THE NEXT PHASE OF THE GLOBAL FIGHT AGAINST HIV/AIDS

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THE NEXT PHASE OF THE GLOBAL FIGHT AGAINST HIV/AIDS

WEDNESDAY, OCTOBER 24, 2007

U.S. SENATE, COMMITTEE ON FOREIGN RELATIONS, Washington, DC.

The committee met, pursuant to notice, at 2:21 p.m., in room SD-419, Dirksen Senate Office Building, Hon. Joseph R. Biden, Jr. (chairman of the committee) presiding

(chairman of the committee) presiding.

Present: Senators Biden, Feingold, Bill Nelson, Menendez, Cardin, Webb, Lugar, Hagel, Corker, Sununu, Murkowski, DeMint, Isakson, and Vitter.

OPENING STATEMENT OF HON. JOSEPH R. BIDEN, JR., U.S. SENATOR FROM DELAWARE

The CHAIRMAN. We now turn to a hearing on the next phase of the global fight against HIV/AIDS. Our witness—and we welcome him—is Ambassador Dybul. Welcome, sir. Thank you for being here.

This is the first of several hearings this committee will hold to explore the critical question, which is where do we go next in the global fight against HIV/AIDS. According to the UNAIDS organization, nearly 3 million people died because of AIDS last year and an estimated 40 million people are living with HIV today, and most of them don't know because they've never been tested. Thousands of people will become newly infected today, thousands in a single day, thousands every single day. That is the relentless enemy that we're up against.

We have made tremendous gains in the last 4 years in the fight against HIV/AIDS, but these numbers tell us just how far we still have to go. Four years ago Congress passed the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act. We authorized \$15 billion to support the President's Emergency Plan for AIDS Relief and for the multilateral Global Fund to Fight AIDS, Tuberculosis, and Malaria. That legislation launched a 5-year battle plan in the war on AIDS, TB, and malaria. Since then the United States has created the largest public

Since then the United States has created the largest public health program the world has ever known, and I believe history will record that this is one of President Bush's greatest accomplishments. He has helped to save millions of lives by leading the global fight against HIV/AIDS and by spearheading the new malaria initiative.

Thanks to the international efforts led by the United States, over a million people with AIDS are now on antiretroviral treatment, or ARVs. That means over 1 million death sentences have been suspended. But that's still less than a quarter of those who need treatment in poor and middle-income countries. Enrolling more people into treatment programs and maintaining efforts already under way is a substantial challenge. So is helping the countries that begin to assume ownership of these efforts on the road to sustainability.

Thanks to U.S. programs designed to prevent the transmission of HIV from mother to child, since 2003 over half a million pregnant and nursing women have received treatment. As a result, over 100,000 babies who likely would have contracted HIV did not.

Every healthy baby today is a triumph.

But we cannot declare victory. Far from it, because the disease continues to spread. Every day an extimated 1,800 children world-wide become infected with AIDS. The vast majority are newborns in sub-Saharan Africa whose mothers were infected and lack the means to protect their children. We are not keeping pace with this pandemic. For every person who enrolled in a treatment program last year, six more became newly infected, according to UNAIDS.

The United States and its partners need to devote more funds to this effort. But it's not just a question of more money; it's a ques-

tion of how we spend it.

These are the facts before us and as the committee takes up the reauthorization of our global HIV/AIDS, TB, and malaria programs these must be kept in mind. This will be a bipartisan effort and I look forward to working with Senator Lugar as well as other members of the committee and Senators Kennedy and Enzi on the Health, Education, and Labor and Pensions Committee.

In thinking about reauthorization, for myself—speaking only for myself—I have several priorities. The first priority is simply this. We have to reauthorize this bill. No one—no one, should doubt the bipartisan commitment of this Congress to see the process through. It's more important we do this right than we do it overnight, but we will reauthorize this legislation.

Second, in reauthorizing the bill we must do more on prevention. The math is brutally clear. We cannot keep up with the current pace of the epidemic through treatment programs. To slow its deadly progress, we have to expand and improve the prevention efforts.

Third, we should follow the recommendation of the Government Accountability, Accounting Office, and the Institute of Medicine, which is part of the National Academies of Science. In a congressionally mandated report, the Institute of Medicine recommended eliminating current budget allocations or earmarks that limit vital flexibility.

We currently have 15 AIDS focus countries. That means we are not facing a single pandemic, but rather 15 or more local epidemics. What works in Botswana may not work in Nigeria or Vietnam. We need to give those who are fighting the battle against HIV/AIDS the flexibility to combat their local epidemics. We should have targets and mechanisms to measure progress. But we should not divide our funding into rigid arbitrary categories that dictate our priorities.

Finally, we need to listen to the people in the front lines of this fight. This summer Senator Lugar and I asked the staff of the committee to visit these countries and look at the programs in the dozens of focus countries to assess their progress and problems, to talk to care providers and patients, to consult with government officials and NGOs. Their findings will help us strengthen the program.

My other key priorities for reauthorization are: First, to better integrate our HIV effort with other health and development pro-

Two, build healthy capacity in Africa. The shortage of health care workers may be the greatest obstacle in the fight against HIV/ AIDS in the continent of Africa.

Third, expand our efforts to address the gender-based violence and other inequities. Millions of women and girls do not have the power to make sexual decisions. Abstinence is not an option when you lack the power to choose. Girls' education and women's empowerment in my view are critical in the fight against AIDS.

Fourth, we have to improve our efforts to combat TB and malaria. These diseases were part of the 2003 legislation. They should

be part of our discussion now.

Finally, as we work to reauthorize this legislation we should expand funding for it. The President has called on Congress to pass a bill authorizing \$30 billion over the next 5 years. He has called this a doubling of our efforts. That does amount to double the initial authorization, but not our current funding. The foreign operations appropriations bill recently passed by the Senate includes \$5.7 billion for AIDS, TB, and malaria for fiscal year 2008. If we divide \$30 billion over the next 5 years, it would provide for \$6 billion a year, a relatively small increase over our current efforts, not a doubling. I believe that \$30 billion should be the starting point for discussion, not our final destination.

The fight against HIV/AIDS, TB, and malaria is one of the great moral and strategic challenges of our time. Congress must once again rise to the challenge, building on and improving the legislative framework we laid out in 2003. We're in this for the long haul and reauthorizing this bill will be the next step.

I'd like now to yield to a leader on this subject, my friend, Senator Lugar.

STATEMENT OF HON. RICHARD G. LUGAR, U.S. SENATOR FROM INDIANA

Senator Lugar. Thank you, Mr. Chairman. It's a great privilege to be with you in working for reauthorization.

I would just comment that the HIV/AIDS pandemic threatens millions of people and is rending the socioeconomic fabric of communities, nations, and an entire continent and is creating a potential breeding ground for instability and terrorism. In the most heavily affected areas, communities are losing a whole generation of parents, teachers, laborers, health care workers, peacekeepers, and police.

United Nations projections indicate that by 2020, HIV/AIDS will have depressed GDP by more than 20 percent in the hardest hit countries. Many children who have lost parents to HIV/AIDS are left entirely on their own, leading to an epidemic of orphan-headed households.

Beyond our own national security concerns, we have a humanitarian duty to take action. During the last several years, the American people have catalyzed the world's response to the HIV/AIDS epidemic. It's not often that we have an opportunity to save lives on such a massive scale. Yet every American can be proud that we

have seized this opportunity.

I am grateful that the chairman has called this hearing today because it provides a chance to jump-start the process of reauthorizing the U.S. Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003, known as the Leadership Act. I believe that Congress should reauthorize the Leadership Act as soon as possible, preferably this year, rather than wait until it expires in September 2008. Partner governments and implementing organizations in the field have indicated that without early reauthorization of the Leadership Act they may not expand their programs in 2008 to meet the goals of the President's Emergency Plan For AIDS Relief, PEPFAR. These goals include providing treatment for 2 million people, preventing 7 million new infections, and caring for 10 million AIDS victims, including orphans and vulnerable children.

Many partners in the fight against HIV/AIDS want to expand their programs, but to do so they need assurances of a continued U.S. commitment beyond 2008. We may promise that a reauthorization of an undetermined funding level will happen eventually, but partners need to make their plans now if they are to maximize their efforts. Today they have only a Presidential proposal and not an enacted reauthorization bill. This is an important matter of perception, similar to consumer confidence. It may be intangible, but it will profoundly affect the behavior of individuals, groups, and

governments engaged in the fight against HIV/AIDS.

I recently received a letter from the Ministers of Health of 12 African focus countries receiving PEPFAR assistance. They wrote: "Without an early and clear signal of the continuity of PEPFAR support, we're concerned that partners might not move as quickly as possible to fulfill the resource gap that might be created. Therefore, services will not reach all those who need them. The momentum will be much greater in 2008 if we know what to expect after 2008."

Now, the committee has also received support for early authorization from AIDS Action, which believes that our global partners need to "be assured that the U.S. commitment and leadership will

continue and grow."

We have heard from the foundation and donors interested in Catholic activities, which argues that early reauthorization will, "encourage implementing partners to expand the number of patients receiving antiretrovirals in 2008 to target levels, rather than holding back on new services for fear of the program's ending or being seriously curtailed. This means more lives will be saved."

I realize that a PEPFAR reauthorization bill will face a crowded Senate calendar, but maintaining the momentum of PEPFAR during 2008 is a matter of life and death for many. Part of the original motivations behind PEPFAR was to use American leadership to leverage other resources in the global community and the private

sector. The continuity of our efforts to combat this disease and the impact of our resources on the commitments of the rest of the world will be maximized if we act now.

In my judgment, Congress can reach an agreement expeditiously on this reauthorization. Most of the Leadership Act's provisions are sound and do not require alteration. The authorities in the original bill are expansive and they are enabling the program to succeed in diverse nations, each with its own unique set of cultural, economic,

and public health circumstances.

With this in mind, I introduced S. 1966 after consulting extensively with American officials who are implementing PEPFAR. My bill would increase to \$30 billion the authorization for the years 2009 through 2013, a doubling of the initial U.S. commitment. It would also improve the transparency of the Global Fund, adjust the abstinence funding mechanism, and maintain the directive that 10 percent of funding be devoted to programs for orphans and vulnerable children.

But my bill avoids sweeping revisions of the Leadership Act. Officials with experience in implementing the PEPFAR program have told me that preserving the existing provisions of the bill would provide the best chance at continued success. Adding new restrictions to the law could limit the flexibility of those charged with implementing in 2009 and beyond. We don't know what the challenges of 2013 will be, although we can say with confidence the landscape will be different than it is today.

This is not to say that Senators may not have good ideas for improvement that should be adopted. But new provisions must not unduly limit the flexibility of the program and Congress should avoid descending into time-consuming quarrels over provisions that are unnecessary or that have little to do with the core missions of the bill.

As Senators study the record of PEPFAR to date, I believe they will find that the vast majority of the authorities needed for the next phase of our effort already are in the existing legislation. The PEPFAR program is dealing successfully with special areas of concern, including strengthening health systems, addressing gender issues, improving nutrition, expanding educational opportunities, and funding pediatric care.

Five years ago, HIV was a death sentence for most individuals in the developing world who contracted the disease. Now there is hope. We should never forget that behind each number is a person,

a life the United States can touch or even save.

At the time the Leadership Act was announced, only 50,000 people in all of sub-Saharan Africa were receiving antiretroviral treatment. Through March of this year, the act has supported treatment for more than 1.1 million men, women, and children in 15 PEPFAR focus countries. U.S. bilateral programs have supported services for more than 6 million pregnancies. In more than 533,000 of these pregnancies, the women were found to be HIV positive and received antiretroviral drugs, preventing an estimated 101,000 infant infections through March 2007. We have supported care for more than 2 million orphans and vulnerable children, as well as 2.5 million people living with HIV/AIDS through September 2006. The

United States has supported 18.7 million HIV counseling and test-

ing sessions for men, women, and children.

PEPFAR, led by Ambassador Dybul, has listened to the Congress and many other stakeholders. As the Institute of Medicine has said, the Leadership Act is a learning organization. We should pass a bill now that allows PEPFAR to expand and evolve its program

implementation using the experience of the past $3\frac{1}{2}$ years.

I've offered S. 1966 in the hope that other Senators will come forward with their proposals this year. We have had a lot of time to study the program since 2003. I'm certain Members of Congress will have considerable and constructive ideas, but it's important to move now. We will save more lives and prevent more infections if we reauthorize this remarkable program this year.

I thank the Chair.

The CHAIRMAN. Thank you very much. Mr. Ambassador, the floor is yours.

STATEMENT OF HON. MARK R. DYBUL, U.S. GLOBAL AIDS COORDINATOR, DEPARTMENT OF STATE, WASHINGTON, DC

Ambassador Dybul. Thank you, Mr. Chairman. Mr. Chairman, Senator Lugar, members of the committee and staff, let me begin by thanking you for your leadership and commitment on global AIDS, for your actions in 2003 to pass the Leadership Act to authorize the President's Emergency Plan for AIDS Relief, or PEPFAR, and for your actions today and leading to today's hearing on the reauthorization of this historic legislation and program.

President Bush and a bipartisan, bicameral Congress have reflected the compassion and generosity of the American people. 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 outlaid or expended 67 percent of them.

But success is not measured in dollars spent. It's measured in services provided and lives saved, and PEPFAR is well on its way to achieving its ambitious prevention, treatment, and care targets. Senator Lugar has outlined many of those results and I need not go through them. They're in the written testimony.

But I did want to point out it is important that we have all three: Prevention, treatment, and care. Within the past decade the pendulum of preferred interventions has swung from prevention to treatment and back to prevention. Using these pendulum swings to

determine policy and programs can be dangerous.

The President and a bipartisan Congress got it right the first time because a comprehensive program that includes all three reflects public health realities. Without treatment, people are not motivated to be tested to learn their HIV status. Without testing, we cannot identify HIV-positive persons and so we cannot teach them safe behavior and they cannot protect themselves and others. Without care and treatment programs, we do not have regular access to HIV-positive persons to constantly reinforce safe behaviors. Without testing and treatment, we cannot medicalize the disease, which is essential to reducing stigma and discrimination. Without testing and treatment, we have no hope of identifying discordant couples and women have no possibility of getting their partners

tested so 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, as you pointed out, Mr. Chairman. Prevention is the bedrock of an effective global AIDS response

Prevention is the bedrock of an effective global AIDS response and also the greatest challenge in this fight. Changing human behavior is very difficult, but in addition to earlier dramatic declines in HIV prevalence in Uganda there is growing evidence of similar trends in other African nations and the Caribbean. Our best hope for generalized epidemics, such as those in Africa, is what's called and was created by Africans as ABC—or Abstain, Be Faithful, and Correct and Consistent use of Condoms.

But it should be pointed out that ABC is far more complicated than those letters indicate. We have to reach children through life skills programs and other programs at an early age to teach them to respect themselves and others, which can lead them to delay sexual debut, limit their number of partners, and change gender norms. These are generational and deep cultural changes that require time and persistence.

For older adolescents and adults who are sexually active, ABC includes reducing casual and multiple concurrent partnerships, which can rapidly spread HIV infection. We must also identify discordant couples in which one partner is positive and the other is

negative and focus effective prevention on them.

We also need to teach correct and consistent condom use for those who are sexually active and ensure a supply of condoms. So far the American people have provided 1.67 billion condoms since the Emergency Plan began. As Peter Piot of UNAIDS has said, more than all others combined.

While PEPFAR is aggressively pursuing prevention, it's also true that we need to improve what we are doing and, in fact, we need to improve every area of what we are doing. We need to take prevention to the next level. First, you must know your epidemic and tailor your prevention strategies accordingly. So, as the chairman pointed out, that is why we have different approaches depending on whether a country has a concentrated or a generalized epidemic.

Next, just as we need combination therapy for treatment, we need combination prevention that blankets geographic areas with various prevention modalities so that all the youth, for example, hear the messages and can change their behavior accordingly.

We also need to create effective approaches to older populations, including discordant couples, and have these programs in the same geographic concentration as the youth programs. We need to link clinical approaches, such as prevention of mother-to-child transmission and testing and counseling, to behavior change programs.

And we must rapidly incorporate the latest scientific advances. Recent studies have shown that medical male circumcision can significantly reduce the risk of HIV infection for men as one part of a broad prevention arsenal, and PEPFAR has been the most aggressive of any international partner in pursuing this. We are also hoping for more scientific evidence on preexposure prophylaxis, microbicides, and vaccines.

Addressing the distinctive needs of women and girls is critical to effective prevention, as you pointed out, Mr. Chairman. PEPFAR

has been a leader in addressing gender issues and has incorporated gender actions in prevention, treatment, and care programs.

While HIV/AIDS remains a global emergency, we are also focused on building capacity for a sustainable response. Some wonder whether putting money into HIV/AIDS in such large levels is having a negative impact on health systems. Well, fortunately the data to date suggest the opposite. 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 services, prenatal, pediatric, and general health care. It found statistically significant increases in delivery of non-HIV services in 17 of 22 indicators.

In Botswana, infant mortality rose and life expectancy dropped by one-third because of HIV/AIDS. Now, because President Mogae has led an all-out battle against HIV/AIDS, infant mortality is de-

clining and life expectancy is increasing.

It's important to remember PEPFAR works in 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, that benefits everyone who comes into contact with that clinic or nurse. A recent study of PEPFAR-supported treatment sites in four countries found that we supported a median of 92 percent—92 percent—of the investments in the health infrastructure to provide comprehensive treatment and care, and more in the public than in the nonpublic sector.

As effective HIV programs are implemented, hospital admissions plummet, easing the burden on the health care staff throughout the system. In Rwanda, the average monthly number of new hospitalizations at seven sites that have been providing HIV treatment for more than 2 months dropped by 21 percent, increasing health care capacity by 21 percent.

The CHAIRMAN. Excuse me. Over what period? Would you repeat

that again?

Ambassador Dybul. Two months.

The CHAIRMAN. Two months.

Ambassador Dybul. Just 2 months. And this is common because about 50 percent of hospitalizations in many places are because of HIV/AIDS. So if you treat HIV/AIDS the hospitalizations go down.

As the chair of the Institute of Medicine panel put it, "Overall PEPFAR is contributing to make health systems stronger." PEPFAR is an important part of the President's and the Congress's expansive development agenda. Broadly speaking, PEPFAR is contributing to general development in several important ways, which I look forward to discussing with you.

When President Bush called for reauthorization of the Leadership Act, he emphasized the need to better connect the dots of development, as you suggested, Mr. Chairman. The Leadership Act provides us with expansive authorities for such work and we are constantly trying to improve our efforts. But I'd like to note that our view of the appropriate limits of PEPFAR's role means that when we connect the dots of development we cannot become USAID, MCC, PMI, or any of its sister initiatives, but we are part of a larger whole and contributing to the larger development agenda.

We believe Congress got this right in the original legislation and that it's the right position going forward. I think this understanding is critical in the conversation about reauthorization. There is no question there is a lot to discuss and debate. Yet the Leadership Act already has the authorities we need and provides the right amount of flexibility to put them to use.

The Institute of Medicine called PEPFAR "a learning organization," as Senator Lugar noted, and we've used the flexibilities of the original legislation to learn and to constantly change our ap-

proach based on the lessons learned.

Congress enacted a good law the first time and this is clear from the results. While some modifications are needed, rather than letting the perfect be the enemy of the good, we believe we can move

expeditiously together.

While I was in Haiti a few weeks ago, the Minister of Health expressed the same concern as every country I've been to: Will this continue? Can we scale up or should we see what happens? Countries are asking for rapid action and they are looking to be convinced of the need of being prudent in significantly expanding their programs in 2008 in order to save the maximum number of lives. Because of this reality, President Bush called for early bipartisan, bicameral action.

Mr. Chairman, Senator Lugar, 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. Our partnerships are founded in the profound sense of dignity and worth of every human life and in trust and mutual respect between peoples. The people of many countries have a new window into the hearts of Americans. They know what we stand for and that we stand with them.

Beyond that, as President Bush has said, this effort is also good for our national character and who we are as a people. This noble and ennobling work has only begun and we look forward to working with you, your committee, the other committees, and a bipartisan Congress to move forward in this noble work.

Thank you very much.

[The prepared statement of Ambassador Dybul follows:]

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

Mr. Chairman, Senator Lugar, 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 re-

ceiving 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, nongovernmental organi-

zations 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 $3\frac{1}{2}$ 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.

Through September 2006, PEPFAR-supported programs reached 61 million people with prevention messages, and the U.S. Government has supplied 1.67 billion condoms through this August—as Dr. Piot of UNAIDS has said, more than all other developed countries combined. PEPFAR has supported antiretroviral prophylaxis during over half a million pregnancies, preventing an estimated 101,000 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 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 collective demand for safe blood—up from just 45 percent when PEPFAR started. PEPFAR has supported HIV testing and counseling for 18.6 million people, and supported care for 2.4 million adults and 2 million orphans and vulnerable children infected and affected by HIV. And through March 2007, PEPFAR supported antiretroviral treatment for over 1.1 million men, women, and children—more than 1 million in sub-Saharan Africa.

Country teams will submit their annual program results data to us shortly, and we expect that the data will demonstrate impressive continued progress.

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.

grams 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

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 reatment, 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. In addition to earlier dramatic declines in HIV prevalence in Uganda, there is growing evidence of similar trends in other African nations, including Botswana, Ethiopia, Kenya, Tanzania, Zambia, and Zimbabwe. There is also evidence for stabilization or declines in the Caribbean, including Haiti.

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 com-

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 infec-

tion 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 sexu-

ally 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 pro-

grams, 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. Éven 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, Côte 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 preexposure 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.

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. Sexdisaggregated 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 61 percent of those receiving antiretroviral treatment through downstream U.S. Government support in fiscal year 2006 were women. Girls represent 51 percent of OVCs who receive care. Women represent 70 percent of all people who receive PEPFAR-supported counseling and testing services. In fiscal year 2006, across four key program areas, approximately 45 percent of the total prevention, treatment, and care budget was directed toward reaching women and girls.

The Emergency Plan also annually monitors its progress on the five priority strategies specified in the Leadership Act. In fiscal year 2006, a total of \$442 million supported more than 830 interventions that included one or more of these gender strategies.

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 backles were tree.

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

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.

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 nongovernmental 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 dollars of fiscal year 2007 funding were directed toward systems-strengthening activities, including preservice

and in-service training of health workers.

Another key fact is that in the hardest-hit countries, an estimated 50 percent of Another key tact 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 at 7 sites that had been offering antiretroviral treatment for more than 2 months dropped by 21 percent.

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."

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 preservice 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 pro-

viding 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 fund a scholarship program that helps to keep in school nearly 4,000 orpinans 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 Uganda, where PEPFAR and AEI are working together to strengthen life-skills and prevention curricula in schools. This program, with \$2 million in funding in FY 2007, targeted 4 million children and 5,000 teachers.

We are also working with the President's Malaria Initiative and the Millennium Challange Composition to according to a predictive in countries where are com-

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 will deliver more than 500,000 bed nets before this malaria season 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 colocating 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 develop-ment 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

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 offseted 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 headquartersdon'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.

REALITHORIZATION 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 Min-

ister 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 Lugar, 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. The foundation of that success has been true partnership, and the rejection of the donor/recipient mentality.

Our partnerships are founded in the profound sense of dignity and worth of every human life, and in trust and mutual respect between peoples. These partnerships are giving individuals, communities, and nations great hope, and are transforming individuals, communities, nations, and—in the case of Africa—much of a subconti-

The people of those countries have a new window into the hearts of Americans; they know what we stand for and that we stand with them. This was made clear by Presidents Mogae of Botswana and President Kikwete of Tanzania in their powerful statements last month.

Beyond that, as President Bush has said, this effort is also good for our national character and who we are as a people. This noble and ennobling work has only begun. Working together to unlock the power of partnerships, we can and will achieve much more for others, and for ourselves.

The CHAIRMAN. Thank you, Mr. Ambassador. You can assure, I believe, with certainty any health official in any nation that is benefiting from this program that it will be continued.

Let me ask. The President's goal—target—for the next 5 years would add 500,000 people to the original target of putting 2 million people on treatment by 2008. Would additional funding help us achieve more?

Ambassador Dybul. I think for prevention, treatment, and care, resources are an important piece of the puzzle, as is building health capacity. I think we're all aware that as the President called for \$30 billion for PEPFAR, the G-8 has committed \$60 billion, but they included TB and malaria. So for the next 5 years, with that \$30 billion we would actually be more than the rest of the developed world combined.

So we think for going forward, for issues of sustainability, an expansion of care and treatment is necessary. But the goals actually for the second 5 years, as President has called for, are actually a little bit heavier on prevention. It actually calls for about a doubling of the prevention goal, as you pointed out, prevention being the most important piece, while we increase care and treatment 20 to 25 percent.

So I believe the answer to your question is the additional resources could increase, but they don't necessarily have to come from the American people, which is why we're turning to the world community as well, and we believe that about—if we're going to be more than half of the rest of the world, that puts us in about the right situation going forward.

The CHAIRMAN. Obviously one of the controversial pieces of the original legislation was the abstinence piece, and it's still debated somewhat heavily. You pointed out that you have observed and tried to accommodate the cultural differences from country to country in how best to attack this pandemic, this epidemic, in their countries. In some parts of the world, there are some devastating statistics relative to consensual sex versus nonconsensual sex. Between 20 and 50 percent of women in the countries under consideration or that are involved indicate that their first sexual experience was forced. Nearly 50 percent of all sexual assaults in these countries are committed against girls 15 years or younger.

Obviously, violence puts women and girls at a higher risk of HIV. One study that you describe in your 2006 report to Congress found that in Tanzania young HIV positive women were 10 times more likely to report violence than HIV negative women.

Now, obviously we're not going to reach our goals around prevention, care, and treatment if—I shouldn't say "obviously." It's my view that we will not meet them if we don't address this: How gender-based violence is impacting on it.

The President's Emergency Plan is making real strides forward, but you've stated obviously we have to do more. How much money do our programs now spend to prevent or help people recover from gender-based violence? Is it a focus at all?

Ambassador Dybul. As a matter of fact—Senator—Mr. Chairman, it is a focus. We actually are focused on gender inequality in

general, not just gender-based violence, because the gender-based violence really is a part of a culture of gender inequality that promotes gender violence. It also promotes transgenerational sex, where older men have sex with younger women, where younger boys prey on younger girls. So it's a whole deep cultural issue.

So we're trying to address the broader issue and gender-based violence is a piece of a multipronged approach to address these issues. I agree we can do more and I must admit it's going to be very difficult for an AIDS initiative to radically change all the cultural aspects, but we're trying to do our piece here. We dedicated around \$442 million last year for programs that had a gender component to them.

I think the fundamental thing, though, is changing gender norms. So that's why we begin with these life skills programs at an early age to try to change the whole dynamic, to teach children to respect themselves, to respect others, which includes respecting girls. It's a generational approach that's going to take time.

At the same time we're engaged in gender-based violence, we work with the Women's Justice and Empowerment Initiative to deal with some of these issues, provide post-exposure prophylaxis, provide counseling and testing around gender-based violence. It's a

very complicated approach.

I think you're correct, in such a situation, whether it's violence or other gender inequality, negotiating abstinence is very difficult, but it's as difficult to negotiate a condom. So it's actually important that we address the gender norm overall. And it's going to take

time, but we're seeing great success.

I'll give you an anecdote which I think reflects it. I went to a high school in Botswana where we had begun these life skills programs to change the dynamic, to teach people to respect each other. This program had been going on for a little over a year. Now we're expanding it throughout the country, as we're doing in many other countries. We asked—we got a small group of them after and began asking some questions. The girls answered all of the questions and the girls talked about how they wanted to become doctors and engineers. That's not normal in an African situation. Normally the boys would dominate, the girls would be quiet. That's the type of thing we're trying to foster and change, which we then think will influence gender-based violence.

But also we need direct programs on gender-based violence. Again, I think we can improve everything we're doing. It's definitely a focus for us and we're doing some innovative programs and evaluating them to see what the greatest outcome is, including job creation and some other things to see if we can change this whole

dynamic.

But we've got to work with USAID, we've got to work with the Millennium Challenge Corporation, we've got to work with the countries themselves. That's one of the reasons going forward we talked about these partnership compacts, where we would actually work with countries to help them deal with gender inequality, because we agree with you, we can't tackle this problem if we don't deal better—

The CHAIRMAN. The reason—I'm impressed by your answer. This first round is 7 minutes and my time is almost up. But let me just

ask this question. Obviously, what I'm about to ask is not something that would be funded through PEPFAR. But if you knowif you don't know for sure, you can take an educated guess—what percentage of the countries that are recipients of this assistance have universal elementary school education that includes women?

Ambassador Dybul. I'd actually have to doublecheck. Most of them do actually have universally available primary education. The problem is when they do that they have school fees or uniform fees, which limits the ability of kids to go. And then there's not much secondary schooling, so they end at primary school.

We're actually developing through our orphans program with the African Education Initiative scholarship programs to get kids through secondary school. I have to get you a specific answer, but many of them do, but on paper might be different than the actual

implementation.

The Chairman. Generically, do you think that if, assuming we had unlimited, which we don't, unlimited money to deal with foreign aid, if we were to direct more of our economic aid to the countries in question toward building and sustaining and funding their elementary and secondary education systems that required the same treatment for young boys as young girls in that system, is that likely to have any positive impact on what we're talking about here?

Ambassador Dybul. It's something we intend to look at. I don't know. You could say that it would and it very well might, but we're not 100 percent certain. So we want to evaluate that—implement programs and then evaluate it.

I should point out that there are other players in this field. The

United Kingdom has-The CHAIRMAN. Oh, I realize that. I just wondered what our

thinking was.

Ambassador Dybul. Right. So we want to work with all of these different players to basically put the pieces of the puzzle together

and see how we can have the greatest impact.

The CHAIRMAN. What I'm about to say—and I'm 30 seconds over my time already. I don't want you to respond now. What I'm about to suggest is not something that I would attempt to attach to this legislation. But I have a bill that's an International Violence Against Women Act, money promoting, like we did here domestically in the Violence Against Women Act, money made available to countries who would engage in certain activities that would, in fact, promote efforts to diminish violence against women in various societies.

I'd like to, because you seem to be—and it's not in your wheelhouse, it's not in your secretariat. But I would like to maybe ask you just as a favor to give me your sense of how you think that and I will send it to you—that legislation might, if at all, and it may not, have a positive impact on these larger problems, because there is a whole lot of things that flow from the treatment of women essentially as second class citizens, property, and the like.

I have many more questions, but I thank you and I yield to the

Senator from Indiana, Mr. Chairman.

Senator Lugar. Thank you very much, Mr. Chairman.

I have three questions I wanted to ask so we have as complete a record as possible. The first question, as I mentioned in my opening statement, in late August the committee received a letter signed by the Ministers of Health from the 12 African PEPFAR countries asking us not to wait until next year to reauthorize the legislation. The letter states: "Without an early and clear signal of the continuity of PEPFAR's support, we are concerned that partners might not move as quickly as possible to fill the resource gap that might be created. Therefore, services will not reach all those who need them, The momentum will be much greater in 2008 if we know what to expect after 2008."

Based on this statement, it seems to me that to delay the reauthorization will result in fewer people being placed on ARV treatment. My question to you, Ambassador: Is that correct? Does that mean that early reauthorization will help save more lives? And further, how would early reauthorization help leverage more funding from other donors and thus save additional lives?

Ambassador Dybul. Well, Senator, I think the best way to answer is that just to relay the discussions I've had with Ministers of Health. And I think there is a big difference between ministers and people in-country and some of our partners who are very used to Washington and our U.S.-based partners, who understand how our system works and really don't see a problem in terms of the longer process.

But in-country, the ministers and the people who are implementing on the ground—and 83 percent of our partners now are local organizations—do have some concerns here. And, Mr. Chairman, I must assure you that we do tell them all the time: Don't worry, this is coming, bipartisan support, it doesn't matter who the

next President is, Congress has been there all the way.

But it's not something that they live and breathe in terms of the process. So there is a real issue for them of comfort level, because in 2008, as much as we've done, we have a massive scale-up to achieve those goals. And as they're looking at them and saying, once I put that person in treatment, once I put that orphan in care, they've got to stay there, there is a concern, there is a discomfort with that type of scale-up in the absence of a sure commitment, as much as we can tell them, don't worry, it's coming.

So as I speak with ministers—and every time I'm in the country

a minister says this—I think there is this concern there.

Senator Lugar. The second question is, you've mentioned in your testimony that the need to know your epidemic is crucial as each country addresses its own unique HIV/AIDS situation. The fact that no country's epidemic is the same as their neighbor's is one reason that I believe we need to keep the reauthorization as flexible as possible and limit the mandatory spending directives. We've tried to reflect this in S. 1966. Can you give us examples of how some of the PEPFAR countries' epidemics differ from one another and how greater flexibility would allow them to address their needs more effectively?

Ambassador Dybul. Yes. And I think actually, Senator, the language you've proposed makes a lot of sense, because it directs programs targeting behavior change at sexual transmission, not the overall picture, to allow that flexibility to expand programs such as

mother and child, nonbehavior change programs, so that that's taken out of the calculation.

And different countries do have very different epidemics, which is why we've never applied the directive to each individual country, but to countries overall, so that we have a very different approach in Botswana than in Vietnam, as the chairman pointed out. So we believe the language that you put forward provides us the flexibility both to ensure that we have programs that will lead to long-term changes in prevention, but also to allow us the flexibility to have programs that are different in each country, with greater flexibility, and, importantly, to not apply behavior change directives to clinical and other aspects of prevention.

tives to clinical and other aspects of prevention.

Senator Lugar. The third question, on the issue of resources. Fiscal year 2008 money will hopefully be available to these countries soon. Are any of the recipients expressing reluctance to use the increased funding to ramp up their programs in light of the un-

certainty of future funding pending a reauthorization?

Ambassador Dybul. As I mentioned in the first answer, I do hear that from Ministers of Health when I travel around, that they're a little concerned about the massive increase in resources thanks to the current budgets that Congress has before them and the President's request and because of that significant increase in new people in treatment and care that's needed in 2008. I do hear the concern about putting that many more people on without knowing for sure what to expect after, even understanding that there will be a reauthorization.

So I think what you said about consumer confidence gets it about right. It really is about perception. It's not a matter of fact. It's not a matter of reality. It's more a matter of perception that makes them uneasy, and as that uneasiness can cause problems in the financial markets, that uneasiness can lead to people not moving as quickly as they otherwise might to increase people, particularly in care and treatment, because that's something that they need to continue, which, therefore, might limit our ability to save the largest number of lives.

Senator LUGAR. The President has requested that our funding for HIV/AIDS be increased from \$15 billion to \$30 billion over the next 5 years. Some want a little less. Many want much more funding. What percentage of funding do you currently provide to focus countries versus nonfocus countries, and with additional funding do you anticipate increasing the number of focus countries or increasing assistance to nonfocus countries? Which nonfocus countries are in the most dire situations in relation to HIV/AIDS?

Ambassador Dybul. It's interesting, Senator. When I went back to read the legislation it surprised me that there actually are no focus countries in the legislation. That's something that we developed. So going forward actually, when the President called for reauthorization he didn't talk about focus countries. He actually talked about using the new money where it can be the most effective, basically saying if we can save two lives with a tax dollar or one life with a tax dollar you're better off saving two.

So going forward, we are going to look at the best opportunities to save the largest number of lives in countries that want to tackle their epidemic with their own resources where possible—many countries don't have many—but also with policies around gender equality and orphan protection and things that we know will enhance prevention of mother-to-child transmission, for example.

So going forward we would look at countries—I don't know where for sure yet. It depends on the countries that want to tackle their epidemics. But we know, for example, Lesotho, Swaziland, Malawi, Cambodia, Ukraine—I want to be careful here because there are a lot of countries I could name, so I'm just giving you a for-example. There are many, many more, and I don't want to indicate in any way where we think we would want to move.

But it's just an increased flexibility and thought process to using money where it can be most effectively utilized and not select coun-

tries up front this time.

Senator LUGAR. I appreciate your testimony. Thank you.

The CHAIRMAN. Could I ask a point of clarification on that if I may? Senator Lugar makes a very good point about certainty of funding, but in this new round we are going to consider any increased funding not only being used in the countries that are focus countries, but maybe other countries. Does that create any uncertainty in those very countries?

Ambassador DYBUL. It's a very good question. However, we have said, and I think you would agree, that we would not reduce funding in any of those countries going forward, because that would be a very difficult position for us and for them.

The CHAIRMAN. I agree. I think you should. I just wanted to

make sure.

Ambassador Dybul. But it does also create a sense of healthy competition, in a sense.

The CHAIRMAN. No; I'm not suggesting it's bad. I just wanted to make sure.

Ambassador Dybul. Yes. Because we continue, that's not an issue.

The CHAIRMAN. That's good.

Senator Feingold.

STATEMENT OF HON. RUSSELL D. FEINGOLD, U.S. SENATOR FROM MINNESOTA

Senator Feingold. I sincerely thank you for holding this hear-

ing. It's very important and I appreciate it.

Ambassador, it's good to see you again. As you stated, there has been considerable acknowledgment of the challenge of implementing HIV/AIDS programs in African countries that have inadequate or inefficient health infrastructure. The World Health Organization estimates that Africa has 24 percent of the global disease burden, but only 3 percent of the world's health workers, a deficit of more than 1 million doctors and nurses.

On a recent trip to Uganda in August, I met with key representatives from the HIV/AIDS community and we discussed the importance of building national capacity so these countries will be increasingly able to meet the health needs of their citizens. Only by strengthening indigenous infrastructure will our global health efforts be sustainable in the long run.

Ambassador, 2 years ago you personally testified that weak health infrastructure was delaying the progress of PEPFAR programs. What specific policies and programs have you introduced and what impact have they had to help address this problem? What other initiatives have helped strengthen national health infrastructure?

Ambassador Dybul. Well, Senator, I think it's one of the key issues going forward. There has been a lot of debate around health systems versus vertical programs and that kind of thing. Our approach actually has been—and this was the importance of the focus countries—to do national expansion, which requires building national systems.

So the majority of the cost actually right now, for example, for antiretroviral therapy goes to building systems, to paying salaries for doctors and nurses, to expanding or renovating or creating new clinics, to building a logistics system that will support the delivery of drugs. The same in our care programs and in our prevention programs.

So right now we are dedicating, last year I believe it was, \$640 million to what you would consider health system expansion, everything along that way. As I mentioned, we just did an evaluation on this because we thought it was important, to look in four countries at our care and treatment sites to see what we were doing for infrastructure and what the contributions were. On average, 92 percent of the infrastructure development in those sites was supported through PEPFAR. It was actually higher in the public sector than in the private sector, which is another important thing. Eighty-three percent of our partners are local organizations and we're building that capacity in-country.

Uganda is a great example. Our biggest partners there are local partners, TASO and Joint Clinical Research Center and AIM and

many others, in the communities fighting their epidemic.

One of the interesting things, too, I think, is that many of our private partners are actually working in the public health sector building the public health infrastructure as well as the nonpublic health infrastructure. Very variable by country. I can give you an example from Namibia. In Namibia about 90 percent of the health care is in the public sector, not in the private sector, versus in Uganda or Kenya where it's closer to 50–50. We're supporting virtually every person doing care and treatment and counseling and testing in the public sector, but we're doing it through a contract mechanism, and we have a long-term plan with the Namibian Government to turn those people into ministerial employees over the long period because they just couldn't take all—it would be impossible for their system to take them all in immediately.

So this is the type of thing we're working on in innovative and creative ways. What we fundamentally believe is we're a piece of the puzzle in the countries, including the Global Fund, World Bank, many foundations, the governments themselves, and we're trying to support the piece of the national program that we're best

at, including a lot of infrastructure work.

So we've got a lot of innovative stuff going on. Like every place else, we can improve this just like we can improve everything we're doing. We look for people's suggestions and opportunities, but a lot's been done and we'll continue to work on it.

Senator Feingold. What do you think are the best ways to retain health workers in their country of origin?

Ambassador Dybul. I think the best way to retain them is to provide them hope. Actually, when I was a young doctor in San Francisco it was the same. People were leaving every 6 months to a year. They just couldn't be around that much death all the time.

When you talk to doctors and nurses now and you ask them the most important thing that's keeping them there, it's hope. It's the sense that they can actually do something for their own people.

I would say the second most important thing is to use what's called task shifting to allow not only doctors and nurses, but medical officers and community health workers to do a lot of the work. The reason I mention that in response to your question is there is no commensurate certification in the United States or anywhere else to employ such people, so they pretty much have to stay where

They also tend to be trained in their local community rather than traveling for training, so they're tied in in part of their community.

So I think those two things are very important.

The third thing, and we're doing this in Namibia and Mozambique and Zambia, is supporting—and now in Côte d'Ivoire now that the north has opened up—we're supporting ministerial and public sector retention packages to keep professionals in rural areas, just as in the United States we have to do some of this. So it can involve housing, it can involve school fees, it can involve other incentive packages to keep people in rural areas. It's not just doctors and nurses. It's technicians and other types of people as

Senator Feingold. In sub-Saharan Africa, health workers are also infected with HIV, as I understand it, at the same rate as the general population. In countries such as Lesotho and Malawi, death from HIV/AIDS is the No. 1 cause of health worker attrition. According to the Institute of Medicine's report, PEPFAR's workforce strategy does not prioritize protecting health workers from HIV exposure and identifying and treating those who are infected.

What can PEPFAR do to keep medical staff healthy?

Ambassador Dybul. Well, I think it's a critical point, and in fact a review was just done in Kenya. They thought most of the Kenyan nurses were leaving the country. In fact the reason they were los-

ing the nurses is they were all dying.
We are trying to engage countries in this. I have to say that what we're trying to do is support the national strategy, so we leave it to the local environment to determine prioritization. In many countries they do prioritize health care workers, they do prioritize pregnant women. For example, Uganda has policies around this. So we support the national strategy there. We are encouraging people more and more to support the health care workers.

I have to say, and as a physician I know this is true, we can stigmatize a lot in the medical community. Some doctors and nurses are scared to death to say they're even positive, so we even have our own staff who are dying from the disease because they're afraid to tell. So we need to do more work on reducing stigma and discrimination in the medical profession as well.

Senator FEINGOLD. On the gender issue and its relationship to AIDS, what role have women's and civil society organizations played, both in the United States and in-country, in developing new strategies on gender-based violence, changing norms and attitudes among men and a focus on adolescent girls? And will these groups be involved in the implementation and evaluation of the ensuing program?

Ambassador DYBUL. Yes, absolutely; and they're involved very much now. I think—and I know, Senator, you have spent much time in Africa, and you've seen in many places it's the women who are doing the work in the care and treatment sites and everywhere else. And if they're not engaged we're not going to be able to tackle

this epidemic sufficiently.

Senator Biden asked a great deal about this. Working on gender issues we believe is one of the fundamental aspects, because we can't have effective prevention if you're not teaching young boys not to prey on young girls. If you're not teaching older men not to prey on young girls, we can't overcome this epidemic. So gender equality is going to affect our ability to have effective prevention programs, and engaging women's groups is critical. Men's groups, too.

One of the problems is we don't have a lot of men who are engaged in the activities, and we're learning how to do this better. I'd be happy to describe—time's running short, so I don't want to go into too many programs. But we are now targeting men and girls separately and then bringing them together and finding that's far more effective, or doing couples counseling and testing, for example, and doing testing in the afternoon or on Saturdays, which

will draw couples in to bring the men in as well.

I want to point out one thing here, which is unless you have treatment you'll never get a man to get engaged at all. One of the reasons we're getting men to come for testing now, particularly in discordant couples, is because they know treatment's available. So it's radically changing the dynamic between men and women, and women can now convince their partners to come get tested because there's an opportunity for treatment.

So it all fits together. It's a complicated picture, a highly complicated picture. We've got a lot more to do, a lot more to learn.

But we've found a lot of progress in these areas.

Senator FEINGOLD. Thank you very much, Ambassador.

The CHAIRMAN. Thank you.

Senator Menendez.

STATEMENT OF HON. ROBERT MENENDEZ, U.S. SENATOR FROM NEW JERSEY

Senator MENENDEZ. Thank you, Mr. Chairman.

Ambassador, there are currently 15 PEPFAR focus countries, 12 in Africa, 2 in the Caribbean, and 1 in Asia. While the urgency and support concerning the AIDS epidemic in Africa has increased significantly in the past year, the awareness of Latin America's growing AIDS crisis remains lower. As of 2005, this hidden crisis affects more than 1.8 million people in the region. So if PEPFAR is truly to be a global initiative to address this issue, why aren't we paying more attention to Latin America, a region in which we have the movement of people within this own continent?

Ambassador DYBUL. I think it's a very good question and one that goes back to some things which were discussed earlier about focus countries and going forward. It is the reason that we have Haiti and Guyana as focus countries, because it needs to be a global response. At the time they were selected, Haiti and Guyana had the highest prevalence of the countries in the region.

Great success in Haiti; I just got back from there. In the midst of some of the most difficult time periods, they've expanded care and treatment programs. Across the island on Hispaniola, we actually have been expanding our program in the Dominican Republic

as well and are doing more cross-border.

We're also looking at the region as a whole. As you point out, particularly in the Caribbean, people move a great deal from country to country. We have some Caribbeanwide training. We actually have increased resources, not only in those two countries, but more broadly for the Caribbean region, and also some in Latin America,

in particular in Central America.

So we do see them as opportunities. I think we also need to be very congratulatory of what the work the people themselves have done in that region and the commitments of the governments themselves. The Caribbean as a region has seen stabilization or decline in their epidemic and as a whole Latin America and the Caribbean are actually meeting the international standards for access to treatment in one of the most aggressive ways. But we do see opportunities there. We do see opportunities for these partnership arrangements. But it is the reason that Haiti and Guyana were focus countries.

Senator Menendez. I appreciate that. My concern is the rest of the hemisphere and its increasing numbers.

Let me ask you this. You have mentioned in recent times the possibility of graduating certain countries, like South Africa or Botswana. If those graduations take place, is there going to be a reattribution of those resources?

Ambassador Dybul. Yes.

Senator Menendez. And if so, how will that be distributed?

Ambassador Dybul. I think graduation as we understand development might be too strong a term. It's quite likely we'll need to be engaged in those countries going forward. It's just the level of resource commitment could decline over time as those countries do more and more. South Africa this year is committing \$800 million of their own dollars. Botswana is around \$150 million.

So we see and have spoken with the countries about gradually working with them to have them—and their national plans already do this—take up more of the resources. That would be part of our approach toward the next phase, which is these partnership compacts utilizing the entire pool of money, working in countries that want to tackle their epidemics, which would include the opportunity for other countries to be engaged. And Latin America and the Caribbean region in particular is one area that we would look at

I think the criteria are still being worked out. We have a lot of work to do on this. We look forward to working with Members of Congress and the staff on thinking through some of this. But certainly a couple criteria would be prevalence rate and whether or not we already have a strong bilateral program. Going into a country and reestablishing a new bilateral program might not be the right role for us. Maybe the Global Fund or another should do this.

So we need to think together about them, but Latin America, in

particular the Caribbean region, offers some opportunities.

Senator MENENDEZ. Let me ask you two final questions. As the leading killer of people living with HIV/AIDS, tuberculosis is inextricably linked to the epidemic. Given the high rates of TB/HIV coinfection in the 12 PEPFAR focus countries in Africa, TB programs present an opportunity to identify additional HIV positive individuals who are eligible for treatment.

Given these opportunities, should addressing TB/HIV by increasing integration and coordination among programs, should it be a

greater focus in PEPFAR's reauthorization?

Ambassador Dybul. Absolutely, Senator. But I don't think we need to wait for reauthorization. In fact, for most of these issues we need to do this now, which is why we've increased our resources for HIV/TB activities from—we increased it by \$50 million last year and we're going to do it again this year. We are heavily targeting this issue. We're working with the World Health Organization. Great successes. We actually worked with the World Health Organization to pick a couple of countries and see how we'd most effec-

tively do this, including Rwanda and Kenya.

We are now up to 86 percent testing for TB in HIV-positive patients across the way and 75 percent or so in coinfection treatment. We're working the same in Kenya. So we know how to do it. Since that time we have brought together more countries to learn from those lessons, to see how we can expand those care and treatment programs, integrating HIV and TB, because you're absolutely right, TB is the No. 1 killer for these patients. Also, with the advent of extremely drug-resistant tuberculosis, we need to be paying more and more attention, in particular in deep sub-Saharan Africa, and we've increased our resources for laboratory and other means around tuberculosis so we can get a better understanding of that extremely concerning disease.

So I don't think we need to wait for reauthorization. We're doing it now.

Senator Menendez. One final question. Regular testing of the CD4 counts of those diagnosed with HIV is the standard of care in the developed world. It's critical to appropriately stage care from a clinical perspective. It's also important from a program perspective as it is a means to effectively use the resources available to buy antiretrovirals. Has the program sufficiently integrated CD4 testing into the program and into the national health systems in

our target countries?

Ambassador Dybul. We are working hard on that and it's part of our guidance to do just that. Now, we haven't held up treatment for the CD4 cell count because you don't always need it. If someone's coming in with an opportunistic infection or a clinical way to diagnose AIDS, you don't need to wait for a CD4 cell capability to begin treatment. But that's actually what we're doing, and we're trying to scale up national CD4 cell counts. We're integrating transport systems because it's difficult to get them everywhere. For example, in northern Kenya—I was there about a year ago and we

actually developed a system so that all of the satellite facilities in an area could send their CD4 cell counts in and send the results back out so we could use them in the system.

So we are moving rapidly toward use of CD4 cell counts. To be honest, I think we're overusing them in some places, too. Getting one every 6 months isn't going to change what you do clinically. It's nice for the clinician to have it, but it's not going to change. So we're working with countries to come up with, and the World Health Organization, to come up with the best approach. But you

certainly need it for diagnosis.

One of the most exciting things is—what we're starting to see is people coming in at time of diagnosis have a higher CD4 cell count, which means they're healthier, which is exactly what you want. That's why care is so important, so that you have people in a care system and you can monitor them so you know when to most effectively begin treatment. So this is where we're evolving tools as rapidly as we can, because that's going to be the most effective use of resources. It takes time. We've only been at this for 3 years and have scaled up dramatically. But these are the things we are trying to put into all of our programs.

Senator MENENDEZ. Mr. Chairman, I have a series of other questions I'll submit for the record. And I appreciate your answers, sir.

The CHAIRMAN. Thank you, Senator.

Dr. Dybul, I'm impressed with your—not only your knowledge, but your commitment to making this program work. Let me ask you—I have a number of questions as well, probably a half a dozen I'm going to submit in writing. But I'd like to conclude by asking you to talk to me about how you envision the coordination between the rest of the world getting into this fight and this program?

I mean, in other words, how much interfacing is there between you and your colleagues in Europe? The decision is made to put X number of dollars in Country Y. Is that coordinated in any way with the Europeans? Talk to me about that for just a few moments on the record.

Ambassador Dybul. Yes; I think that's a great question. I can begin by saying this morning I met with the junior Minister from DIFD to talk about some of these issues. Two weeks ago I was in Haiti with the head of the Global Fund. We've taken two joint missions together, Côte d'Ivoire and Haiti. He speaks French, I don't, so I was at a significant disadvantage in two French-speaking countries.

But we are trying to do exactly that, and I think we've seen great successes. Now, there are two pieces of that. One is the global interaction together, and we actually have called a meeting between the head of the Global Fund, myself, the people in the United Kingdom, the head of the World Bank for these programs, and others in December or January to talk more about how we can do this.

But the real key is in-country. The real key is how are we coordinating our programs so that we are supporting one national strategy. I think we've got some great successes over the last few years. If you look in Ethiopia, if you look in Rwanda, what you see is the Global Fund, for example, PEPFAR, and the World Bank jointly co-

ordinated to support the national strategy, where we each do pieces

of the puzzle to expand the national program.

That's the thing we need to do more and more of and get better and better at. So I think we've made great strides both at the headquarters level and at the country level. But it's one of our principal focuses going forward, because otherwise we're duplicating effort. Otherwise we're not effectively supporting the national strategy. So there are opportunities here.

To be honest, for the American taxpayer this is a great way to do it, because we're all in it together. We're all in it supporting together, not one piece being the most essential or pieces that we

can't sustain over the long term.

The CHAIRMAN. Too many countries in the beginning of this whole initiative responded slowly. As a matter of fact, 10 years ago when we started discussing this, one of the difficulties was the willing suspension of disbelief in some countries, where there were some countries, which I'm not going to name because it will cause controversies again, who either denied the existence of the problem in their country, were slow to react to it, or when they reacted to it, reacted to it in a less than helpful way.

You say countries have national strategies. I imagine a number of the countries, some of which you already mentioned, need some guidance in developing their national strategy. Is there a go-to agency that countries are inclined to, once they have reached, they have crossed the Rubicon that they have a problem or they have

an obligation to deal with it?

I mean, how and if—do you and how do you try to help develop national strategies, or do you? I don't mean you alone. I mean—

Ambassador Dybul. Absolutely. I have to say there is no one particular go-to. There are a lot of international guidance and documents to help direct people, but each country does it differently, and they tend to pool everyone together to come together to develop one national strategy. South Africa actually just put forward a great national strategy. Ethiopia has a new one, Kenya has a new one.

So they evolve over time and they're getting better all the time. So that is a principal part of our work, to work with our other partners in-country to build a national strategy that ultimately is owned by that government and that country. So it is a principal part of what we do, and they're improving all the time. Again, we've only been at it for 3 years, but it's getting better.

The CHAIRMAN. I realize that. Look, I'm a fan. I think you're

doing a very good job. As I said, I'm impressed.

One of the things I'd like you to submit for the record, if you would—I'm not looking to make unnecessary work for you here, but if you could lay out for us what is the informal, if not formal, coordinated process that goes on for all the countries and the Global Fund and this fund for attacking basically the same problem. There's slightly—there's nuanced differences in approach.

It would be a useful tool for us, for those of us who have been so supportive of this effort, to be able to have to make the case to our colleagues. And I'm not asking you to do my work for me. I'm asking you to help me lay out the most persuasive document to—it need not be a document—the most persuasive paper to indicate

that we are multiplying, in effect, our dollars; we are not duplicating the dollars.

Would you be willing to try to take a shot at that?

Ambassador Dybul. Absolutely, Mr. Chairman. Your work is our work, so we're happy to do that.

[The written information submitted by Ambassador Dybul fol-

A key difference between PEPFAR and the Global Fund, and an important reason for U.S. support to both programs, is that while PEPFAR mobilizes U.S. diplomatic leadership, technical expertise, and financial resources to work at the country level, the Global Fund is, in its own words, a "simplified, rapid, innovative process [to] attract, manage, and disburse additional resources." The Global Fund is a financing mechanism, which boosts funding and political leadership around the world. It does not have field staff, and does not develop specific implementing strategies. The Global Fund relies on implementing and the global funding an implementing and the global funding an implementing and the global funding and global funding al Fund relies on implementing partners—both host country organizations and international development partners—to manage the funds and build the programs at the country level.

U.S. missions use their PEPFAR resources to support Global Fund grants and "make the money work" in a variety of ways. In focus countries, implementers supported by PEPFAR and the Global Fund work closely to deliver a comprehensive program under one national plan and strategy, which uses one system of monitoring and evaluation. This effort is consistent with the commitment of both agencies to the "Three Ones" principle, which calls on all international partners to support in each country: (1) One agreed HIV/AIDS Action Framework that provides the basis for coordinating the work of all partners; (2) one National AIDS Coordinating Authority, with a broad-based multisectoral mandate; and (3) one agreed country-level Monitoring and Evaluation System.

For example, in Uganda, all operational costs of TB/HIV sites are financed by the Global Fund, and PEPFAR supports the personnel, training, and quality assurance at these sites. Similarly, in many countries, PEPFAR country teams have arranged for the Global Fund to supply antiretroviral drugs and commodities to PEPFAR-supported HIV treatment sites, where PEPFAR supports personnel, training, infra-

tructure improvement, operations, and quality assurance.

The Global Fund's 2005 progress report cites Tanzania as another example.

"[P]artners are now refocusing their resources to support implementation after the slow start to programs financed in early rounds. A key area of collaboration has been through USAID funding of Management Sciences for Health (MSH) for assistance to the Tanzania Commission for AIDS (TACAIDS). TACAIDS is responsible for coordinating the implementation of most HIV/AIDS-related activities in Tanzania. MSH provides capacity to support the development of work plans, and procurement and supply management.

In other countries with USG bilateral programs, where the Global Fund is often the largest international partner on HIV/AIDS, PEPFAR works to maximize the impact of Global Fund resources and to fill gaps in support of a comprehensive HIV/AIDS program. At the request of Global Fund Country Coordinating Mechanisms (CCMs), PEPFAR provides technical assistance to Global Fund grantees, helping them overcome bottlenecks, expand access to services, and resolve major issues that can cause grant failure in areas such as program management; governance and transparency; procurement and supply-chain management; and monitoring and

Of all countries that completed PEPFAR country operational plans (COPs) and minicountry operational plans (Mini-COPs) 1 for FY08, 48 percent are planning for Global Fund technical assistance in their annual budgets, totaling over \$11 million for calendar year 2008. Additionally, in the past 3 years PEPFAR has provided over \$35 million for targeted assistance using funds withheld from the U.S. contribution to the Global Fund, within the legislatively authorized 5 percent ceiling. These funds support Management Sciences for Health (a USG contractor), Roll Back Malaria, UNAIDS technical support facilities, the WHO Green Light Committee, and the WHO Stop TB initiative in order to provide specialized technical assistance to Global Fund grants.

One of the most important ways PEPFAR coordinates with the Global Fund at the country level is by participating in the Global Fund CCMs. A CCM is the national planning and oversight body for the implementation of Global Fund resources in a given country; these bodies are multisectoral, and involve top leadership from all areas of the government. In 2007, 87 percent of countries that completed PEPFAR COPs and Mini-COPs had PEPFAR representation on the CCMs. As regular members of the CCMs, PEPFAR personnel contribute significantly to the design of national Global Fund grant proposals, selection of interventions, and over-

sight of implementation

In Ghana, the Global Fund's 2005 progress report notes that PEPFAR participation has been "integral to changes made to streamline and strengthen the CCM. In the past the CCM was largely seen as an impediment to the smooth functioning of grants in Ghana. Key members of the CCM led by the PEPFAR representative advocated for a change in the size of the CCM as well as for the election of the chair and vice chair and the selection of members by their constituencies . . . The bilateral and multilateral partners deserve credit for keeping the issue on the table throughout the last year and for assuring that it was brought to resolution . . . The CCM has been streamlined and members are now elected by the constituencies they

CCM has been streamlined and members are now elected by the constituences and represent."

To further promote coordination, PEPFAR has entered into Memoranda of Understanding (MOUs) with the Ministries of Health and the Global Fund in several countries. These documents help clarify collaboration and partnership activities in such areas as antiretroviral treatment (ART) provision. For example, the critical relationship between PEPFAR and the Global Fund in Ethiopia was formalized on February 7, 2006, when the Minister of Health and the Chargé d'Affaires at the U.S. Embassy signed a Global Fund-PEPFAR Ethiopia MOU. Through this MOU, PEPFAR, and Ethiopia's HIV/AIDS Prevention and Control Office (HAPCO) within the Ministry of Health, which operates with Global Fund support, engage in joint the Ministry of Health, which operates with Global Fund support, engage in joint planning to support one national HIV/AIDS program; to use resources effectively according to comparative advantages; and to share programmatic, financial, and institutional information in order to identify and minimize programmatic gaps and overlaps

Specific coordination mechanisms within this MOU include a weekly PEPFAR-HAPCO management meeting to address planning and operation issues; a monthly PEPFAR-Ministry of Health meeting to address policy issues; and a Global Fund-PEPFAR liaison position to strengthen and lead coordination efforts in planning, implementation, and monitoring and evaluation of HIV/AIDS activities among the

Close PEPFAR-Global Fund coordination is also reflected in the PEPFAR Country Operational Plans (COPs). In Rwanda, PEPFAR focuses on strengthening aspects of the national health system that will enhance Global Fund implementation, as well as directly further the objectives of the national government and PEPFAR in addressing HIV/AIDS and public health. For example, PEPFAR:

- · Provides training, infrastructure and logistics support of the National Reference Lab and district and site laboratories, which are also used by Global Fund-supported activities;
- Strengthens the capacity of the local authority—the Treatment Research and AIDS Center (TRAC)—which oversees all HIV/AIDS planning and implementation nationwide:
- Provides technical assistance for a coordinated supply chain between donors for harmonized quantification, procurement, and distribution of antiretroviral (ARV) drugs, laboratory commodities, and other consumables.
- Supports broad-based quality initiatives to enhance synchronization of Global Fund- and PEPFAR-supported packages of service;
- Helps procure commodities for Global Fund-supported Voluntary Counseling Testing (VCT) and Prevention of Mother-to-Child Transmission (PMTCT) sites;
- · Supports national monitoring activities through TRACnet, an innovative telephone and Web interface system to connect every Rwandan health facility that provides ARV treatment and related services, including Global Fund sites; and Participates in the CCM, such as by serving as chair of the HIV/AIDS, TB, and
- orphans technical advisory committees.

In Thailand, the PEPFAR team oversees technical assistance to Global Fund projects that is provided through UNAIDS with USG funding. Current funding supports:

- Building the CCM's capacity to provide technical and programmatic oversight to Global Fund grants, and strengthening the role of civil society in the CCM;
- Assessing needs to improve financial and programmatic monitoring and report-
- ing, and providing training and technical assistance to address these needs; and
 Developing and disseminating strategic information briefs to promote policies supportive of Global Fund-supported HIV programs.

Additional planned technical assistance will support capacity-building for local government and Global Fund subrecipients and sub-subrecipients, to improve their capacity to design and implement effective HIV programming at the local level. The resulting local policy and capacity development guidelines will be disseminated

throughout Thailand.

Malawi has been approved to receive large amounts of Global Fund resources, but lack of local capacity has impeded rapid disbursement and use of the funds. The PEPFAR team dedicates substantial efforts and resources toward helping the Global Fund grants work in Malawi. PEPFAR's model of long-term technical assistance to support national scale-up of HIV/AIDS interventions in Malawi has been very successful. As of June 2007, Malawi had 114,375 people on ART, and wide usage of counseling and testing services nationwide. However, despite these tremendous achievements, local capacity has not grown as well as was intended. The PEPFAR team is currently examining what future models of support will bring long-term sustainability. In 2008, PEPFAR will move further into supporting the scale up of PMTCT and, through the new Community Care Advisor, provide assistance to facilitate improved implementation of the Global Fund Round Five Orphans and Vulnerable Children (OVC) grant.

Effective coordination at the country level also requires leadership and collaboration at the headquarters level. The Global AIDS Coordinator serves as the Chair of the Global Fund Finance and Audit Committee, providing a critical leadership role in budget oversight and management. Senior PEPFAR officials also represent the USG on the Global Fund Policy and Strategy committee. In addition to top-level leadership, a PEPFAR interagency "Global Fund core group" reviews Global Fund country programs and grant requests, communicates with USG field staff familiar with the strengths and challenges of Global Fund programs, and engages in other activities to help the Global Fund successfully meet the requirements of performance-based funding. This core group also helps to coordinate Global Fund and PEPFAR activities on an international level. Last, the United States, through PEPFAR, is the largest contributor to the Global Fund, having provided nearly one-

third of total Global Fund resources, or a total of \$2.5 billion, to date.

The CHAIRMAN. All right. Well, thank you very much. I appreciate your time and your commitment.

The hearing is adjourned.

[Whereupon, at 3:46 p.m., the hearing was adjourned.]

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

Responses of Ambassador Mark Dybul to Questions Submitted by Senator Joseph R. Biden, Jr.

PREVENTION OF HIV/AIDS

 $\it Question.$ As Congress undertakes reauthorization, how do we most effectively elevate prevention as a strategic authority?

Answer. PEPFAR has supported a balanced portfolio of prevention, care, and treatment, identified in its authorizing legislation. PEPFAR recognizes that prevention is the bedrock of an effective global response to HIV/AIDS. In PEPFAR's Five-Year Strategy, in each annual report, and in nearly every other public document, PEPFAR has clearly stated that we cannot treat our way out of this pandemic, and that prevention is the most important component for success. Counting counseling and testing as part of prevention, in fiscal year 2007 prevention received 29 percent of program resources.

of program resources.

We believe that goals are a key determinant of programs. The first phase of PEPFAR included a goal of preventing 7 million new infections. In the next phase of PEPFAR, the President has proposed nearly doubling that prevention target, seeking to prevent 12 million new infections. Care and treatment goals in this next phase are also increased, but more modestly. Countries will need to make a significant scale-up in prevention activities to meet this ambitious target, while continuing support for care and treatment interventions.

Additionally, PEPFAR has more experience with and evidence about "what works" in prevention than ever before. Evidence from Kenya, Zimbabwe, and a number of other countries demonstrates that HIV prevalence declines when young people delay sexual debut, sexually active persons reduce their number of partners, and people

¹Generally, countries receiving more than \$10 million per fiscal year from PEPFAR are required to submit a full country operational plan (COP). Those receiving between \$5 and \$10 million are required to submit a shorter, minicountry operational plan (mini-COP). Countries that do not submit COPs or Mini-COPs do not report funding for Global Fund technical assistance.

engaging in risky sexual activity increase condom use. In addition, PEPFAR promotes interventions that address gender issues (including gender-based violence), cross-generational and transactional sex, substitution therapy for injecting drug users, and prevention for those already HIV-positive to prevent secondary infections. Scaling up prevention of mother-to-child HIV transmission (PMTCT) is also an

Scaling up prevention of mother-to-child HIV transmission (PMTCT) is also an important priority for PEPFAR. In Botswana, PEPFAR support for PMTCT has contributed to Botswana's success in reducing the rate of HIV transmission from mother to infant to just 4 percent, and the infant mortality rate in general is on the decline. PEPFAR is disseminating programmatic lessons learned from successes like the promising PMTCT model in Botswana to other countries.

A promising prevention breakthrough made with PEPFAR support is male circumcision, which randomized control trails have shown can reduce a man's likelihood of contracting HIV by 60 percent. PEPFAR now supports male circumcision programs, including the development of policies, training, implementation and qual-

ity assurance in several countries, by host government request.

PEPFAR also quickly adapts and supports international normative guidelines in prevention, such as the scale-up of WHO-approved provider-initiated testing and counseling in antenatal, TB, and HIV clinics, and in other in- and out-patient settings. Testing uptake under this "opt-out" model has been 90 percent and above in several settings, and expanding it will significantly increase the number of people who know their status and who can take measures to avoid contracting it themselves, or further spreading the disease.

This progress has been achieved under the current authorities of the Leadership Act. The success PEPFAR has experienced thus far has been largely driven by the President's 2-7-10 goals. With an even more ambitious goal for the next phase of PEPFAR—support for prevention of 12 million infections—and supported with more evidence, knowledge, and experience than ever before, we believe country teams will respond with a significantly greater focus on prevention interventions over the next 5 years.

Question. In the next phase of programs to combat HIV/AIDS, what are the most appropriate measures to determine the effectiveness of prevention programs so that we are maximizing our opportunity to build on and expand programs with proven impact?

Answer. PEPFAR is currently revisiting indicators across all program areas. We anticipate moving toward outcome indicators that reflect behavioral change, rather than relying solely on output indicators which provide simple service delivery and utilization counts. This shift has important implications for prevention programs, as measurement of behavioral changes provides first-level evidence of programmatic effectiveness. PEPFAR will use this data to identify programs with proven impact, so that they can be scaled up and shared with other countries.

As part of our strategy to strengthen and refine monitoring and evaluation, PEPFAR is also supporting the increased use of "bio-markers"—which test for a particular disease state—in tandem with behavioral studies that collect health knowledge, attitudes, and behaviors. This approach links an individual's and population's health outcomes (e.g., HIV status) with reported behaviors (e.g., number of concurrent sexual partners), thereby presenting stronger evidence of program success or failure and contributing to the science of behavior change. Similarly, these data help ensure more focused program alignment with those communities where HIV infections occur most often.

Advanced technology now allows us to collect HIV incidence data for surveyed populations, which provides "real-time" documentation of the loci of new HIV infections and helps assess the impact of prevention programs over time. These efforts to better understand program impact, the relationship between behaviors and HIV incidence, and HIV incidence in particular communities are all challenging. However, the information gathered will allow for better mid-course adaptation and improvement of prevention activities, strengthening the PEPFAR program overall.

PEDIATRIC TREATMENT

Question. While children account for almost 14 percent of all new HIV infections, they reportedly make up only 9 percent of those on treatment under the President's Emergency Plan for AIDS Relief (PEPFAR).

What are the barriers to increasing the access of HIV-positive children to life-saving treatment?

ing treatment?
What steps do you believe should be taken in PEPFAR reauthorization to reduce these disparities, so that children are accessing treatment at the same rate as adults?

Answer. PEPFAR supports treatment services for over approximately 1,101,000 men, women, and children in its focus countries alone, and care for over 2 million orphans and vulnerable children. However, a number of challenges remain to scaling up these services to all the children who need them.

Barrier 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 breastfeeding. 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.

tive 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, Côte 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 excellence 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.

Last, the 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.

vested 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.

Barrier 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.

Under existing authorities, 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 in the next phase. 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 preservice training institutions, such as schools of medicine, nursing, and pharmacy, to produce more qualified graduates that can 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 Comprehensive 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 ensures 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 will further map the provision of pediatric care and treatment services by all levels of providers, and will contribute to the establishment of WHO guidelines on task-shifting for HIV prevention, care, and treatment. These guidelines will help countries scale up pediatric and adult care and treatment more rapidly, by making strategic use of their existing health workforce.

Barrier 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 are complex and difficult to follow. Lack of availability of appropriate ARV formulations that are inexpensive and easily usa-

ble 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 will work to identify scientific obstacles to treatment for children that the cooperative relationship could address. They will also take practical steps

and share best practices on the scientific issues surrounding dosing of ARVs for pediatric applications. Finally, the partners will develop systems for clinical and technical support to facilitate rapid regulatory review, approval, manufacturing and availability of pediatric ARV formulations.

Barrier 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, 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 the FDA. Further, through an existing agreement with the WHO, this 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.

COUNSELING AND TESTING: OPT-OUT

Question. Voluntary counseling and testing is an important tool in efforts to prevent and treat HIV/AIDS and to better understand and thus respond to the dynamics of local epidemics. As you know, the World Health Organization endorses the principle of opt-out testing for HIV in countries with generalized epidemics. Several focus countries, including Botswana, Kenya, and Uganda, have developed opt-out programs.

programs.
What is the extent of opt-out or provider-initiated testing in PEPFAR focus countries?

In countries where it has been implemented, does it apply only as part of prenatal care or is it practiced in more general health care settings?

What are the critical components of effective counseling associated with initial testing?

Answer. In varying degrees, every PEPFAR focus country is promoting the delivery of provider-initiated testing and counseling (PITC), including through developing appropriate policy and training mechanisms. PITC is being implemented in prenatal care, STD, TB, and ART settings, and is being extended to more general in- and out-patient care settings, depending on local capacity and epidemiology. To encourage this substantial scale-up of PITC, country teams are supporting the increased use of rapid HIV tests (that produce results in one clinical visit), as well as the training and deployment of lay counselors to conduct the testing and counseling for the medical provider. There is still a mix of opt-in and opt-out methods, and the specifics are difficult to determine from country operational plans.

We are planning a public health evaluation study on the issue of effective components of counseling, which will provide additional information. In the meantime, some preliminary evidence and experience shows that lay counselors can provide quality counseling and testing, including rapid testing, where the policy environment enables them to do so. This is an important aspect of task-shifting to maximize use of available workforce. Evidence has also demonstrated that group pretest

counseling is effective in terms of high acceptance rates for opt-out counseling and testing. We have also learned that a conducive space and/or environment is important for counseling and testing, and this continues to be a major need in our focus countries.

Question. Voluntary counseling and testing is an important tool in efforts to prevent and treat HIV/AIDS and to better understand and thus respond to the dynamics of local epidemics. As you know, the World Health Organization endorses the principle of opt-out testing for HIV in countries with generalized epidemics. Several focus countries, including Botswana, Kenya, and Uganda, have developed opt-out programs.

What are the barriers to countries accepting and implementing opt-out testing? What are we doing to help overcome those obstacles?

Answer. As care and treatment services are scaled up in countries through PEPFAR support, more people who are tested and diagnosed as HIV-positive can be connected to ongoing care and treatment. This reduces many barriers to acceptance of the opt-out model of counseling and testing. The remaining obstacles are more issues of policy and conscity, such as the following:

more issues of policy and capacity, such as the following:

Policies support the traditional VCT model. The PEPFAR HIV counseling and testing interagency technical working group is addressing this by assisting countries with revising national policies, in particular by adapting the new WHO provider-initiated testing and counseling (PITC) guidelines. In addition to this policy work, we are specifically working to offer a PEPFAR-sponsored HIV counseling and testing workshop in Zambia in January 2008, to Ministry of Health representatives from a variety of countries.

Training of health care workers. PEPFAR is addressing this by developing curricula and supporting training of nurses and lay counselors in opt-out testing and counseling. Recently, the PEPFAR-developed counseling and testing curriculum was approved and adopted by the WHO. A PITC training package was further developed by PEPFAR, in collaboration by WHO, and will be disseminated to Ministry of Health staff for use in their countries, during the counseling and testing meeting in Zambia.

Number of health care workers. The critical shortages of health care workers in PEPFAR countries pose a significant barrier. In response, PEPFAR focus countries engaged in large-scale activities in FY 2007 (continuing in FY 2008) to support the scale-up of qualified nurses and lay counselors to provide HIV counseling and testing. PEPFAR activities in this area include: Direct salary support for thousands of nurses and counselors, preservice and in-service training (including development of job aids); supervision and mentorship programs; coordination at facility, district, and regional levels; and training and support for national-level leadership in scaling up testing and counseling plans. Further methods for task shifting of counseling and testing will be discussed during the January 2008 meeting.

up testing and counseling plans. Further methods for task shifting of counseling and testing will be discussed during the January 2008 meeting.

Procurement and quality assurance of rapid test kits. PEPFAR is ramping up efforts across its 15 focus countries through its main supply chain management partner, the Supply Chain Management System, to strengthen procurement and quality assurance mechanisms for rapid HIV test kits in order to meet the anticipated growth in the demand and capacity for counseling and testing services.

GENDER

Question. What are the targets and indicators for gender in PEPFAR programs? Answer. PEPFAR addresses gender as a set of issues that cut across all programs, and measures progress with the following two approaches:

1. Gender mainstreaming. At the beginning of PEPFAR, priority gender issues that impact PEPFAR goals were identified, and criteria were developed for gender programming in each program area. These "technical review criteria" are updated annually and are used to evaluate the quality of gender activities in PEPFAR programs. Two primary evaluation methods are used: (1) Technical reviews of the Country Operational Plans by the PEPFAR Gender technical working group, and (2) assessments by the country teams (using a structured tool based on the criteria) of their own programs.

2. Gender strategies. PEPFAR annually tracks programming on five priority gender strategies that were highlighted in the Leadership Act. These are: (1) Increasing gender equity in HIV/AIDS activities and services; (2) reducing violence and coercion; (3) addressing male norms and behaviors; (4) increasing women's legal protection; and (5) increasing women's access to income and productive resources. The number of country program activities that include one or more of these strategies is tallied and reported on in the PEPFAR Annual Report. The level of funding asso-

ciated with these activities is also reported. Additionally, PEPFAR was the first international HIV/AIDS program to establish primary indicators for prevention, care, and treatment that are disaggregated by sex, providing data for monitoring

gender equity in programs and services.

Also, in 2006, PEPFAR launched three gender special initiatives in nine focus countries, involving: (1) Scaling up programs to address male norms and behaviors; (2) strengthening services for victims of sexual violence; and (3) confronting adolescent girls' vulnerability to HIV/AIDS. Evaluation methodologies for each initiative will be developed that can be applied across all country programs. For example, under the sexual violence initiative, standardized program indicators are being piloted to monitor uptake, delivery, and quality of clinical and other services for sexual violence victims, including HIV post-exposure prophylaxis to prevent HIV infec-

PEPFAR is currently developing second generation indicators that will not only strengthen our ability to report but also will improve the monitoring at the individual, clinic/facility and program level. Each technical working group (TWG), including Gender, will develop a set of these indicators in consultation with country teams and international experts. Many organizations that play a leading role in Gender and HIV programming have already begun discussions to identify meaningful indicators, and the PEFPAR Gender TWG will work with these groups during the indicator development process.

COMPACTS

Question. You have previously discussed the potential role that compacts could

play in the next phase of our global HIV/AIDS programs.

Please provide the committee with a detailed description of the compact approach, including an analysis of the authorities under which this program will operate, a framework for the proposed compacts, and a timetable for implementation.

How will these compacts be similar to or differ from Millennium Challenge

How do you foresee implementation of actions for noncompliance with the terms of the compacts short of cutting off funding for essential HIV/AIDS programs?

Would such compacts allow for the direct transfer of funds to governments in support of national strategies?

Answer. In terms of authorities, the Leadership Act gives the Coordinator broad authority to oversee the U.S. Government's international HIV/AIDS programs, and this authority is sufficient for the establishment of compacts. Specifically, the Leadership Act assigns the Coordinator the duty of "pursuing coordination with other countries and international organizations" and "establishing due diligence criteria for all recipients of funds and all activities subject to the coordination and appropriate monitoring, evaluation, and audits carried out by the Coordinator necessary to assess the measurable outcomes of such activities." [Sec. 102] Moreover, the Leadership Act stipulates that "the President is authorized to furnish assistance, on such terms and conditions as the President may determine, for HIV/AIDS, including to prevent, treat, and monitor HIV/AIDS, and to carry out related activities, in countries in sub-Saharan Africa, the Caribbean, and other countries and areas."

The following is a current description of the compact framework. Compacts will be pursued with countries with significant HIV/AIDS burdens in which the U.S. Government (USG) has a well-established on-the-ground presence and where USG resources would play a substantial role and have a comparative advantage in the fight against HIV/AIDS. Compacts will serve as a framework for moving forward together to save as many lives as possible with the resources that are available. Compacts will be structured to promote deeper integration of HIV/AIDS services into health systems, seeking to promote sustainability by ensuring that HIV/AIDS programs build capacity and benefit health systems overall.

Compacts must be tailored to local circumstances, so their development will be led by USG country personnel, who have relationships with key stakeholders. Compacts are anticipated in both PEPFAR's current focus countries and in additional countries, and will link new USG resources to host country commitments in two key

1. Financial commitment

Resources differ dramatically from country to country, based on each nation's level of development. Almost every nation severely affected by HIV/AIDS can do more. For example, in the 2001 Abuja Declaration, African governments committed themselves to devote at least 15 percent of their budgets to health; only a few have reached this level. Several current focus countries have significant resource allocations to HIV/AIDS, yet nearly all can do more. In some countries, "more" can be measured in hundreds of thousands of dollars, in others millions, tens of millions, or more. It is important that resources for HIV/AIDS do not offset other health or development areas, and this will be reflected in the compacts.

2. Policy commitment

Policy changes can create an environment conducive to an effective health and HIV/AIDS response, ensuring that available resources are optimally used to save as many lives as possible. While agreements would vary from one country to another, key issues addressed might include:

- Workforce: Regulations and policies that allow effective task-shifting for health care workers.
- Gender: Regulations and policies to stop gender-based violence and discrimination, prevent transgenerational sex, and protect women's inheritance rights.
- Orphans: Regulations and policies to protect the inheritance rights of children.
 HIV-specific: Regulations and policies that promote diagnostic counseling and testing, pediatric diagnosis, rapid tariff-free regulatory procedures for drugs and commodities, and full inclusion of people living with HIV/AIDS in a multisectoral national response.

A timetable for implementation has yet to be determined. A consultative process to gather input from USG field and headquarters personnel and other stakeholders on this and other issues is underway.

A key distinction between MCC compacts and PEPFAR compacts will be their focus issues. PEPFAR compacts will focus on the HIV/AIDS policy issues described above, rather than broader criteria relating to governance and the economy. MCC staff are being included in the consultative process described above, in order for PEPFAR to learn more about MCC's approach and possible areas of similarity and difference for compacts under the two initiatives. USG staff with relevant experience with models other than MCC are also being consulted.

Options for noncompliance have yet to be determined. A consultative process to gather input from USG field and agency personnel and other stakeholders on this is under way.

As with current PEPFAR programs, additional PEPFAR resources under compacts will be provided in support of multisectoral national HIV/AIDS plans. As at present, there will likely be some transfers of funds to governments as implementing partners for specific programs, but there are no plans for general budget support of governments.

OPERATIONS RESEARCH AND MONITORING AND EVALUATION

 ${\it Question}.$ How much does PEPFAR currently spend on operations research and evaluation?

Answer. PEPFAR dedicated approximately \$72 million to operations research and evaluation in FY07, including approved spending for COP-funded public health evaluations, centrally funded public health evaluations, and other operations research activities. Of this, \$54.5 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. Lastly, some monitoring and evaluation activities are budgeted by countries under prevention, care, and treatment categories; while these amounts cannot clearly be identified, the total investment in operational research is larger than the \$72 million set aside for operations research in 2007.

Question. Do you agree that more resources should be put toward evaluating PEPFAR programs through operations research, so that we are maximizing every dollar spent?

Answer. 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 1–4 percent as a reasonable spending range to support public health evaluations in the COP planning process. This level of spending is appropriate and compares to that provided under the Ryan White Care Act, which provides a useful domestic benchmark for the PEPFAR program.

PEPFAR approved over \$72 million for operations research in 2007, and further invested \$135 million on strategic information, of which an important component is monitoring and evaluation. Combining these investments with additional studies that may be supported through other budget categories, PEPFAR believes the current level of funding for operations research is appropriate, and in balance with competing priorities of prevention, care, and treatment activities.

Question. What are the opportunities to enhance the role of NIH and CDC in improving and expanding operations research?

Answer. Within PEPFAR, operations research and evaluation activities have been led by CDC and USAID and their implementing partners to guide program implementation and on-going improvement efforts. NIH has focused on biomedical research and other investigational trials to develop new interventions, rather than on operations research on existing interventions. We believe that the agency contributions in their respective areas of expertise meet the needs of PEPFAR to guide program implementation and improvement, and that the scale and scope of these operations research efforts are appropriate.

Question. How can monitoring and evaluation be most effectively elevated as one of PEPFAR's functions?

Answer. Monitoring and evaluation (M&E) is a vitally important component of PEPFAR's program and its continued success. 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 the previously mentioned 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 be hear a program of programs and programs are programs.

have centered on the number of people trained or served. These second generation indicators will help us improve reporting on programs having a positive or negative impact on the outcomes we care about, 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 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 "Implementers' Meeting" to disseminate program results to attending PEPFAR and partner staff and thereby strengthen PEPFAR programs. The PHE framework will increase the impact, use, and dissemination of evaluation studies conducted in PEPFAR countries throughout the next phase.

Last, the role of monitoring and evaluation will be enhanced through PEPFAR's continued support for the UNAIDS "Three Ones" principle; 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 multisectoral 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 must not be 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.

COORDINATION

Question. Please elaborate on what kind of coordination takes place within the PEPFAR program (including OGAC, CDC, NIH, and USAID) and with other programs (USAID maternal and child health programs for example). Would you support a joint interagency review of Country Operational Plans to foster strengthened collaboration and coordination for more effective wraparound service programs?

Answer. First, 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 USG country team including

In each country that receives PEPFAR support, a USG country team including representatives from USG agencies in-country (e.g., USAID, CDC, Peace Corps, and Department of Defense (DOD)) 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, NIH, Department of State, Department of Health and Human Services, Health Resources and Services Administration, CDC, Department of Labor, Department of Commerce, Peace Corps, and Department of Defense. These interagency COP reviews form 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 programs such as maternal and child health, education, family planning, and food and nutrition. Substantial dialogue takes place at the headquarters level to strategize coordinated efforts to address linkages between HIV/AIDS and family planning, nutrition, and education in particular. PEPFAR's own 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 establish policy guidance on integrated HIV/food and nutrition activities. Further integration takes place through joint programming in-country, where country teams "wraparound" 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/or wraparound 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 continuous basis to other agencies and offices so they can strengthen wraparound 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 wraparound partners to have their input fully reflected in the COP document.

 $\it Question.$ Please explain the coordination between PEPFAR programs and the President's Malaria Initiative.

Answer. HIV/AIDS and malaria are dual epidemics that cause illness, suffering, and death among many of the same communities in the same areas of the world. This reality demands that HIV/AIDS and malaria programs coordinate to: Avoid duplication of efforts; capitalize on opportunities to extend essential interventions to

populations at risk of both diseases, such as pregnant women and children under the age of five; and ensure that there is efficient use of resources, commodities, and

personnel.

The President's Malaria Initiative (PMI) and the President's Emergency Plan for AIDS Relief (PEPFAR) share seven common focus countries: Ethiopia, Kenya, Mozambique, Rwanda, Tanzania, Uganda, and Zambia. PMI and PEPFAR have developed a collaborative framework for action in these countries that will avoid duplication, ensure safety, maintain appropriate and efficient funding streams, and result

in an overall increase in coverage of key interventions.

PEPFAR and PMI have agreed to hold quarterly headquarters meetings to discuss the status of current collaborations, and may also hold "calls home" from the field to both collect and distribute information about collaborative best-practices. Additionally, several of PEPFAR's technical working groups, including those on laboratory, blood safety, care and pediatrics, are organizing program-specific meetings with PMI staff. Field personnel are also sharing annual operational plans between HIV/AIDS and malaria programs to rationalize the use of USG resources.

In all shared focus countries, PEPFAR supports strengthening health systemssuch as laboratory and commodities capacity—as well as the health workforce, which can be leveraged to deliver malaria interventions. Several recent examples of successful collaborations between PMI and PEPFAR programs in the field include:

(1) PEPFAR's outreach to increase the percentage of pregnant women attending antenatal clinics (ANCs) for prevention of mother-to-child HIV transmission (PMTCT) has allowed malaria programs working in ANCs to reach more of a key

target population.

- (2) In Zambia, approximately 1 million people are receiving the benefits of insecticide-treated bed nets through a \$2.5 million public-private partnership among PEPFAR, PMI, and the Global Business Coalition on HIV/AIDS, Tuberculosis and Malaria (GBC). PMI is distributing the mosquito nets through PEPFAR's existing home-based care network in Zambia, RAPIDS, which reaches more than 154,000 households. This allows PMI to reach the most vulnerable populations while decreasing its distribution costs. Find more information on this initiative at: http:// www.pepfar.gov/c22130.htm.
- (3) Insecticide-treated bed nets are also distributed to HIV-positive persons in Uganda and Kenya as part of a basic HIV care package, which seeks to keep HIVpositive people healthy and delay the need for antiretroviral treatment.

 (4) In Uganda and Kenya, PEPFAR procurement of microscopes for clinics in

order to diagnose tuberculosis also enables improved diagnosis of malaria.

(5) In Mozambique, supply-chain coordination for malaria and HIV/AIDS commodities has been streamlined under one manager, decreasing overhead costs and ensuring coordination.

(6) In Tanzania, the upcoming PEPFAR-supported HIV Indicator Survey will also function as a Malaria Indicator Survey, reducing the costs of essential epidemiolog-

ical surveillance.

PEPFAR will continue to explore ways to leverage infrastructure, personnel, and resources in partnership with PMI, host country governments, and multilateral organizations to increase coverage with both programs.

Question. As we discussed, please provide us with an overview of coordination between PEPFAR, the Global Fund, and other major donors such as the World Bank.

Answer. PEPFAR plays an important role in convening, supporting, and participating in partnerships with the Global Fund to Fight HIV/AIDS, TB, and Malaria (the Global Fund), the WHO, UNAIDS, the World Bank, and others. In 2007, PEPFAR, the World Bank, WHO, the Global Fund, and UNAIDS introduced the first jointly-convened Implementers' Meeting to bring together the headquarters and field staff of PEPFAR and other major implementing partners. Many sessions focused on ways to improve partnership at the country level, and representatives of the various implementing organizations held numerous ad-hoc meetings to discuss collaboration more informally. Additionally, PEPFAR guidance for Country Operational Plans stresses the importance of field coordination with other partners—particularly the Global Fund—around shared activities, targets, and goals, and provides guidelines for this coordination.

The Global Fund

The United States, through PEPFAR, is the largest contributor to the Global Fund, having provided nearly one-third of total resources, or a total of \$2.5 billion, to date. A PEPFAR interagency "core group" reviews Global Fund country programs and grant requests, communicates with USG field staff familiar with the strengths and challenges of Global Fund programs, and engages in other activities to help the Global Fund successfully meet the requirements of performance-based funding. This core group also helps to coordinate Global Fund and PEPFAR activities on an international level. Further strengthening the partnership of PEPFAR and the Global Fund, the Global AIDS Coordinator serves as the Chair of the Global Fund Finance and Audit Committee, and the USG is also represented on the Policy and Strategy committee. Additionally, USG field personnel sit on a majority of national-level Global Fund country coordinating mechanisms (CCMs), contributing to the develop-

ment and selection of proposals and oversight of implementation.

In PEPFAR focus countries, field personnel from PEPFAR and the Global Fund leverage the resources of both programs to deliver a comprehensive program that meets shared objectives. For example, in Uganda, all the operational costs of TB/HIV sites are supported by the Global Fund, and PEPFAR supports the personnel, training, and quality assurance costs at these sites. Similarly, in many countries, PEPFAR country teams have arranged for the Global Fund to supply antiretroviral drugs and commodities to HIV treatment sites, while PEPFAR supports the personnel, training, infrastructure improvement, operations, and quality assurance of these sites. As the two largest international partners in most PEPFAR focus countries, the Global Fund and PEPFAR work together under one national plan and strategy, consistent with the UNAIDS "Three Ones" principles.

In other PEPFAR countries, where the Global Fund is often the largest international partner on HIV/AIDS, PEPFAR works to maximize the impact of Global

Fund resources and to fill gaps in support of a comprehensive HIV/AIDS program. At the request of Global Fund Country Coordinating Mechanisms, PEPFAR provides technical assistance to Global Fund grantees, helping them overcome bottlenecks, expand access to services, and resolve major issues that can cause grant failure in areas such as program management; governance and transparency; procurement

and supply-chain management; and monitoring and evaluation.

To further promote coordination, PEPFAR has entered into Memoranda of Understanding (MOUs) with the Ministries of Health and the Global Fund in several countries. These documents help clarify collaboration and partnership activities in such areas as antiretroviral treatment (ART) provision.

The United Nations

Working with U.N. partners strengthens PEPFAR's response to HIV/AIDS. A visible example of the advantages of working through the U.N. emerged in 2006 at the ble example of the advantages of working through the U.N. emerged in 2006 at the U.N. General Assembly High Level Meeting on AIDS, where First Lady Laura Bush called for an International Voluntary HIV Counseling and Testing Day. After a successful feasibility study by UNAIDS, the USG and 24 other governments from Africa, the Americas, and Asia proposed a decision calling on all U.N. Member States to observe an International Voluntary HIV Counseling and Testing Day in 2007, and this decision was adopted by consensus at the U.N. General Assembly. PEPFAR now is working with WHO and UNAIDS to support countries in holding successful Testing Day events. successful Testing Day events.

PEPFAR also actively supports the work of UNAIDS, and provided over \$30 million in funding in 2007. The previously mentioned "Three Ones" agreement, of which PEPFAR has been a key supporter, was also developed under the auspices of UNAIDS. PEPFAR also participates on the Global Task Team on Improving AIDS Coordination Among Multilateral Institutions and International Donors (GTT), which was created in 2005 to help implement the Three Ones. The GTT has made specific recommendations for partner coordination under the Three Ones, particularly within the multilateral system, resolving areas of duplication and gaps in the

global response to HIV/AIDS.

PEPFAR's strategic information team has worked intensively with UNAIDS and other international partners to implement the GTT's recommendations in the monitoring and evaluation area. One result has been the close partnership between PEPFAR and the WHO to develop patient monitoring guidelines, which are an important step toward a standardized approach to monitoring patients on ART. At the country level, the Global Fund, Millennium Challenge Corporation, non-PEPFAR USG agencies and offices, and PEPFAR country teams cosponsor Demographic Health Surveys, which provide one set of national behavioral and health data for

Additionally, PEPFAR technical experts participate in U.N.-led joint reviews of TB and HIV/AIDS programs and collaborate closely with WHO experts to support the development of normative WHO guidelines in areas such as treating children with TB and managing smear-negative TB. PEPFAR country teams also work in partnership with UNICEF to help deliver care and support services for orphans and vulnerable children across PEPFAR countries, using a 6-point strategy.

The World Health Organization

As a WHO Member State with considerable expertise in HIV/AIDS, the United States plays a key role in formulating HIV/AIDS-related policy and guidelines. The USG actively participates in the World Health Assembly—where Emergency Plan policy often informs the discussion—and partners with WHO and host country governments to adapt and implement such policies at the country level. PEPFAR also seconds a number of senior USG technical owners to WHO and the Country level.

ernments to adapt and implement such policies at the country level. PEPFAR also seconds a number of senior USG technical experts to WHO each year to further establish technical coordination and program integration.

PEPFAR cooperation with WHO is especially important in several areas, including rolling out male circumcision, prevention of mother-to-child HIV transmission, safe blood programs, and fighting TB/HIV coinfection. For example, PEPFAR supports a roughly \$2 million, 2-year PEPFAR-WHO collaboration that is conducting innovative TB/HIV work in Ethiopia, Kenya, and Rwanda. This project provides HIV counseling and testing for clients attending TB clinics, as well as linkages between TB and HIV/AIDS programs. in order to improve access to ART for TR particular to the property of the property of the particular transfer of the particular transf tween TB and HIV/AIDS programs, in order to improve access to ART for TB patients or suspects. PEPFAR also supports WHO's Green Light Committee and the international partnership STOP-TB in their country efforts to prevent and treat TB, including drug-resistant TB.

A second major PEPFAR-WHO partnership addresses the chronic shortage of adequately trained health care workers in PEPFAR countries. A PEPFAR-WHO joint effort addresses the constraints countries face in promoting effective "task-shifting" from physicians and nurses to less highly skilled health care workers. The joint project focuses on three activities: (1) Identification and documentation of best practices; (2) standardization of training and certification criteria; and (3) definition of the policy, legal, financial, and social framework for task-shifting. To accomplish these three activities, research would be conducted and methods piloted in a targeted but diverse group of countries which includes Ethiopia, Haiti, Malawi, Mozambique, Rwanda, and Uganda.

National-level partnerships between PEPFAR and the WHO further implement these international-level initiatives. For example, Namibia has adopted WHO clinical care guidelines that are based on a task-shifted model of integrated HIV and primary health care. PEPFAR and WHO staff in Namibia work together to coordinate policy development, operations support, quality assurance, and the training and oversight of the health workforce at the sites implementing these guidelines.

Additionally, PEPFAR and WHO are working together to make essential anti-retroviral drugs (ARVs) more rapidly available in countries where they are most urretroviral drugs (ARVs) more rapidly available in countries where they are most urgently needed. HHS/FDA and the WHO Prequalification 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 prequalification list. The rapid WHO prequalification of these medications hastens in-country drug regulatory review and, consequently, the availability of lower cost, high-quality ARVs in-country.

Last, together with UNICEF and WHO, PEPFAR has launched a public-private partnership to promote scientific and technical discussions on solutions for pediatric

partnership to promote scientific and technical discussions on solutions for pediatric HIV treatment, formulations, and access. This partnership brings together the resources of innovator and generic pharmaceutical companies, civil society organiza-tions—such as the Elizabeth Glaser Pediatric AIDS Foundation and the Clinton Foundation—and the U.N. system, to maximize the utility of currently available pe-

diatric formulations and to accelerate children's access to treatment.

GENDER-BASED VIOLENCE

Question. As I mentioned during the hearing, I will soon be introducing, along with Senator Lugar, a comprehensive piece of legislation which will address violence against women and girls internationally. How, generally speaking, can increased programming and training to prevent and respond to violence against women and girls impact the work and initiatives of your office, particularly with respect to gender-based violence and the transmission of HIV?

Answer. Gender-based violence (GBV) is a critical factor in the spread of HIV/ AIDS and challenges the health and well-being of women and girls worldwide. PEPFAR has invested significantly in programming to address the intersection of GBV and HIV/AIDS and welcomes broader USG involvement to prevent and respond to violence against women and girls globally. As a general matter, increased efforts to address the societal issues of violence against women and girls will support HIV/AIDS efforts, because GBV is a driver of HIV/AIDS transmission. Effective efforts to address male norms, alcohol, and other drivers of GBV can thus have a positive, secondary effect on HIV/AIDS programs.

PEPFAR's strategic investments in GBV related to HIV/AIDS impact the HIV/ AIDS pandemic, while also contributing to a broader USG mission to combat GBV globally. PEPFAR investment in GBV has increased each year, and in FY 2007, this support rose to over \$188 million, an 80-percent increase from FY 2006, and included more than 313 activities in the 15 focus countries. GBV interventions supported through PEPFAR are programmed both as "stand-alone" activities (where addressing GBV is a primary objective) and "integrated" activities (where addressing GBV is a secondary objective within a broader program). In FY 2007 PEPFAR launched three Gender Special Initiatives, one of which responds to victims of sexual violence, rape, and assault in clinical settings. Implemented in three focus countries (South Africa, Rwanda, and Uganda), this intervention will develop and test optimal models of service delivery for victims, including post-exposure prophylaxis (PEP) and linkages to police and judicial support. Lessons from these initiatives will

then be shared across all countries.

PEPFAR is committed to leveraging existing comprehensive programs to deliver GBV activities. The Women's Justice and Empowerment Initiative (WJEI) is an example of this leveraging; PEPFAR funds will support PEP and other HIV/AIDS-

example of this leveraging; PEPFAR tunds will support PEP and other HIVAIDS-related GBV activities, while WJEI addresses other needs, including capacity-building for police and access to legal services. Additionally, PEPFAR works in the following program areas to reduce GBV and its effects globally:

Services for victims of sexual violence. Examples include clinical management supported by psychosocial/trauma counseling, linkages to legal assistance, emergency shelter and social support, and longer term community reintegration. PEPFAR is also working to develop "wraparound" activities, such as with WJEI, on policy and legal reform, justice system strengthening, capacity-building of police, access to legal services economic empowerment activities. and temporary shelter.

services, economic empowerment activities, and temporary shelter.

Screening and counseling for GBV within PMTCT, HIV counseling and testing, and other HIV/AIDS services. PEPFAR supports GBV screening and counseling in health care settings, expanding the reach of existing GBV programs and strengthening local NGOs (including faith- and community-based organizations) to fill gaps

in social support services, supplement efforts in the health sector.

Empowering girls and women to prevent, identify, and leave abusive relationships. PEPFAR activities support women and girls in avoiding or stepping out of violent

situations through life-skills and income-generating activities, among others.

Working with men to prevent violence against women and girls. PEPFAR supports HIV prevention programs that work with young men and boys to change male norms associated with HIV infection, including behaviors that lead to sexual violence. PEPFAR will continue to expand these efforts, which serve as a promising area for potential future collaborations to promote effective interventions for rehabilitation and prevention among perpetrators.

Changing community and social norms that condone or facilitate GBV. PEPFAR supports intensified and coordinated public education campaigns and awareness-

raising about GBV that utilize a variety of community-based and media strategies. Strengthening policy and legal frameworks. PEPFAR supports efforts in host nations to develop and enforce stronger laws against GBV, as well as policies that reduce GBV indirectly, such as codification of women's inheritance rights.

PEPFAR will continue to work collaboratively to respond to the intersection of GBV and HIV/AIDS.

RESPONSES OF AMBASSADOR MARK DYBUL TO QUESTIONS SUBMITTED BY SENATOR Robert Menendez

HEALTH SYSTEM STRENGTHENING

Question. We have heard from various stakeholders that although PEPFAR has shown some real success, there is a concern about the sustainability of the program at the country level due to the great need to strengthen developing country health systems. We all know that effective HIV care requires more than treatment. It also requires laboratory capacity to perform CD4 testing, to diagnose tuberculosis and treat opportunistic infections.

· Will PEPFAR be taking these issues into account in the next phase of the program?

Answer. PEPFAR has significantly invested in sustainable improvements to national health systems, and plans to continue to do so. PEPFAR's core approach is based on strengthening the network model of care in national health systems by investing in central referral centers, provincial and district facilities, primary health care centers, and ultimately, communities. While PEPFAR's focus has been to strengthen HIV/AIDS efforts, the use of this model has resulted in much broader impact across health care systems. In FYs 2004–06 in the 15 focus countries, the Emergency Plan supported the training or retraining of more than 1.6 million health care providers and provided infrastructural improvements, technical assistance, and/or operations support for over 25,100 service delivery sites. These trained health care workers not only deliver better services, improving the quality of care across the entire system, but also can free up other health care workers for additional tasks.

Some have expressed concern that a significant expansion of HIV/AIDS programs could draw resources and personnel from other health fields. However, the data do not support that view. In recent decades, child mortality increased in Botswana due to HIV/AIDS despite a significant increase in government resources for child survival and health. Now that investments in HIV/AIDS programs have scaled up significantly, infant mortality is declining again. In a study in Rwanda of 22 non-HIV/AIDS indicators, 17 showed statistically significant increases after the introduction of basic HIV care. In addition, in many countries, 50 percent of hospital admissions are due to HIV/AIDS. As effective HIV care and treatment programs are implemented, hospital admissions plummet, easing the burden on health care staff throughout the system.

Further, PEPFAR supports the salaries of tens of thousands of health care workers. In Namibia, PEFPAR-supported clinical staff provide the vast majority of HIV treatment in the entire country. These health care workers, though trained in HIV treatment, are also trained and supported to provide health services to HIV and non-HIV patients. PEPFAR further strengthens preservice training institutions, through infrastructure, curriculum, and faculty development, which significantly increase the number of health care workers available to the health system each year.

PEPFAR also builds and renovates clinics, pharmacies, and laboratories, which offer patient care for HIV- and non-HIV-related needs. Additionally, PEPFAR supports ongoing training, mentoring, and other support to Ministries of Health and indigenous partners in key areas of HIV/AIDS programming, such as policy development, health systems planning, program implementation, and monitoring and evaluation. As a measure of this commitment, over 80 percent of PEPFAR partners are indigenous organizations. Overall, PEPFAR estimates its FY 2007 investment in network development, human resources, and local organizational capacity development and training at approximately \$638 million, or approximately one-quarter of total PEPFAR program resources.

Moreover, PEPFAR support for the development of sustainable strategic information systems to measure PEPFAR's progress toward its prevention, care, and treatment targets has directly resulted in the strengthening of country health monitoring, reporting, surveillance and evaluation systems, all of which lead to improved programming. The surveillance, patient record, and country reporting systems that are either in place or being created are leading to improved methods of disease tracking.

Laboratory capacity

Laboratory capacity is an essential component of PEPFAR support. In every focus country, PEPFAR supports the establishment of national, tiered laboratory networks, built upon an accredited national reference laboratory. In 2007, PEPFAR invested approximately \$160 million in strengthening laboratory networks, through activities such as construction and renovation of laboratories, training of laboratory personnel, strengthening laboratory supply chains, and building of quality assurance programs. The increased laboratory capacity supported by PEPFAR to provide HIV/AIDS services also provides essential lab tests that benefit a wide range of patients in addition to those with HIV.

Similarly, PEPFAR works with host countries through its Supply Chain Management System to build transparent and accountable procurement and supply systems that ensure an uninterrupted supply of high-quality and low-cost drugs, lab equipment, testing kits, condoms, and other critical commodities. Along with HIV/AIDS commodities, these supply chains can deliver medicines and supplies for malaria, tuberculosis, and other diseases.

berculosis, and other diseases.

In 2007 PEPFAR launched a pioneering, \$18 million public-private partnership with Becton, Dickenson, and Company, an international global medical technology firm, to build laboratory capacity in several PEPFAR focus countries that are severely affected by HIV and TB. The 5-year partnership will support host governments and partners to develop integrated laboratory systems, services, and quality-improvement strategies; improve the quality of laboratory diagnostics for HIV and TB; implement quality-control and quality-assurance guidelines and supervisory tools for hematology, chemistry, CD4 testing and rapid HIV testing; and strengthen

TB reference sites to serve as centralized training facilities. The partnership will increase laboratory capacity in target countries by 15–20 percent in its first year.

Overall, PEPFAR investment has created a self-reinforcing ripple effect of positive change in national health systems. Building the capacity of leadership and infrastructure to plan and address the health conditions associated with HIV/AIDS increases capability and confidence to address planning and service delivery in other health issues. Instead of any negative impact on health systems, the data from PEPFAR sites has demonstrated increases in the uptake of services in family planning, care, maternal and child health, and STD services, after HIV/AIDS investments were made.

ments were made.

PEPFAR will continue to support health systems and capacity-building initiatives to further advance these capabilities, and will continue to work to foster increased financial commitment and needed policy change by host governments. PEPFAR will also deepen existing relationships to other international partners and USG programs to strengthen joint efforts to address related issues that impact people living with HIV, such as nutrition, education, and gender.

SAFE INJECTION PRACTICES

Question. One of the prevention initiatives that has been proven to be both highly effective and cost-effective is integrating safe injection practices and the use of safe injection devices into the practice of medicine. This phase of PEPFAR does not include a line item for these programs.

• Nonetheless, is it correct that the program will continue these efforts in light of their effectiveness in preventing transmission?

Answer. According to UNAIDS, unsafe injections in health care settings account for approximately 2.5 percent of new infections in sub-Saharan Africa. In FY 2007 PEPFAR invested over \$12.4 million in promoting injection safety, and plans to continue to support interventions for safe injection practices in the next phase of the Emergency Plan. Ongoing activities include improving injection safety practices through training and capacity-building; ensuring the safe management of sharps and waste; and reducing unnecessary injections through the development and implementation of targeted advocacy and behavior-change strategies.

TUBERCULOSIS DIAGNOSIS

Question. For a number of years, HIV and infectious disease experts have recognized that linking tuberculosis diagnosis and care and HIV diagnosis and care are critical to effectively managing care for people living with HIV/AIDS. The Global AIDS Roundtable has recommended that PEPFAR allocate at least 10 percent of its funding to diagnosing and treating TB in HIV-infected patients.

Will the program integrate this recommendation into its strategic plan?

Answer. The coinfection of TB and HIV is a serious threat to the public health progress of many countries supported by the Emergency Plan. The Emergency Plan has invested significant resources in combating the coinfection 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.

resting resources in three primary ways.

First, for FY 2007, the Emergency Plan has dedicated over \$131 million to TB/HIV activities. Funding supports providing HIV testing for people with TB and TB diagnostics 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 United States Government, through PEPFAR, contributed \$724 million in 2007, representing nearly one-third of the fund's contributions from all sources. With these resources, the Global Fund has committed roughly 17 percent of its funding to national TB programs around the world. As a result, \$123.1 million of Global Fund TB activities can be considered as coming from PEPFAR's 2007 ontribution. [This figure was estimated by multiplying PEPFAR's annual contribution to the Global Fund by 17%, which represents annual PEPFAR funding that supports Global Fund TB activities.] This support includes technical assistance to the Global Fund country coordinating mechanisms to strengthen the planning, im-

plementation, and evaluation of TB grant activities. 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 Partnership. The Emergency Plan works closely with the WHO to implement a 2-year collaborative effort to support scale-up of TB/HIV services in Rwanda, Kenya, and Ethiopia. With the STOP TB Partnership, the Emergency Plan provides technical assistance for the Advocacy, Communication and Social Mobilization (ACM) 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.

Question. As a leading killer of people living with HIV/AIDS, tuberculosis is inextricably linked to the HIV/AIDS epidemic. Given the high rates of TB–HIV coinfection in the 12 PEPFAR focus countries in Africa, TB programs present an opportunity to identify additional HIV-positive individuals who are eligible for treatment. Similarly, HIV clinics provide an opportunity to screen for TB.

 Given these opportunities, should addressing TB-HIV by increasing integration and coordination among programs should be a greater focus in PEPFAR reauthorization?

Answer. PEPFAR is already 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 secondary infection of TB in susceptible individuals—including people living with HIV—and the community at large.

As noted, for FY 2007, the Emergency Plan has dedicated over \$131 million to TB/HIV activities, which include support for: Providing HIV testing for people with TB and TB diagnostics for people living with HIV, including cross-referrals to care; ensuring eligible TB patients receive HIV/AIDS prevention, treatment, and care; bolstering integrated surveillance activities; and strengthening integrated laboratory capacity and supply chain management to address HIV- and TB-related equipment and commodities. Country teams are working closely with Ministries of Health to develop national HIV/TB integration policies and plans, including integrated service delivery and monitoring and evaluation.

As described in the response to question 3, PEPFAR is also a major contributor of funding, technical assistance, and strategic leadership to the most significant international partners on TB efforts, including the Global Fund, the WHO, and the STOP TB Partnership. PEPFAR involvement in the TB/HIV activities of these partners supports scale-up and integration of TB activities within PEPFAR country programs and beyond.

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.

Question. Drug-resistant forms of TB, including "extensively drug resistant" or "XDR"–TB, threaten to undermine progress in reducing AIDS-related mortality. A well-publicized 2006 outbreak of XDR–TB in South Africa among 53 patients resulted in death in all but one patient. All those tested for HIV were found to be positive and 15 of the patients who died were on antiretroviral (ARV) treatment for HIV, indicating that ARVs were not protective against this form of TB. The threat of XDR–TB moving beyond Southern Africa to the rest the continent could have dire consequences.

How can the threat of drug-resistant TB be comprehensively addressed in HIV/AIDS programming?

Answer. Drug-resistant tuberculosis, including multidrug resistant (MDR–TB) and extensively drug resistant (XDR–TB) strains, is a threat to people living with HIV. In many high-HIV prevalence countries, TB is the leading cause of mortality in people living with HIV/AIDS, and in some PEPFAR countries, 80 percent of indi-

viduals with TB are also infected with HIV. The HIV/AIDS pandemic has also se-

verely compromised TB control efforts internationally.

One week after the WHO issued a global alert over emerging strains of XDR-TB, PEPFAR attended an emergency experts meeting with TB officials from 11 Southern African countries and others in Johannesburg, South Africa, in September, 2006. During this meeting, a seven-point emergency action plan for a coordinated global response to XDR-TB was established. PEPFAR supports the global task force on XDR-TB in conducting the following activities: (1) Developing national emergency response plans for MDR and XDR-TB in line with national TB control plans that strengthen basic TB control and the proper use of second-line drugs; (2) conducting rapid surveys of MDR-TB and XDR-TB; (3) enhancing current laboratory capacity; (4) implementing urgent infection control precautions in health care facilities, especially those providing care for people living with HIV; (5) establishing and improving technical capacity of clinical and public health managers to effectively respond to MDR-TB and XDR-TB; (6) making antiretroviral treatment available to HIV-positive TB patients through joint TB/HIV activities; and (7) increasing research and support for rapid diagnostic tests and anti-TB drug development.

Examples of PEPFAR activities in this effort include: Support for improved TB case finding; enhanced access to TB culture and drug susceptibility testing; environmental assessments to prevent nosocomial transmission of TB; and rapid initiation of appropriate drug treatment. PEPFAR is also providing resources for development of policies, guidelines, and implementation of TB infection control activities focused on HIV care and treatment settings and TB programs to prevent TB transmission

to health care workers, patients, and visitors.

The Emergency Plan is also supporting rapid TB testing, drug resistance surveillance, and other activities that specifically help prevent and control MDR— and XDR—TB, and working closely with the United States Federal TB Task Force to coordinate the USG response. The Emergency Plan also provides technical assistance funding to the WHO-coordinated Green Light Committee (GLC) to assist Global Fund Grent recipient countries in improving their conscitute to provide tractment for Fund Grant recipient countries in improving their capacity to provide treatment for MDR-TB.

PEPFAR support to develop basic infrastructure and capacity for addressing nondrug-resistant TB establishes the foundation upon which investments in more advanced capabilities for MDR- and XDR-TB can occur. In this way, all of PEPFAR's FY 2007 investment of approximately \$131 million in TB/HIV activities described in an earlier response—contributes to the global effort to combat drugresistant TB.

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