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FIGHTING HIV/AIDS IN AFRICA: A PROGRESS REPORT

HEARING

BEFORE THE

SUBCOMMITTEE ON AFRICAN AFFAIRS

OF THE

COMMITTEE ON FOREIGN RELATIONS
UNITED STATES SENATE

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WEDNESDAY, APRIL 7, 2004

U.S. SENATE,
SUBCOMMITTEE ON AFRICAN AFFAIRS,
COMMITTEE ON FOREIGN RELATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:50 p.m., in room SD–419, Dirksen Senate Office Building, Hon. Lamar Alexander (chairman of the subcommittee), presiding.

Present: Senators Alexander and Feingold.

OPENING STATEMENT OF SENATOR LAMAR ALEXANDER

Senator ALEXANDER. Good afternoon. Thank you for waiting. We had a couple of votes. I thought it best to go ahead and cast mine and get on over here. It helps to have your last name begin with an A because you can get through earlier.

Senator Feingold will be here, I'm sure, before very long, and other Senators perhaps, but out of respect to the time of the witnesses, I'd like to go ahead and begin the hearing.

The Subcommittee on African Affairs is now called to order. We're here to update America's 5-year $15 billion commitment to fight HIV/AIDS. We're looking specifically at the African portion of this commitment. Twelve of the 15 countries that we call focus countries are in Africa.

I believe this is Ambassador Tobias' first appearance before a Senate subcommittee since Congress funded this initiative in January, and we welcome him here, as we welcome the other witnesses who we will hear very shortly. So, this is an important opportunity for a progress report.

Our objective today has three parts. First, what are our goals for the next 5 years as a nation? The President has outlined three major goals: to treat 2 million people, to provide care for 10 million, and to prevent 7 million new HIV/AIDS infections. But what are the smaller goals that were set to get us on the path to meeting those three big goals?

Second objective. Are we meeting those goals? Do we have real benchmarks to measure progress as we move forward in meeting those goals? It's important that we have a way to tell if we're on the right path or not, so the next time we hold a hearing on this topic, we may be able to say we are.

By way of analogy, during the war with Iraq, winning the war, it was fairly easy to tell what progress we were making. We had daily reports. Generals made the reports. They had clear bench-

marks about their progress and we could see the progress. Winning the peace has proved to be a lot more difficult and it's more difficult to establish the benchmarks, but nevertheless benchmarks are important, and it is the oversight responsibility of Congress to help establish benchmarks for progress, and to make those benchmarks public. Over a period of time to measure whether we're reaching those benchmarks is important to do in our second objective.

And third, are we spending the taxpayers' money wisely to reach these goals? Our majority leader of the Senate, Senator Bill Frist, has recently reminded us that this is the largest public health initiative we've ever undertaken abroad. Fifteen billion is a lot of money. We need to ensure that money is spent on the most effective means of reaching our goals.

May I say at the outset, I don't think there are any in the Congress or in the administration who doubt we will spend the $15 billion. That is a commitment of the President. That is the commitment of the Congress in a remarkable accord. The questions that we need to discuss are how to spend it and when to spend it and what comes first?

We often hear the statistics about how horrible the AIDS pandemic is in Africa. Over 40 million people infected with HIV around the world, three-fourths, 30 million of them in the 48 African countries south of the Sahara Desert. The figures are staggering, are so large that they get bandied about so much that we sometimes forget what they mean or have a hard time imagining what they can mean.

I've been trying to think of a way to explain this in more personal terms that will remind us of how serious this crisis is, and let's take the example of Botswana. We're going to hear some about Botswana today, but if you step back from Botswana and look at it, it has a lot going for it. It has a stable government, good governance, almost no corruption, very transparent, stability, elections. It has a good national park system. Most of its citizens have access to medical care. It stands out as an emerging country not only in Africa but it would in any other part of the world.

Yet, one thing is threatening to literally destroy the country, in the words of its President, HIV/AIDS. Nearly 40 percent of Botswanians are infected with HIV/AIDS. Think of what that might mean to a family of 5. It would mean that you could expect that 2 of those 5 family members are infected. In effect, they have received a death sentence. They may already be sick. Likely, they do not even know they are sick.

Now, multiply that by an entire country, 1.7 million in that case, and you'd have something of the sense of the devastation that this disease is causing and that is just one country, one country that in many other respects is a model for progress.

America's stepping up to the plate to combat this disease or to help with it. Here's what's happened so far.

No. 1. A year ago in January in his State of the Union Address, President Bush led us in confronting AIDS by proposing an Emergency Plan for AIDS Relief.

No. 2. Congress passed legislation authorizing the President's Emergency Plan for AIDS Relief [PEPFAR] 5 months later in May.

No. 3. Ambassador Randall Tobias, who is here today, whose Office of Global AIDS Coordinator was created by that legislation, was confirmed last October.

No. 4. The first year's money for the President's plan was appropriated in January of this year, just 3 months ago. Since that appropriation 3 months ago, Ambassador Tobias and his team have been busy, and we look forward to an update of what he and they have accomplished so far.

Today, I hope we will make an honest assessment of what things we can do to move us quickly toward reaching our goals. For example, reducing unsafe medical practices could be an early goal. We've heard testimony in other Senate committees, Senator Sessions of Alabama has, for example, been a leader in looking into this, that unsafe medical practices account for at least 5 percent of the transmission of this infection. It could be a lot more.

We know what to do about that, and we can move to do it quickly, or stepping up efforts to prevent mother-to-child transmission of HIV since this requires getting a single drug just before and after birth. We know how to do this, too, and in addition, work has already started during the last several years supported by this country. So, there's some things that we can do immediately that can make a big difference, and save the lives of lots of people.

But we need to have an honest discussion, especially about those things that will take longer and about what the priorities are for those. Things like building capacity to deliver care and treatment and choosing the right drugs. Do you spend the money cleaning the water? Do you spend the money buying drugs? Do you spend it helping find more doctors to volunteer? Do you spend it building hospitals? Do you spend it, as I mentioned earlier, on mother-to-child transmission or on unsafe medical practices? Do you spend it on fighting TB and malaria? Which do you work on first or, if you do several things at one time, what is the allocation of funds, and then to whom do you give the money? Who's ready to spend it wisely and properly?

Even if we have $15 billion, that money can be spent very quickly if it's not spent wisely. A person on antiretroviral drug therapy must take multiple drugs one or two times every day for the rest of his life. Each individual's response to these drugs must be monitored to ensure resistance doesn't develop. When it does, that the drug combination is altered to deal with the resistance.

These simple facts make treatment of AIDS both complicated and expensive, and when one adds the challenges of attracting patients, perhaps as many as 90 percent of HIV-positive individuals don't know that they're ill and many who are living with AIDS are too ashamed to seek help, it becomes even more complicated.

Then take the example of Mozambique, where we were in August, which has 400 to 500 doctors for a population of 17.6 million. Obviously, we need to build a lot of new capacity there. Let me compare that to the conditions in the United States. Florida has about the same number of people Mozambique does, about 17 million. In Florida, they have 36,000 doctors. In Mozambique, 400 to 500. There are 90 times more doctors in Florida than there are in Mozambique per person.

So, that's why I think it's important for us to be realistic in setting expectations for progress in the battle against this terrible disease. I believe we can reach the goals set by the President. I don't expect us to make steady progress toward them in each of the 5 years, especially in the area of treatment.

While our initial ramp-up of already active programs will provide a quick boost to our numbers, it may very well be that the first few years will be dedicated to building the capacity to deliver treatment and more of the last few years dedicated toward utilizing that capacity to provide treatment. I would be interested in the comments of the witnesses on this idea.

Said another way, we may expect a quick rise in the number of people on treatment followed by a period of slow growth followed by a surge toward the end of the 5 years, a surge that will hopefully reach or exceed the President's goal of 2 million on treatment.

Today's hearing provides a unique opportunity to assess our progress to date and consider how to reach or exceed the goals the President has set. We have a distinguished group to help us do that.

First, Ambassador Randall Tobias, who coordinates America's responsibility to the global AIDS response to the crisis, will testify.

Then, on our second panel following Ambassador Tobias, we'll hear from three individuals who have run or are running successful AIDS treatment programs in Africa. Dr. Jonathan Mermin of the Centers for Disease Control and Prevention will go first to talk about CDC's home-based treatment program in rural southeastern Uganda. That will be our second panel.

Third, we will have two witnesses, Dr. Ernest Darkoh, whom I had the privilege of meeting last August, operations manager for the treatment program in Botswana, which is funded in part by the Gates and Merck Foundations, and Dr. Lulu Oguda, who's served as field director at two Doctors Without Borders treatment programs in Malawi and Zambia.

It's not often we get advice from people who are doing so much important work on the ground in Africa where we hope to be of help, and we look forward very much to their testimony and are grateful for their coming here.

But before we begin, let me turn to my colleague, Senator Feingold, the ranking member of our subcommittee, who has for several years been a leader in the Senate, both generally on African affairs and especially on the plague of HIV/AIDS.

Senator Feingold.

OPENING STATEMENT OF SENATOR RUSSELL D. FEINGOLD

Senator FEINGOLD. Thank you very much, Mr. Chairman, for the kind words and for calling this important hearing today.

The chairman has made it his business to become very knowledgeable about the challenges confronting AIDS-affected communities in Africa and to follow very closely the U.S. Government efforts that are underway, and I commend him for his steady focus and leadership on this issue.

Of course, we all want these efforts to succeed. The President's historic State of the Union commitment to fighting AIDS raised the hopes of communities all over the world, and it gave the ongoing

and bipartisan effort to respond to this crisis new momentum and vigor. Today, we have come such a long way.

We have moved past the days when talking about scaling up treatment made one a radical, past the days when policymakers had to be convinced that this is an urgent and critically important crisis. We've moved past any notion that we can protect our interests and meet our basic human obligations by addressing AIDS on the cheap. But now comes the hardest part, getting the response right.

Now, we have to think about the management challenges that come with such a large increase in U.S. resources directed at fighting HIV/AIDS. Now, more than ever, we have to emphasize the importance of coordinating our efforts wisely with other U.S. assistance priorities, so that we can maximize positive spill-over effects wherever possible.

Now, we have to find ways to transform the discussion about factors that make women and girls so vulnerable to AIDS into concrete action to address these sensitive but crucially important issues. Now, we need to think about how to buildup, rather than siphon off, Africa's human resources—the doctors, the nurses, the community health workers—as we proceed with this massive effort. Now we need to ensure that we are making sound treatment choices that save as many lives as possible.

I look forward to discussing the issue of fixed dose combination therapy with our witnesses. I don't believe that the American taxpayers will tolerate decisions that favor saving fewer lives with patented pricey medications, if we can help more people with cheaper generic drug regimens that are actually easier to adhere to, diminishing the prospects of resistance.

We can all agree that safety and efficacy are critically important, but it puzzles me that the U.S. Government seems to be sort of behind the curve when it comes to resolving this problem. Yesterday's Washington Post heralded an agreement involving the World Bank, the Global Fund, UNICEF, and the Clinton Foundation that should help most of the developing world get access to more affordable drugs to treat AIDS, but the news is not all good.

According to the Post, "missing, however, was one prominent funder, the U.S. Government which has its own plan to help AIDS patients in poor countries. The $15 billion U.S. plan seeks to buy medicines involving multiple combination of pills from Western pharmaceutical companies that hold patents on their drugs while yesterday's deal will rely on fixed dose medicines made in India and South Africa which combined three drugs in one pill."

So, what I want to know is why does the U.S. Government seem to be in such a lonely place? Surely we are not alone in being concerned about drug safety.

I appreciate all of the work that went into the report submitted to Congress on February 23 of this year, and I find the report full of laudable goals and sound thinking, but I do share some of the views of House International Relations Committee Chairman Hyde, who noted that the plan we have before us is long on general principles but short on implementation specifics.

I welcome this opportunity to dive into some of those specifics and details today. I want to thank Ambassador Tobias for being

here today and thank all of our witnesses for taking the time to share their insights with this subcommittee, and I do look forward to the discussion.

Thank you, Mr. Chairman.

Senator ALEXANDER. Thank you, Senator Feingold.

Ambassador Tobias, we want you to take the time you need to make your presentation. If you are comfortable summarizing it in 5 or 7 or 8 minutes, then Senator Feingold and I can ask you questions and then we'll excuse you and go on to the second panel.

You were confirmed, I believe, about 6 months ago. The Congress appropriated money about 3 months ago. We're here to find out what's happened so far and where we go from here.

Thank you for coming.

STATEMENT OF AMB. RANDALL L. TOBIAS, GLOBAL AIDS COORDINATOR, U.S. DEPARTMENT OF STATE

Mr. TOBIAS. Mr. Chairman, Senator Feingold, thank you very much for the opportunity to report today, and I thank you both for your interest in and your support for the President's Emergency Plan for AIDS Relief.

At the beginning, I want to apologize for my voice. I have been fighting laryngitis here for almost 2 weeks which I think may be in part cherry blossom pollen-induced. So, I will, with your permission, abbreviate my opening remarks and save my voice for responding to your questions.

As you noted, Mr. Chairman, the President in his State of the Union Address last year called indeed for an unprecedented act of compassion to turn the tide against the ravages of HIV/AIDS in his $15 billion Emergency Plan for AIDS Relief.

Today, President Bush's vision is becoming a reality. Yesterday, I would note, as you just did, happens to be the 6-month anniversary of my being sworn into this job, and on February 23, just 4½ months after we launched the Office of the Global AIDS Coordinator and less than a month after Congress appropriated the fiscal year 2004 funding, I was able to announce the first release of funds totaling $350 million.

This money is being used as we speak to scale up programs that provide antiretroviral treatment, abstinence-based prevention programs focused on young people, safe medical practice programs and programs to provide care for orphans and vulnerable children.

Our intent has been to move as quickly as possible to bring immediate relief to those who are suffering the devastation of HIV/AIDS, and with this first round of funds, an additional 50,000 people living with HIV/AIDS in the 14 focus countries are beginning to receive antiretroviral treatment which will nearly double the number of people who are currently receiving treatment in sub-Saharan Africa.

Today, activities have been approved for treatment in Kenya, Nigeria, and Zambia, and patients are receiving treatment in South Africa and Uganda because of the Emergency Plan for AIDS Relief.

In addition, prevention messages will reach about 500,000 additional young people and we will also be providing resources to assist in the care of about 60,000 additional orphans in the plan's 14 focus countries. Care services will include providing critical social

services, scaling up basic community care packages of preventive treatment and safe water as well as AIDS prevention education.

As we meet today, the U.S. Government staff from a number of agencies and departments are working together with my office to review as we speak each of the focus countries' annual operational plans to be addressed with the remaining fiscal year 2004 appropriation and those plans will provide the foundation for the operational plans for the other 4 years in the program.

These plans represent the overall U.S. Government-supported HIV/AIDS prevention, treatment, and care activities in each of the focus countries. By the end of April, the plans should be approved and funds available to the countries in early May.

Mr. Chairman, in addition to announcing this first round of funding and preparing to obligate the remaining fiscal year 2004 funds against approved operating plans, I also submitted to this committee and other appropriate congressional committees the comprehensive 5-year strategy for the President's Emergency Plan for AIDS Relief.

The fact that the Emergency Plan has been able to begin to move so quickly rests in part on the combination of a new aggressive strategy and our ability to capitalize on the experiences of numerous Federal Government agencies that are not new to this. They have been fighting AIDS internationally for the past 20 years, and there are many lessons learned about what works and what does not.

So, we are implementing not a new bureaucracy but rather a new leadership model for those existing capabilities and new ones that we need to build. A model that brings together, under the direction of the United States Global AIDS Coordinator, all of the programs and personnel of the agencies and departments of the U.S. Government who are engaged in this effort.

This leadership model has been translated in the field where the U.S. Chief of Mission in each country is leading the interagency process that has led to the submission of the operating plans we are reviewing at the moment.

In early fall, each country team will submit to my office a 5-year overreaching strategic plan to define how the President's prevention, care, and treatment goals will be achieved in each country.

Within the framework of the overall strategy and the strategic plans for each country, we will strive to coordinate and collaborate our efforts in order to respond in a very targeted way to local needs and do so in a way that is consistent with host government strategies and priorities.

At the same time, we intend to amplify our own worldwide response to HIV/AIDS by working closely with a number of international partners, such as UNAIDS and the World Health Organization and the Global Fund, as well as through non-governmental organizations, faith-based and community-based organizations, private sector companies, and others who can and are assisting in engendering new leadership and resources to fight this pandemic.

There's absolutely no doubt that this is one of the greatest challenges of our time and it will indeed require constant and concerted commitment from all of us to address it and defeat it. The limits of what we can accomplish in eradicating HIV/AIDS and its con-

sequences are, I believe, defined only by the limits of our collective moral and operational imagination, and that is why developing a new sense of urgency, getting the first wave of funding released quickly after the appropriation was so critical, and I very much appreciate the Congress's assistance in ensuring that was able to happen.

Mr. Chairman, Senator Feingold, I am grateful to both of you for your support and for your resolve to provide leadership in defeating the HIV/AIDS pandemic. Your leadership has facilitated the speed with which we are responding to people in need and that commitment will ensure our success, success that will be measured in lives saved and families held intact and nations moving forward with development.

Mr. Chairman, you noted the problem associated with our focusing on the huge magnitude of the numbers and to forget that this disease strikes people one person at a time. One number that has been meaningful to me is to imagine what our reaction would be if we got up every morning and opened the morning paper to find that 20 fully loaded Boeing 747s had crashed the preceding day, killing everybody on board, and then we got up the next day to discover another 20 Boeing 747s fully loaded had crashed, killing everybody on board, and if that happened every day because that is what's happening with this disease, 8,000 people around the world are dying every day. I cannot think of a better place for us to be spending our time and our energy and our creativity than addressing this issue.

Thank you very much, and I'll be pleased to respond to your questions.

[The prepared statement of Ambassador Tobias follows:]

PREPARED STATEMENT OF AMB. RANDALL L. TOBIAS

Mr. Chairman, members of the Committee,

In his State of the Union address last year, President Bush called for an unprecedented act of compassion to turn the tide against the ravages of HIV/AIDS.

The President committed $15 billion over five years to address the global HIV/AIDS pandemic—more money than ever before committed by any nation for any international health care initiative.

- $9 billion will go to new programs to address HIV/AIDS in 14 of the world's most affected nations—with a 15th country to be added shortly. Even without the addition of a 15th country, the 14 countries already account for approximately 50 percent of the world's HIV/AIDS infections.
- $5 billion will go to provide continuing support in the approximately 100 nations where the U.S. Government currently has bilateral, regional, and volunteer HIV/AIDS programs.
- And $1 billion will go to support our principal multilateral partner in this effort, the Global Fund to Fight AIDS, Tuberculosis and Malaria, which the United States helped to found with the first contribution in May 2001.

Today, President Bush's vision is a reality.

On February 23, just 4½ months after we launched the Office of the Global AIDS Coordinator, and less than a month after the Congress appropriated Fiscal Year 2004 funding for the first year of the President's Emergency Plan for AIDS Relief, I announced the first release of funds totaling $350 million.

This money will be used to scale up programs that provide antiretroviral treatment; abstinence-based prevention programs, including those targeted at youth; safe medical practices programs; and programs to provide care for orphans and vulnerable children.

These target areas were chosen because they are at the heart of the treatment, prevention and care goals of President Bush's Emergency Plan.

The programs of these specific recipients were chosen because they have existing operations among the focus countries, have a proven track record, and have the capacity to rapidly scale up their operations and begin having an immediate impact.

Our intent has been to move as quickly as possible to bring immediate relief to those who are suffering the devastation of HIV/AIDS.

By initially concentrating on scaling up existing programs that have proven experience and measurable track records, that's exactly what we have been able to do.

With just this first round of funds, an additional 50,000 people living with HIV/AIDS in the 14 focus countries will begin to receive antiretroviral treatment, which will nearly double the number of people who are currently receiving treatment in all of sub-Saharan Africa. Today, activities have been approved for antiretroviral treatment in Kenya, Nigeria, and Zambia; and patients are receiving treatment in South Africa and Uganda because of the Emergency Plan.

In addition, prevention through abstinence messages will reach about 500,000 additional young people in the Plan's 14 focus countries in Africa and the Caribbean through programs like the American Red Cross's Together We Can and World Relief.

The first release of funding from the President's Emergency Plan will also provide resources to assist in the care of about 60,000 additional orphans in the Plan's 14 focus countries in Africa and the Caribbean. Care services will include providing critical social services, scaling up basic community-care packages of preventive treatment and safe water as well as AIDS prevention education.

As I meet with you today, U.S. Government staff are reviewing each of the focus country's annual operational plans to be addressed with the remaining Fiscal Year 2004 appropriation. These plans represent the overall U.S. Government-supported HIV/AIDS prevention, treatment, and care activities in each focus country. By the end of April, the plans should be approved and funds available to the countries in early May.

With this next round of funding, I expect to see many new partners, including more faith-based and community-based organizations that can bring expanded capacity and innovative new thinking to this effort.

Mr. Chairman, in addition to announcing this first round of funding and preparing to obligate the remaining Fiscal Year 2004 funds, I also submitted to this Committee and other appropriate Congressional committees a comprehensive, integrated, five-year strategy for the President's Emergency Plan for AIDS Relief.

This Strategic Plan will guide us in deploying our resources to maximum effect:

- We will be concentrating on prevention, treatment and care, the focus of the President's Emergency Plan.
  - In the 15 focus countries, over the five years of the Emergency Plan:
  - We will provide antiretroviral treatment for two million people living with HIV/AIDS;
  - We will prevent seven million new HIV infections; and,
  - We will provide care to 10 million people who are infected or affected by the disease in the focus countries, including orphans and vulnerable children.
- We are not starting from scratch. Rather, we are capitalizing on existing core strengths of the U.S. Government, including:
  - Established funding and disbursement mechanisms;
  - Two decades of expertise fighting HIV/AIDS in the Untied States and worldwide;
  - Field presence and strong relationships with host governments in over 100 countries; and,
  - Well-developed partnerships with non-governmental, faith-based and international organizations that can deliver HIV/AIDS programs.

And we are implementing not a new bureaucracy but a new leadership model for those existing capabilities—a model that brings together, under the direction of the United States Global AIDS Coordinator, all of the programs and personnel of all agencies and departments of the United States Government engaged in this effort. This leadership model has been translated to the field, where the U.S. Chief of Mission in each country is leading an interagency process on the ground. In early fall, each country team will submit to my office a unified five-year overarching strategic plan to define how the President's prevention, care and treatment goals will be achieved in that country.

The Emergency Plan is built on four cornerstones, which guide my office:

1. Rapidly expanding integrated prevention, care, and treatment in the focus countries by building on existing successful programs that are consistent with the principles of the Plan—as we have already begun with the $350 million announced in February.

2. Identifying new partners, including faith-based and community-based organizations, and building indigenous capacity to sustain a long-term and broad local response.

3. Encouraging bold national leadership around the world, and engendering the creation of sound enabling policy environments in every country for combating HIV/AIDS and mitigating its consequences.

4. Implementing strong strategic information systems that will provide vital feedback and input to direct our continued learning and identification of best practices.

Within that framework, we will strive to coordinate and collaborate our efforts in order to respond to local needs and to be consistent with host government strategies and priorities.

In addition, we intend to amplify our own worldwide response to HIV/AIDS by working with international partners, such as UNAIDS, the World Health Organization, and the Global Fund, as well as through non-governmental organizations, faith- and community-based organizations, private-sector companies, and others who can assist us in engendering new leadership and resources to fight HIV/AIDS.

There is no doubt that this is one of the greatest challenges of our time, and will require constant and concerted commitment from all of us to defeat.

The limits of what we can accomplish in eradicating HIV/AIDS and its consequences are defined only by the limits of our collective moral imagination.

What inspires me the most as we embark on this effort is the remarkable self-help already under way in fighting HIV/AIDS by some of the most under-resourced communities in the world.

These communities have responded, in whatever way they can, to fellow community members in need. With our support, we hope to amplify and sustain their efforts to combat the devastation of HIV/AIDS.

That is why getting the first wave of funding released quickly after the appropriation was so critical, and I appreciate the Congress's assistance in ensuring that was able to happen.

Mr. Chairman, I am grateful for your and this Committee's resolve to defeating the HIV/AIDS pandemic. Your leadership and support has facilitated the speed with which we are responding to people in need, and that commitment will ensure our success—success that will be measured in lives saved, families held intact, and nations moving forward with development.

I would be pleased to respond to any questions you may have.

Senator ALEXANDER. Thank you, Ambassador Tobias, and I might thank you for your service to our country. You have a distinguished background in business with Eli Lilly and with AT&T, and we're glad to have you where you are.

I'll ask a few questions, and then I'll turn it over to Senator Feingold, and then we might go back and forth a little bit.

With your business background, I would assume that a lot of what you used to do at Eli Lilly and AT&T was establish benchmarks and say to people within your organizations, OK, this all sounds pretty good, but how are we going to know if we're getting anywhere, and I heard—I think I heard you just say that you were beginning to develop country-by-country plans in the 12—is it 12 countries in sub-Saharan Africa that are part of this Emergency Plan, and that by this fall, those plans would be reviewed and approved or changed and approved and operational. Did I hear that right?

Mr. TOBIAS. Actually, the operational plans we expect to have approved or not in the next 2 or 3 weeks, and based on those plans, the remainder of the 2004 appropriation will be obligated.

At the same time, the countries are developing 5-year strategic plans, these first plans being more operational in nature, but 5-year strategic plans that will take a longer view at all of the things that have to be done while at the same time we're getting the effort going.

Senator ALEXANDER. What I'm trying to get in my mind is an idea, and I wouldn't necessarily expect you to have it today but before long, of exactly what a report card would look like. If we're reporting to the American people here's how we're spending $15 billion of your money that we could be spending for schools or clean air or AIDS in the United States, or reporting to people in 12 countries in Africa here's how we're spending $15 billion to help you because Americans are compassionate and care about you, I mean, I can think of categories.

I can think, as I mentioned, of safe medical practices, here's where we are today, here's where we're supposed to be this month, here's where we're supposed to be next, TB, malaria, number of doctors, number of people treated.

I'd like to get an idea whether you have such a report card today or, if you don't, what it will look like and at what point could we expect to see such a thing and see what progress we're making toward very specific objectives to reach the larger goals that the President has outlined.

Mr. TOBIAS. Well, let me begin by saying one of the things I learned in business school 40 some years ago and has been confirmed repeatedly over time is that it's a good idea to start with the premise that if something can't be measured and isn't being measured, you need to question whether it's worth doing, because I find that as difficult as it may seem on the surface, most things can in fact be measured in one way or another and that's the attitude that we are taking with our approach.

We begin with the overarching goals that you mentioned, the so-called 2, 7, and 10 goals, and are asking ourselves the question about everything we're doing, everything we're funding, all the decisions we are making, how does this activity reach back to the achievement of those goals, of getting 2 million people under treatment by the end of 5 years, of preventing 7 million infections and of providing care to 10 million people who are in need of the care.

One of the first important jobs I filled on my staff is the person who is responsible for the measurement and evaluation activity, Dr. Kathy Marconi, who's a career Federal employee who has been in the Department of Health and Human Services engaged in measuring these kinds of things for a long time.

She and her colleagues across the government have been hard at work developing a framework for what we will measure and how we will measure it, and they have been also working with, I might say, a good deal of progress with a number of our international partners, including the Global Fund and the World Bank and others, in trying to harmonize the measurements that we are putting in place, all of us, in the Emergency Plan, the Global Fund, and so forth.

So that, to the maximum degree we can, we are reducing the strain on the resources in the countries in which all of us are oper-

ating by trying to leverage creating one data base and one set of data, and we've had a very cooperative effort there.

But in the meantime, we've set some goals that are more overarching goals for the first year, the first one being to get this office launched which we've done in the last 6 months, get an organization laid out and begin to attract and hire staff with the appropriate skills and commitment and experience to help get this done.

Developing a comprehensive 5-year strategy was an important effort. Working then against this strategy to create a framework in each of the target countries so that there was a mechanism to develop specific plans in each country that are both consistent with the strategy but at the same time are addressing the unique needs in each country, and other activities of that nature that are the startup activities that are necessary to get this going.

We've needed to identify appropriate strategies and mechanisms that we can use to address the capacity issues, both the infrastructure issues and the human capacity issues, going forward. As you know from your own visits to Africa, those issues are critical roadblocks to our ability to really scale this up, and when we do scale it up over the long-term, we've got to ensure that we're providing sustainable human capacity and infrastructure capacity that will last long into the future and will permit these countries to take on more and more of the burdens themselves.

So, those are illustrative of some of the kinds of things that we focus on.

Senator ALEXANDER. If I could drive that a little further, the large goals, the number of people on treatment, the number of infections prevented, those are two or three specific goals, but are we likely to be able to get a report on a regular basis——

Mr. TOBIAS. Yes.

Senator ALEXANDER [continuing]. On—for example, we know in the United States, I believe, the percent of HIV/AIDS transmitted from mother to child, and it's very, very low, and we know that it's significantly higher in Namibia.

Is it likely that mother-to-child transmission will be a benchmark in Namibia, for example, and that we'll have where we are today and whether that's a priority and where we are a year from now and where we hope to be 5 years from now?

Mr. TOBIAS. Yes, and in fact, I would hope to be able to report to you every 6 months on sets of data that flow from those goals, but then cascade down on a country-by-country basis and program-by-program within those countries, all of which are additive over the 5-year period to achieving those goals, but recognizing it's one person at a time, one program at a time, one day at a time.

The quality of the data that is available of the type that you refer to varies across the map. In some countries, the data is pretty good. In other countries, we and other international partners are going to have to put some work into strategic information systems that are going to be important and critical to our ability to evaluate these programs and planning for that activity is underway.

Senator ALEXANDER. Well, but as you say, it can be measured. It may not be worth doing. So, it would be more helpful to me than any other aspect of our oversight. I don't think it's appropriate for us to try to manage what you're doing, that's your job, but I do

think that one of the Senate's, the Congress's under utilized great powers is the oversight responsibility, and the single thing that would help me, and I believe other committee members the most, is if we could agree on some sort of report card about what the benchmarks are.

And on a regular basis, either through a hearing or through a discussion of some type to which all members of the Foreign Relations Committee or African Affairs Subcommittee could be invited, if you could come in and say, here's where we were, here's where we are, here's where we're going, we're a little ahead on this one, we're a little behind on this one, and this is why we're spending more money here and less money here and less money here.

The more specific that report card is, the better. We understand that there is, for example, in the safe medical practices, WHO says it may be 5 percent, others say it may be more. We don't need to argue about that too long, but if we can find some way to measure progress from wherever we are and wherever we hope to go——

Mr. TOBIAS. Right.

Senator ALEXANDER [continuing]. That will mean more to me, and I think to other members, than almost anything else. And after that, we can come to our own conclusions and make our own speeches about what we think the priorities ought to be, but we at least will know what the plan is and what the benchmarks are and whether we're proceeding according to the plan.

Mr. TOBIAS. Senator, I could not agree more with everything that you've said, and I think it probably would be a good idea if my staff and your staff collaborated in looking at the material we're putting together to get kind of a specific feel of the kinds of things that you think would be most meaningful to you, so that we can provide that data, but I'm happy to provide all the measurements that we're putting together.

Senator ALEXANDER. I would welcome the opportunity, and I imagine other Senators would as well.

[The following information was subsequently supplied.]

The U.S. Global AIDS Coordinator's Office intends to use an annual planning and performance cycle to measure our goals of providing treatment to two million persons living with HIV/AIDS by 2008; providing care to ten million people infected and affected by HIV/AIDS, including orphans and vulnerable children; and preventing seven million new HIV infections. Our annual planning cycle:

Sets treatment, care, and prevention targets, and budgets for each fiscal year; and,

- Twice a year, measures the number of people treated and cared for, estimates infections averted, and budget obligations.

To measure progress toward these targets, we track 15 budget/program area categories:

Prevention

PMTCT
Abstinence/Be faithful
Medical transmission/blood safety
Medical transmission/injection safety
Other prevention activities

Care

Palliative Care: Basic health care and support
Palliative Care: TB/HIV
Orphans and Vulnerable Children

Counseling and testing

Treatment

HIV/AIDS treatment/ARV drugs
HIV/AIDS treatment/ARV services
Laboratory infrastructure

Other

Strategic Information
Other/policy analysis and system strengthening
Management and staffing

For each budget/program area we use an annual planning/performance cycle that:

- Proposes annual budgets, partners, and activities and targets by USG funding agency.
- Measures obligated funding levels and carryover.
- Identifies various types of partner and sub-partner organizations—such as faith-based, local, new or existing partnerships.
- Measures the number of people reached, number of provider sites or programs, and number of service providers trained for prevention, care, and treatment program areas.
- Collects gender and age information for prevention, care, and treatment programs, when possible.

Additionally, intermediate outcomes, such as changes in prevention behaviors and care-seeking behaviors, are tracked every 2 to 3 years using independent household surveys. UNAIDS estimates of HIV prevalence are used to track the epidemic.

The above referenced information will be made available by January 31 each year, as required by the "U.S. Leadership Against HIV/AIDS Tuberculosis and Malaria Act of 2003" (P.L. 108–25) Sec. 301(e).

Senator ALEXANDER. Senator Feingold.

Senator FEINGOLD. Mr. Chairman, let me first commend you for the emphasis on the benchmarks, and I would very much like to work with you and the Ambassador and others to make that happen.

Let me first ask a question relating to one aspect of this issue. The legislation passed by Congress that created the coordinator's position and authorized much of the PEPFAR activity, also required that the strategy report submitted to Congress contain "a description of the specific strategies developed to meet the unique needs of women, including the empowerment of women in interpersonal situations."

It also required "a description of specific strategies developed to increase women's access to employment opportunities, income, reproductive resources, and microfinance programs."

We can all obviously agree that women and girls are especially vulnerable to HIV/AIDS because they're often not in a position to make choices that can keep them healthy. Girls may have their school fees paid by so-called sugar daddy figures, and women may not be able to negotiate condom use with their husbands. These issues are difficult to talk about, but they're very real, and no plan to roll back the epidemic can actually succeed without addressing these issues.

So, what specifically are the strategies you are pursuing to address these kinds of issues?

Mr. TOBIAS. Senator, I couldn't agree more that the issues relating to women and particularly younger women in the countries in which we are focusing our attention are of critical importance.

We addressed those issues in a number of ways throughout the plan, and I expect that as the operational plans and the strategic plans come in that I referred to earlier, that we will be looking at on a country-by-country basis. That is one of the aspects of these plans that we're going to be very, very interested in.

Certainly, in a general sense, addressing the issue of strong leadership, strong governmental leadership and leadership in other segments of society in these countries is a very important starting point in ensuring that each of these countries is taking this issue seriously, the issue of women and the empowerment of women and the cultural positioning of women and the attitudes of men toward women and the empowerment of women, in a number of ways.

And I expect that we're going to have a better handle on the specifics of that in the next 90 days or so as we gather the best thinking of the people in the field who are working on this.

But without question, this is clearly one of the critical issues that will need to be innovatively addressed if we're to be successful.

Senator FEINGOLD. Well, I certainly look forward to getting those specifics. I realize you certainly would not have them all worked out today, but based on my conversations, especially in my last trip to both South Africa and Botswana, there was this sort of overwhelming sense that this problem is in some ways at the core of a lot of the problems.

I'm interested in what the strategies would involve. Would they involve women's property rights? Would they involve things having to do with the criminal law? Would they have to do with government initiatives to educate men about their responsibilities in this regard?

I think how this is done specifically really does matter, and I know you agree with that, but it is important to me, just as the chairman was interested in some of the benchmarks. I really want to know what you're going to try to do in this area and how I can follow it.

Mr. TOBIAS. Some of these issues, such as the ones that you addressed, are less easy to quantify, just given the nature of the issue. I mean, we can measure fairly precisely how many beds we're adding in a clinic or how much testing capacity or that sort of thing.

What we're really talking about here, more than anything else, is changing cultures and influencing the change in behavior and, among other things, that's going to take some extraordinary diplomatic effort, if you will, to get that done and we're going to need a lot of innovative and creative work here.

I was, in my last trip to Africa, I was in an area in one country, just to cite a specific example to illustrate your point, where the incidence rate of HIV-positive young women between 15 and 19 in that particular area was 24 percent. The infection rate, the incidence rate in young men in exactly the same geography, 15 to 19, was 4 percent.

Now, I just think that underlines the importance of why we have to address this issue.

Senator FEINGOLD. And I do think that choosing this area to really emphasize with the officials in these countries is important because it is uncomfortable. It is uncomfortable to bring this up to

the President of the country, but once it's done, I think it's significantly troubling to those hearing it, that it sort of frees them up to maybe take some action on it, and I urge some very specific strategies on this and look forward to working with you on it.

Let me follow on another aspect of it. According to a recent New York Times article, the director of UNICEF and other United Nations officials recently announced the results of studies that found that teenage brides in some African countries are becoming infected with the AIDS virus at higher rates than sexually active unmarried girls of similar ages in the same areas.

At least for me, this calls into question the idea that condom use should be a prevention strategy directed primarily at high-risk groups. Since the vast majority of people with HIV do not know that they are infected, it seems that married women are at a troubling risk. What's your response to that?

Mr. TOBIAS. Well, Senator, you've identified a high-risk group of people in the particular category and the particular circumstances that you are talking about, and in many cases, these are issues of older men marrying younger women which gets back into the whole set of cultural issues about marriage and forced marriages and marriages that are arranged between older men and younger women and things that enlightened leadership really need to address. And we can see the results in places where strong national leadership is addressing these issues.

Senator FEINGOLD. And it is important to recognize that this is in fact a high-risk group and it really in fact relates to the relationship between B and C which are sometimes seen as separate steps and they're actually interrelated.

Mr. TOBIAS. Well, there's a very a high percentage across the broad population that we're focusing on of so-called discordant couples, where one partner is infected and the other partner is not.

What's worse is that of the 40 million or so people estimated to be HIV-positive in the world, some estimate that as many as 90 percent or more do not know their status, and so we've got to encourage and find new and innovative ways to be more successful in getting more people tested. And one of the categories of people who need to be tested are people who are in a dedicated committed relationship.

Senator FEINGOLD. Thank you, Mr. Ambassador. Could you explain how PEPFAR will help to build infrastructure capacity in Africa, particularly in the area of training health care practitioners, especially community health workers, and discouraging medical brain drain? Will implementing partners all adhere to a set of principles regarding hiring local staff to ensure that we do not siphon resources away from the domestic health infrastructure, which would obviously in the end make all of our hard work and efforts unsustainable?

Mr. TOBIAS. There are a number of things in the short-term to address the human resource issue. Twinning, for example, finding partnerships between health care facilities in these countries and those in the United States where partnering training can be done.

We need to address those roles that have traditionally been played by health care professionals, doctors and nurses, and find the examples that can be carved out of that where health care

workers can be trained to focus very specifically on certain functions that can be carried out.

In the short-term, there are things that we can do selectively with volunteers that can help, but over the long-term that's not going to contribute to the sustainability of this. Training programs, the development of curriculum.

I think some of the witnesses that I'm familiar with that I know you're going to hear from later today are involved already in programs where they're doing some very innovative things in that regard, but this clearly is, in many people's minds, the No. 1 roadblock to our making progress, is addressing both in the short-term and sustainability in the long-term how we get the human capacity into the equation here that is going to be so critical to getting this done.

Senator FEINGOLD. Thank you, Mr. Chairman. Perhaps I can turn it back to you for a round of questions.

Senator ALEXANDER. Some people say with so many people desperately ill, we should rush to spend every dollar we can get our hands on to provide drugs for treatment. Other people, as I have, look at Africa as an example or a situation and see 9 out of 10 people don't even know they're infected.

Persuading them to become aware of that and then counseling them on what to do about that and then working with them to help them continue to take a treatment, to train doctors and other health workers to be able to provide the treatment, to build hospitals and other places to care for people, to clean up unsafe medical practices. All these so-called capacity issues need to be done, too.

I used the example a little earlier of how the State of Florida has 90 times more doctors per person than the country of Mozambique which has the same population.

So, how are you going to resolve these competing claims, those who say let's spend every penny we can grab right now, people are dying, they need treatment, and those who say Mr. Ambassador, the first thing we need to do is to provide capacity, and to recruit volunteers and doctors and counselors and persuade people to come in? How do you do that?

Mr. TOBIAS. Well, there's merit to each of these individual arguments and that's part of what makes it even more difficult, but I think that the plan that the President proposed and that the Congress has approved is a very sound plan, which is to approach this by integrating treatment and prevention and care and not approach it as either/or on any of those issues, but to address all of those issues and to do so in a way that integrates those three activities to the maximum degree we can.

At the same time, I'm a proponent of focusing on those activities, of treatment, prevention, and care, while recognizing there are a number of other things that need to be done that this program needs to coordinate and harmonize with.

For example, putting someone on antiretroviral treatment in the end is not going to accomplish the desired end result if that person is starving to death, but this is not a nutrition program. I met, as it happens, this morning with an Under Secretary of the Department of Agriculture to talk about ways in which—at his initiative,

I might add, to talk about ways in which we can harmonize the things we're doing in this program with nutrition programs that exist there and in the U.N. World Food Program and USAID Food Program and elsewhere.

I would take the view that it's a circle. It's hard to know whether to start with prevention or treatment or care. You can argue that if we don't do something more successfully than we have done in the past about prevention, then we run the risk of eventually having wonderful treatment programs that have more and more and more people on those treatment programs. We've got to stop the increase in the number of people who are getting infected.

Part of that is education, part of it is doing something about testing and having testing become more of a routine part of accepted practices in life.

At the same time, we are finding that in those places where we have implemented treatment programs, we're beginning to see at least anecdotally examples of communities being positively impacted by seeing the improvement in the health of someone who is infected who is on a treatment program and other people deciding they need to go and get tested and find out their status because there is now hope.

At the same time, in a compassionate humanitarian way, we need to address the care needs of not only those who are dying but the orphans and the vulnerable children. So, I think we would be making a big mistake to put a disproportionate part of the money in any one of those things because I think they all need to work together in a very harmonious way and that's exactly what we are attempting to do in the strategy that we've put together.

Senator ALEXANDER. I've heard many say that, especially in the case of HIV/AIDS, treatment is the best prevention.

Mr. TOBIAS. Well, I'd add to that, that the best orphan care program that I can think of is keeping a mother alive. So, it all really is very interrelated.

Senator ALEXANDER. Senator Feingold.

Senator FEINGOLD. Ambassador, let me first commend you on your comments you just made about the testing. My friend Ambassador Holbrook certainly has focused on this and it was one of the things I was going to ask you about, and I'm pleased to hear your emphasis on it.

Mr. TOBIAS. Ambassador Holbrook and I have talked about this a great deal and have also talked about ways in which the work he is doing, particularly with the private sector, can be leveraged by what we're doing. And I in fact have been invited, and I've accepted, to make the keynote address at the worldwide annual meeting of his organization in Berlin coming up in a couple of weeks.

Senator FEINGOLD. Glad to hear that. Let me ask a few more nuts and bolts questions about drug procurement.

Has your office provided any directives to the field regarding the use of generic versus patented drugs to date? Are grantees currently free to procure fixed dose combination drugs if they're approved for use by the host country and, if not, why not?

Mr. TOBIAS. Senator, this is a very complex and has become in some quarters a controversial issue that I think is a very, very critical issue for all of us to provide our best thinking around.

I have said from the beginning, and this is very consistent with what the President and others have said, that our policy is and will be to buy the lowest cost drugs that we can find that we can demonstrate are safe and effective. And getting to the answer of what does that mean, what drugs are safe and effective, is not as simple as it appears that it might be on the surface.

The consequences of not doing that for the long-term are quite significant. The risks of exacerbating the issues of drug resistance, if we don't approach this very carefully, are in fact significant.

The ability to have as part of the arsenal that physicians are using, combinations of drugs that are in fixed doses is a very important element because it certainly eases the adherence and the means by which patients can be put on programs and can adhere to those programs.

When we hear the word "generic" here in the United States, I think we all conjure up the notion of taking a prescription to the pharmacy and getting it filled and if it's filled with a generic drug, we know what that means. We know that it's a drug that has been reviewed by a stringent regulatory authority, in our case the Food and Drug Administration, and it is not essentially—it is in reality, the identical version of the original drug that was made by the research-based pharmaceutical company that invented it and brought it to the market.

Many of the drugs that are referred to as generic drugs are really not generic drugs in that sense, but rather they are copies of original drugs that may well be totally fine. They may well be totally safe. They may well be totally effective.

But in the same way that we would not rely on and do not rely on the regulatory authorities in another country to review the dossier for a new drug application and then automatically take their evaluation and introduce that drug in the United States market, so, too, I believe, do we need some stringent international standards and principles that can be used to evaluate these drugs.

Senator FEINGOLD. I accept that. Let me understand the thinking behind it. Let me just get a couple of specific answers. Let me go back to the question, and I don't think you're being non-responsive. I just want to know exactly.

Has your office provided any directives to the field regarding the use of generic versus patented drugs to date?

Mr. TOBIAS. And the answer to that is that people are permitted to purchase, and use money from our program for drugs that have been approved by a stringent regulatory authority, and so the practical translation of that means that many of what people refer to as generic drugs have not been reviewed and approved by a stringent regulatory authority.

Senator FEINGOLD. So, grantees are not——

Mr. TOBIAS. No, the answer is no.

Senator FEINGOLD. And grantees are not currently free to procure fixed dose combination drugs if they are simply approved for use by the host country? That's not sufficient under your current program?

Mr. TOBIAS. No, no, no. If there was a stringent regulatory authority in the host country, they absolutely would. It's where there is not a regulatory authority that exists.

Senator FEINGOLD. So in some places, it may be permitted and some places not?

Mr. TOBIAS. If it's been approved by an internationally recognized group.

Senator FEINGOLD. Well, let's go to that then. There are fixed dose combination drugs that are actually prequalified by the WHO. Isn't it true that the WHO uses standards and procedures comparable to those used by the FDA and regulatory agencies of other industrialized nations to evaluate the safety and the effectiveness of generic fixed dose combinations? Are there aspects of the WHO process that you feel are inadequate?

Mr. TOBIAS. The WHO program, their prequalification program, is an important program. I have the highest respect for the World Health Organization, and they play a very important role in this in a number of ways, but they have put together this program in a way so that the program is not transparent and the data that they have collected from the companies whose dossiers that they have reviewed is not available nor is there any kind of ongoing monitoring of the good manufacturing practices that the FDA would use. And there are a number of other aspects that differentiate that program from the kind of program that a regulatory authority would use.

Working with the WHO, in fact the WHO has been a co-chair of the effort that has been underway involving a number of countries and regulatory authorities around the world, we are examining ways in which international technical and medical authorities can put together a set of principles that can be used in order to make careful evaluations.

Senator FEINGOLD. Let me just end, and the chairman does need me to finish, so we can move on. Let me just make a point here, because this is so critically important. I know you agree.

I take it that there's a sense here that the WHO is not a regulatory body and that somehow could not give the same assurance that the FDA or another regulatory body can give, but as I understand it, the evaluation process the administration is setting up via the Botswana conference will also not be a regulatory body, but the administration seems apparently perfectly willing to use that body's recommendation.

On the point that the WHO may not inspect manufacturing plants.

They do inspect, apparently in contract with agents from the developed world's, regulatory agencies, prior to approval and require followup inspections at least every 5 years which is the same timeframe for reinspection as FDA's.

So, I guess the last followup I'd ask for is, if you believe there are specific deficiencies in the WHO drug evaluation process, has the administration made any effort to assist in strengthening the WHO process, and wouldn't this be a better strategy than simply setting up this new and possibly duplicative review process in Botswana?

Mr. TOBIAS. Senator, I repeat, the WHO is a co-chair of the Botswana meeting and the Botswana effort, and we are working very collaboratively and cooperatively with the WHO toward an effort of getting an internationally accepted set of principles that people can

use, the drug companies can use in submitting information, that makes the process transparent, that makes the data available to people who are making those decisions.

And I'm very hopeful that in the weeks ahead that that will lead to some ability to make an informed set of decisions about these drugs.

In the meantime, there are, I think the last number I saw, there are about a 150,000 people in the world who are on antiretroviral therapy, using drugs that have been approved by regulatory authorities.

Senator FEINGOLD. Well, my concern continues to be a possible reinventing of the wheel in some aspects here, but I'm willing to work with you and learn from you on this. I did want to raise those concerns.

Finally, can you assure me that there will be full transparency in drug procurement, including the cost of drugs purchased and the consideration given to lower cost alternatives?

Mr. TOBIAS. Absolutely.

Senator FEINGOLD. Thank you for your patience, Mr. Chairman. Thank you, Ambassador.

Senator ALEXANDER. Well, thank you, Senator Feingold. Those are important questions.

Mr. Ambassador, we thank you for coming. We thank you for your work. I think it's fair to say both Senator Feingold and I look forward to working with you, supporting you, and we look forward to developing those benchmarks so that we can have a clear picture of what progress we're making toward this great goal that this country has embarked on, and so that we can see where we need to work a little harder or where we're having some success.

Thank you very much.

Mr. TOBIAS. Thank you very much.

Senator ALEXANDER. We'll now move to Dr. Jonathan Mermin. Dr. Mermin, welcome.

I would like to say, Dr. Mermin, that one of the—I won't say it was a surprise, but one of the most pleasant things that occurred when Senator Frist led a delegation of six Senators last August to sub-Saharan African countries and we looked at HIV/AIDS, we were reminded that the United States has had for awhile some of our most talented employees hard at work in Africa helping with HIV/AIDS, and you're certainly one of those, and we thank you for that service and glad that the President and the Congress are now putting more of a spotlight on the work that you're doing.

Dr. Jonathan Mermin is Country Director for GAP Uganda, and I hope you'll take at least a minute or two and say what that means when you begin your testimony. The home-based treatment program based in Uganda is run by the Centers for Disease Control and Prevention in cooperation with a Ugandan non-profit and is often cited as a model for how to provide AIDS treatment in rural Africa.

Uganda itself is often cited as the model, as the country in Africa that has been most successful in, over a period of time, reversing, actually reversing the trends in HIV/AIDS. In most African countries, the terrible statistics we read about are only increasing. In Uganda, they've been able to turn that around.

So, Dr. Mermin, we look forward to your testimony and to having the opportunity to ask you some questions. Thank you for being here.

STATEMENT OF DR. JONATHAN H. MERMIN, M.D., M.P.H., PUBLIC HEALTH EPIDEMIOLOGIST, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, COUNTRY DIRECTOR FOR GAP UGANDA, KAMPALA, UGANDA

Dr. MERMIN. Thank you, Mr. Chairman, and I'm grateful to have a chance to talk with you today.

I'm an HHS physician and a public health epidemiologist at CDC. Since 1999, I've lived and worked in Uganda where I run the local HHS/CDC Global AIDS Program [GAP]. Our program supports comprehensive prevention, care, and treatment activities.

As you know, Uganda is a poor country with a per capita GDP of $280 per year. Earnings are even less for persons living in rural areas where 85 percent of Ugandans live. The health infrastructure is worse now than 30 years ago. On any given day in Uganda, only 5 percent of health facilities can perform an HIV test and only 20 percent can diagnose and treat tuberculosis, the leading cause of death for persons with HIV in Africa.

Even with these statistics and extreme poverty, Uganda was the first country in the world to show a decrease in HIV prevalence. Building upon the success, Uganda has embarked on the next stage, delivering effective treatment to the hundreds of thousands of people with HIV living in the country.

One example is the Tororo Home-Based Care Program which is a collaboration of the AIDS Support Organization, TASO, a local NGO, the Ministry of Health, and CDC.

Margaret Akware is HIV-positive and she's a participant in the program. Her husband died of AIDS in 1996. She's a subsistence farmer, living in a thatched-roof home with her two children and five orphans. Margaret speaks in public about having HIV and participates in community drama groups educating people about AIDS. She lives each day knowing that if she dies, her seven children will have no place to live. Without participating in the program, she would have died.

Margaret is a unique individual, but her story represents millions of people living with AIDS in Africa. Like her family, 74 percent of children living with 30,000 HIV-positive TASO clients are at immediate risk of becoming orphans because all of their living parents have HIV. Effective HIV treatment is one of the best orphan prevention programs in the world.

In Uganda, as this photo indicates, we have focused on a family centered approach to care and prevention. This includes family based HIV testing and counseling, basic care, and access to antiretroviral therapy or ART.

HIV counseling and testing is the first step to introducing people to effective care. However, a national study in Uganda showed that 70 percent of adults reported wanting to receive testing but only 10 percent had actually been tested.

Another reason HIV counseling and testing is critical is for couples where one spouse is HIV-infected and the other is not. Among

members of TASO, 35 percent of married clients have HIV-negative spouses. Because the spouses have not been tested, most couples think that both husband and wife are HIV-positive, and therefore they're not taking precautions to prevent infection.

When offered home-based HIV testing and counseling, over 95 percent of more than 5,000 family members of persons living with HIV in rural Uganda accepted testing. Widespread family based testing and what is known as prevention with positive counseling are important parts of any treatment program.

In addition to ART, there are several other inexpensive effective interventions. For example, a cap full of diluted chlorine solution added to water and stored in a plastic vessel reduces diarrhea among persons with HIV by 35 percent. This provides the whole family with clean water and it costs less than $10 a year. In this photo,[1] you can see one of our clients with her water vessel and her antiretroviral therapy.

Malaria is twice as common with people with HIV than people without HIV. Insecticide-treated mosquito nets can prevent malaria and cost about $5 apiece. Additionally, a simple antibiotic invented 40 years ago, known as cotrimoxazole or Bactrim, is available even in the most rural villages in Africa and costs less than $10 a year per person. When taken daily, this drug reduces death by nearly 50 percent, malaria by 70 percent, and diarrhea and hospitalizations.

Currently, over 30,000 people in Uganda are taking it every day, and with funding from the Emergency Plan, it's expected that this number will increase to 300,000 in the next 4 years.

Although these simple interventions can be rapidly implemented, their impact is modest when compared to antiretroviral therapy which dramatically reduces mortality. There are many challenges to developing rural ART-based care, including access to lab monitoring for evaluating drug failure, setting up a reliable drug distribution system, and supporting good adherence to taking drugs. Yet, even though most people in Africa are not used to taking pills to prevent illness, we have found that when provided education, people adhere extremely well to their drug regimens.

In addition, we have reduced the cost of a CD4 cell count, a test used to monitor the effectiveness of ART, from $15 to $3 and have shown that the blood can wait 5 days to be tested with completely accurate results. This allows transport of blood specimens once a week from remote sites to a central or regional laboratory. These types of practical evaluations are necessary if we are to adapt effective interventions to the complexities of life in Africa.

One of the biggest obstacles to routine AIDS care is the inability to travel to a clinic to receive medication. To address this barrier with the Home-Based Care Program, we decided to bring health care to people instead of making them come to us.

For example, community health workers travel to people's homes on motorcycles to provide basic care, counseling, and ART. We've already treated over 1,000 adults and 30 children in two districts

[1] The photos referred to during Dr. Mermin's testimony can be found in his prepared statement on page 30.

and many Emergency Plan partners are applying some of the same interventions in many other Ugandan areas.

Much of the initial work in setting up a care program in Africa is spent on planning the program, developing counseling protocols, and a drug distribution system, purchasing infrastructure and hiring staff. However, once in place, rapid expansion depends almost solely on funding.

For example, we support a program in urban Kampala, a faith-based initiative, called Reach Out, that provided its first person with ART using Emergency Plan funds only 5 weeks after Congress passed the fiscal year 2004 budget.

Jennifer Birungi, who you can see pictured with her community health volunteer, is one of the first persons to receive ART under the Emergency Plan. She's a 36-year-old woman with HIV and a widow with two children. Last month, she was diagnosed with cryptococcal meningitis. Without treatment, her life expectancy would have been 6 days.

However, she was started on the drug for her meningitis, as well as ART, and is greatly improved. Although she never attended school and struggled to find enough food for her children, she's taken every dose of her medicine on time.

Within the next year, partially or wholly supported by U.S. Government funds, over 24,000 Ugandans like Jennifer will be taking antiretroviral drugs. Over a 100,000 people with HIV will be receiving effective basic care and thousands of infections will have been prevented.

As the Emergency Plan is implemented, these numbers will increase and what is currently working in Uganda will work even better on a larger scale.

So, on behalf of my colleagues here and in Uganda who work against AIDS, I'd like to thank the President, Congress, and the role you have played in helping to fight what is the worst epidemic in recorded history.

Thanks for the opportunity to speak today, and I'll be pleased to answer any questions.

[The prepared statement of Dr. Mermin follows:]

PREPARED STATEMENT OF DR. JONATHAN H. MERMIN

Good afternoon, Mr. Chairman and members of the Subcommittee on African Affairs. I am grateful to have a chance to talk with you today about fighting HIV/AIDS in Africa. My name is Jonathan Mermin. I am a Department of Health and Human Services (HHS) physician and a public health epidemiologist at the Centers for Disease Control and Prevention (CDC). Since 1999, I have lived and worked in Uganda, where I run the local HHS/CDC Global AIDS Program (GAP). In Uganda our program has piloted comprehensive care and treatment projects that include strong preventive components. Information from these programs lays the groundwork for full-scale implementation of the President's Emergency Plan for AIDS Relief (Emergency Plan).

I thank you and your colleagues on the Subcommittee on African Affairs, and the larger Foreign Relations Committee, for bringing attention to this important issue. My colleagues and I have been honored by several congressional visits to our program and, on behalf of the HHS Secretary Tommy G. Thompson and the Global AIDS Coordinator Ambassador Randall Tobias, I would like you to know that we welcome future visits from you and your colleagues.

Under the guidance of the Global AIDS Coordinator's Office, HHS/GAP's commitment in the fight against global HIV/AIDS is part of a collaborative United States (U.S.) Government effort. HHS/GAP helps resource-constrained countries prevent HIV infection, improve treatment, care, and support for people living with HIV; and

build capacity and infrastructure to address the global HIV/AIDS pandemic in 25 priority countries in Africa, Asia, Latin America, and the Caribbean.

In Uganda, as in all of the HHS/GAP countries, HHS/GAP works with U.S. Agency for International Development (USAID) and other U.S. Government agencies, as well as with host-country governments and non-governmental partners to help people with HIV/AIDS live longer and healthier lives and to prevent the spread of HIV.

BACKGROUND

Uganda is an under-developed country, with a per capita Gross Domestic Product (GDP) of $280 per year. Earnings are even less for persons living in rural areas, where 85 percent of Ugandans live. The health infrastructure is worse now than 30 years ago. Most hospitals do not have working x-ray machines, basic laboratory testing, or a reliable supply of simple medicine. On any given day in Uganda, only 5 percent of health facilities can perform a HIV test and only 20 percent can diagnose and treat tuberculosis—the leading cause of death for persons with HIV in Africa.

In 2001, the Joint United Nations Program on HIV/AIDS (UNAIDS) estimated that there were 600,000 persons living with HIV and AIDS in Uganda, including 100,000 under the age of 15, out of a population of 24 million. There were 880,000 children orphaned by AIDS and an estimated 84,000 AIDS-related deaths. UNAIDS currently estimates life expectancy in Uganda to be 42 years mostly because of AIDS.

Even with these statistics and extreme poverty, Uganda was the first country in the world to show a decrease in HIV prevalence—a decrease of 50 percent since 1992. Uganda's success in mitigating HIV infection now frequently informs the many global efforts to combat HIV and often serves as a model. This success was in large part because of early, high-level political leadership in addressing HIV, resulting in a broad response that included many innovative prevention programs such as the promotion of the *ABC* method, *A* for *abstinence, B* for *being faithful,* and *C* for *condoms,* as appropriate. The President's Emergency Plan has adopted the promotion of the ABC method as a key component of its prevention strategy.

HHS/GAP Uganda, a part of this historic, broad multi-sectoral response, has developed a wide range of indigenous partners whose HIV/AIDS effort and expertise are critical to success in fighting the epidemic. These partners include The AIDS Support Organization (TASO), the first and largest indigenous organization in Africa providing care and support to people living with HIV/AIDS. With TASO and other key partners, HHS/GAP is studying how people living in rural, resource-limited settings can best access quality, comprehensive HIV care, treatment and preventive servies that includes antiretroviral therapy (ART). This research study is known as the *Home-Based Care Program* and is based in the rural Tororo and Busia districts in eastern Uganda near the border with Kenya. Components of this program are further highlighted below. Building upon these types of projects, the Ugandan Government, with the help of HHS and others, has embarked on the next stage—delivering effective treatment to the hundreds of thousands of Ugandans with HIV who currently live with almost no access to basic medical care and who have no experience with taking medicine on a daily basis to prevent illness. The challenges to this task are best understood from the perspective of people living in Uganda. As many of you know, Secretary Thompson and Ambassador Tobias led a delegation of over 100 government, business, faith, and charitable leaders to Africa in December, when they visited Tororo and met many of our patients in their homes; some of you have heard Secretary Thompson speak of the two HIV-positive people he met, Samson and Rosemary. I'm going to share with you the stories of some other clients, every bit as sobering, yet hopeful.

For example, Margaret Akware is HIV-positive and her husband died of AIDS in 1996. Margaret is a subsistence farmer, living in a thatch-roofed home with her two children. In addition to these two children, she takes care of five AIDS orphans. She lives several miles from the nearest health center and her family cannot afford even a bicycle for transportation. She is a unique individual, but her story represents millions of people living with HIV in Africa.

Margaret speaks in public about having HIV and participates in community drama groups and educational sessions throughout her District, encouraging people to get tested for HIV and to support people with AIDS. She lives each day knowing that if she dies, her seven children will have no place to live. Without the ART she is receiving through the U.S.-supported *Home-Based Care Program* described above, she most certainly would have died. In addition to ART, she also receives counseling to prevent transmission of HIV and a basic preventive care package consisting of a method for making safe drinking water, mosquito nets, and a simple antibiotic that prevents infections. With the help of this program, Margaret will stay alive

longer and will help educate others while continuing to support her seven children. Like Margaret's family, 74 percent of children living with the 30,000 TASO clients in Uganda are at immediate risk of becoming orphans, because all of their living parents. Effective HIV treatment is one of the best orphan prevention programs in the world.

COMPONENTS OF A HOME-BASED CARE PROGRAM

Family-centered Basic Preventive Care Package

In Uganda, HHS/GAP and its partners have focused on a family-centered approach to care and prevention. Working with families increases the chance for success because it utilizes the family's support systems, encourages disclosure of HIV status, and emphasizes the benefits to the whole household of providing effective care for a family member with HIV. Through a home-based, family-centered, delivery approach, HHS/GAP is focusing on expanding HIV testing and counseling, providing a standardized, effective basic care package to all persons with HIV, and expanding access to ART.

HIV counseling and testing

HIV counseling and testing is the first step to introducing people to effective HIV/AIDS care. However, a national study in Uganda showed that 70 percent of adults reported wanting to receive testing; only 10 percent had actually been tested. Currently about 50 percent of people hospitalized in Uganda have HIV infection, but HIV testing is rarely available in hospitals and almost never offered to patients.

Another reason HIV counseling and testing is critical in Uganda is for couples where one spouse is HIV infected and the other is not. Among HIV-infected members of TASO, 35 percent of married clients have HIV-negative spouses. Because the spouses have not been tested, many couples think that both husband and wife have HIV and are, therefore, not taking precautions to prevent infection. In Uganda, an estimated 40 percent of new HIV infections are occurring among married couples because they do not know that they or their partners are at high risk of infection. These data call for widespread, family-based testing, as well as what is known as "prevention with positives" counseling, i.e. working with HIV-infected persons to change their behavior to reduce the chance that they will spread the virus to others. In addition, HIV testing and counseling is the first step to introducing people to effective AIDS care.

HHS/GAP Uganda has developed a three-tiered testing program. Its goals are to expand traditional counseling and testing sites so that people can have easy access to testing; to begin routine, voluntary HIV counseling and testing at clinics and hospitals throughout the country; and to explore door-to-door, home-based testing and counseling using mobile teams to increase access to testing and, if needed, link people to care. When offered home-based HIV testing and counseling, over 95 percent of more than 5,000 family members of persons living with HIV in rural Uganda have already been tested.

Additional tools for care

While ART is essential for those living with HIV, a comprehensive package of care needs to include more than just antiretroviral therapy. There are several other inexpensive, effective treatments that are critical for preventing illness and death which are discussed below.

For example, in Africa, according to the World Health Organization (WHO), diarrhea is responsible for as much as 8 percent of all deaths regardless of HIV infection status. A capful of diluted chlorine solution added to water and stored in a plastic vessel reduces diarrhea among persons with HIV by 35 percent. This provides the whole family with clean water and costs less than $10 a year.

Malaria is a life-threatening parasitic disease transmitted from person to person through the bite of a mosquito. According to the WHO, the disease exerts its heaviest toll in Africa, where around 90 percent of the more than one million deaths from malaria worldwide occur each year,. Malaria is twice as common among adults and children living with HIV. Insecticide-treated mosquito nets can prevent malaria and cost about $5 a piece.

Additionally, a simple antibiotic, known as cotrimoxazole or Bactrim, can be used to help prevent both diarrhea and malaria and prolong life. It is available even in the most rural villages in Africa and when purchased in bulk, treatment costs only $6 a year per person. When taken daily by persons with HIV in Africa, this drug reduces death by nearly 50 percent, malaria by 70 percent, and diarrhea and hospitalizations by 30 percent. HHS/GAP is working with the Ugandan Ministry of Health to develop a policy regarding its use. Currently over 30,000 people are taking

it every day, and with funding from President Bush's Emergency Plan, it is expected that this number will increase to 300,000 in the next four years.

In Uganda, HHS/GAP, as well as its partners in the President's Emergency Plan, are promoting the aforementioned strategies—a comprehensive package of care, that uses a family-centered approach that includes these simple, life-extending interventions—a method for making safe drinking water, mosquito nets, cotrimoxazole, testing and counseling, and ART, which is discussed in the next section. The strategies discussed above highlight the existence of simple interventions that prevent illness and death and can be rapidly implemented. However, the impact of these interventions is modest when compared to the life-extending, life-improving effects of ART.

ANTIRETROVIRAL THERAPY

When AIDS was first recognized in 1981, patients with the disease were unlikely to live longer than a year or two. Since then, scientists have developed an effective arsenal of drugs that can help many people infected with HIV live longer and healthier lives. These drugs are called antiretroviral drugs because they attack HIV, which is a retrovirus. Antiretroviral therapy (ART) can significantly affect the disease progression of HIV/AIDS. The diagnosis of AIDS occurs when the count of a person's CD4 cells (a critical part of a person's immune system) is less than 200. As a comparison, a healthy HIV-negative person has a CD4 cell count of about 1,000. The death rate for persons with CD4 cell counts of less than 200 is 50 percent per year; however, the death rate is reduced to less than five percent per year with ART.

Nevertheless, there are many challenges to developing rural ART-based care in resource-limited settings. Drug adherence presents potential difficulties, leaving the possibility for the development of viral resistance. CD4 cell count and HIV viral load monitoring are traditional tools used to monitor the health of those living with HIV and to assess drug resistance, but providing this testing presents challenges in settings with limited infrastructure and trained personnel. There is often no system for sustained distribution of drugs. There is extreme poverty with no access to electricity. Sanitation and clean water are limited, and access to transportation is often unavailable creating a tremendous barrier for this widely dispersed population.

In the U.S., persons with HIV started taking zidovudine, also known as AZT, when it was first developed, and later, with treatment advances, people had the opportunity to take two drugs at a time. While people with AIDS lived longer taking two drugs, it was soon realized that taking three drugs at a time was the optimal drug regimen to keep people alive longer and prevent the emergence of drug resistance. This is one of the reasons, in addition to adherence issues, that the United States is currently coping with the burden of multi-drug resistant cases of HIV infection. Governments, physicians, and people with HIV in Africa are concerned that they might have similar difficulties with drug resistance, especially since Africa does not have the sophisticated resistance testing available in other countries. In Africa we are starting with triple-therapy antiretroviral drugs (ARVs). This means that emergence of resistance will be delayed if people can adhere to the drug regimen. Adhering to the appropriate drug regimen is easier now than ever before—most regimens can be taken twice a day instead of four times a day as was the case 10 years ago. Even though most people in Africa are not used to taking pills to prevent illness, we have found that, when provided education on the importance of following drug regimens, people adhere extremely well.

However, the traditional tools used for assessing drug resistance, CD4 cell count and HIV viral load monitoring, present challenges. In most African countries the cost of traditional CD4 cell count and HIV viral load monitoring is greater than the cost of ARV drugs. In addition, the machines for conducting the testing are usually available in only one or two laboratories in the country. To make the situation even more difficult, manufacturers of these testing machines currently recommend that CD4 cell counts must be conducted within two days of blood draw.

HHS/CDC has spent the past four years developing less expensive ways of conducting CD4 cell counts. Now, using state-of-the-art technology, HHS/GAP Uganda has reduced the cost of a CD4 cell count from $15 to $3 and has shown that the blood can wait five days to be tested with completely accurate results. This allows transport of blood specimens once a week from remote sites to a central or regional laboratory. HHS/GAP is also conducting a study to see whether laboratory monitoring is necessary at all. It is possible that, through weekly or monthly monitoring by a trained lay person who also delivers the ART to a person's home, signs of drug failure such as weight loss and yeast infections can be detected quickly and the need to change drug regimens can be evaluated. These types of practical evaluations are

necessary if we are to adapt effective interventions to the complexities of life in Africa.

HHS/GAP has found that the biggest obstacle to ART, especially in rural areas, is the inability to travel to a clinic to receive medication. Many people live so far from clinics that transportation by bicycle or bus to pick up drugs is not available along the paths that lead to their homes. If transportation is available, it is too expensive. Many people with HIV have died at home simply because they could not afford to come to the clinic when they were sick or they could not afford their medication.

To address this barrier, HHS/GAP and its partners have brought the health care system to people in these rural areas, using the *Home-Based Care Program,* the project Secretary Thompson and Ambassador Tobias visited in December. In this project, community health workers travel to people's homes on motorcycles to provide home-based HIV testing and counseling, cotrimoxazole prophylaxis, mosquito nets, clean water, tuberculosis treatment, prevention with positives counseling, and ART. They deliver drugs, ask a short, standardized symptom questionnaire, and support adherence to drug treatment. The project is based at one District hospital and is already treating over 1,000 persons in two Districts. Many Emergency Plan partners are applying some of the same interventions in other Ugandan areas.

Time

Much of the initial work in setting up a program that delivers HIV testing, basic care, and ART in Africa is spent on planning the program, developing counseling protocols and drug distribution systems, purchasing infrastructure and hiring staff. Because HHS/GAP developed many of its own tools, the *Home-Based Care Program* in Tororo took a year to begin implementation. However, now that it is in place, rapid expansion depends almost solely on funding. For example, a HHS/GAP-supported program in urban Kampala, a faith-based initiative called *Reach Out,* provided its first person ART using Emergency Plan funds only five weeks after Congress passed the FY2004 budget. Since this program had already planned for a family-centered program that adopted many of the interventions and materials that HHS/GAP had developed, they could immediately implement the program.

Let me convey the importance of home-based care in the provision of ART through the story of Jennifer Birungi, one of the first persons to receive ART funded by the President's Emergency Plan. Jennifer is a 36-year old woman with HIV and she is a widow with two children. Last month, she was diagnosed with cryptococcal meningitis, a painful and devastating infection for people with HIV. Without treatment, her life expectancy would have been six days. However, she was started on a drug for her meningitis infection as well as ART and has greatly improved. Although she has never attended school, lives in a one room house with no blankets or furniture, and struggles to find enough food for her children, she has taken every dose of her medicine on time.

Christopher Omoit is a client of the *Home-Based Care Program.* He is 53 years old and lives in rural Uganda with his wife, Florence, their five biologic children, and two orphans from his sister who died of AIDS. He was a laboratory technologist until 1999, when he became too sick to continue working and tested positive for HIV. Through U.S. Government support, his whole family was provided HIV testing and counseling. His wife was HIV-negative because they were counseled about how to prevent transmission, and today, she remains negative. HHS/GAP provided him with a basic care package, and since then he has reported, "I used to get sick a lot with diarrhea and malaria, but now I can do my work without falling sick."

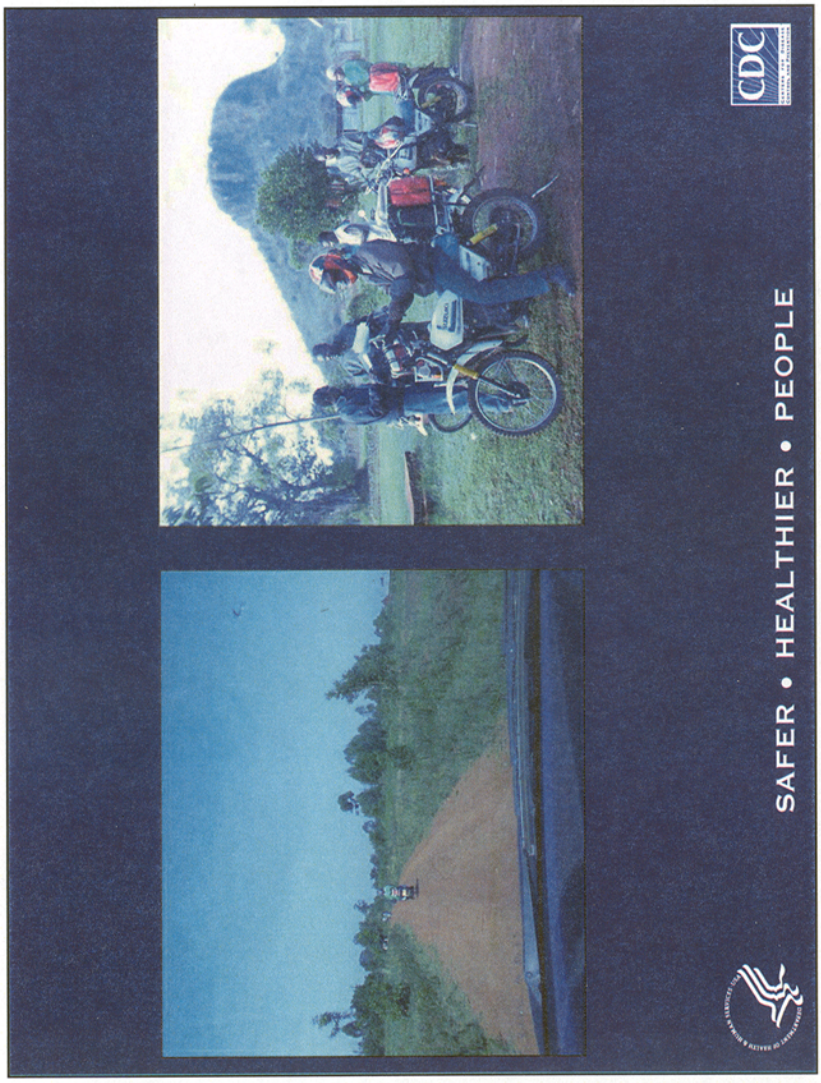
The basic care package helped Christopher, but his CD4 cell count was 13 and he knew he would not live on the basic care package alone. At this point, to survive, ART was absolutely necessary. Just six months ago, his field officer came on a motorcycle and provided him with his first supply of ART. He has since established a support group for people taking ART and the group has started income-generating activities. Because he is part of a home-based program that focuses on preventive care, he rarely becomes ill, can avoid having to walk four miles to the nearest clinic, he and his family stay healthy, and he is strong enough to work. Because his ARVs are delivered to him on a regular basis and his family has been educated to help him remember to take his drugs, he is adhering to his regimen better than the average person with HIV in the United States.

Within the next year, partially or wholly supported by U.S. Government funds, over 24,000 Ugandans like Christopher will be taking antiretroviral drugs, over 100,000 people with HIV will be receiving effective basic care, and thousands of infections will have been prevented. As the President's Emergency Plan is implemented, these numbers will increase. What is currently working in Uganda will

work even better on a larger scale, and we can continue to make progress addressing the worst epidemic in recorded history.

Lastly, the success of home-based care in Uganda in large part stems from the efforts President Bush and Congress have devoted to global AIDS over the past decade. The tremendous leadership of President Bush and members of Congress and their contribution toward the fight against global AIDS cannot be overstated. On behalf of my HHS and State Department colleagues and all those who work to combat global AIDS, I would like to thank Congress for the role you have played in helping to fight this global pandemic.

In conclusion, I thank you for the opportunity to speak today and I would be pleased to answer any questions.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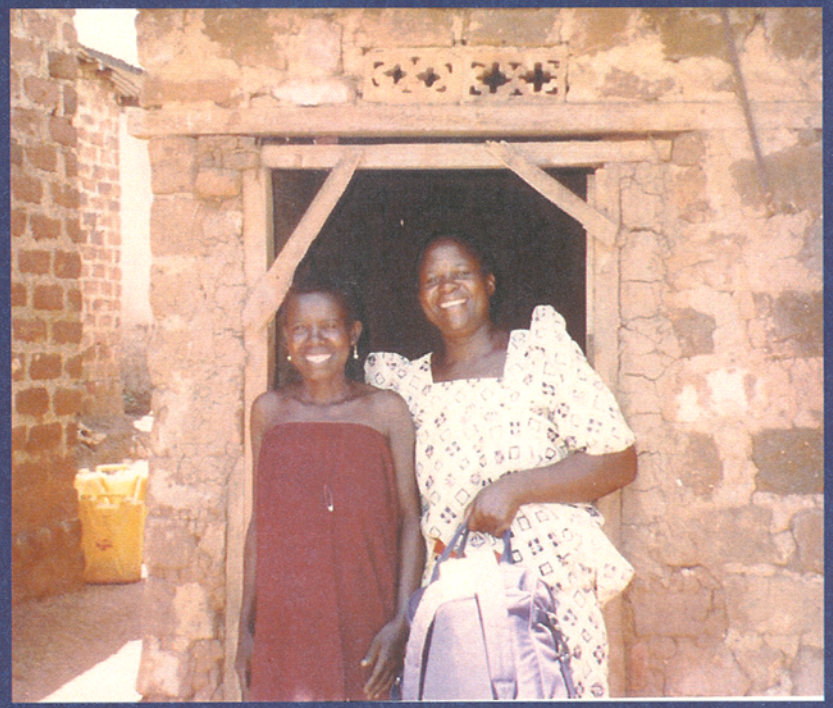

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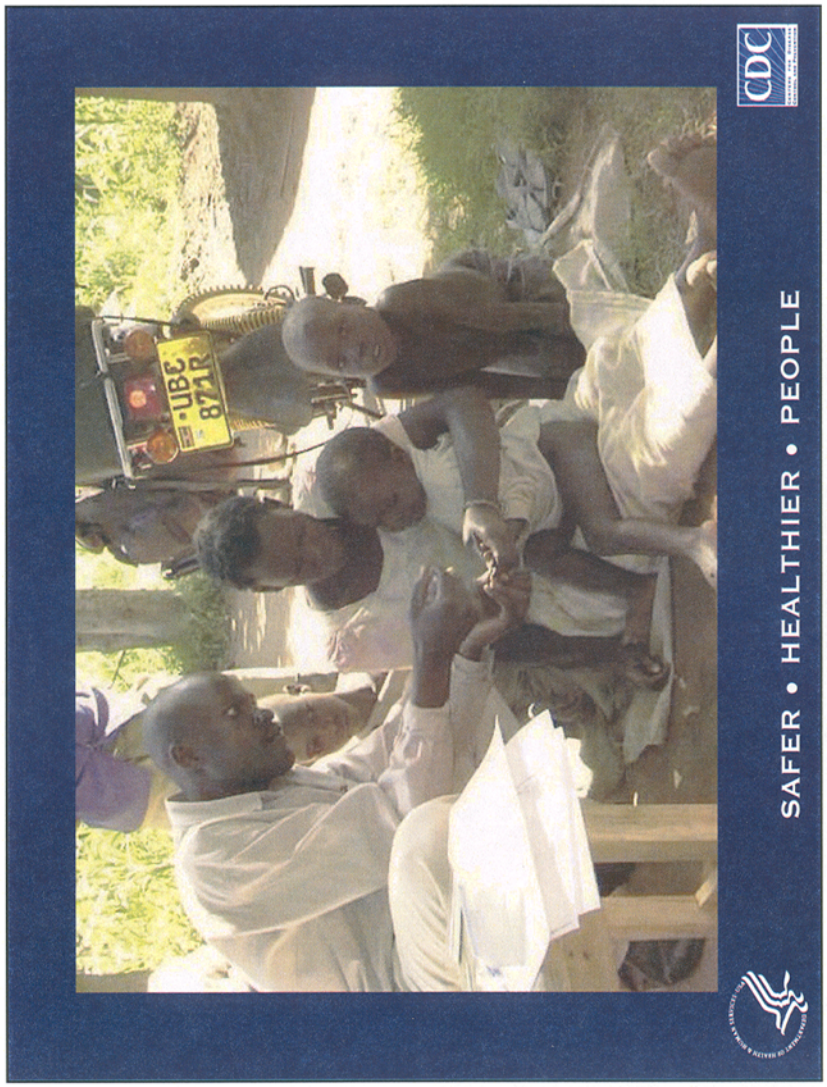
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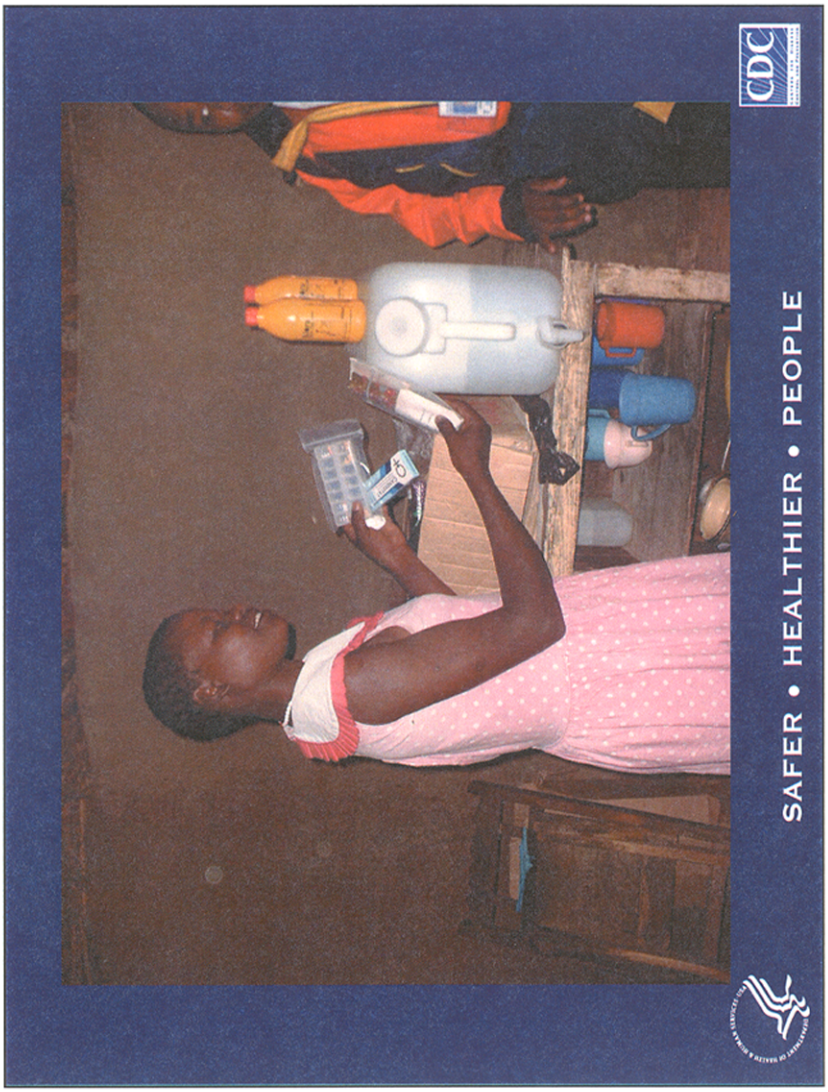
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Senator ALEXANDER. Well, thank you, Dr. Mermin. We should be thanking you. You're doing the work.

Let me ask you. Put yourself in our shoes a little bit, if you would. I'm sure you may have done that before and just not said it out loud to people. But if Senator Feingold and I are sitting here and charged with the responsibility for oversight of how we're helping to spend $15 billion over 5 years to help fight the worst epidemic in the history of the world, what should the benchmarks be? What kind of questions should we be asking?

Let's just be specific. Let's take Uganda, where there's more success than any other place. Over the next few years, if you were sitting in our shoes, what questions should we be asking? What benchmarks should we be insisting on?

Dr. MERMIN. Thank you, Mr. Chairman. There are two kinds of benchmarks. The first kind is the direct outcome measures, and I think that the outcomes of number of HIV infections prevented, number of people getting routine basic care, and number of people getting ongoing ART, are very effective measures and they're very useful as a way to make sure that the programs that are being implemented stay on track.

There's one level of measures beneath that called process indicators. Those indicators are as critical to making sure that we're on the right path. They include aspects of how many people have received voluntary counseling and testing. In what situations are we providing voluntary counseling and testing? What are we doing to actually counsel HIV discordant couples? What kind of educational activities do we have with youth, and are they changing their behavior?

Those kind of process indicators are very important, and I would say that the measures that are currently being discussed with the Emergency Plan partners seem to be very effective.

Senator ALEXANDER. Are you a part of developing the Uganda plan?

Dr. MERMIN. Yes.

Senator ALEXANDER. And you're suggesting that such a plan will have outcome measures, but that we should also pay attention to the process measures? See, our tendency might be to say or mine would be to say—well, would be to pay a lot more attention to outcome than process.

Are you suggesting that the process measures are helpful in understanding what the outcomes are or that they're important just by themselves?

Dr. MERMIN. Sometimes, they're important to make sure that the programs have good quality in areas that aren't measured within those three major outcome measures, but I think primarily they're useful for the program, for people involved in the program. And it's the ultimate outcomes that are going to be of most interest to people in your position.

Senator ALEXANDER. If you were looking ahead 3, 4, or 5 years and looking at the resources that seem to be available, what's the prospect for fighting HIV/AIDS in Uganda over the next 5 years?

Dr. MERMIN. I think it's very hopeful. Uganda is a remarkable country with a great deal of both governmental and non-govern-

mental support for AIDS activities. It's already decreased HIV prevalence by at least a half. We are involved in——

Senator ALEXANDER. From what to what?

Dr. MERMIN. Among women visiting antenatal clinics in urban settings, it's decreased from close to 30 percent to 12 percent. In rural areas, it's decreased from about 15 percent to 6 percent. It's hard to take that information and translate it to an actual population-based number, but it's presumed that it was close to 10 percent and it's now close to 5 percent.

One way of getting accurate information is something we've been working on for the past 3 years and is being implemented as we speak and that's a national HIV behavioral survey, and with the leadership of the Ministry of Health and support from the U.S. Government as well as UNAIDS and WHO, Uganda's currently carrying out a nationally representative survey where they go to people's homes in the country.

They ask people to answer a questionnaire related to demographics and behavior, and then they also do HIV testing, and that information will provide the answer to your question much more accurately about what's actually going on with HIV prevalence today.

Senator ALEXANDER. This will be my last question before turning to Senator Feingold, but it relates to a subject he mentioned, that Ambassador Tobias also mentioned.

What about new kinds of testing, the rapid tests? How important are those in helping to discover those people who are infected and then in persuading them to accept treatment and then to encourage them to use the treatment on a regular basis?

Dr. MERMIN. I appreciate your asking that question. CDC was initially involved in the mid-1990s with the AIDS Information Center in Uganda. This is the first and largest HIV testing center in Africa, and what we did is when we evaluated the program, we realized that about 25 percent of the people who were HIV-positive when they came in to get tested would never come back to receive the results 2 weeks later.

So, we piloted using rapid HIV testing. It was still conducted in the laboratory at the AIC sites, but what it ended up doing, because people would get their results within 1 hour, was that we had everyone receive their results.

Everyone received counseling and they left the center knowing their HIV status, and at this point, they also leave being screened for tuberculosis, getting treatment if they have tuberculosis, and getting access to other information that's necessary for them to take care of their lives and health.

We didn't want to just rest with that, because what we found was that still the traditional rapid HIV tests also demand the kind of infrastructure that isn't available in most rural areas in Uganda.

So, we completed about 6 months ago, again in collaboration with the Ministry of Health and WHO and AIC, a field assessment of the use of finger stick rapid testing in rural sites. People could just get a finger stick of blood, put it on a test and get an immediate result, and what we found was it works just as effectively as the traditional laboratory-based testing.

Senator ALEXANDER. You mean they could tell for themselves? They administer it to themselves and read the results themselves? They don't need a doctor or a health worker?

Dr. MERMIN. I'm sorry. I should clarify. It is being conducted in a facility, a health facility by—the test is being conducted by a laboratory technician or a nurse, but it's being done in the room with the person who is being counseled about HIV.

That testing modality has been very—it looks like it will be successful and is quite popular already among different organizations to try to implement that because it can reach out to rural areas somewhat more quickly.

In addition, one of the things we'll be exploring in the next year is the use of that kind of testing in people's homes because currently, our home-based VCT activity has involved going to people's homes, doing the finger stick, putting blood on filter paper, bringing it back to the laboratory and then returning to the home to give the results.

And it might be more effective and less costly to actually be able to do the testing with a counselor directly in the home, provide people with the results right then and there, and then give them ongoing followup care if they need it.

Senator ALEXANDER. Senator Feingold.

Senator FEINGOLD. Thank you. Dr. Mermin, can you tell me a little bit more about the strategies that you're pursuing in Uganda to meet the specific needs of women and girls?

Dr. MERMIN. Thank you. There are actually several approaches to that question. The first involves HIV prevention education that's going on in many different ways in Uganda. One is through Straight Talk which is a newspaper insert that discusses HIV prevention and care, focused on youth, and that's been going on for several years in Uganda, and it's in the national newspaper and they translate it to multiple languages, so that it can reach even rural areas.

There's a large school-based educational program that is actually led by the President of the country, and the U.S. Government has supported that program and the development of the books that are actually used by teachers to be able to educate their students.

Then, in addition, we also have a special focus on families in some of the work that we're doing, where, by providing HIV counseling and testing to entire families, that gives us the opportunity not only to discuss with both men and women what it means to have HIV, to have them support each other, depending on the situation, especially if it's an HIV discordant couple, or if a woman has HIV and she needs to access prevention of mother-to-child transmission programs, or whether one of them actually ends up having to take antiretroviral therapy in the long term.

We incorporate in that counseling issues related to writing wills, to domestic violence, and really have tried to look at the holistic aspects of a family because, at least from our experience, that's the best way to get effective results.

Senator FEINGOLD. Those are all encouraging. Let me ask if there's some kind of a gender advisory group that helps guide the country strategy with regard to the needs of women and girls.

Dr. MERMIN. Yes. The Ministry of Gender in Uganda actually is heavily involved in HIV/AIDS activities and a representative of that ministry is on our advisory board, the Emergency Plan Advisory Board. So, we gain guidance from both that ministry as well as from her.

Senator FEINGOLD. Does that group have people, like representatives from civil society, from women's groups, networks of women living with AIDS, service providers, those type of people?

Dr. MERMIN. Yes, all of the above.

Senator FEINGOLD. In an overall sense, with regard to Uganda, are you satisfied with the degree of interagency coordination, international donor coordination and coordination with the diverse Ugandan community working to fight AIDS on the ground, or is there some aspect of this that you'd like to see improved?

Dr. MERMIN. I think that Ambassador Tobias needs to be complimented on his approach to coordination within countries. Historically, the U.S. Government agencies in Uganda have gotten along very well and we've communicated about our activities well. We work very well with both UNAIDS, WHO, and other bilateral/multilateral donors through a partnership forum that's sponsored by the U.N.

But what we hadn't done, at least within the U.S. Government, is actually planned together, and what's really remarkable over the past 6 months is that we're not just talking about each other's activities, we actually got together in a special strategic planning retreat and designed the Emergency Plan together.

We held stakeholder meetings with the civil society, groups of people living with AIDS, and ministries and Uganda AIDS Commission, giving us advice about activities. And we ran those together, and we designed the proposal that Ambassador Tobias mentioned with information from both groups, looking at the strategic benefits of one or other agency either supporting that activity in particular or providing technical assistance.

So, I think that I'm very encouraged over recent time about the way that the coordination is occurring in the country under the leadership of the Ambassador in the country. I think there will be continued improvement in those relationships and our ability to function effectively will continue to improve.

Senator FEINGOLD. Thank you, doctor. One more question in light of the fact that we want to see the successes of Uganda repeated in other places. Do you rely on the U.S. Embassy to handle contracting issues and the overall administrative burden of maintaining CDC's programs on the ground and, if so, how sizable of a burden is that on the embassy?

Dr. MERMIN. That's an insightful question. We do. CDC has certain authorities, and under our existing structures, we have to use the existing embassy personnel and systems to be able to purchase reagents, test kits, implement contracts, other than our large cooperative agreements which go through Atlanta. That's put a tremendous burden on the embassy.

We are hiring new staff, as are they, to try to adapt to the situation, but it's an awkward situation because it doubles some of the administrative and bureaucratic burden on both agencies.

And I think in the future, if there were a way for you and the chairman to be able to influence the ability for Health and Human Services to be able to act more independently and have some of the authorities of the State Department or similar authorities internationally, it probably would release some of the burden on the State Department and allow us to function a little bit more efficiently.

Senator FEINGOLD. That's the kind of candid response that can help us get out ahead of problems. So, I appreciate it.

Thank you, Mr. Chairman.

Senator ALEXANDER. Good question, good answer and helpful answer. Thank you. Thank you, Dr. Mermin.

We have two more witnesses and three potential Ambassadors to consider today. So, I'm going to thank you very much for your testimony and for your service, and I hope to see you in Uganda some time.

Dr. MERMIN. Thank you.

Senator ALEXANDER. On our final panel of witnesses, are two persons whom I will now introduce. Dr. Ernest Darkoh, operations manager for the ARV Project. I understand that a lot has happened since last August and we look to hearing more about that.

Then following him, Dr. Lulu Oguda. She is now at Harvard University as a Fellow in the School of Public Health, but she has already earned her medical degree in Kenya. Previously, she spent 2 years as a field doctor for the non-profit Doctors Without Borders, working on HIV/AIDS projects in both Malawi and Zambia. She was involved in the provision of antiretroviral treatment in Zambia. She introduced the prevention of mother-to-child transmission program and trained numerous staff.

Dr. Darkoh and Dr. Oguda, thank you very much for being here, and why don't we begin with Dr. Darkoh and then Dr. Oguda.

STATEMENT OF DR. ERNEST DARKOH, M.D., M.P.H., M.B.A., OPERATIONS MANAGER, BOTSWANA NATIONAL ARV PROGRAM (MASA), BOTSWANA MINISTRY OF HEALTH AND AFRICAN COMPREHENSIVE HIV/AIDS PARTNERSHIP (ACHAP), GABORONE, BOTSWANA

Dr. DARKOH. Thank you, Senator Alexander, and Senator Feingold is not here, but I'll thank him in absentia.

I applaud the President's initiative to commit major U.S. funding to address HIV/AIDS in parts of the world with the highest infection rates. I also appreciate that notice has been taken of Botswana's program which is, as it stands, the longest-running and largest public sector program in Africa, and I feel there's much to be learned from Botswana, and it's my pleasure to share our experiences with you.

The Botswana National ARV Treatment Program was initiated through a partnership between the Merck and Gates Foundations and the Government of Botswana, and on the ground this partnership is called the African Comprehensive HIV/AIDS Partnership or ACHAP for short. So, I'll use that abbreviation in the presentation going forward.

The Merck Company and the Gates Foundation each provided $50 million to support Botswana in its fight against HIV/AIDS.

Some of this money is used to support the treatment program, but it also does support a whole broad range of other prevention programs in the country.

As you mentioned earlier, out of a population of 1.7 million, Botswana's estimated to have about 300,000 people who are HIV-positive, and 100,000 of whom would be instantly eligible for ARV therapy if you were able to test everyone in the country and do a CD4 test and use either CD4 of 200 or less or the presence of an AIDS-defining illness as criteria of being an HIV-positive child.

So, under the courageous and inspirational leadership of President Festus Mogae, Botswana decided that treatment with antiretroviral therapy in the public health system should be introduced as a matter of national policy to address the emergency.

The Government of Botswana approached ACHAP for assistance in establishing a national treatment program. A detailed implementation plan was developed in late 2001. I have provided a handout, I hope you have a copy, but it does sort of detail the statistics of our program. I'll briefly go through those.

The National Treatment Program began in January 2002 and in 27 months has enrolled over 20,000 patients in 12 operating sites. Of this 20,000, 12,000 are on ARV therapy. The split is about 64 percent women to 36 percent men. An additional 6,000 plus patients are on ARV therapy in the private sector, making a total of 18,000 people on ARV therapy in Botswana.

This represents approximately 16.4 percent of all eligible patients on ARV therapy and also 24 percent of eligible patients who know their status. This makes Botswana the leading country in terms of the proportion of HIV/AIDS-infected individuals on ARV therapy in Africa.

Overall, the program and patients are doing remarkably well. Followup rates are above 90 percent, adherence rates above 85 percent. Eighty-five to 90 percent have fully suppressed viral loads at the 6-month point and CD4 levels are increasing. Patients with wasting syndrome are gaining weight and are able to return to work. The incidence of toxicity is low, below 7 percent, where it's severe enough to require a medication switch.

The overall mortality after initiation is only 9 percent, despite the average CD4 count of the patient population still being at about 81. For the first year of the program, just to inform you, the CD4 count was between 50 and 60.

There's also strong anecdotal evidence that hospital ward occupancy significantly decreases, even with relatively few patients on treatment. This is probably due to the high readmission rate of critically ill patients.

As I said, our program is operating in 12 sites. Our plan is to scale up to all remaining district and primary hospitals in the country this calendar year. Each of those hospitals will have approximately two to four satellite clinics associated with it once fully rolled out. Therefore, we expect to have 32 operating ARV sites in the country.

Current cost per patient for drugs and diagnostics ranges between, U.S. dollars, $580 per patient per year to, U.S. dollars, $1,580 per patient per year, depending on the specific drug regimen prescribed. To date, ACHAP has spent about, U.S. dollars, $12 mil-

lion on the ARV program. The government currently supports more than 90 percent of the overall costs.

Some significant challenges do remain, however, despite the successes. The burden of disease is unprecedented and extremely large. Keep in mind that we're trying to at some point get almost 40 percent of the entire adult population on ARV therapy across a widely dispersed geographic distribution.

Most people in the country still do not know their HIV status and present late, at a stage where they're very resource-intensive and that stretches already short staff on the ground. Civil society, NGOs and CBOs lack adequate capacity to provide the necessary supportive services, and there's also marked lack of management capacity and very intense communication needs across a broad array of internal and external stakeholders that needs to be accounted for.

As I said, we've been running for a little over 2 years, and I would have to say that the overriding key success factor has been our ability to learn lessons quickly and readapt strategies as necessary.

The first lesson that we have learned is that capacity buildup is not a linear process. It does take time. This is largely due to the fact that when the program begins, you have few trained staff. The newly trained inexperienced staff can see fewer patients per unit time, and the initial cohort of patients who present are very sick.

So, that actually leads you to a situation where you have more of a compound interest-type curve and not a big bang where you can enroll people very rapidly. Treatment volume expectations must therefore be tempered and managed carefully.

The second lesson is that a phased roll-out, if too slow, can result in initial sites being overwhelmed. This excessive demand can lead to perverse resource buildup in a few sites at the expense of rolling out to new sites that are closer to where people live.

In addition, the fewer the sites, the longer distances people have to travel and that could negatively affect adherence.

Third lesson. Each new site experiences the same teething problems and, as such, there's little to be gained by a slow scale-up. The best strategy is to spread as widely and quickly as possible after learning from your initial pilot sites.

Fourth lesson. Training is the most critical rate-limiting step to scaling up. In our experience, the most effective and efficient mechanism of activating new sites is to provide onsite HIV specialist preceptors, doctors and adherence nurses, and usually from either the U.S. or Europe where there's been a long experience in treating with these medications, and they provide hands-on training and management support for a period of 3 to 6 months at a site to get them activated. Afterwards, they leave and the site does actually function on its own.

The Debswana Mining Company in Botswana, they started their program before ours. It was a private sector program, and they addressed this critical lack of trained staff to provide the training through telemedicine and actually their staff on the ground had their decisions ratified and supported by a panel that sat in Cape Town, South Africa. That model was also quite effective.

The sickest patients come forward first and even at relatively small numbers overwhelm the system. This is due to their intense resource requirements. This creates queues which are greatly exacerbated by the natural triage of the sickest of the sick on each given day to the front of the line. Now, if this dynamic is allowed to persist, you end up with a situation where ARV therapy is practiced as emergency therapy which is not the way it should be. With this happening then, patients begin to succumb in the queue.

So, the solution we have had to implement is to split the queue with certain days reserved for people with highest CD4 counts who you identify from your data base and then other days left as open enrollment where the more critically ill can still receive services. This model allows us to enroll more patients per unit time.

The only rational way a program can manage demand and meet the challenge of enrolling such large numbers of patients and preserve their productivity is to find people before they are critically ill. I cannot emphasize this enough.

Botswana, therefore, had to roll out a program of routine testing which I think quite a few people may have heard about and this is an effort really to identify as many people as possible before they are critically ill and enable the provision of preventive and supportive services to the current situation where the majority of patients, even though we keep them alive, at that point have lost their livelihood and are not supporting their families or themselves.

The other thing then is that the most fundamental kind of ARV therapy is that a health professional knows who their patient is and can monitor what's happening with them. Patients will spend the vast majority, 99 percent, of their lives in the community, not in a hospital or not in a health facility, and with that being the case, it is somewhat dangerous to overemphasize the building of brick and mortar health care infrastructure at the expense of building systems that track and monitor patients as they move between health facility and the community and across different geographies.

For any new program, therefore, that's starting, the highest priority and the bulk of the initial effort, I feel, should go toward establishing a robust and reliable patient tracking and monitoring and evaluation system.

Public-private partnerships can help accelerate by acting as catalysts for action and by providing money that is faster and more flexible than that available from governments. The Merck/Gates/Botswana Partnership, as a conduit model through which key technical expertise has been introduced to supplement the Ministry of Health's management capacity, has proved particularly effective.

Not only does this model allow for an unprecedented level of co-responsibility, mutual monitoring, and early problem identification, but it allows for real skills transfer to occur between the seconded experts and local staff.

With the broader global epidemic in mind, it's clear that governments cannot fight this battle alone. All sectors and individuals must play an active role. However, in my experience, I've noticed that natural tendency to focus on developing and building only public sector capacity. However, a holistic and non-judgmental assessment often reveals numerous other potential sources of significant untapped capacity in the private sector, including private sec-

tor doctors, hospitals and laboratories, but also NGOs, CBOs, civil society, and faith-based sectors and the community at large.

The ACHAP Partnership has clearly demonstrated the catalytic value of tapping into non-traditional private sources, skills, expertise, and money. It has also demonstrated a feasible and viable mechanism through which tremendous skills and resources from the private sector can be leveraged for public good.

The burden of disease in most countries is such that no sector is likely to be able to address the complexities singlehandedly. Looking continent-wide, it's clear that traditional models of linear thinking will never overcome this epidemic. Patients must be empowered and equipped to participate maximally in their own care. New mutually enriching partnerships and innovative models must rapidly be deployed and the appetite to take risks must be increased dramatically. This can be done safely if built on a foundation of sound management, monitoring, evaluation, accountability, and true ownership by countries.

I thank you for your time and consideration and look forward to questions later.

[The prepared statement of Dr. Darkoh follows:]

PREPARED STATEMENT OF DR. ERNEST DARKOH

Thank you, Senator Alexander and distinguished members of the Africa Subcommittee. I am the Operations Manager of Botswana's National Antiretroviral Program. I applaud the President's Initiative to commit major US funding to address HIV/AIDS in the parts of the world with the highest infection rates. I also appreciate that notice has been taken of Botswana's National ARV Program and the Merck/Gates/Botswana Partnership, known as the "African Comprehensive HIV/AIDS Partnerships" (ACHAP), and our pioneering work in developing public-private partnerships to address this epidemic. As the longest running and largest public sector treatment program in Africa, I feel there is much to be learned from Botswana and it is my pleasure to share our experiences with you.

I am an American citizen who has spent most of his formative years and professional career in economically underdeveloped countries. To date I have worked on major HIV related public health projects in Botswana, South Africa and China. I have also supported numerous other initiatives in an advisory capacity across other developing countries. I did my MD and MPH at Harvard and subsequently an MBA at Oxford as a Fulbright Scholar. I then worked for the New York office of McKinsey & Company as a management consultant prior to my current position in Botswana. I am one of the Founding Partners of BroadReach Healthcare, a company that assists developing countries, funders and institutions strengthen health systems and implement appropriate, scaleable HIV/AIDS treatment models using public-private partnerships.

Through BroadReach, I am hired by the Merck/Gates/Botswana Partnership (ACHAP) and then seconded into the Ministry of Health as the Operations Manager of Botswana's National ARV Treatment Program. ACHAP is a tri-partite partnership between the Bill & Melinda Gates Foundation, The Merck Company Foundation/Merck & Co., Inc. and the Government of Botswana. The Merck and Gates Foundations have contributed a total of US $100 million to Botswana, spread over 5 years, to assist the country to combat HIV/AIDS. In addition, Merck donates its antiretroviral medicines to the ARV treatment program.

In addition to a broad array of prevention, care and support programs, ACHAP was instrumental in launching, and currently supports, Botswana's ARV treatment initiative, called Masa, which is a Setswana word meaning "New Dawn".

Botswana, with a relatively small population of 1.7 million, was in the unenviable situation of having the highest prevalence of HIV in the world in 2001 with a staggering 38.5% of 15-49 year olds infected. Under the courageous and inspirational leadership of President Festus Mogae, Botswana decided that treatment with antiretroviral drugs (ARV therapy) in the public health system should be introduced as a matter of policy to address this emergency.

The Government of Botswana approached ACHAP for assistance in establishing a National ARV treatment program. The first step was to conduct a detailed de-

mand and supply analysis and to develop an implementation strategy. The services of McKinsey & Company were commissioned to assist a joint team consisting of Ministry of Health personnel, ACHAP staff and McKinsey consultants, who conducted a 2.5 month detailed assessment of:

1. How many people would require ARV therapy (demand).

2. Based on that number, how well was the country prepared to service this demand (supply).

3. The resources that would be required to fill gaps in the healthcare delivery system.

4. The optimal implementation model and approach based on organizational, political and contextual realities on the ground.

The assessment revealed that there were approximately 300,000 HIV infected people in the country, of whom approximately 110,000 would require ARV therapy based on eligibility criteria of either CD4 count of <200, presence of an AIDS defining illness (regardless of CD4) or being an HIV positive child. The assessment also revealed significant deficits in capacity to meet such a demand.

The feasibility study culminated in a strategy document which explored and detailed a roadmap for how the Ministry of Health could build the requisite capacity and scale up of treatment. The national ARV Project team then developed a detailed implementation plan addressing the main areas requiring capacity/capability build-up which included:

- Policy, planning and project management (central and facility level).
- Information, Education and Communication (IEC) and community mobilization.
- Training of health professionals (in ARV therapy, IT, laboratory, counseling, project management, monitoring & evaluation, operational research).
- Staff recruitment and retention.
- Drug logistics (procurement, storage, distribution)
- Laboratory and testing logistics.
- Information technology for nation-wide tracking and monitoring of patients, laboratory samples and medication utilization.
- Procurement and upgrading of space.
- Monitoring, evaluation and operational research.

The national treatment program began in January 2002 and in 27 months has enrolled over 20,000 patients in 12 operating sites, of whom over 12,000 are on ARV therapy. The handout provides a detailed breakdown of patients by site. An additional 6000-plus patients are on ARV therapy in the private sector, making a total of over 18,000 people on ARV therapy in Botswana. This represents approximately 16.4% of all eligible patients on ARV therapy and makes Botswana the leading country in terms of proportion of HIV infected individuals on ARV therapy in Africa.

Overall, the program and the patients are doing remarkably well. Follow-up rates are above 90%, adherence rates above 85%, 85-90% of viral loads are suppressed by 6 months, CD4 levels are increasing and patients with wasting regain weight and people are able to return to work. Overall mortality after initiation is only 9% despite the average CD4 count of the patient population still being very low (about 81). In the largest treatment center in Gaborone, doctors reported a 50% decrease in hospital ward occupancy when the site reached the 3,000 patient level (that site currently has almost 5,000 on ARV therapy). This decrease was likely due to the fact that the initial cohort of very ill patients accounted for a disproportionately high number of hospital readmissions. Perhaps most heartening is the fact that there is a palpable elevation in the level and amount of dialogue about HIV in the general population and facilities are reporting an increase in the number of people who are coming forward and willing to get tested *prior* to becoming critically ill.

The program is currently operating in 12 sites across the country and our plan is to scale up to all remaining district and primary hospitals (each with 2-4 associated satellite clinics) this financial year. When fully rolled out, there will be 32 operating ARV sites in the country.

Current cost per patient for drugs and diagnostics ranges between US $580 to $1,580 per patient per year depending on the specific drug regimen prescribed. To date, the Merck/Gates/Botswana Partnership has spent about US $12 million on the ARV program. Over 90% of the overall program costs are supported by the Government of Botswana.

Areas of support include:

Category	Merck/Gates/Botswana Partnership (ACHAP) Support
Needs assessments and establishing systems, policies and guidelines	ACHAP funded development of the initial ARV therapy feasibility study with McKinsey & Company
Management support	ACHAP has provided the Operations Manager, seconded to Ministry of Health
Drug logistics	Merck donating Stocrin (Efavirenz) and Crixivan (Indinavir)
Recruitment of staff	ACHAP has committed a total of 66 health workers and IT positions
Training	ACHAP funding the National ARV training through KITSO and Preceptorship Programs
Information, Education and Communication (IEC) and Community Mobilisation	ACHAP has provided IEC consultant and IEC Officer and funded development of all IEC materials
IT system	ACHAP has seconded an IT specialist and funded the rollout of an interim IT solution, and provided computers to sites and project office
Laboratory and testing	ACHAP has funded CD4 and VL testing equipment in the National Reference Laboratories
Space Procurement and upgrading	ACHAP has constructed 4 treatment centers and funded the expansion of space at 16 satellite clinics

Despite the significant gains made in initially launching a national treatment program, we realize that we can not yet begin to congratulate ourselves because some significant challenges still remain, namely:

- The burden of disease is unprecedented and large (with a need to reach close to 40% of adults with treatment) and the geographic distribution of the population is wide.
- Most people in country (including patients) still do not know their HIV status and only present for care at a very late stage (with advanced disease).
- There is still a large initial burden of very sick patients with extremely high "resource intensity". These patients take up a disproportionately large amount of health worker time leading to queues, which in turn can lead to a situation of perpetually insatiable demand.
- There are significant staff shortages, and patient mobility makes it difficult to train staff across the country in a timely rate.
- Civil society, NGO and CBOs lack adequate capacity to absorb the role of providing necessary supportive psychosocial and social welfare programs for patients, meaning that most of the burden falls on government.
- Maintaining high adherence levels as the patient population gets larger (and less critically ill) will be a challenge.
- Ensuring drug supply security is always a priority, and will become more challenging with additional end-point distribution sites.
- Management and communications across a broad array of internal and external stakeholders.

The program has now been running for a little over two years and one of the key success factors has been the ability to learn lessons and quickly readapt strategies as necessary. The key lessons we have learned to date include the following:

1. Capacity/capability build-up following a sigmoid rather than linear curve. Exponential growth (scale-up) in patient enrollment only after initial capacity is developed (like a compound interest curve). This is largely due to the fact that, as the program begins:

- There are few trained staff (providers, assistants, administrators, etc);
- Those staff who have been trained are still "green";
- Newly trained staff see fewer patients per unit of time than an experienced and tenured staff member; and
- The initial cohort of patients who come forward is very sick and more complex (CD4 <80)—these patients require 5-10x the amount of time and effort compared to that for patients with a CD4 closer to 200.

Treatment volume expectations must therefore be tempered and managed carefully.

2. A phased rollout, if too slow, can result in the initial sites being overwhelmed. This excessive demand can lead to "perverse" resource buildup at a few sites at the expense of rolling out to new sites closer to where people live. In addition, the fewer the sites, the longer the distance patients have to travel for routine visits and this increases the risks of non-adherence.

3. Each new site experiences the same "teething problems", as such, there is little to be gained by slowly scaling up. The best strategy is to spread as widely and quickly as possible after the initial "pilot" sites.

4. Training is one of the most critical rate limiting steps to scaling up. Despite receiving classroom-based training, most sites could still not commence service provision. The most rapid and efficient mechanism of activating new sites is to provide onsite HIV specialist preceptors (doctors and adherence nurses), usually from the US or Europe (where there has been a long experience using the drugs) to provide hands on training and management support for a period of 3-6 months while the site gets on its feet. The Debswana Mining Company, the largest employer in Botswana, began their treatment program (private sector) prior to the National program and addressed their training needs through telemedicine where decisions of health workers on the ground were consulted, ratified and supported by an expert clinician panel based in South Africa. This innovative model has proved successful and helps to overcome a rate-limiting lack of clinician trainers by providing the ability to leverage one HIV/AIDS expert clinician over a large number of on-the-ground providers through technology.

5. The pre-ARV opt-in testing mindset, procedures and protocols were creating a functional bottleneck to people receiving timely access to life saving services. The only way to rationally manage demand for treatment and implement effective prevention programs is to ensure that as many people as possible have been tested and know their status. In Botswana testing rates are still low with less than 10% of the population knowing their HIV status. This is largely due to the fact that until recently, ARV therapy was not available and, as such, people had little incentive to test and know their status. This scenario is a key driver of patients presenting only after they fall critically ill. Other drivers are fear, stigma and the natural tendency for people to wait until they feel unwell before seeking health services. Testing is therefore the most critical entry point for ARV therapy and associated care and prevention services. The point of testing provides direct access to positive and negative individuals and allows targeted interventions to be administered. Botswana has therefore become the first African country to implement routine opt-out testing on a national level, starting with health facilities. Routine opt-out testing will supplement the opt-in VCT efforts in an attempt to reach as many people as possible before they are critically ill. This will enable the provision of supportive services and therapy and avert the current situation where the majority of patients have completely lost their livelihood even if they eventually end up successfully on therapy.

6. The sickest patients (and those previously on treatment in the private sector) come forward first, and even at relatively small numbers, overwhelm the system. Almost 2 years into the program, the average CD4 count of patients at entry into the program is about 80 (during the first year it was between 50-60). The time and resource intensiveness associated with addressing the needs of such critically ill patients is estimated to be 5-10 times that of patients who are not yet critically ill and are initiated closer to a CD4 count of 200 (eligibility criteria). Over 90 percent of our patients do well despite being initiated at such a late stage of the disease. However, the result is that an unacceptably long queue begins to grow. The situation is further exacerbated by the natural triage that occurs at facility level. Health workers triage the sickest of the sick to the front of the line on any given day, creating a *de facto* lower CD4 eligibility criteria for actually accessing therapy. If these dynamics are allowed to persist,

ARV therapy becomes "emergency" therapy resulting in an effort-intensive race to save the patient, and resulting in a higher potential for adverse outcomes and increased mortality. The ideal scenario is for all HIV positive people to have CD4 tests and be monitored until the time it is appropriate to start them on therapy, at which point they would have received all the necessary counseling and would be in much less danger of "succumbing to the queue". So, in addition to routine opt-out testing, the solution has been to split the queue, with specific days and/or times reserved for those with higher CD4 counts (identified from the database) and other days open to the normal first-come, first served patients (where patients with very low CD4 counts and/or critically ill can still access care). In this way, more patients can be enrolled per unit of time and can be prevented from ever having to first become critically ill inpatients in the hospitals (at which point most have lost their livelihood).

7. The bulk of work associated with implementing an ARV program is not the initiation of patients on ARV therapy, but rather the high levels of adherence and compliance required. Since patients will spend the majority of their time in the community, it is dangerous to over-emphasize the creation of brick and mortar healthcare infrastructure at the expense of building systems that track and monitor patients as they move between the health facility and their community and across different geographies. For any new program that is about to start, the highest priority and bulk of initial effort should go towards establishing a robust and reliable patient tracking and Monitoring and Evaluation (M&E) system. With this in place, it allows a country many degrees of freedom in experimenting with different models of service provision (community outreach worker models, traditional wheel and spoke "network" referral models, observed therapy models etc) with the reassurance that any negative deviations will be quickly identified and remedied. The most fundamental tenet of ARV therapy is that the health professional knows who their patient is and can monitor what is happening with them.

8. Public private partnerships can help accelerate implementation by acting as key "catalysts" for action, and by providing money which is "faster and more flexible" than that spent by governments. The Merck/Gates/Botswana Partnership's "secondment" model—through which key technical expertise has been introduced to supplement the Ministry of Health's management capacity—has proved particularly effective. Not only does this model allow for an unprecedented level of co-responsibility, mutual monitoring and early problem identification, it allows for real skills transfer to occur between the seconded experts and local staff.

9. There are no easy solutions to the human resource shortages. Botswana does not have a medical school and, as such for doctors and certain other key cadres of staff, the country is dependent on expatriate labor. Most expatriates do not speak the language meaning that a large proportion of nurse time is spend doing interpretation. The global market rates for staff and lucrative opportunities presented by development partners in the local market make it difficult to attract top talent at current public sector rates.

10. Although critical and fundamental for success, money is but one of a series of numerous bottlenecks of increasing complexity that must be overcome if ARV therapy is to be offered successfully. Other equal, if not more important issues to be addressed, are to do with availability of leadership, management, political will (especially important is the streamlining of bureaucracy), information for policy and planning, accountability, and ultimately local capability and capacity (human resources, skills, equipment, infrastructure and systems). All these elements are essential for the ARV supply chain to function and deliver a consistent reliable service.

With the broader global epidemic in mind, it is clear that governments cannot fight this battle alone. All sectors and individuals must play an active role. The natural tendency for governments is to focus on developing, building and utilizing only public sector capacity. However, a holistic and non-judgmental assessment often reveals numerous potential sources of significant untapped capacity in the private sector (including private sector doctors, hospitals, laboratories, etc), NGOs, CBOs, civil society, the faith-based sector, and the community at large. The Merck-Gates Partnership (ACHAP) has clearly demonstrated the "catalytic" value of tapping into non-traditional private sources of skills, expertise and money. It has also demonstrated a feasible and viable mechanism through which the tremendous skills and resource base of the private sector can be leveraged for public good in a results-oriented fashion.

The burden of disease in most countries is such that no sector is likely to be able to address the complexities single-handedly. Looking continent wide, it is clear that traditional models and linear thinking will never overcome this epidemic. Patients must be empowered and equipped to participate maximally in their own care. New mutually enriching partnerships and innovative models must rapidly be deployed and the appetite to take risks must be increased dramatically. This can be done safely if built on a foundation of sound management, monitoring, evaluation, accountability and true ownership by countries.

Availability of treatment has introduced hope in an environment that had adapted to death and despair. Not only does availability of treatment save lives, there is strong anecdotal evidence that it provides concrete incentives and entry points for meaningful prevention programs and behavior change. We have an opportunity to capitalize on this link. A combination of strict results orientation coupled with willingness to explore new approaches that stretch our comfort zone will give us a realistic chance of turning the tide against this devastating disease.

Thank you for your time and consideration.

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2. ACHAP, Ministry of Health and McKinsey Feasibility Study.
3. ACHAP Monitoring and Evaluation Unit research and abstract data.
4. Botswana-Harvard Partnership research and abstract data: Wester et al. *Preliminary Analysis Of Toxicity And Tolerability Among The First ARV Treatment Naïve HIV 1c Infected Persons Of The Botswana National ARV Treatment Program,* Paris 2nd *IAS Conference On HIV Pathogenesis, And Treatment 13-16 July 2003.*

The National Antiretroviral Therapy Program Botswana (*Masa*): Program Statistics

Presented as Part of Testimony by Ernest Darkoh, (MD, MPH, MBA), Operations Manager of Botswana's National ARV Program (*Masa*) Before the African Subcommittee U.S. Senate

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Submitted by

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I. Patient Enrollment

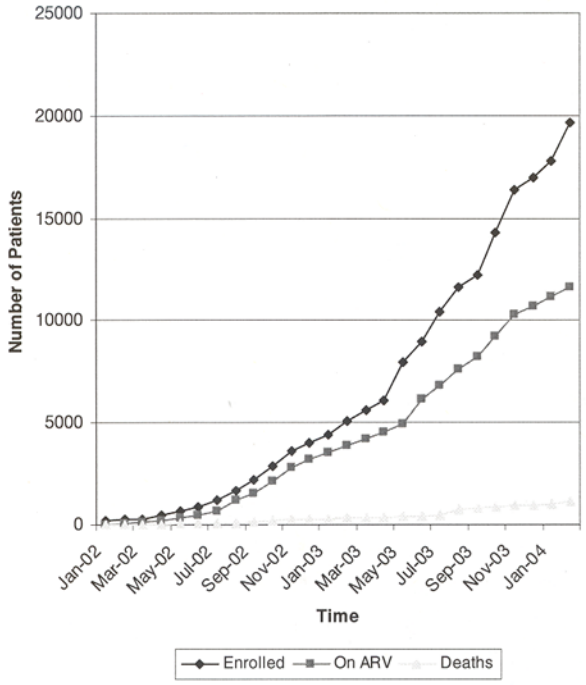
Table 1: Patient Enrollment Update (as of February 23, 2004)

Site	Launch Date	Tested with: CD4<200 or AIDS Defining Illness or children	Patients on ARV	Deaths on ARV	% Death on ARV
Gaborone	Jan 21, 2002	9,366	4,834	490	9%
Francistown	May 13, 2002	4,182	3,040	243	7%
Serowe	May 13, 2002	2,324	1,384	139	9%
Maun	July 10, 2002	1,265	838	137	14%
Jwaneng	April 1, 2003	870	448	27	6%
Orapa	May 1, 2003	447	262	16	6%
Tutume	Oct 8, 2003	254	177	19	10%
Molepolole	Oct 9, 2003	264	115	8	7%
Mahalpye	Oct 13, 2003	462	419	22	5%
Kanye	Oct 23, 2003	241	143	5	3%
Total Public		**19,675**	**11,660**	**1,106**	**9%**
Private Sector (AFA, BOMAID & Debswana)			6,139		
Public+Private Total			**17,799**		

Source: Botswana National ARV Team Statistics, AFA, BOMAID and Debswana communications

I. Patient Enrollment (continued)

Chart 1: Graphical Representation of Patient Enrollment Statistics (as of February 23, 2004)



Source: Botswana National ARV Team Statistics, ACHAP M&E Unit and Botswana Harvard Partnership Abstract Data

II. Program Results

Table 2: Results of Key Program Statistics

Monitoring Statistics	
Indicator	**Result**
Female:male	64:36(%)
Median baseline CD4 count	86
Median CD4 increase after 15 months	220
Mean weight gain after 15 months	10 kg
Patient follow-up	>90%
Adherence (zero tolerance)	85%
Toxicity requiring medication switch	< 7%
Complete VL suppression after 6 months	85%
Deaths after treatment initiation	9%

Source: Botswana National ARV Team Statistics, ACHAP M&E Unit and Botswana Harvard Partnership Abstract Data

III. *Masa* Clinical Protocols

Table 3: *Masa* Drug Regimens

Drug regimens	
Therapy	**Components**
1st line male & post-menopausal	Combivir + EFV
1st line pre-menopausal women & children	Combivir + NVP
2nd line	DDI + D4T + Nelfinavir
3rd line	Ritonavir + Saquinavir

Table 4: *Masa* Patient Diagnostics Protocol

Diagnostics per patient	
Test	**Frequency in 1 year**
Viral load	4
CD4	4
Chemistry	4
Hematology	4
Hepatitis	1
Syphilis	1
Resistance	0

Senator ALEXANDER. Thank you.

Dr. Oguda, welcome.

STATEMENT OF DR. LULU OGUDA, RETURNED VOLUNTEER AND FIELD DOCTOR, REPRESENTING DOCTORS WITHOUT BORDERS/MÉDECINS SANS FRONTIÈRES, CAMBRIDGE, MA

Dr. OGUDA. Thank you, Mr. Chairman and Senator Feingold, for this opportunity.

My name is Dr. Lulu Oguda, and this afternoon, I'd like to share with you my perspective as an African physician who has been providing treatment for people with HIV in sub-Saharan Africa. I'll focus on my experience as a volunteer with Doctors Without Borders/Médecins Sans Frontières, MSF, in Malawi.

Malawi is one of the poorest countries of the world. It has 11 million inhabitants and an HIV prevalence of 15 percent. I worked there as a field doctor in Chiradzulu district where 25,000 people are living with HIV, 5,000 of whom are in urgent clinical need of antiretroviral treatment, ARV, or they will die.

Before ARV treatment arrived in Chiradzulu, there was an atmosphere of despair. People with HIV had no hope. They simply waited for death. In the district hospital, wards were so crowded, you would have two to three patients assigned to one bed, so you'd find the patients in the bed and under the bed. I'll never forget seeing my patients like that. If you've not witnessed such a scene, you simply can't imagine it.

In 2001, all this changed with the arrival of the ARVs in our program. Although it was not easy getting started, the benefits to the patients were amazing to witness. We saw farmers going back to their fields, teachers started to go back to school, families were going back to churches. Generally, the spirit of the community was uplifted.

But there were challenges. In the beginning, our treatment protocol required our patients to take at least 6 to 8 pills each day. Second, only physicians could prescribe and monitor ARV therapy. We were only three physicians in the whole district. We could not possibly attend to all our patients.

This meant that we were only able to enroll 20 patients on ARV treatment in a month. Today, with the same number of physicians, the program is providing treatment for more than 2,500 people. We're enrolling 250 new patients every single month.

In order to achieve this scale-up, we learned we had to simplify, adapt, and decentralize our approach. We set up mobile clinics at each of the 10 health centers feeding to the district hospital. We delegated responsibilities for basic patient care and followup to nurses and the clinical officers. We trained community counselors, including people with HIV, to carry out treatment literacy and adherence support.

Clinical results from our project in Malawi are encouraging today in parallel to what was found in wealthy countries. At 12 months, the probability of survival is 88 percent. The CD4 count increase is at least at 192 cells, and the median weight gain is 4 kilograms, about 9 pounds. The average adherence rates of 90 percent even exceed those in wealthy countries.

Our fundamental tool in simplifying, adapting, and decentralizing the program was the introduction of triple fixed dose combination, the FDCs. Today, approximately 70 percent of the patients in this program are taking one of the World Health Organization recommended FDCs. The availability of these FDCs made the lives of our patients easier.

Taking just 2 pills a day, one in the morning, one in the evening, facilitated adherence, encouraging better clinical outcomes and potentially reducing the risk of resistance. In addition, we were able to quickly train our nurses and clinical officers to administer the standardized ARV treatment at the health center level and help alleviate the massive human resource constraint we were facing.

It was easier now to project program needs and to procure our FDCs compared with the single drugs, all coming from different companies, requiring different transportation and coaching requirements, among other things, and this really reduced the risk of stuck-outs.

Finally, the price of these FDCs, available only from the generic manufacturers due to the patent barriers, is the lowest of any ARV cocktail in the world. As little as $140 per person per year, which is four times less expensive than the single pills from the brand name producers.

This certainly does not mean that the FDCs are the answer to all of our problems. In order to face the next generation of operational challenges, we urgently need new tools, such as affordable and simplified second-line drugs and diagnostics.

In our experience globally, MSF is currently providing ARV treatment for about 12,000 patients in 20 countries. Adapting our clinical approach and using the FDCs was the most critical in scaling up our own programs, and we feel this is a lesson, a useful lesson to share with governments and various international initiators, including the President's Emergency Plan for AIDS Relief, who are focusing on scaling up.

That's why it's quite bewildering to listen to the debate over the past few weeks about FDCs. I have heard some U.S. Government officials claim that generic AIDS medicines are not the same as the generic drugs sold in the United States, and they won't tolerate Africans being subjected to drugs not approved for use in the United States.

As an African doctor, who has personally treated hundreds of patients with HIV with these FDCs and witnessed my patients return from death's door, I find these assertions appalling.

The WHO has certified that these FDCs meet stringent international standards for quality, safety, and efficacy. They did so through a prequalification system of drug regulatory experts from North America and Europe to inspect the manufacturing sites and establish bioequivalence. This system is being utilized and respected by all key actors, except the United States, including the World Bank, UNICEF, and the Global Fund.

These sorts of arguments only result in depriving Africans with HIV of affordable easy-to-use treatment. This could also lead to the creation of disruptive and parallel systems which will confuse Ministries of Health, health personnel, patients, undermine the con-

fidence of existing programs, and waste scarce resources on more expensive brand name medicines.

The consequences of all this could mean we prolong and improve one life instead of four. From a medical ethical point of view, this is intolerable. Millions of lives are at stake and we really don't have the luxury of time, not in Malawi and not anywhere.

Thank you very much for your time.

[The prepared statement of Dr. Oguda follows:]

PREPARED STATEMENT OF DR. LULU OGUDA

Ladies and gentlemen, my name is Dr. Lulu Oguda, and I would like to share with you my perspective as an African physician that has been working to provide treatment for people with HIV/AIDS in sub-Saharan Africa, with a particular emphasis on my experience as a volunteer for Doctors Without Borders/Médecins Sans Frontières (MSF) in Malawi.

Malawi is a country of 11 million people, bordered by Mozambique and Tanzania to the north and Zambia to the west, with an HIV prevalence of 15%. It is one of the poorest countries in the world. HIV/AIDS is the leading cause of death in Malawi among people adults 20-49 years of age. In the program that I worked in as a field doctor for one year, in Chiradzulu district in the south, over 20% of women in antenatal clinics test positive for HIV. Twenty-five thousand people—one fifth of the population—are estimated to be living with HIV/AIDS, and 5,000 of them are estimated to clinically require antiretroviral (ARV) treatment now or else they will die.

It is difficult for me to paint a picture of what Chiradzulu was like before ARV treatment arrived without making it sound like a caricature. There was a mixture between despair and anticipation. People with HIV/AIDS had no hope; they just thought they would die, but they were beginning to hear that ARVs would soon be available at the hospital. One patient of ours named Fred Minandi said:

> When I was sick then, I knew I had HIV, but I would never admit it or speak about it. Speaking about it would have not changed anything for me except making me depressed. My neighbors were seeing me becoming weaker and weaker every day. Of course, they all knew what I had, but nobody asked me. They just gradually started to not come see me. Most of the people are like that in Malawi: they don't speak because they don't want to know. It is why my country is dying in silence.

Health workers, many of whom were HIV positive themselves, were desperate, looking at the wards full of people they could do nothing for and not wanting to get their hopes up that ARVs would really come. Sometimes the wards in the hospital we worked in were so crowded you would have two or three people for each bed. It is an 80-bed hospital with an average daily occupancy of 200 patients. If you have not seen such a scene yourself, you simply cannot imagine it.

Then, in 2001, all this changed with the arrival of ARVs in our program in Malawi. Although it was not easy getting started, the benefits to our patients were amazing to witness. After approximately one year on treatment, Fred said:

> I had 107 CD4 cells [medical indicator from a blood test for the body's natural resistance capacity to infections] when I started the treatment and today I have got 356 CD4 and I am very proud. Today, I am back in my field, back in my church. I can feed my family. I used to harvest only about two bags of maize for the past years because I was too weak. Now I am talking of harvesting 10 bags of maize just this year alone. I feel I have a future. My neighbours started coming to see me again like before.

At first, our first-line treatment protocol was AZT/3TC/nevirapine or AZT/3TC/efavirenz. Patients would take six to eight pills each day, not including additional pills they may have needed to take for the treatment or prophylaxis of opportunistic infections. The program has always provided treatment for free.

We also had to draw up eligibility criteria for enrollment in the program, because there were so many more people that needed treatment than we could accommodate at the time. First, we enrolled patients with advanced HIV disease (World Health Organization stage 3 or 4) and CD4 counts of less than 200/ml of blood. In addition to the medical/clinical criteria, patients had to be within two hours' walking distance from the hospital, so that they could make it in for appointments. But this was too stringent—people were coming from hours away to get treatment and we

knew it—so we made it six hours. Imagine: a person with HIV co-infected with tuberculosis and an immune system so weakened getting out of bed was a struggle, having to walk six hours to get to the hospital.

Although there were only expatriate doctors working in the hospital at the time and we could not possibly see all the patients who needed to start ARVs, only physicians could prescribe and monitor ARV therapy. We were enrolling an average of 20 patients per month.

Today, MSF is able to provide treatment for more than 2,500 people in Chiradzulu, and we are enrolling 250 new patients in the program every month. In 2003 alone, the number of patients on ARV treatment increased by 420%. There are several factors that have enabled us to rapidly scale up access to ARV treatment in this district. Beginning in August 2002, we simplified, adapted, and decentralized our approach.

We simplified treatment protocols by minimizing pill burden; adapted our clinical approach to suit the prevailing conditions in the district, meaning that we reduced the complexity of the inclusion process and started relying less on sophisticated laboratory tests; and decentralized the point of care from the hospital to health posts in rural areas while taking better advantage of the skills and resources of existing health care professionals such as clinical officers and nurses.

We have set up mobile treatment clinics at each of 10 primary care health centers in the district, facilitating greater access to treatment in remote, rural communities. In effect, rather than asking patients to walk six hours to get their treatment, we are bringing it to them at the community level. Services at the health centers include voluntary testing and counseling with on-site rapid HIV tests, management of opportunistic infections, and treatment with ARVs including adherence counseling.

Basic patient care and follow-up is delegated to nurses and health workers for medical monitoring and community counselors, including people living with HIV/AIDS, for education, adherence support and treatment literacy. The project follows uniform guidelines for treatment and minimizes use of laboratory tests, which facilitates access to care and treatment even for the most vulnerable people in this remote area where there are few doctors and even fewer laboratories. In many cases, treatment begins after a positive HIV test and clinical assessment by trained staff. We measure CD4 count at baseline and every 12 months, and have reduced reliance on biological follow-up tests, performing Hemoglobin and liver function tests, for example, on clinical indication only. Viral loads are not performed on an individual basis. Difficult cases are referred to the district hospital.

Clinical results from Malawi are encouraging. The probability of survival at 12 months is 88%. Average CD4 increase among our patients is 192 cells/ml at 12 months, and the median weight gain is 4 kg at 12 months. The adherence rate of our patients is high, averaging approximately 90%.

Our fundamental tool in simplifying, adapting, and decentralizing the program has been triple fixed-dose combinations (FDCs) of ARVs—three different ARV drugs taken in the form of one pill, twice a day. Approximately 70% of patients in the Chiradzulu program are taking the World Health Organization (WHO)-recommended fixed-dose combination of d4T/3TC/nevirapine for their first-line regimen.

The availability of these FDCs has made the lives of our patients easier—taking just two pills a day facilitates adherence, which encourages better clinical outcomes and reduces the risk of resistance. It has also enabled nurses and clinical officers to administer standardized ARV treatment at the community health post level, and made training of on-ground personnel easier. It is easier to project program needs and procure FDCs compared with single agents with different transportation and cold-chain requirements, which lowers the risk of stockouts. And, of course, the price of these triple FDCs, available only from generic manufacturers because of patent barriers, is the lowest of any ARV cocktail in the world. In Malawi, we currently pay approximately $240 per person per year, compared with a minimum of $562 if we were to purchase the same agents from originator companies. This is no small thing. It means we are able to treat two to three people rather than one with every $500-600 we allocate for the program.

This certainly does not mean that the FDCs we use are the answer to all of our problems. For example, for any of you who has ever tried to decide the paediatric dose of a drug that is available in capsule form, or had to watch the face of a child take horrible tasting ARV syrups, or try to divide up an unscored tablet, you will agree that paediatric treatment is a literal nightmare. Clinicians and care-givers, who are usually elderly grandmothers because children's' mothers and fathers have already died of AIDS, need to be able to have fixed-dose liquid formulations for infants and low-dosage or breakable FDC tablets for children. Likewise, we need a first-line FDC that can be used in both people co-infected with HIV/TB and women

of child-bearing age. We need affordable and simplified second-line drugs and simplified diagnostic tools to help monitor efficacy, detect treatment failure, and diagnose opportunistic infections, particularly TB in patients with HIV/AIDS. In order to face the next generation of operational challenges, we need these new tools and strategies.

But when you consider that a safe, effective, and affordable first-line treatment, which is easy-to-use could be prolonging millions of lives—not just thousands—it is a medical ethical imperative to make it more widely available to humans in peril as urgently as possible. And this is not a job that MSF has the capacity or mandate to do; that responsibility rests with governments.

That is why I am truly bewildered by the debate I have been hearing over the past few weeks about FDCs.

I have heard US government officials claim that the generic AIDS medicines, including FDCs, which are being used by MSF and others are not the same as "generic drugs" sold in the US and are sub-standard. But the World Health Organization (WHO) has certified that numerous medicines from both generic and brand-name companies, including generic FDCs, meet stringent international standards for quality, safety, and efficacy through a prequalification system that borrows drug regulatory experts from North America and Europe to inspect manufacturing sites and establish bioequivalence and is utilized and respected by all key actors, including the World Bank, UNICEF, and the Global Fund to Fight AIDS, TB and Malaria. In fact, these medicines are manufactured by the same pharmaceutical labs that produce hundreds of generic medicines used by Americans every day.

I have heard US government officials say that there are no agreed upon principles for evaluating FDCs, and that without the approval of the US Food and Drug Administration (FDA) or a similarly stringent regulatory authority they cannot be proven safe or effective. But in 2000, the FDA approved a brand-name triple combination therapy, GlaxoSmithKJine's Trizivir, on the basis of bioequivalence data, the very same data WHO has reviewed to certify the generic FDCs we use. There were no clinical trials conducted to compare the individual compounds with the fixed-dose combination.

I have heard US government officials assert that use of these drugs could create resistance, which would be a disaster for the continent of Africa. Unfortunately, drug resistance is inevitable and, indeed, disastrous. It is something we are deeply concerned about as well. But this has nothing to do with the question of FDCs. In fact, it seems to me that if the US is concerned about resistance, it should be doing everything possible to ensure that FDCs are used—since they promote adherence, the key to delaying the onset of resistance—that communities are mobilized to carry out treatment education and adherence support, and that future FDCs are developed urgently so that when resistance does emerge, patients have viable treatment options.

Finally, I have heard US government officials say that they will not tolerate a different standard for Africans. As an African doctor who has personally treated hundreds of people with HIV/AIDS using these medicines and witnessed my patients' spectacular return from death's door, I find this particularly appalling. It is simply untrue that generic FDCs are substandard. These sorts of baseless assertions will only result in depriving Africans of affordable, easy-to-use treatment; setting up disruptive and parallel systems, which will waste precious resources, confuse patients, and undermine confidence in existing programs; undermining national policies and protocols in African countries; and wasting money on "brand name" medicines, despite the fact that the difference in price will mean prolonging and improving the life of one person instead of four.

That is intolerable.

Millions of lives are at stake.

* * *

APPENDIX

GENERAL BACKGROUND INFORMATION

In the developing world today, over 40 million people are living with HIV/AIDS. Of the more than six million people in urgent clinical need of ARV treatment, only 400,000 have access to it, and one-third of them live in one country, Brazil. An estimated 8,000 people die each day of AIDS-related complications. These are premature, avoidable deaths.

Currently, MSF is providing ARV treatment as part of a comprehensive continuum of care for over 11,000 people living with HIV/AIDS in more than 20 coun-

tries in Africa, Asia, Latin America, and Eastern Europe. MSF is an international medical humanitarian organization with field operations in nearly 80 countries and the recipient of the 1999 Nobel Peace Prize.

We have learned important lessons about both the benefits and challenges of providing ARV treatment in resource-limited settings and are in the process of adapting our approach to AIDS treatment to better fit the real-life conditions faced in developing countries. Our projects are using treatments with fewer pills, relying less on sophisticated laboratory tests, taking better advantage of the skills and resources of existing health care professionals such as clinical officers and nurses, and decentralizing the point of care to district hospitals and health posts.

In addition, we have produced several reports, some of which are joint publications with the World Health Organizations (WHO), UNAIDS, and UNICEF, to help other providers of ARV treatment—including governments, non-governmental organizations (NGOs), and community-based organizations—identify sources, prices, and patent status of needed medicines and assist with strategies for efficient procurement of medicines. We have also participated actively in the development of the WHO initiative to scale up treatment to at least three million people by 2005 ("3x5").

While our ARV treatment programs have had a significant impact on the individuals and communities with whom we work and have demonstrated the feasibility of providing ARV treatment in resource-limited settings, they are relatively small-scale, and we have neither the capacity nor the mandate to provide the wide-scale access to treatment that is so urgently needed. That responsibility rests with national governments.

We do, however, feel a responsibility to share our experience and impart the lessons we have learned in order to inform efforts to scale up access to treatment, including the United States President's Emergency Plan for AIDS Relief (PEPFAR). This is why we would like to highlight the following critical issues, which in our experience must be considered as utmost priorities as the US government begins to implement its PEPFAR:

- Simplifying treatment protocols, particularly by minimizing patients' pill burden;
- Decentralizing and adapting clinical approaches to treatment and monitoring;
- Decreasing the prices of medicines, ensuring efficient procurement of medicines, and making treatment available for free;
- Involving communities, including people living with HIV/AIDS, in treatment programs; and
- Promoting research and development for desperately needed new tools.

MSF'S AIDS TREATMENT EXPERIENCE

MSF has been caring for people living with HIV/AIDS in developing countries since the early 1990s. In 2000, MSF started to provide ARV therapy in addition to other services. Approximately 11,000 people living with HIV/AIDS, including nearly 500 children, are currently on ARVs in more than 20 countries worldwide. These countries include Burkina Faso, Burundi, Cambodia, Cameroon, China, Democratic Republic of Congo, Guatemala, Honduras, Indonesia, Kenya, Laos, Malawi, Mozambique, Myanmar, Rwanda, South Africa, Thailand, Uganda, and Ukraine.

MSF provides ARV treatment in both urban and rural settings, and in almost every project works within public sector health facilities—including primary care clinics/community health posts, district hospitals, and provincial hospitals—in collaboration with national, provincial, or district departments of health. Clinical eligibility criteria are, for the most part, uniform throughout MSF projects (<200 CD4 cells or 15% for children), though some projects are increasingly initiating treatment in very advanced patients on clinical grounds. In MSF projects, treatment is provided free of charge.[1]

Clinical outcomes in our projects are encouraging, and parallel those found in the US: patients' CD4 counts are increasing, they are gaining weight, and they are suffering from fewer opportunistic infections. Adherence rates are excellent, exceeding 90% in many projects. People are returning to work and again becoming productive members of their communities. In short, treatment is transforming the face of AIDS.

MSF does not offer ARV treatment in a vacuum, so we aim to integrate treatment into a continuum of care that includes prevention efforts (e.g. health education, condom distribution, and prevention of mother-to-child transmission programs), vol-

[1] Except in Cameroon, due to government policy requiring entrance fee.

untary counseling and testing, treatment and prevention of opportunistic infections, nutritional and psychosocial support, and palliative care.

MSF expects the total number of patients treated in its projects to reach 25,000 in 25 countries by the end of 2004.

LESSONS LEARNED FROM MSF'S ARV EXPERIENCE

Although there are no simple formulas or models for providing ARV treatment, MSF has learned several clear lessons by delivering ARV in diverse settings, which could be helpful in designing and implementing initiatives aimed at scaling up access to ARV therapy, including PEPFAR. Below is a summary of some of the key lessons we have learned.

Simplify treatment

One of the most important tools in simplifying and adapting treatment is fixed-dose combinations (FDCs) of ARVs. Today, 50% of patients in MSF projects, and 70% of those newly enrolled, are taking triple FDCs as their first-line treatment. That is, patients are taking the three different ARV drugs they need in the form of one pill, twice a day. Taking a smaller number of pills per day facilitates adherence, which encourages better clinical results and also lessens the risk of drug resistance, as it is impossible to take partial doses. The FDCs MSF uses, which have been pre-qualified by the World Health Organization (WHO), are also the most affordable combinations available worldwide and have significant distribution advantages (procurement and stock management).

Decentralize and adapt

Treatment and monitoring protocols must be designed in a way that facilitates access even for the poorest and most vulnerable people in remote settings where there are few hospitals, few doctors and even fewer laboratories. In several MSF projects in Africa, including those in Malawi, Kenya, Mozambique, and South Africa, basic patient care and follow-up is being delegated to nurses and health workers (for medical monitoring) and community counselors (for education, adherence support and treatment literacy). MSF follows uniform guidelines for treatment minimizing use of laboratory tests; in many projects, treatment begins after a positive HIV test and clinical assessment by trained staff. More difficult cases are referred to district hospitals. In Chiradzulu, Malawi, this approach has allowed the number of patients under treatment in the district to rise quickly, to a rate of 250 new patients each month.

Decrease the price of medicines and ensure availability even for the poorest

The lower the price of medicines, the more patients can be treated and the more sustainable treatment is in the long term. Globally, the prices of AIDS drugs have dropped by over 98% in less than three years (see graph attached). Under certain circumstances, WHO prequalified FDCs cost less than $140[2] per person per year. These FDCs are available only from generic manufacturers due to patent barriers. In MSF's experience, crucial factors in bringing about lower prices for ARVs include government commitment to centralized procurement, overcoming patent barriers when necessary, and fostering generic competition. Come 2005, when most World Trade Organization (WTO) member states will have to become compliant with the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), generic production of patented medicines will rely upon compulsory licensing; therefore, flexible conditions for granting compulsory licenses must be in place. The right of countries to use this and other TRIPS-compliant public health safeguards is currently under threat, particularly in regional and bilateral trade negotiations launched by the US with a number of countries and regions heavily affected by HIV/AIDS. On a related note, the cost of treatment for the patient should never be a barrier, and that means treatment will have to be free for the majority of patients. The cost of drugs is frequently cited as a reason for treatment interruptions.

Involve the community

The knowledge and meaningful participation of people living with HIV/AIDS is key to the success of treatment. At its HIV clinics in Khayelitsha, South Africa, MSF and grassroots treatment advocates have fostered community-based education programs. Through carefully designed patient-centered adherence programs (not directly observed therapy), people on ARVs in MSF programs have the support of their peers and of trained counselors. Community mobilization, in partnership with medical services, has had a powerful effect on the community, decreasing stigma

[2] Due to negotiations with genetic manufacturers brokered by the Clinton Foundation.

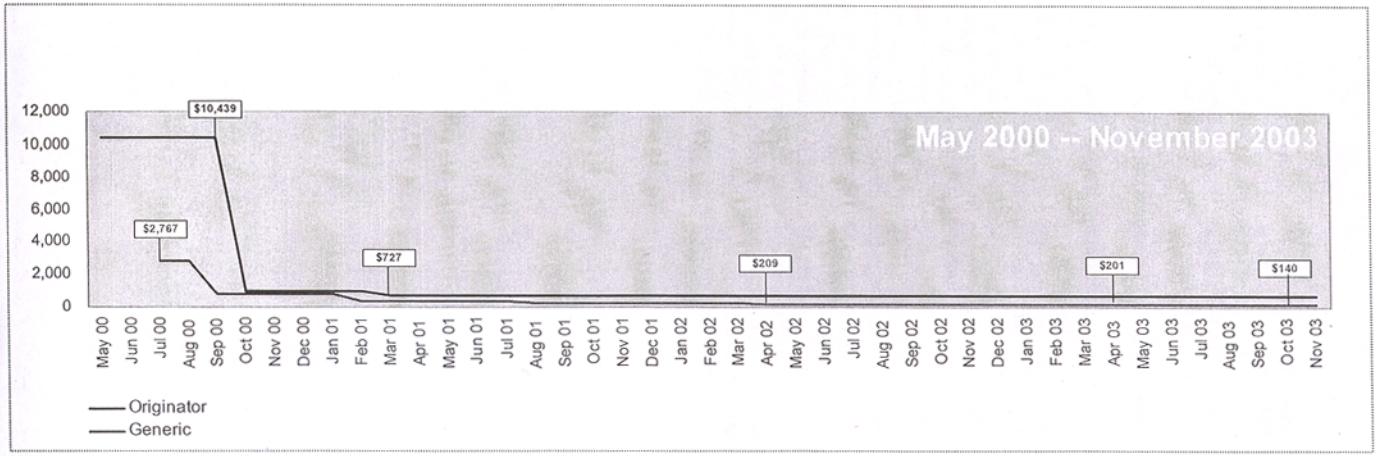
and discrimination, and supporting prevention efforts. In Khayelitsha, there have been significant increases in the distribution and use of condoms, the number of sites providing voluntary counseling and testing, and the uptake rate of testing. According to a study conducted by the Center for AIDS Development, Research and Evaluation (CADRE) and the South African Department of Health, the self-reported condom use at last sexual intercourse, willingness to use a female condom, and consent to an HIV test in the Khayelitsha community is the highest in South Africa.

Urgently promote research and development of new tools

It will not be possible to solely base scaling-up efforts on existing tools. New tools and strategies for treatment will have to be developed urgently. For example, at present, ARVs are not well-suited for use by children, so fixed-dose liquid formulations for infants and low-dosage or breakable FDC tablets for children are needed. The pharmaceutical industry is not going to spontaneously fill existing and future gaps such as easy-to-use first-line treatments for children, simplified second-line treatments and simplified diagnostic tools (e.g. semi-quantitative tools to measure CD4 and viral load). The public sector, with leadership from WHO, should therefore seek to define and lead the work on this research agenda. This needs to be a part of the overall U.S. global AIDS strategy. There is also an urgent need for operational research, for example on pediatric treatment, management of HIV/TB co-infection, ideal second-line regimens, and structured treatment interruptions. Furthermore, we will not be able to face the next generation of operational challenges without new tools and strategies: these challenges include the inevitable development of resistance to first-line drugs; the need for new strategies for monitoring efficacy and detecting treatment failure, particularly as we reduce reliance on lab monitoring; the price and practicality of second-line drugs; the management of side effects; and the role of prevention of mother-to-child-transmission (pMTCT) using monotherapy in the era of ARVs.

Graph 1

The Effects of Generic Competition:
A first-line antiretroviral (ARV) triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP).
Lowest world prices per patient per year (in US$).



Senator ALEXANDER. Thank you, Dr. Oguda, for your comments and for being here.

Dr. Darkoh, would you have any comment on what Dr. Oguda just said about the drugs?

Dr. DARKOH. Well, I think we are in a slightly different position to most countries, because we started our program essentially 2 years before therapy became "in fashion," and in fact, a lot of the veritable agencies that have been mentioned at the time actually came out formally against us at that time, saying that they did not support treatment.

So, we were really on our own when we had to make these decisions, and at that time, it was definitely a situation where there was very little good information out there as to which way to go.

Now, Botswana had already had its procedures in place for drug procurement and had a lot of good standing relationships with many different companies. Botswana does use generic medications for certain disease conditions. However, with ARV therapy at that time, it was not felt that there was enough information to actually make a decision to go with generics, especially keeping in mind that we're thinking about lifetime therapy and the need to have as many options as possible for people going forward.

Now, fortunately, Botswana was not as cash constrained as most other African countries and therefore could afford to basically buy the brand name drugs at the time. Now, there have been significant price reductions, but still I say it would be out of reach for most other countries that would be considering something similar.

Now, this said, we therefore, to simplify things, we made sure that we had first, second, third line of therapy, and there's a national mandate that all patients, be it public or private, must be initiated on a government regimen to basically ensure that we see the same patterns of resistance emerge when they emerge, and then on a country-wide level, we can make changes as necessary to the regimens.

In principle, we are for basically drugs being as cheap as possible, but I guess the only thing I would add as a little bit of a caution is that in Botswana, we were in the maybe somewhat unique situation that we actually had money available to buy these drugs.

We still face the same challenges of getting people enrolled, and I would hope that in this debate at the end of the day, we in Botswana would really like to learn from programs that have experience using FDCs. What I'm hearing, it sounds like something we definitely need to look at, but I'd also really, really like to caution the fact that in most countries, the systems just do not exist to make sure that whatever drugs we provide will reach patients.

And to me, I think our biggest lesson has been that, despite having money, despite being able to get the drugs, the challenges still do remain very significant.

Senator ALEXANDER. We can go back to that subject. Maybe Senator Feingold will, too. But may I ask a somewhat different question of both of you?

What about volunteer help? Americans have a tremendous instinct to volunteer to help, and in Africa, I've met a number of people who are there to help, some obviously being a great help. Doc-

tors Without Borders is a wonderful example of physicians who try to help in the world.

And so, one of my first instincts was, well, why don't we have a USAIDS Corps where we find some efficient way to gather up all the volunteerism instincts that we have in this country and channel people to Zambia or to Botswana to fit into whatever you're doing and relieve the burden, either for training people or for counseling people or for doing whatever needs to be done.

But I got a lot of different responses to that. Some people said, well, that's pretty expensive to do, to find somebody here and fly them all the way over there. Others would say short-term volunteer help wouldn't be of very much value, long-term help would be.

Are there any suggestions that either of you could give to us about how the U.S. Government or the private sector could supplement the work that you've been doing by finding a way to channel more individuals from this country, whether in health care or in related fields, who would volunteer to help in what needs to happen in the next 5 years?

Dr. DARKOH. OK. I'll start with that. I think there's a clear role for volunteerism, and I think it is necessary as a facilitating step toward building capacity in countries in Africa.

I would, though, however, urge thinking in the direction of very targeted reasons and very specific groups of volunteers who are brought into accomplish goals, such that they leave something sustainable.

For myself personally, having spent most of my formative years in Africa and having lived in quite a few different African countries to this point, I guess what concerns me the most is that after 40 years of NGOs, development assistance, the World Bank loans, et cetera, Africa's worse off now than it was 40 years ago, and I think we do seriously need to rethink the model and manner in which we do provide "assistance" to countries and make sure that the—I like the fact that you've been stressing results orientation during this hearing—that even from that perspective, when we do provide resources, it does yield a tangible meaningful, but somewhat maintainable result.

Now, I do not believe that anything in life is truly sustainable. I mean, someone pays for it one way or another, but for that matter, I think what we have seen quite a bit of in Africa is a very, very severe syndrome of lack of ownership and therefore projects and programs collapse immediately after the donor sort of exits, and therefore, in our particular program, for example, we have the preceptorship model, and also, for example, even physicians like myself, it is by definition a short-term position.

I am currently transferring skills to a local counterpart who will take over. Our preceptorship model is people who come in for a short term and their specific job is to get that site offering ARV therapy, but we don't keep them there forever.

Now, that says you need to bring in people with the right skills, the right temperament, who can basically work in this environment and actually be productive, but I do believe in a model whereby, as much as possible, we should over time make sure that countries can do this for themselves.

Senator ALEXANDER. Dr. Oguda.

Dr. OGUDA. Thank you. I'll limit my answer to HIV programs in this particular instance. I do agree with what my colleague has said. Yes, expert expatriates do jet in and out of Africa, stay there for like 3 months, but they don't really leave anything that is tangible, that is sustainable.

Unfortunately, because there's not much transfer of skills and knowledge, this leaves the staff on the ground more dependent on the aid and on the expatriates. The next expatriate coming in does not leave them with any sense of ownership or power.

With the UNICEF programs, what we have done is we work within the public system. Immediately we get into the country, we work with the Ministry of Health, such that a doctor such as me who has worked with antiretroviral therapy will work alongside another doctor from that country, a clinical officer, in the same ward.

I will not be working in a different hospital, not in a different clinic, not in a different lab. In the same ward that that national staff member is used to working in and transfer my skills, adapting to the local prevailing situation.

I think volunteers are very important. If we can get skilled volunteers to go to Africa and transfer these skills, it will be very important, as long as our volunteers, as he said, are willing to adapt to the situation.

Thank you.

Senator ALEXANDER. Thank you.

Senator Feingold

Senator FEINGOLD. Thank you, Mr. Chairman. Let me ask a couple questions. First, I'll have Dr. Oguda respond and then Dr. Darkoh, if I could.

First, Dr. Oguda, can you tell me what led the MSF to decide that fixed dose combination medicines are safe and effective? You started to talk about that a bit. Do you believe that there should be a different standard for making this determination for large-scale versus small-scale programs?

Dr. OGUDA. When we started the ARV programs, we started off with a brand name, the brand name drugs, but we realized it was too costly and we had to save lives.

So, MSF headquarters approached the WHO and asked what can we do to hasten this process to provide these generic drugs in the field because we had to save lives. I believe that's how the prequalification system was set up, and basically, the WHO, with the pharmaceutical and medical doctors from North America and from Europe, visited the manufacturing sites with some representatives from MSF, too, visited the manufacturing sites, saw how the drugs were being made, tested the competence of the drugs and found them safe.

They got back equivalence data which they used. I do believe that the FDA has also approved some drugs based on bioequivalence data, such as Trizivir, the fixed dose combination. Thus the change in the brand drugs to the generic drugs—but realize, no, there is no difference. There's actually no difference.

The side effects reported by the manufacturing companies are the same side effects that will be reported by the brand name companies. So, if you're anticipating anemia from a drug like AZT, whether it's coming in the form of Combivir or it's coming in the

form of duavir, it's anemia, you still have to treat with the same drug.

No, I do not believe that different standards should be set up for different programs, whether it's a small program or large program. I think if the drugs work, let's get them out there to the patients.

Senator FEINGOLD. Dr. Darkoh, do you think different standards should apply for different size programs with regard to this point?

Dr. DARKOH. I, in principle, do not, but I do realize that necessity at times may dictate your actions as opposed to necessarily what you may believe in principle. If you're faced with a dying patient, you'll use whatever is necessary, and I think—I mean, we've seen the number of people, for example in Botswana who, prior to ARV therapy being available, would go for all manner of traditional remedies in many cases that would end up being very toxic, especially with liver and kidney toxicity, but, I mean, when you're desperate, you'll try anything.

That said, I do think that there is a role for there to be a body that actually does this for all of us as opposed to expecting each individual country to set up quality assurance and quality control labs, et cetera.

Now, how that is arrived at, and I'll be very frank, I mean, obviously there's a lot of politics and interests and agendas. But I think regardless of how we arrive, and that is the natural process of life, but how we arrive there quickly such that we can basically receive guidance from, call it an authority that we all agree that will abide by the quality data that comes out of it and be reassured enough that there is enough rigor.

One thing I do know from implementing a program my size is that when things do go wrong, nobody stands up to say I was the person who said that. So, I think it's important that for this one we really think about what's in the best interests of patients and make sure that that always remains central in our thinking and then hopefully come to some sort of consensus around this.

We can receive information that is of an acceptable nature whereby the endorsement is really as complete as you can get and that we can all be accountable for whatever happens later.

Senator FEINGOLD. Dr. Oguda, I consider your detailing of MSF's experience providing antiretroviral therapy in resource-poor settings to be one of the really important moments of this hearing.

Dr. OGUDA. Thank you.

Senator FEINGOLD. First to you, as you listened to the discussion about U.S. efforts to scale up treatment programs, what strikes you as the most dangerous potential pitfall of our effort? I'd like Dr. Darkoh to answer the same question.

Dr. OGUDA. Thank you. I sense that the number of patients who receive treatment will probably be not as large as the plan managers are hoping and that probably is because of the prohibitive costs of the treatment regimens that are being selected. That to me seems the biggest pitfall.

Senator FEINGOLD. OK. Dr. Darkoh.

Dr. DARKOH. For me, the biggest pitfall would be rolling out the program without the requisite systems in place to actually make sure that things work.

In my experience, I think one of the biggest deficits that we found is that risky systems just don't work and that's across the board and those have an impact. The question I always ask people is if you were told right now to deliver aspirin to 40 percent of the population or pick whatever you want, give a clean glass of water and make sure that people drink this twice a day, just a clean glass of water, freely available, how would you do that?

I think you need to approach it from that perspective and say we need to put in place systems that ensure that at the end of the day, you can deliver what you want to deliver, but, more importantly, because of adherence and resistance-related concerns, follow and track what is going on with the patients.

Senator FEINGOLD. One more question for both of you and then I'll be concluded, Mr. Chairman.

I'll start with Dr. Darkoh. Are you concerned about the prospect of the international community poaching more and more of the trained health workers from domestic health system as we scale up the world response to HIV/AIDS, and, if so, what do you recommend we do to address that problem?

Dr. DARKOH. I am concerned. It is an area where—well, the human resource problem we have been facing in our program is twofold. One is that people know what their rate is in the global marketplace. Many of the health professionals in Africa in fact have been trained abroad. So, when you come back to Africa, you know what you could be making if you're still back in the U.K. or in the U.S. So, that's challenge No. 1.

Challenge No. 2 is that when you do get back into your environment, I think the natural human tendency is to look for the best opportunities possible, and in many cases, when external agencies come in, they do offer better terms than the local conditions.

Now, that creates internal market dynamics that are extremely disruptive to being able to maintain a high quality in particular public sector service. What happens then is the best people from the public sector end up being poached or leave the system in search of more lucrative deals within either the private sector or within the development partner world and that adds—more money flows in as more initiatives get launched, and we see this mushrooming of initiatives in countries.

My fear is that we'll end up in a situation where already systems that were being held together by a very fragile balance will actually crumble and fall apart. We've experienced this quite significantly in Botswana and you feel—I'm always torn because doctors come to me and say, will you write me a recommendation, and I know this is our site manager from a particular site, and in reality, I cannot tell them don't do it because they have a family and children to maintain. But on the other hand, I know that what this is going to mean for the program will be quite detrimental.

So, recommendation-wise, one thing we as ACHAP have very specifically done is when we do hire staff, we strictly keep them on the government pay scale so we exactly match the government terms, conditions, schemes of service, et cetera, when we hire staff, and that has helped somewhat in terms of making sure also that those staff can be owned later, once we depart, but it's definitely not been my consistent experience with all other agencies.

Senator FEINGOLD. Dr. Oguda.

Dr. OGUDA. Thank you. When I was working in Zambia, we had a meeting and discussed this issue. Zambia was training 20 doctors in a year. They have only one medical school. They were training 20 doctors each year, and they were retaining 3 doctors out of the 20 they trained. Why? Doctors were moving to greener pastures. South Africa, Botswana, the U.K., the U.S.

It is a big problem, and it's inevitable because of poverty and the economics. Doctors want to move from—and nurses, too, clinical officers. They want to move from the rural area to the urban area. They want to move to places where they know their children can go to school. There are hospitals. Those are the basic facts of life.

I would suggest that if programs are going to be set up for one, let's not set up parallel programs. Let's try and work within the existing structures. If we can use the money that we would spend setting up parallel programs to upgrade what we already have, I believe that will be money well spent.

Second, I think in this instance, like for ARV treatment, we can start using lower health staff. We don't have to have a physician to start a patient on antiretroviral therapy. We don't have to have a lab technician to do an HIV test. Let's train those community health workers how to do the test. They are doing it in Zambia with the MSF program. We trained them. This is how you do the rapid test for malaria. This is how you do the rapid test for HIV. Train lower types of health personnel.

Third, because of economics, definitely health personnel will want to move from the government system into the NGO system. Perhaps it's the time for donors and individual governments to think about topping up those health personnel salaries. Instead of hiring one more expatriate, taking out one doctor from the health system to hire him as an expatriate, top off the doctors' salaries there. Let them stay there and let the individual governments deal with the other issues.

Senator FEINGOLD. Mr. Chairman, let me thank you and this excellent panel very much.

Senator ALEXANDER. Thank you, Senator Feingold, for your leadership and your interest.

I do want to thank the panel. This has been a very useful day for me and I think for all those watching and listening. We especially thank you, Dr. Oguda and Dr. Darkoh, for your hard work helping people and your willingness to come talk to us about it. We invite you to let us continue to hear from you as time goes on. We'd like to have your opinions and your views as we try to spend this $15 billion to help as many people as we possibly can.

This hearing is adjourned.

[Whereupon, at 5:01 p.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

ADDITIONAL STATEMENT SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF GLOBAL AIDS ALLIANCE

GLOBAL AGREEMENT REACHED ON GENERIC AIDS MEDICATIONS—WILL PRESIDENT BUSH USE TAXPAYER DOLLARS WISELY IN FIGHTING AIDS?

Washington (April 6)—A breakthrough plan to provide safe, generically-manufactured AIDS medication to poor countries around the world was announced today by the Global Fund, WHO, UNICEF, and the Clinton Foundation.

The announcement was made just as Ambassador Randall Tobias, President Bush's Global AIDS Coordinator, prepares to testify Wednesday April 7 before the Senate Foreign Relations Committee. Programs funded through his office are not permitted to purchase generic medications.

"The President's unilateralism is forcing our partners abroad to combine forces" noted Dr. Paul Zeitz, Executive Director of the Global AIDS Alliance. "To fight AIDS they know they must counter a policy based on ideology, not practical solutions. It's tragic that President Bush's approach to AIDS is another example of how unilateralism can hurt American leadership. We need to work together to stop AIDS. We call on President Bush to allow purchase of generics and stop trying to cut funding for international agencies that use them, like the Global Fund."

"The World Health Organization's goal of ensuring 3 million people have access to AIDS medication by the end of 2005 is now a step closer to reality," stated Zeitz. "Meeting WHO's goal is essential to preventing the orphans crisis from worsening. Now it's time for President Bush and Ambassador Tobias to get with the program, or else risk wasting US tax dollars. This plan is simply tremendous news for countries fighting AIDS, and it's exactly the kind of leadership that's needed."

The global agreement announced today is a powerful challenge to President Bush's ideological insistence that US global AIDS programs buy brand-name AIDS medication. Many countries and programs have been alarmed at the public health impact of this aspect of Bush's AIDS plan. Now the US government has an opportunity to join the international community in a coordinated response, rather than keep pursuing a US go-it-alone strategy that was causing delay and confusion in the US response to AIDS.

The Global Fund and WHO played important roles in brokering the agreement announced today. President Bush has proposed cutting the US contribution to the Fund by 64%, and he has not responded to appeals to increase US contributions to WHO.

Last week Senators McCain, Snowe, Chaffee and Kennedy, as well as Representative Waxman, wrote to President Bush to urge he join an international consensus that generics are in fact safe and essential to reaching the President's goals for expanding treatment for people living with AIDS.