

**THE UNITED STATES GOVERNMENT STRATEGY
FOR FIGHTING HIV/AIDS:
IMPLEMENTATION OF PUBLIC LAW 108-25**

HEARING
BEFORE THE
**COMMITTEE ON
INTERNATIONAL RELATIONS
HOUSE OF REPRESENTATIVES**

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

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THURSDAY, MARCH 4, 2004

HOUSE OF REPRESENTATIVES,
COMMITTEE ON INTERNATIONAL RELATIONS,
Washington, DC.

The Committee met, pursuant to call, at 10:41 a.m. in Room 2172, Rayburn House Office Building, Hon. Henry Hyde (Chairman of the Committee) presiding.

Chairman HYDE. The Committee will come to order. Good morning, and welcome to this morning's hearing of the Committee on International Relations.

The purpose of our hearing is to receive testimony from, and ask questions of, Ambassador Randall Tobias, the newly-appointed Global AIDS Coordinator, on the comprehensive 5-year global strategy to fight AIDS, as required by Public Law 108-25, the "United States' Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003."

The Members of this Committee crafted this law 1 year ago, and worked on similar legislation in this Committee in the 107th Congress. At last week's hearing on the United States' foreign assistance since September 11, Members of the Committee heard from a panel of witnesses who argued in favor of establishing a national foreign assistance strategy to guide and measure effectiveness of the myriad of United States foreign aid programs.

As I stated in my opening statement last week, strategy is defined as the science and art of using all the forces of a nation to execute approved plans as effectively as possible, during peace or war.

As the Members of this Committee are well aware, AIDS is an issue that transcends traditional political boundaries. On May 1 of last year, H.R. 1298, the "United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003," passed the House by a vote of 375 to 41, and passed the Senate in July 2003 by unanimous consent. New political alliances have been established by the need to confront HIV/AIDS with bold action.

There is no question that our government must do everything possible to reverse the swath of destruction brought on by the virus that causes AIDS. The question at this point is how do we accomplish that objective. By what means will the forces of our nation be employed to execute Public Law 108-25 as effectively as possible.

At today's hearing I don't seek to articulate partisan differences with any of the general principles presented by the document reported to Congress last week. I also do not seek to reopen old debates on the politics of HIV/AIDS.

Instead, I seek an objective evaluation of the strategy reported to Congress to ensure it sets the U.S. in the right direction to fight this pandemic.

The 5-year global strategy reported on February 23 articulates 16 general principles, including the following.

We will respond with urgency to the global HIV/AIDS crisis.

We will fight HIV/AIDS worldwide.

We will actively seek new approaches.

We will use a new leadership model.

We will demand accountability for results.

We will employ the prevention lessons learned from the ABC model.

And we will maintain our own focus while coordinating with other partners.

These are fine principles. But how will the existing programs of the Agency for International Development be modified in order to achieve real results? How will Ambassador Tobias influence and redirect the bureaucracy in order to provide treatment to people living with HIV/AIDS? How will new organizations, like small NGOs, and especially faith-based organizations, be encouraged to participate in United States HIV/AIDS prevention, treatment, and care activities?

Will contractors continue to implement the lion's share of USAID's HIV/AIDS activities? Will the new model of centralizing program design at the country team level work? How will the Administration handle the complex issue of fix-dosed combination therapy? Will the Administration allow implementing partners to purchase off-patent drugs? Will implementing partners be able to pursue drugs not manufactured in the U.S.? What about countries not on the focus list? Is there any room for more countries on this list?

The document transmitted to Congress on February 23 is not a comprehensive 5-year global strategy on how to implement Public Law 108-25. It is, instead, a political document that articulates general principles that guide the President's initiative to administer a program of assistance for 15 focus countries.

The document transmitted to Congress last week is an elaboration of the President's emergency plan for AIDS relief, announced in the 2003 State of the Union Address. The goals of that initiative are by now well known: To provide treatment to two million HIV-infected people; to prevent seven million new HIV infections; and to provide care to 10 million people infected and affected by HIV/AIDS.

But the document reported last week lists these as goals for the emergency plan's 15 focus countries only. The strategy does not make clear whether the President intends to furnish assistance authorized under Public Law 108-25 to other countries with high HIV prevalence in a manner that is both global and comprehensive.

By relegating non-focused countries to USAID, does this mean business as usual in the remaining 60 or so countries? Does this

mean there will be no treatment programs in countries in Europe, Asia, and South America, continents with countries, with the exception of Guyana, not represented on the President's list of 15 countries?

What about other countries in Africa not on the list, such as Zimbabwe, with its 34-percent prevalence rate?

The document reported to Congress states that funding levels for focus countries will be allocated on the basis of 5-year strategic plans. And that funds will be released upon approval of annual country operational plans by the U.S. Global AIDS Coordinator.

What is the timetable for the development of these 5-year country plans? When will the coordinator determine how much funding shall be made available to each of the countries?

These are but a few of my questions about the strategy, and I don't expect answers to all these questions today. But they *do* need to be addressed as we proceed to implement this program.

In sum, I must confess some disappointment with this document. It does not meet, in my judgment, the requirements of section 101 of Public Law 108-25. It is neither global nor comprehensive.

Before you is a copy of section 101, the provision of the HIV/AIDS law that requires the development of a comprehensive 5-year strategy. I hope Members of this Committee will carefully evaluate the President's report to Congress against the information required by section 101.

With that said, I look forward to today's discussion. And I now recognize my friend and colleague, Barbara Lee, who is sitting in for the distinguished Ranking Democratic Member, Tom Lantos. Ms. Lee.

[The prepared statement of Mr. Hyde follows:]

PREPARED STATEMENT OF THE HONORABLE HENRY J. HYDE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS, AND CHAIRMAN, COMMITTEE ON INTERNATIONAL RELATIONS

Good morning, and welcome to this morning's hearing of the Committee on International Relations. The purpose of today's hearing is to receive testimony from and ask questions of Ambassador Randall Tobias, the newly appointed Global AIDS Coordinator, on the comprehensive five-year global strategy to fight AIDS, as required by Public Law 108-25, the "United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003." The members of this Committee crafted this law one year ago and worked on similar legislation in this Committee in the 107th Congress.

At last week's hearing on "United States Foreign Assistance since September 11th," members of the Committee heard from a panel of witnesses who argued in favor of establishing a national foreign assistance strategy to guide and measure effectiveness of the myriad of United States foreign aid programs. As I stated in my opening statement last week, strategy is defined as "the science and art of using all the forces of a nation to execute approved plans as effectively as possible during peace or war."

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There is no question that our government must do everything possible to reverse the swath of destruction brought on by the virus that causes AIDS. The question at this point is how do we accomplish this objective? By what means will the forces of our Nation be employed to execute Public Law 108-25, as effectively as possible?

At today's hearing, I do not seek to articulate partisan differences with any of the general principles presented by the document reported to Congress last week. I also

do not seek to reopen old debates on the politics of HIV/AIDS. Instead, I seek an objective evaluation of the strategy reported to Congress to ensure it sets the United States in the right direction to fight this pandemic.

The five-year global strategy reported on February 23rd articulates sixteen general principles, including the following:

- We will respond with urgency to the global HIV/AIDS crisis.
- We will fight HIV/AIDS worldwide.
- We will actively seek new approaches.
- We will use a new leadership model.
- We will demand accountability for results.
- We will employ the prevention lessons learned from the “ABC” model.
- We will maintain our own focus while coordinating with other partners.

These are fine principles. But how will the existing programs of the Agency for International Development be modified in order to achieve real results? How will Ambassador Tobias influence and redirect the bureaucracy in order to provide treatment to people living with HIV/AIDS? How will new organizations—like small NGOs and especially faith-based organizations—be encouraged to participate in United States HIV/AIDS prevention, treatment and care activities? Will contractors continue to implement the lion’s share of USAID’s HIV/AIDS activities? Will the new model of centralizing program design at the country team level work? How will the Administration handle the complex issue of fixed-dose combination therapy? Will the Administration allow implementing partners to purchase off-patent drugs? Will implementing partners be able to purchase drugs not manufactured in the United States? What about countries not on the “focus” list? Is there any room for more countries on this list?

The document transmitted to Congress on February 23rd is not a comprehensive, five-year global strategy on how to implement Public Law 108–25. It is, instead, a political document that articulates general principles that guide the President’s initiative to administer a program of assistance for 15 focus countries.

The document transmitted to Congress last week is an elaboration of the President’s “Emergency Plan for AIDS Relief,” announced in the 2003 State of the Union Address. The goals of that initiative are by now well known: to provide treatment to two million HIV-infected people; to prevent seven million new HIV infections; and to provide care to 10 million people infected and affected by HIV/AIDS. But the document reported last week lists these as goals for the “Emergency Plan’s 15 focus countries” only. The strategy does not make clear whether the President intends to furnish assistance authorized under Public Law 108–25 to other countries with high HIV prevalence, in a manner that is both global and comprehensive. By relegating non-focus countries to USAID, does this mean business as usual in the remaining 60 or so countries? Does this mean there will be no treatment programs in countries in Europe, Asia or South America—continents with countries (with the exception of Guyana) not represented on the President’s list of 15 countries? What about other countries in Africa not on the list, such as Zimbabwe, with its 34 percent prevalence rate?

The document reported to Congress states that “funding levels for focus countries will be allocated on the basis of five-year strategic plans,” and that “funds will be released upon approval of annual country operational plans by the U.S. Global AIDS Coordinator.” What is the timetable for the development of these five-year country plans? When will the Coordinator determine how much funding shall be made available to each of the countries?

These are but a few of my questions about this strategy. I do not expect answers to all of these questions today, but they do need to be addressed as we proceed to implement this program.

In sum, I am disappointed with this document. It does not meet the requirements of Section 101 of Public Law 108–25. It is neither global nor comprehensive. Before you is a copy of Section 101, the provision of the HIV/AIDS law that requires the development of a comprehensive, five-year strategy. I hope members of this Committee will carefully evaluate the President’s report to Congress against the information required by Section 101.

With that said, I look forward to today’s discussion, and I now recognize my friend and colleague, Barbara Lee, who is sitting in for the distinguished Ranking Democratic Member, Tom Lantos.

Ms. LEE. Thank you, Mr. Chairman. First, let me just thank you for your leadership, and for ensuring that addressing this HIV/

AIDS pandemic is not a partisan issue. It has been very important to work together on this. It is about saving lives. And I want to thank you for your leadership and thank you for this hearing today.

On behalf of our Ranking Member, Congressman Lantos, first let me just welcome Ambassador Tobias. I am looking forward to your testimony today. And also let me just thank my Democratic colleagues on the Committee for allowing me the opportunity to act today as Ranking Democratic Member in the absence of Mr. Lantos from this hearing.

Over the last 5 years we have, in many ways, revolutionized the United States' response to the global AIDS pandemic, beginning actually with the concept, the AIDS Marshall Plan, which the former Congressman Ron Dellums presented to many of us. Following up with the AIDS Marshall Plan, we put together the Global AIDS and Tuberculosis Relief Act of 2000, which was signed into law by President Clinton, which actually established the framework for the creation of the global fund to fight AIDS, tuberculosis, and malaria.

Of course, last year, under Congressman Lantos and Chairman Hyde's leadership, we passed the "United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003." So there has been a systematic focus and attempt to really step up to the plate, as the most powerful and wealthy country in the world, to address this huge, huge pandemic, which I must say is still with us, and will be for a while.

But it must be said, though, that our compassion for the millions who are afflicted with HIV and AIDS abroad really stems also from the fact that we have 20 years plus experience with AIDS here in the United States. And for me personally, understanding and working with the ongoing AIDS crisis among the African-American community especially in my district in Alameda County, has really put this in a very broad and global context.

So as we listen to Ambassador Tobias today, and as we roll out and expand our global AIDS program, we must also, I must say parenthetically here, that we must redouble our efforts here at home to provide those services, care, and treatment and prevention for those who are already affected, and with high-risk populations, and to really provide culturally-appropriate and comprehensive prevention messages and services to all who are potentially at risk.

Again, this is a global pandemic. But now let me just get to the heart of what we are here to discuss today, the 5-year strategy plan.

I must say right off the bat that I am somewhat disappointed also in the lack of real detail in this plan. It seems to dwell quite a bit and too much in generalities, and paints broad strokes that in many cases really do not deal with the reality on the ground.

Perhaps the most glaring fault in the strategy plan that needs to be addressed is the lack of a real specific focus on women. The document recognizes that gender inequality fuels the epidemic, and that specific interventions must be tailored to specific populations, including women. But the detail is practically non-existent.

In particular, there is no real direction behind efforts to reduce stigma and discrimination against women infected with HIV, nor

is there really much attention paid to the reality that the ABC prevention strategy, as currently laid out in this document, will be ineffective for many women at risk. Particularly in the case of young women who marry older men, as pointed out by the recent *New York Times* article on this subject.

And speaking of the ABC prevention message, it seems to me that your strategy plan takes a very narrow and very limited view as to when or where condom use will be promoted as part of an overall prevention strategy. Instead of advocating for the correct and the consistent use of condoms as part of a comprehensive primary prevention strategy, targeting the entire population, this report seems to be saying that education on the proper use of condoms and subsequent distribution efforts will only be targeted to groups that are identified as engaging in high-risk behavior.

And this idea, of course, for many of us seems to run completely contrary to the content of our own primary prevention programs here in the United States, and I would submit really does represent a significant backwards step in our efforts to prevent the spread of the disease.

Another issue of huge concern to many, and to me of course, is the ability of programs to utilize and dispense generic medications, including allowing the procurement of fixed-dose combinations as a way to reduce costs, and to increase drug adherence rates in resource-limited settings. In this case, it really seems to me—and I have had many discussions with individuals about this—it seems that we should be utilizing the existing drug recommendations of the World Health Organization, rather than seeking to reinvent the wheel.

I must also raise the issue of support for our global fund, and the ability of this organization to really—and this is what we envisioned when we put this together, was the global fund would be able to leverage funding from a variety of international and private donors. The Administration seems to be looking for, quite frankly, any excuse to really reduce our level of funding this year. And I want to stress that I believe this is the wrong approach to take.

We inserted, which I didn't agree with, but we inserted this, the requirement for U.S. funding to reach, at most, 33 percent of total contributions of last year's legislation, not as a way to contribute less, but it was my understanding for those that wanted that in was to really challenge other countries to contribute more. To that end, the Administration cannot view a contribution of just \$200 million as a ceiling, because that will only serve to discourage other contributions from other countries and private donors.

Finally, Ambassador Tobias, I want to speak very briefly on the pending issue of the 15th country that has yet to be named as part of our global AIDS initiative.

You and I have had a discussion on this topic. Many have been discussing it. And I raise the fact that when I visited India and witnessed the efforts being taken to address this pandemic, I realized that there are many, many difficulties in India. But that given the fact that the rates now are hovering around 1 percent, there is a real opportunity to develop a comprehensive approach to ensure that this pandemic doesn't explode.

But particularly within our funding constraints, I wasn't sure that including India in this plan, because of the huge amount of resources that it would take, would make sense. But rather, that if we act now by looking at a possible third wave, a strategy to address Russia, India, and China, perhaps that will be an initiative we need to look at to begin to look at how to prevent the possible explosion in these third-wave countries.

So I am hopeful to have further hearings on this subject. And that as we look forward to a more comprehensive examination of this 5-year strategy plan, we can continue to work together with you, with all of our organizations, with Chairman Hyde and this Committee, in a bipartisan way to provide oversight and accountability, and really thoughtfully address any gap or problems that you are faced with within our own initiative.

So I want to thank you, Mr. Chairman, and I look forward to your testimony, Ambassador Tobias.

Chairman HYDE. Thank you, Ms. Lee. I am informed that there are no other opening statements. I trust that is correct. Pardon? The gentlelady from California, Ms. Watson.

Ms. WATSON. I want to welcome Ambassador Tobias. I am here because I do want to be updated on our efforts to fulfill the provisions of the legislation. And I know it has changed from the time we heard it in the Committee. So I just want to let you know I am eager to hear your update. Thank you so much for coming.

Chairman HYDE. Thank you. Ambassador Randall Tobias currently serves as the Coordinator of the United States Government Activities to Combat HIV/AIDS Globally, where he is in charge of overseeing all U.S. international HIV/AIDS assistance.

He previously served as American Telephone and Telegraph's Vice Chairman, Chairman and CEO of AT&T International, Chairman, President, and CEO of Eli Lilly and Company, and Chair of the Board of Trustees at Duke University.

I am happy to inform Ambassador Tobias that I spent three happy semesters at Duke during World War II, and enjoyed it immensely.

Ambassador Tobias earned a Bachelor's Degree from Indiana University, where he has been awarded Honorary Doctor of Law Degrees by multiple universities, including Indiana and Wabash University.

We welcome you, and we are honored to have you appear before our Committee today. Please proceed with a 5-minute summary, give or take. We won't be too strict, but we would like to aim for 5 minutes. And your full statement will be made a part of the record.

Ambassador Tobias.

**STATEMENT OF THE HONORABLE RANDALL L. TOBIAS,
GLOBAL AIDS COORDINATOR, U.S. DEPARTMENT OF STATE**

Ambassador TOBIAS. Mr. Chairman and Members of the Committee, thank you all very much for the opportunity to appear before you this morning.

I also, before I begin, want to thank you for your interest in this issue, and your support and initiative in authorizing the legislation

that led to the establishment of this initiative, and the role that I have been asked to take on.

As you know, in the State of the Union Address a year ago, 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 5 years to address the global HIV/AIDS pandemic, more money than has ever been committed by any nation for any international health care initiative.

Nine billion dollars of the \$15 billion will go to new programs to address HIV/AIDS in 14 of the world's most affected nations, with a 15th focus country to be added in the next few weeks.

Those focus countries already account for approximately 50 percent of the world's HIV/AIDS infections. Five billion of the \$15 billion will go to provide continuing support in approximately 100 nations, where the United States Government currently has bilateral 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 by making the first pledge in May 2001.

Today President Bush's vision has become a reality. Last week, just 4½ months after we launched the office of the Global AIDS Coordinator, and less than 1 month after Congress appropriated the first funds in fiscal year 2004 funding, the President's Emergency Plan for AIDS relief announced the first release of funds, totaling \$350 million.

This money will go to scale up programs that provide anti-retroviral treatment; abstinence-based prevention programs, including those targeted at youth; safe medical practices programs, including safe blood programs; and programs to provide care for orphans and vulnerable children who have been the victims of this disease.

These target areas for initial funding were chosen because they are at the heart of the treatment, prevention, and care goals of President Bush's plan. Partners for these specific programs were chosen because these are organizations that have existing operations on the ground; they have a proven track record; and they have the capacity to rapidly scale up their operations and begin to have 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. Eight thousand people are dying every day, and urgency is incredibly important.

By initially concentrating on scaling up existing programs that have proven experience and measurable track records, that is exactly what we have begun to do.

With our next round of funding I expect to place an additional focus on attracting new partners, including more faith-based and community-based organizations, that can bring expanded capacity and innovative new thinking to this effort.

With just this first round of funds, an additional 50,000 people living with HIV/AIDS in the focus countries will begin to receive anti-retroviral treatment, which will nearly double the number of people who are currently receiving treatment in all of sub-Saharan Africa.

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.

The first tranche 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 focus countries in Africa and the Caribbean.

In addition to announcing this first round of funding, last week, as you have mentioned, I also submitted to this Committee and to other appropriate Congressional Committees a comprehensive, integrated 5-year strategy for the President's Emergency Plan for AIDS Relief.

Mr. Chairman, I note that you have made this strategic plan easily available on the Committee's Web site, and I thank you very much for that support in disseminating the plan so that as many people as possible have the chance to look at it and comment on it.

This strategic plan will guide us in deploying our resources to the 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 5 years of the plan, we will provide anti-retroviral treatment for 2 million people. We intend to prevent seven million AIDS deaths, and we will provide care to 10 million people who are infected or affected by the disease in the focus countries.

Now, some have questioned why we are establishing a new bureaucracy. But I would contend we are not. Because we are not starting from scratch.

Rather, where it is appropriate to do so, we are capitalizing on the existing core strengths of the United States Government, including established funding and disbursement mechanisms, 2 decades of expertise fighting HIV/AIDS in the United States and worldwide, and learning important lessons from that about what works and what does not. We are also capitalizing on our existing 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 these existing capabilities. A model that brings together, under the direction of the United States Global AIDS Coordinator, the programs and personnel of all the agencies and departments of the United States Government who are engaged in this effort.

The implementation of this leadership model is being translated to the field, where the United States Chief of Mission in each country is leading an interagency process on the ground to implement the policies and strategic direction that we have established here.

The Emergency Plan is built on four important cornerstones.

First, 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 done with the first \$350 million announced last week.

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

Third, by encouraging bold national leadership around the world in every country, and engendering the creation of sound, enabling policy environments in every country for combatting HIV/AIDS and mitigating its consequences.

And fourth, implementing strong, strategic information systems that will provide all of us with vital feedback and input to help direct our continued learning, and our identification of the best practices.

Within this framework we will strive to coordinate and collaborate our efforts to respond to local needs, which differ greatly from country to country; 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 NGOs, faith-based and community-based organizations, private sector companies, and others who can assist us in engendering new leadership and new resources to fight HIV/AIDS.

There is no doubt that this is one of the greatest challenges of our time. And it will require constant and concerted commitment from all of us to defeat it. The limits of what we can accomplish in eradicating HIV/AIDS and its consequences are defined, I believe, only by the limits of our collective moral imagination.

And what inspires me the most, as we embark on this effort, is the remarkable self-help already underway 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 their fellow community members in need.

With our support, we hope to amplify and sustain their efforts to combat the devastation. And that is why 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 that was able to happen.

Mr. Chairman, I am grateful for your and this Committee's resolve to defeating HIV/AIDS. Your leadership and support, in a very bipartisan way, has facilitated the speed with which we are responding to people in need. And that commitment, I believe, will help insure our success, success that will be measured in lives saved, in families held intact, and in nations moving forward with their own development.

Thank you very much, Mr. Chairman. And now I would be pleased to respond to any questions.

[The prepared statement of Ambassador Tobias follows:]

PREPARED STATEMENT OF THE HONORABLE RANDALL L. TOBIAS, GLOBAL AIDS
COORDINATOR, U.S. DEPARTMENT OF STATE

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 in the next few weeks. 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 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 has become a reality.

Last week, 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 go to scale up programs that provide anti-retroviral treatment; abstinence-based prevention programs, including those targeted at youth; safe medical practices programs, including safe blood 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 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 our next round of funding, I expect to place an additional focus on attracting new partners, including more faith-based and community-based organizations, that can bring expanded capacity and innovative new thinking to this effort.

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 anti-retroviral treatment, which will nearly double the number of people who are currently receiving treatment in all of sub-Saharan Africa.

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.

The first tranche 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.

Mr. Chairman, in addition to announcing this first round of funding, last week 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 anti-retroviral treatment for two million people;
 - We will prevent seven million AIDS deaths; and,
 - We will provide care to 10 million people who are infected or affected by the disease in the focus countries.
- 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 United 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.

The Emergency Plan is built on four cornerstones —

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 last week.
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.

Chairman HYDE. Thank you, Ambassador. Ms. Lee.

Ms. LEE. Thank you, Mr. Chairman. Thank you, Mr. Ambassador, for that very thorough testimony. And it does beg a couple questions.

First let me just ask you, with regard to the issue of condoms and how that fits into your whole strategy. I referenced *The New York Times* article in my opening statement that indicated that teenage brides in some African countries are becoming infected at higher rates than sexually-active unmarried girls. And the article indicated that the studies at this 2-day international meeting showed that there was an inadequacy in programs that focus on abstinence among teenagers as really a main source of preventing HIV and AIDS, because they fail to take into account the transmission of the disease in marriage.

I know that we have many spirited debates about just inserting the language of condom use as part of the strategy into the plan, but it did get in the overall legislation. And so I am wondering, in

your view with regard to the whole ABC approach, the type of priority that should be given to the distribution of condoms and prevention efforts, and in terms of targeted populations. How do you see condom distribution used, education, as it relates to total populations, rather than just a segment of a population?

Ambassador TOBIAS. Well, Ms. Lee, as you said, our prevention program is built on the platform of ABC. And that is a concept that originated in 1986, when President Museveni in Uganda began to take that approach.

I think the ABC approach is sometimes described from 30,000 feet, and people don't really get into the details of how all three of these components fit together. So if I might take a minute about that.

The A, or abstinence, begins with focusing with young people. And I think we all have to transport ourselves, which is difficult to do, into the environment in which the people that we are talking about live.

I was in a primary school in Uganda not very long ago, watching the program that they put into their assemblies twice a month. And these are young people whose mothers are dying, their fathers are dying, their teachers are dying, their aunts and uncles are dying. There is death all around them. And the first thing they have to be given is self-esteem, and they have to be made to understand that they can live, and that they can take their lives into their own hands.

And as they begin to become old enough to understand a more mature message, they are told how HIV/AIDS spreads. And they are encouraged to delay their involvement in sexual activity until they are in a committed relationship, or married.

The next component, or B, is being faithful within that marriage or committed relationship. But as you point out, an important aspect of B is that both partners be tested, and that they know their status. Because being faithful in a relationship that is discordant, where one partner is infected and the other is not, is, in effect, a program that over time will cause the other partner to get infected.

Ms. LEE. Or in monogamous relationships, which many, there are many.

Ambassador TOBIAS. Yes, yes. And then C is also an important part of the program for those groups, those targeted groups who are engaging in high-risk behavior, including those who choose to engage in high-risk behavior, and those who are forced to engage in high-risk behavior.

Now, one of the effective aspects of the program in Uganda is the emphasis that Uganda has placed on the status of women. Uganda is now ranked first among all African nations in having women who believe that they have the power to refuse unwanted sex, and to insist upon condom use. And this aspect of cultural behavior is a very important aspect of the overall program, without question.

Ms. LEE. But, Ambassador Tobias, I didn't quite hear, and I haven't seen in your overall plan, how the C aspect of the ABC initiative is being implemented through the legislation.

Ambassador TOBIAS. Well, the use of C will be focused on high-risk groups. We know, for example, from the Ugandan experience, that in 1995 6 percent of those sexually active reported the use of

condoms with some regularity. That increased, in spite of all of our efforts, and all the money and all the programs, that increased only 11 percent of those sexually active in Uganda by the year 2000.

Unless condoms are used correctly and consistently by those who are using condoms, the evidence suggests that that is not a strategy that is going to work. It is certainly a part of our overall program, but not focused on the broad population, but those who are engaging, whether they choose to engage or whether they are forced to engage, in high-risk sexual behavior. But it certainly is, it is ABC.

Ms. LEE. So you don't believe that entire populations are at risk, and that condom use could prevent entire populations from becoming infected.

Ambassador TOBIAS. Well, Ms. Lee, the evidence just simply does not support that that has been working. That is one of the things that we have learned. There is a recent Harvard University Public Health School study that provides a good deal of data on that. And if that is the basis of what we are relying on, I don't think the results are going to be any better than they have been in the years leading up to this point.

Ms. LEE. Thank you, Mr. Chairman. If we have another go-around of questions, I would like to pursue this.

Chairman HYDE. The gentleman from Colorado, Mr. Tancredo.

Mr. TANCREDO. Thank you, Mr. Chairman. Mr. Ambassador, I really have only one question here. And that is that—and I know this is going to sound somewhat hard-hearted and cruel, and all those things, but I have to ask you—and I realize also that the direction you take from the legislation we passed does require you to invest in both treatment and prevention activities.

But we also know that the ultimate goal of all of our efforts is to save lives. And so recognizing that, recognizing that everybody is committed to that one goal—saving lives—also recognizing that the dollars available for us in this endeavor are limited, that the numbers seem sometimes overwhelming, the number of people both infected and becoming infected every single day.

And so it just does make you wonder whether or not it isn't a more effective use of our resources to concentrate almost entirely on the prevention part of this thing. Really. I mean, even though our hearts go out for every single person who is infected, and we recognize that it is a humanitarian effort on our part to try to deal with that, if the goal is to save as many lives as possible, would we not be better served by concentrating on the prevention side of things? And thereby, in the future, saving far more people than we would be by dividing up those resources?

Ambassador TOBIAS. Congressman, that is an excellent question. That is a debate that has in fact been going on for some time. And until relatively recently, there really weren't many choices, because the only tools that were available were prevention tools. And it has only been really in the last few years that there have been other elements.

One of the unique aspects of this plan is the integration of treatment and prevention and care. And there is evidence to support the fact that in addition to treatment, being a humanitarian act on our part, to address the people who have been infected by this disease.

And with the treatment that is now available, it is possible to extend the lives of these people, and make them productive citizens long, long into the future.

But we are finding that the line between prevention and treatment blurs with the addition of treatment. Because prior to having treatment available, knowing one's status was essentially a death sentence. There are 40 million people in the world who are infected by HIV/AIDS. Estimates are as high as 95 percent of those 40 million people have not been tested, and do not know their status. And obviously that means many of them are spreading the disease unwittingly, without knowing it.

What we are seeing happen now is that as treatment is available, people are encouraged to go find out what their status is. And that helps to engage in the prevention effort.

There is no question that prevention has to be our number one priority. With 40 million people infected today, with estimates that by 2020, that as many as 100 million people will be dead if we don't do something more, we have got to stop the growth.

But I think that treatment and care are very appropriate elements of this plan, not only because they represent the best of our American humanitarian instincts—

Mr. TANCREDO. Yes, well, of course. We know that is what motivates us. I just don't know—

Ambassador TOBIAS. But I think it will also make a contribution to our prevention efforts.

Mr. TANCREDO. And that is because, as you say, that if the people who are receiving treatment, they become willing to identify, or to tell people with whom they have had contact, that they should seek it, that is primarily why you think—

Ambassador TOBIAS. I was in a very remote rural area in Africa a few months ago, in a village where a woman who was HIV-positive, who was quite thin and appeared to everyone to be dying, decided she would go to the clinic where ARV treatment was offered and get treated. All of her neighbors advised her don't do that.

She went to the clinic. She got on the program, and she started to get better. And as her neighbors could see that she was getting better, they said to themselves, we need to go to the clinic, get tested, find out what our status is, and if we need treatment, get on treatment.

Mr. TANCREDO. But how does that prevent—well.

Ambassador TOBIAS. Well, it prevents because the beginning point in prevention with adults is for people to know what their status is. That is a very important element here.

Mr. TANCREDO. Thank you, Mr. Ambassador. Thank you, Mr. Chairman.

Ambassador TOBIAS. Thank you.

Chairman HYDE. Mr. Brown.

Mr. BROWN. Thank you very much, Mr. Chairman, for having this hearing. Welcome, Ambassador Tobias, thank you for your good work.

Ambassador TOBIAS. Thank you.

Mr. BROWN. While passage of the U.S. Global AIDS Initiative was a major victory, in large part due to the hard work of Ms. Lee

and Chairman Hyde and a lot of the staff on this Committee, the real work has just begun.

As you know, I appreciate the leadership that you have already provided for us.

I want to talk a little bit about tuberculosis and HIV/AIDS. And you talked about HIV being a death sentence for so many millions.

TB and the intersection of TB and HIV/AIDS is in some ways the perfect storm of terminal illnesses if not treated. As you know, HIV is the most powerful known risk factor for reactivation of latent TB. As you know, approximately $\frac{1}{3}$ of all people in the world carry tuberculosis. And when you look at what, in fact, people, particularly in Africa, are dying, those that we think die of HIV/AIDS, somewhere between a third and a half are actually dying of TB.

Yet fewer than half of those with HIV and TB in the President's 14 targeted countries have access to TB treatment now.

Our ability to expand TB treatment to all those that are co-infected with TB and HIV could extend the lives of some 200,000 more people that are suffering from that.

Talk to us for a moment if your efforts to expand TB treatment, and linking these programs, counselling, testing, all that we need to do—what part of your efforts is that going to include?

Ambassador TOBIAS. Well, clearly there is, as you point out, Congressman, a very direct relationship between HIV/AIDS and TB, and for that matter, malaria.

I am a firm believer in focus. I think we need to principally stay focused on what we are trying to do here, because I think that is our greatest opportunity to make a big impact. And our focus is principally HIV/AIDS.

But having said that, if someone is suffering from HIV/AIDS and they also have tuberculosis, if we are not identifying and treating the tuberculosis or seeing to it that it is getting treated, we are not going to have much impact with our HIV/AIDS treatment.

So there are opportunities in TB clinics, there are opportunities in testing environments, where we are testing people for HIV/AIDS, to also test them for tuberculosis, or vice-versa, and to try to help get them under a treatment regimen so that both can be addressed.

That is also one of the important reasons why a collaboration with other organizations and other agencies and other sources of funding will be very important. Because while we won't have the wherewithal within this program to address everything that needs to be addressed, there are other organizations who are specifically addressing these kinds of issues. And we need to work very closely together, so we are getting people all of the help that they need to the best of our ability to do so.

Mr. BROWN. Thank you. I have a couple of questions on the whole issue of pricing.

The President, in his 2003 State of the Union Address, said anti-retroviral drugs have extended life for many years. The cost of those drugs has dropped from \$2,000 a year to under \$300 a year, which places a tremendous possibility within our grasp, the President's words.

Considering that the price of \$300 is only available from generic manufacturers, will the President's Global AIDS Initiative be fi-

nancing the use of lifesaving generic anti-retrovirals and other essential AIDS medicines that have been certified by the WHO as meeting international standards for safety, efficacy, and quality?

Ambassador TOBIAS. Congressman, when you or I get a prescription from our physician and we go to the local pharmacy and get it filled—and maybe it is filled with a generic drug or maybe it is filled with a brand-name drug—but if it is filled with a generic drug, we have come to have a certain understanding and expectation about what that means.

And what it means is that the Food and Drug Administration has approved the manufacturer and the manufacturing of that process. According to the FDA's own definitions, that product is identical to the original product that came from the research-based company in terms of dosage, safety, effectiveness, strength, active ingredients, purity, stability, quality, performance, intended use, and so forth. In other words, they are identical. The standards are the same. The manufacturing is the same.

When people use the term generic drugs in referring to HIV/AIDS drugs, they are not the generic drugs that we are talking about here. And one of the things that has to happen is that we need to have principles, standards by which the purchase decisions can be made.

It is our policy to acquire, at the cheapest price we can find them, AIDS drugs that are safe and effective and consistent, and that are going to get the job done.

We have taken the initiative of bringing together a number of organizations. And in conjunction with the U.S. Government under the lead of the FDA, but in partnership and cosponsorship with the World Health Organization, UNAIDS, SADC, the Southern African Development Community that is a consortium of African regulatory authorities, and a broad number of others, a meeting took place in February—another meeting will take place on the 29th and 30th of March—with technical experts, with the expected outcome of that meeting being the development of principles that can be used by countries in establishing specific technical standards to make decisions about AIDS drugs.

Unfortunately, when people today say we ought to buy generic AIDS drugs, they are not describing, in many cases, what we imagine when we think about generic drugs here in the United States. It would be a disaster if we invested in drugs that were not consistent or don't have all the right components, and we just don't know whether some of these do or some of these do not.

The World Health Organization's program to prequalify drugs is not a regulatory process. And that is the reason that the World Health Organization has joined us as a cosponsor of this effort to develop those kinds of principles.

But I would repeat, it is our policy to buy the least expensive products that we can buy, that meet those appropriate standards, without regard to where they come from.

Mr. TANCREDO. Thank you. Mr. Chairman, if I could for just 30 seconds, if I could. I have two questions I would like to submit in writing, one along the lines of what was just discussed—triple cocktails, three anti-retrovirals in one pill taken twice a day, instead

of more times than that, which will help significantly with compliance. I would like to submit a question in writing about that.

Second is the World Health Organization's three-by-five plan, if I could submit a written question about that, also, Mr. Chairman. Thank you.

Ambassador TOBIAS. Could I respond briefly to those, or do you want me to just—

Chairman HYDE. That would be great, okay. Go ahead.

Ambassador TOBIAS. Well, with respect to the three-by-five plan, it is a wonderful program. It is a program designed to promote interest in HIV/AIDS. It is not a program that is going to fund anything. Our 2-million target of getting people under treatment is, in fact, potentially two of the three in the three-by-five. So I am very much in favor of that.

Ambassador TOBIAS. Thank you. Ms. Watson.

Ms. WATSON. Thank you, Mr. Chairman. I have several questions, and you can just answer them altogether.

In visiting South Africa and working with an international AIDS organization to open up a clinic in Durban, we visited one of the hospitals. And we know AID, there was a mother-to-child program under USAID.

But being in this particular hospital, the policy there was to treat the child. The mother would care for the child, and then go home and die.

What are we doing in terms to support whatever the program might be at the current time, if you are aware? Then if you can mention your target groups, you said that several times, in the countries.

Another concern that I had, and I mentioned it when the bill was here in Committee, is that there was much talk about the Uganda model. And I am just wondering if we have looked at other countries on the continent of Africa where you find the custom is for a Chief to have 50 wives. Should the chief be infected, then the wives become infected, as well.

Are we doing any cultural studies that might lead to a more effective way of treatment? And of course, the discussion goes on between prevention versus treatment.

I was disheartened to know that the mother and child in the hospital, the mother would be dead in a matter of months, and the child would become an orphan and probably eventually also die. And so I support both prevention and treatment.

And finally—and you can just combine your answer, you don't have to be specific to each question. These are just concerns that I have had ongoingly. What is the medical support for your ABC program? Are you collecting data, best practices? What is really working?

That is a whole lot, but do the best you can.

Ambassador TOBIAS. Thank you very much. Those are all wonderful questions.

Let me start with your question about the mother-to-child transmission program. It is another example of how the borders between treatment, prevention, and care are really blurring.

I would argue that the very best program that we can possibly put in place for orphan care is to keep the mothers alive. And the

Prevention of Mother to Child Transmission Program, as you have accurately described, began with a relatively straightforward medical protocol designed to use Nevirapine to keep the child alive. But nothing was done beyond that.

Our plan, our aspiration, and we fold the President's Preventing Mother-to-Child Transmission Program into the Emergency Plan, is to move to something that is generally referred to as mother-to-child transmission plus. Which means focusing not just on the child, but also on the mother, and the father, and the children, the siblings in that family.

Now, these are decisions that are going to have to be made, driven by our host governments, with respect to their policies of who is going to get treatment, and who is not going to get treatment. But for all the reasons that you describe, that is a very important element.

With respect to the cultural issues, there are a number of very complex cultural issues. There are some countries where a relatively small percentage of people ever get married in the context that we think of marriage. There are cultures where multiple wives exist. We need to take all of those things into account culturally, in understanding how best to implement the programs.

We are finding that, for example, some of the traditional caregivers, the traditional medical providers in some of the remote villages, for example, when they are educated about HIV/AIDS, and when they understand it from a more scientific point of view, can be extraordinarily important allies, because they have great influence in the communities in which we operate. So there are a number of things that we can do in that regard.

Finally, with respect to the ABC model—and if I don't get all your questions answered, I will be happy to reply in writing afterward. But with respect to the ABC model and everything else we are doing, it is very, very important that we take advantage of the scientifically-driven data that is currently available in making the decisions that we are making. And that the monitoring and evaluation programs that we are putting a lot of effort to get into place, so that we can measure if the money is going to places we intend for the money to go, and if it is making a difference, so that we can extend the funding in those programs that are working, and stop funding the programs that are not working. And to do so not based on our hopes or our intuition, but based on the best facts that we can get.

So that is and will be a very important aspect of what we are doing.

Chairman HYDE. Ms. Davis.

Ms. DAVIS. Ambassador Tobias, thanks for being here.

In the sub-Saharan Africa region, cervical cancer is the leading cancer death in women. And in fact, I believe 80 percent of the world's cervical cancer deaths are in Africa, Asia, and South America. And many of those that are infected with HPV are also infected with HIV.

And because of the importance of properly addressing HPV, I wanted to bring to your attention an error that is contained within the strategy document.

On page 80 of the document, in Appendix B, “Human Papilloma Virus in Sub-Saharan Africa and the Impact of Condom Use on Its Spread,” the report states:

“Correct and consistent use of condoms can be expected to decrease, though not eliminate, the risk of transmitting HPV.”

But if you take a closer look at the rate of the National Institute of Allergy and Infectious Diseases Workshop—and that is cited for this statement—it actually states:

“For HPV, the panel concluded that there was no epidemiological evidence that condom use reduced the risk of HPV infection.”

This conclusion of the NIAID echoes the findings reached by the National Cancer Institute, the American Cancer Society, the Centers for Disease Control and Prevention, and a meta-analysis of the best data published over the past 2 decades. Which all contradict the statement that is published in the President’s Emergency Plan for AIDS Relief U.S. Five-Year Global HIV/AIDS Strategy.

Based on that, I would therefore request a correction on this document, and an updated analysis to reflect the available science on HPV.

I think you are sending the wrong message if you don’t use the science and make a statement that is made in that strategy document.

Thank you.

Ambassador TOBIAS. Ms. Davis, thank you very much. This is, I know, a very important issue. This is an aspect of the strategy, the report that you refer to in the appendix, that I have read. I have had some discussion about it with medical experts. But I would confess, it is a subject that I need to be much more deeply educated on than I am right now. I will be happy to take your comments and what you have pointed out, and take that back, and we will take a look.

Ms. DAVIS. I would appreciate it, Mr. Ambassador. Thank you very much.

Ambassador TOBIAS. Thank you.

Ms. DAVIS. Thank you, Mr. Chairman.

Chairman HYDE. Mr. Schiff.

Mr. SCHIFF. Thank you, Mr. Chairman. Ambassador, there is no doubt that sub-Saharan Africa is the epicenter of the AIDS epidemic, and that a host of factors have acted as an accelerant. It is right that we should focus most of our immediate attention on these countries.

However, AIDS is also becoming epidemic in other regions, as well. CSIS has predicted that India will have 25 million cases of HIV/AIDS by the end of the decade. And according to a UNDP report issued last month, infection rates in Russia, Ukraine, and Estonia are among the fastest growing in the world. The overall rate in these three countries is now over 1 percent, a threshold above which efforts to turn back the epidemic have failed in many other countries.

In China there were over a million cases of the disease by the end of 2002, and estimates are that there will be 10 to 15 million cases by 2010.

All these countries are going through economic, social, and political transitions, which could be threatened by the epidemic. Even as we focus our efforts on slowing down, stopping, and reversing the catastrophe in Africa, we cannot afford to ignore these other regions, as well.

Can you tell us what the Administration is doing in these areas, and whether you are looking to add one or more non-African countries to the non-targeted list?

Ambassador TOBIAS. Thank you very much. This is an incredibly important issue, because this is not a disease that respects political boundaries.

I view the program as really divided into three areas. There are the focus countries, 14 originally, soon to be 15, based on the requirement in the appropriating legislation that a 15th country be selected that is not in Africa or the Caribbean. And \$9 billion of the \$15 billion the President and the Congress intends to be focused on those focus countries.

But \$5 billion in the plan is also intended for those countries where we currently have bilateral programs, including some of the countries that you mentioned. There are about 100 countries in the world where the United States Government has some kind of program; I think something in the range of 30 of those countries we have a very significant presence.

And so it is important that we take the lessons that we have learned and can learn from the focus countries, and be sure, to the degree we can, that those are transported into the programs that we are funding in the rest of those countries.

And then there are a number of places in the world where we are not funding anything, but there is much that we can do.

One of the things that we have learned from experiences in several countries is the absolutely critical role of national leadership from the President or Prime Minister and other leaders all the way down to the local level, the absolute importance of leaders stepping up and providing leadership on this issue. And there are a number of things that we can do through our diplomatic efforts to try to encourage that, and to help countries be sure they have a strategy, and that they have an approach to these kinds of things.

It is really hard to know where to begin, and where to focus the effort here, because there is so much to do. The five countries that you referred to as the next wave countries—Nigeria, Ethiopia, Russia, India, and China—two of those five, Nigeria and Ethiopia, are among the focus countries in Africa where we are addressing programs. And all three of the other countries are beginning to do a good deal more themselves. There are very positive signs in very recent times in all three places.

India, for example, in the most recent U.N. data has a reported prevalence rate of infections of about $\frac{8}{10}$ of 1 percent. It doesn't sound like very much, except that equates to four million people, making it the second-largest country in the world in terms of the numbers of infected. And there are some estimates that would sug-

gest that there are probably far more unreported cases there, which might make it the largest number.

Large numbers of infected people in China, and in Russia, and great concern that these numbers are going to expand if left unchecked.

So working with our multilateral partners, working with these governments, and working with our own bilateral efforts, we are certainly not going to ignore those problems, and we will do what we can do to help address the issues there.

Chairman HYDE. Mr. Payne.

Mr. PAYNE. Thank you very much. Mr. Ambassador, I appreciate your taking on this very important role.

Ambassador TOBIAS. Thank you.

Mr. PAYNE. I feel that we are happy that the amount of funds that have been earmarked over the next few years certainly has increased from several years ago, and we are very pleased to see that.

However, as we all know with this pandemic, although \$15 billion sounds like an awful lot, it is really a drop in the bucket. And the fact that we are hearing talk about other countries, India, China, and so forth, where the spread of AIDS is increasing, I would hope that we would keep the focus of this \$15 billion on sub-Saharan Africa.

We talk about .8 percent of the population in India, but in Botswana it is 33 percent. When we talk about the life expectancy in Botswana dropping from 62 to 37 years and dropping, it is a totally different situation.

And also, as we look at countries' ability—and I am for helping all countries, but there are as many middle-income people in India as is the total population of the United States of America.

And so I think we have to keep in perspective that we are and should be concerned about the world. However, there is a pandemic going on, and we have to ensure that we do as much as possible.

There was the suit, as you recall, of the pharmaceutical companies to South Africa, where most pharmaceutical companies joined in a suit because they wanted to use the third-country purchasing. And what is your position? I know you come from the industry. How do you see the pharmaceutical industry in general now viewing this pandemic, and the problems associated with the cost? I was glad that the suit was withdrawn. I could not believe that it happened in the first place, but I am not a lawyer or a scientist. But just common sense said to me it didn't make sense.

But could you kind of mention what the pharmaceuticals, where they stand at this time, in general?

Ambassador TOBIAS. Well, Congressman Payne, let me start with your first comment, and just make the Committee aware that if you are not aware of this, in 2002 and 2003, the United States Government's contributions to international HIV/AIDS activities equalled, or were even slightly more than, the rest of the world combined.

In 2004, if the rest of the world stays flat with their contributions—and I certainly hope they do not—but if the rest of the donor nations stay flat, U.S. Government contributions will be twice as much as the rest of the world combined.

So with regard to the enormity of the pandemic, is the world stepping up with enough yet? Absolutely not. But one of the things that we have got to do is to get other donor nations to step up to do their part.

The reason that the original 14 countries were chosen had to do, in part, with the fact that collectively, those 14 countries represent 50 percent of the infections in the world. The 12 countries in Africa represent 70 percent of the infections in Africa.

So I think our focus in that regard is very important. Because not only are those countries and people that have great need, it is, in fact, where a very large part of the focus of disease is.

Finally, I made some comments I think before you came in about the whole pharmaceutical situation. And I will be glad to provide more detail in writing.

But the bottom line is that with sponsorship jointly by the U.S. Government, UNAIDS, the World Health Organization, and the FDA taking the lead here in the United States, along with SADC, the organization in Africa that encompasses in southern Africa the regulatory authorities in a number of countries, there will be a meeting toward the end of March, which is the second meeting we have had, for technical experts to try to develop standards by which countries can make determinations about which pharmaceutical products will meet the standards of efficacy and quality and reliability.

There are things that we have come to take for granted here in the United States, if I go to a pharmacy and have a prescription filled with a generic drug, but when we are describing generic AIDS drugs it doesn't mean the same thing. And we need to have those standards, so that whatever products are purchased, we are getting them at the lowest possible cost, but we know what we are getting. And that we are putting people on programs that really are going to help them going forward.

Mr. PAYNE. The Chairman is going to cut me off. I just want to say thank you to the pharmaceutical companies. I am not bashing them now; I did it then. But many of them have stepped up with programs—Merck in my state, Eli Lilly, and right on. So I want to make it clear that I do appreciate the new attitude in the pharmaceutical industry is helping a great deal.

Ambassador TOBIAS. Yes, you are exactly right. There are a number of donor programs, and the prices have come down very dramatically. And we certainly appreciate that help.

Chairman HYDE. Ms. McCollum.

Ms. MCCOLLUM. Thank you, Mr. Chair. Ambassador Tobias, I would like to follow up on some questions that were asked by my colleagues, Ms. Lee and Ms. Davis.

Your comments regarding the ABC prevention strategy, it is clear that the be faithful aspect to me is dependent upon testing.

Without testing and knowledge of HIV status, any faithful, monogamous and/or married couple are engaging in high-risk behavior. So they should be using condoms. If they do not know their status, they should be using condoms.

Given the ABC strategy does not include a T for testing, or is it an ATBC, I would prefer that we see our program, and that we develop in countries move toward abstinence, condoms, and testing,

and be faithful. It is a more coherent strategy that will prevent the transmission of this deadly disease.

Now, Mr. Ambassador, from reading this report—and I did read it—I would like to know why you are not advocating condom use for any couple, any couple that does not know their status. And what is the United States' AIDS strategy for universal testing?

Ambassador TOBIAS. Testing is an incredibly important element of this whole program. Testing has been very inadequately addressed thus far.

We have exported, to some degree, the experiences of our epidemic here in the United States, where a number of things that worked here are very different in an environment where the infection is principally spread by heterosexual sex. And we have got to find new innovative ways to get people tested. Because without the testing, prevention programs of any kind are going to be very difficult.

Of the 40 million people in the world who are infected, the estimate, in some cases, is that as many as 95 percent of people don't know their status.

So you are exactly right, that when people are having sex in a monogamous, committed marriage relationship, and they do not know their status, they may well be at high risk.

But I would argue that the solution to that is not condoms. The solution to that is getting people tested.

Condoms are a risk-reduction strategy, they are not a risk-elimination strategy. And it takes the consistent and correct use of condoms to be effective.

Ms. MCCOLLUM. Mr. Chair, Ambassador, less than 1 percent of the people know their status. And Ms. Lee referred to *The New York Times* article. We have women that are going to be married, being married right now in Africa, that are going to be in monogamous relationships where they will pledge to be faithful. Hopefully their partner will also pledge to be faithful. But they don't know their partner's status. That is high risk for them, to be engaged in sexual activity.

Are you going to include condoms as a way of protecting those women that are in those monogamous relationships until we have testing? Yes or no?

Ambassador TOBIAS. Yes.

Ms. MCCOLLUM. Yes.

Chairman HYDE. The gentlelady from California, Ms. Watson.

Ms. WATSON. If I could just ask a final question for clarification. I am looking at a table that we have here that talks about the appropriations for the U.S. International AIDS, Malaria, and Tuberculosis Program. And I was just talking to my staff about possibly a piece of legislation that would require, as part of our different programs, a long-range study to see how effective they are.

But I notice that there is \$11 million going to CDC International Fight, Prevention Research, and then there is \$218.2 million going to NIH International Research.

I am wondering if these two programmatic agencies could do some of the research that we are concerned about, if I should write a letter to CCU, would this be the place, since there is money already appropriated? Because I am really concerned about how we

break through the traditions and the customs in many of these countries.

My colleague, Ms. McCollum, was asking about the women who unsuspectingly have heterosexual sex, and will become—and condoms would be a new intrusion into these customs.

So I would like to kind of formalize some research looking at how we break through the cultural barriers. And I need your advice as to whether you think NIH would be the place, and I guess it would be—or CDC.

Ambassador TOBIAS. Well, one of the things that we are trying to do under this program is to harmonize the efforts of everybody in the government, including those parts of Health and Human Services that you mentioned—NIH and CDC—to ensure that research is going on what we need, including the operational research, as I would call it, about what is working and what is not working.

I am not familiar with all of the programs that are going on. But as part of our monitoring and evaluation effort, we are going to ensure that we have all of the research that we need. And I will be happy to look specifically into what we are doing at the moment.

Ms. WATSON. What I would like to do is address a letter to you.

Ambassador TOBIAS. That would be fine.

Ms. WATSON. And then you can, with some of the specifics that we would like to take a look at—rather than introducing legislation or resolution or whatever, just write you a letter, and see if those two already-appropriated branches could take a look at these particular factors.

Ambassador TOBIAS. Thank you, I will be happy to take a look.

Ms. WATSON. Thank you.

Mr. PAYNE. Mr. Chairman, 1 second.

Chairman HYDE. Yes, Mr. Payne.

Mr. PAYNE. Just one last statement. You know, I see that the U.S. has most of its funding bilaterally, and there has been a reduction in the Global Fund. And I am a strong supporter of the Global Fund. I think that with UNAIDS organizations being on the ground when the Global Fund accepts the proposals from countries and fund them, with the U.N. agencies being on the ground to really assist in following up of the Global Fund, I would just urge you to consider more support to the Global Fund. I think it is good that we are giving them money.

But I think it might be better coordinated through the Global Fund than our bilateral donations.

Thank you, Mr. Chairman.

Ambassador TOBIAS. Congressman, thank you very much. There has, I think, been a good deal of misunderstanding about the strategy and the relationship as it relates to the Global Fund.

If I might, I would like to just read a small part of a letter I received the day before yesterday from Dr. Richard Feachem, the Executive Director of the Global Fund, who, in the wake of our having introduced the strategy, said, in part:

“Your team has accomplished a great deal in the last few months, and I applaud the breadth and quality of your strategy. I am also very grateful for your support to the Global Fund in your announcement.

“In particular, you avoided, despite pressure from the press, unhelpful comparisons between the bilateral component of the PEPFAR program and the Global Fund. This and negatively-oriented discussions of the U.S. contribution to the Global Fund, which have, in fact, been high and commensurate with our needs year by year, create misconceptions about our relationship. And I, too, commit to avoiding them.

“U.S. leadership of the Global Fund is strong and critical to our success. And I hope that you, Secretary Thompson, and I can continue to find ways to highlight that fact for the American public.”

I might add to that that we are looking for every way we can find, with the Global Fund and others, to avoid duplication, to identify, for example, information requests and needs that they have from the governments that they are serving to determine if we can get the same data. Can we put it on the same form? Can we minimize the demands that we are making on the host countries?

Because I think by working together, we can greatly enhance our efficiency.

But clearly, the Global Fund is a very important part of our overall strategy. And I appreciate your comments.

Chairman HYDE. Ms. Lee has one final, abbreviated, small, minuscule question.

Ms. LEE. And just one small statement, Mr. Chairman, please. One question, one statement. My statement is this.

I was very happy to hear you respond to Ms. McCollum in the affirmative with regard to condom use. But it is not really spelled out in the report. And you indicated earlier that many are spreading the disease without, again, knowing their status.

And so I just think the importance of a comprehensive strategy that outlines a broader approach in terms of the C component would be very, very important. Because there are countries where the infection rate is about 40 percent. And I think that it is critical to balance the strategy out a little bit more, and spell it out.

Ambassador TOBIAS. Well, let me be clear. Ms. McCollum was describing to me a very high-risk situation. And it is certainly our intent that condoms be a part of the strategy in high-risk groups.

What I don't think works, and there is a great deal of evidence to tell us that it doesn't work, is to create ABC as kind of a multiple choice, take your pick. And that is not our strategy.

Our strategy is to try to get young people to delay sexual activity until much later to get people to be faithful within a monogamous relationship, and engage in testing. But for those people who choose to engage in high-risk relationships, or who are forced into high-risk relationships, that is why the C in the ABC is there.

Ms. LEE. Sure. I will write you a follow-up letter, Ambassador Tobias.

Ambassador TOBIAS. Fine. Thank you very much.

Ms. LEE. Because I think ABC should all be given equal weight. It should be a very comprehensive strategy.

Let me ask you, just in closing, about the plan in terms of orphans and vulnerable children. There was a study conducted in Zimbabwe and found that girls who receive primary and secondary

education had lower HIV infection rates, a trend that of course leads to early childhood. In Swaziland, 70 percent of secondary school-age adolescents attending school are not sexually active, while 70 percent of out-of-school youth in the same age group are sexually active.

So I want to find out, in your report and in the President's Emergency Plan, I mean, you talk about the need to ensure that orphans and vulnerable children have access to school, and that they are supported in their efforts.

But I am concerned that we need to highlight the importance of education for the futures of these young people, and the importance of education as a means to prevent HIV and AIDS prevention.

I visited a community care center in Zimbabwe. And one of the problems that the young people had, and that the organizers of this organization had, was they didn't have uniforms for these kids, so the kids couldn't go to school. And many of them were infected. So I just kind of wonder what your thinking is along those lines.

And thank you, Mr. Chairman, for giving me this opportunity.

Chairman HYDE. You are welcome. Did you want to answer?

Ambassador TOBIAS. I would just comment very briefly that, while this program is focused on HIV/AIDS per se, and focused on treatment, prevention, and care, there are a number of other elements that relate. And there are other programs here within the United States Government, in USAID, and elsewhere, that direct resources to a number of these related issues.

It is another reason why we need to coordinate all of our efforts. Because we are going to address those three priorities, but there are a number of other things that need to be done. And we need to harmonize all our efforts to be sure all is complementary.

Chairman HYDE. Ambassador, I want to thank you for your candor, for the breadth of your knowledge, for your contribution to this horrible worldwide problem. I think all of us who are touched by it, or who are wrestling with it, are grateful that someone of your ability has such a responsible position.

Thank you.

Ambassador TOBIAS. Thank you very much, Mr. Chairman.

Chairman HYDE. You bet. The meeting is adjourned.

[Whereupon, at 12:08 p.m. the meeting was adjourned.]

A P P E N D I X

MATERIAL SUBMITTED FOR THE HEARING RECORD

RESPONSES FROM THE HONORABLE RANDALL L. TOBIAS TO QUESTIONS SUBMITTED FOR THE RECORD BY THE HONORABLE SHERROD BROWN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Question:

Since January 2003, the price of triple cocktails has come down to as little as \$140 per person per year, and some combinations are available as fixed-dose combinations, or "FDCs"—that is, three anti-retrovirals in one pill, which can be taken once in the morning and once in the evening.

The availability of these FDCs has dramatically improved the ability of treatment programs in poor countries to reach people in remote settings, even in extremely impoverished rural communities. They promote adherence, reduce the risk of resistance, and facilitate stock and procurement management.

This lowest price—\$140 per person per year—is available as a generic, compared with about \$600 for the individual compounds from the "brand name" producers.

Will the U.S. be financing purchases of existing generic triple fixed-dose combinations?

Response:

As President Bush said in his State of the Union Address in January 2003 when he launched the Emergency Plan for AIDS Relief, "Anti-retroviral drugs can extend life for many years. And the cost of those drugs has dropped from \$12,000 a year to under \$300 a year—which places a tremendous possibility within our grasp." Under the Emergency Plan, we intend to provide antiretroviral treatment to two million persons living with HIV/AIDS in the focus countries of the Plan. In providing this treatment, we intend to provide drugs that are safe, effective, and of high quality at the lowest possible cost regardless of who produces them. This may include generics as well as brand name products and may include fixed-dose combinations as well as other formulas. We will not, however, sacrifice quality, safety, or efficacy for low cost.

A true generic drug is one that has undergone review to ensure that it is comparable to an innovator drug in dosage form, strength, route of administration, quality, performance characteristics, and intended use. Drugs that have not gone through such a process are more accurately described as copies. It is also important to note that claims that only simplified regimes can be used to treat persons living with HIV/AIDS contradict the evidence that exists that indicates that adherence rates in Africa are higher than in the United States even when fixed-dose combinations are not being used.

As you may know, a conference was held on March 29–30, 2004 in Gaborone, Botswana to provide an opportunity for the drug regulatory agencies of many nations and key international organizations to develop common principles to evaluate the safety, efficacy, and quality of fixed-dose-combination medications (FDCs) for use treating HIV/AIDS, tuberculosis, and malaria. Joining the U.S. Department of Health and Human Services as cosponsors of the conference were the Joint U.N. Program on HIV/AIDS (UNAIDS), the World Health Organization (WHO), and the Southern African Development Community (SADC). The conference was very productive, and I expect that a set of commonly agreed upon principles will be available by mid-May that will provide scientific and technical principles to consider when developing, evaluating, and/or considering FDCs for application in treatment programs.

Question:

The World Health Organization (WHO) has announced an initiative, known as the 3x5 plan, to accelerate treatment for people living with AIDS and includes in their plan technical assistance and capacity building measures to arrive at greater numbers of individuals enrolled in ongoing AIDS therapy, including anti-retroviral medicines.

I have heard that a lack of funding for technical assistance to assist scale up programs has become an impediment. The Global Fund, for instance, needs technical assistance to successfully implement the grants they have approved and have begun disbursing. What is the U.S. plan to help address these needs?

Response:

We recognize the limits of health resources and capacity in many, particularly rural, communities. To more effectively address that shortfall, under the Emergency Plan we will build on and strengthen systems of HIV/AIDS health care based on the “network” model. Prevention, treatment, and care protocols will be developed, enhanced, and promoted in concert with local governments and ministries of health. With interventions emphasizing technical assistance and training of health care professionals, health care workers, community-based groups, and faith-based organizations, we will build local capacity to provide long-term, widespread, essential HIV/AIDS services to the maximum number of those in need.

We welcome the leadership of the World Health Organization (WHO) and the Global Fund to Fight AIDS, Tuberculosis and Malaria to confront the HIV/AIDS pandemic and have been working with them and others to coordinate HIV/AIDS activities to maximize effectiveness and eliminate duplication. The WHO’s 3 by 5 initiative has many important elements to promote the availability of antiretroviral therapy that leverage the resources and expertise of the WHO, and the Global Fund has similar advantages; under the Emergency Plan, the President pledged an additional \$1 billion to the Global Fund, bringing to total U.S. pledge to the Fund to more than \$1.97 billion—the largest to date.

Finally, the contributions of these multilateral institutions and other international organizations working with great dedication to combat HIV/AIDS provide a vital opportunity for a comprehensive response. Under the Emergency Plan, the United States will strengthen its relationships with these organizations to amplify global action against HIV/AIDS by encouraging coordination to fill gaps in current activities and to ensure efficient use of funds. In fact, several countries have identified specific areas of technical expertise that the Emergency Plan will fund WHO to perform to contribute toward the attainment of the treatment, care and prevention goals of both the Emergency Plan and the WHO initiative.

PREPARED STATEMENT OF THE HONORABLE ROBERT WEXLER, A REPRESENTATIVE IN
CONGRESS FROM THE STATE OF FLORIDA

I would like to thank Chairman Hyde and Ranking Member Lantos for scheduling today’s hearing on the United States strategy for fighting HIV/AIDS and the implementation of the United States Leadership Against HIV/AIDS, Tuberculosis (TB), and Malaria Act that became public law in May 2003 (ie, the Global AIDS Initiative). I would also like to welcome Ambassador Randall Tobias, who has been designated the US Global AIDS Coordinator by the Bush Administration, for taking on the monumental task of directing US foreign assistance programs fighting AIDS and other diseases, which are the world’s greatest killers today. The Global AIDS Initiative is the largest commitment ever made by *any* nation to fight a global health epidemic, and I support the Bush Administration’s efforts to place a high priority on addressing this critical issue. I am also encouraged that the Global AIDS Initiative has pledged up to \$1 billion in funding for the highly successful, multilateral, public/private partnership known as the Global Fund to Fight AIDS, TB, and Malaria (ie, the Global Fund).

As it stands, the US is set to provide \$15 billion over five years to combat and prevent horrific global diseases that devastate the lives of millions, affect world economic security, and weaken the social and political stability of many of the world’s poorest nations. Enacting this legislation sends a strong message to the international community that Washington is fully engaged and ready to assist those nations desperately in need of assistance to combat these deadly diseases, especially Sub-Saharan Africa—where over 26 million people are infected with HIV/AIDS.

As you know, HIV/AIDS and other related diseases—if not addressed—threaten to further de-stabilize troubled regions throughout the world and jeopardize American interests as well as those of our allies. These global killer diseases greatly

strain resources in underdeveloped countries and in state institutions, erode internal security, and undermine the social systems that enable nations to cope with burgeoning health crises and economic despair.

Global diseases know no boundaries, and today it is estimated that 11 million children are orphaned by AIDS-related deaths of one or both parents. These children, without hope direction or futures, are targeted by the recruiters of child soldiers and sex trafficking. UNAIDS projects that between 2000 and 2020, 55 million Africans can be expected to lose their lives to AIDS-related deaths. Other seriously affected regions include South and Southeast Asia, where between 4.6 million and 8.2 million people are infected; East Asia and the Pacific, with between 1.3 million and 1.9 million infections; and Eastern Europe and Central Asia, with an estimated 1.5 million infections.

Despite American efforts to increase funding to combat these epidemics, I believe more must be done if we are to effectively combat global epidemics and disease. I am deeply disappointed that promises made by the Bush Administration to fully fund the Global AIDS Initiative have not been met. I am confused as to why President Bush only requested \$1.5 billion in 2003 for this new Global AIDS Initiative, instead of the \$3 billion that he strongly implied would be spent to combat these diseases. Also, when this initiative rolled out in January 2003 President Bush urged Congress to provide the Global Fund with \$1 billion, and then without warning he short-changed the program by proposing a mere \$200 million. While I commend the Administration for its statements and commitments to fight some of the world's worst atrocities, I am greatly concerned that those who are in the greatest need of our help are running out of time. Undeniably, America's credibility and leadership and more importantly the lives of millions are compromised when commitments to combat global diseases are not fulfilled.

In this vein, I urge my colleagues on the committee to hold President Bush accountable for the commitments he made in his 2003 State of the Union address to focus on these diseases worldwide as part of the Global AIDS Initiative. Congress must support funding these programs at the levels pledged by the Bush Administration. Additionally, as the leader of the free world, President Bush must play a larger role and encourage other wealthy nations—especially members of the G-8—to increase their bilateral and multilateral efforts for HIV/AIDS initiatives. The US can and must demonstrate to the global community at large that America is committed to the betterment of all nations and to the lives of all citizens.

