PEPFAR: FROM EMERGENCY TO SUSTAINABILITY AND ADVANCES AGAINST HIV/AIDS

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PEPFAR: FROM EMERGENCY TO SUSTAINABILITY AND ADVANCES AGAINST HIV/AIDS

WEDNESDAY, SEPTEMBER 29, 2010

HOUSE OF REPRESENTATIVES,
COMMITTEE ON FOREIGN AFFAIRS,
Washington, DC.

The committee met, pursuant to notice, at 9:40 a.m., in room 2172, Rayburn House Office Building, Hon. Howard L. Berman (chairman of the committee) presiding.

Chairman BERMAN. The hearing will come to order. We are going to be joined very soon by my friend from New Jersey Mr. Smith, and he is okay with us starting the hearing. In a moment I will recognize myself and then Mr. Smith for up to 7 minutes each for the purpose of making an opening statement.

The chair and ranking member of the Africa and Global Health Subcommittee aren't here, and Mr. Payne probably won't be able to get here until 10 o'clock or so, so if the other members here want to make a 1-minute opening statement, you are welcome to do so. I know you are both very interested in this subject.

The purpose of today's hearing is to review the progress PEPFAR has made toward reversing the global threat posed by the AIDS pandemic and how those efforts have set the stage to transform PEPFAR from an emergency initiative to a sustainable program.

This morning, we are going to hear about some outstanding achievements and promising research that gives hope for increasing our ability to reverse the spread of the disease. We also will hear about the challenges we still face if we are to accomplish the ambitious goals set forth in the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis and Malaria Reauthorization Act of 2008.

This legislation, which built on the successes of the original legislation, the U.S. Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003, is a prime example of the bipartisan support that exists to fight the global HIV/AIDS pandemic. The fact that both sides joined together to bring positive change demonstrates that saving lives around the world is not a Republican or Democratic issue. It is a priority that all Americans share.

PEPFAR faced many challenges during its first 5 years, including weak health care delivery systems, poor infrastructure, expensive and unavailable drugs, and limited workforce. These factors kept millions infected with the disease isolated from the care and treatment they needed.

Social barriers like stigma, gender inequality, and prejudices against men-who-have-sex with men, commercial sex workers, and

intravenous drug users, compounded the challenges to expanding services to those in need.

But PEPFAR successfully invested in strengthening health care systems, training new health care personnel, purchasing affordable drugs, and helped to remove stigma and empower women and girls and other at-risk populations.

In the face of controversy and our own economic challenges, Congress remained unified behind a single humanitarian purpose. Even in the face of our differences, we never lost sight of the goal to save the lives of millions of poor human beings who do not have the resources and means to save themselves and prevent the spread of AIDS.

In preventing the spread of AIDS, we are not simply achieving the humanitarian objective of saving lives and preventing suffering. We also are advancing economic growth and building democratic stability by preserving the health of productive citizens, enabling people to support their families and contribute to the economic, social and political life of their communities.

Last week the United Nations General Assembly convened a summit to discuss progress to date on achieving the Millennium Development Goals. Addressing the AIDS pandemic has had an impact across all of the MDGs. We must ensure that our commitment to fighting AIDS is designed to reinforce other critical health and developmental priorities.

Today we have some good news in spite of the sobering impact the pandemic continues to have in poor countries. Globally, the overall rate of new HIV infections has slowed and prevalence rates have leveled off. According to the 2009 UNAIDS report, new HIV infections have been reduced by 17 percent over the past 8 years.

In 2008, sub-Saharan Africa reported 14 percent fewer new infections than in 2001. In East Asia, new HIV infections declined by nearly 25 percent and in South and Southeast Asia they declined by 10 percent.

Scientists from the U.S. and Africa are conducting research on the use of anti-retroviral drug treatment as part of prevention. Preliminary results demonstrated that ARVs could both keep a people well and prevent infections. For example, in Africa, a seven-country study was undertaken in which one partner was infected and the other was not. After 3 years, only one uninfected partner was HIV-positive when the infected partner was on an antiretroviral therapy. And in South Africa, researchers recently identified a new microbicide that may significantly reduce HIV infection rates in women.

Based on these and other promising developments, it is fair to conclude that our ambitious investment in AIDS prevention, treatment and care programs has helped make an historical difference and there is sufficient epidemiological evidence to give us hope that this scourge on humankind can be defeated within our lifetime.

While there is good news to report, we can't forget about the sheer magnitude of the epidemic. We still have 33.4 million people living with HIV worldwide and only 42 percent of those in need of treatment have access. Two-point-seven million people were newly infected in 2008, 14 million children in Africa have been orphaned

by AIDS and around 430,000 children are born with HIV each year.

U.S. global leadership has been extremely important in the fight against HIV/AIDS. President Obama, like President Bush before him, has made it clear the U.S. has a moral commitment to combat this deadly disease. We owe it to ourselves and our fellow Americans to ensure that we live up to these commitments, enshrined in law and policy. To that end, we must continue to strengthen our work with other bilateral donors, multilateral institutions, recipient countries, and local and international NGOs.

[The prepared statement of Mr. Berman follows:]

Wednesday, September 29, 2010

Verbatim, as delivered

Chairman Howard L. Berman's opening statement at hearing, "PEPFAR: From Emergency to Sustainability and Advances Against HIV/AIDS"

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Chairman BERMAN. We have two very distinguished panels of witnesses here today to discuss these important issues. I look forward to hearing their testimony. Before I turn it over to Mr. Smith, who has done a tremendous amount on this issue, I do want to acknowledge and welcome the presence of a number of women members of Parliament from 12 African countries, including the Deputy Prime Minister of Zimbabwe, the Honorable Khupe. Thank you very much for being here, and we welcome you.

Now I am pleased to yield to the gentleman from New Jersey for any remarks he may like to make.

Mr. SMITH. Thank you very much, Mr. Chairman, for holding this very important hearing on the President's Emergency Plan for AIDS Relief. I want to thank you and your predecessor Tom Lantos, and certainly Congressman Henry Hyde, both who chaired this committee, like you, who were very, very aggressive in promoting this program as well as the legislation.

President George W. Bush described in his 2003 State of the Union Address how hospitals in rural South Africa were telling people, "You have got AIDS, we can't help you, go home and die." President Bush committed the United States to assist African countries in overcoming the HIV/AIDS scourge not only with substantial resources, but also by achieving specific goals with measurable targets. And this effort was to be undertaken in countries that for the most part had poor health infrastructures, a sick and dying health care workforce, and other daunting obstacles. Many said it couldn't be done. PEPFAR proved them wrong.

Working with the President, Congress passed the United States Leadership against HIV/AIDS, Tuberculosis and Malaria Act. Thanks to strong continued bipartisan support, PEPFAR can now boast about directly treating over 2.4 million people with lifesaving

antiretroviral drugs. Nearly 340,000 babies born to HIV-positive mothers were born HIV free thanks to PEPFAR prevention of mother-to-child transmission programs. Almost 11 million people affected by HIV/AIDS have received care, including 3.6 million orphans and vulnerable children. And in Fiscal Year 2009 alone, 29 million people were counseled and tested for HIV thanks to PEPFAR.

Despite these successes I would like to highlight several concerns. One is the administration's implementation of PEPFAR as part of the new Global Health Initiative, of which PEPFAR is the major component, in the absence of authorizing legislation. I understand the administration intends through the Global Health Initiative to change the way the U.S. Government conducts its foreign assistance in this area at a fundamental level. I would strongly argue that such a change requires legislative authorization, given the amount of taxpayer money and important policies that are at stake.

Another major concern is GHI's emphasis on integrating HIV/AIDS programming with family planning as well as various health programs. This is being undertaken in the context of a family-planning program, which, due to President Obama's rescission of the Mexico City policy, now includes foreign nongovernmental organizations that provide, support and seek the expansion of access to abortion. When one considers that this involves over $715 million in family-planning funding under the Fiscal Year 2011 proposed budget, the ability for abortion groups to leverage this funding in relation to U.S. HIV/AIDS funding under the GHI is deeply disturbing.

Furthermore, it now appears that the considerable sums that the United States contributes to the Global Fund to Fight AIDS, TB and Malaria—$1 billion in Fiscal Year 2010—may contribute to a new Global Fund initiative to fund abortions. This possible intervention, part of the Global Fund's effort to contribute to the Millennium Development Goals, is described in a document presented to the Global Fund Board at its meeting in April of this year. This paper is intended to facilitate the Board's discussion of the Fund's role as a "strategic investor in maternal and child health." It asserts that the Global Fund will optimize—this is a quote—"existing interventions to improve the health outcomes for women and children" by identifying areas for greater integration of HIV, TB and malaria services with "sexual and reproductive health services." In the chart identifying "interventions that could be supported with the new funding," the paper explicitly proposes abortion.

Abortion, I would say to my colleagues and to our distinguished panelists, is by definition infant mortality, and it undermines the achievement of the fourth millennium goal. There is nothing, nothing benign or compassionate about procedures that dismember, poison, induce premature labor or starve to death a child. Indeed the misleading term "safe abortion" misses the point that abortion, all abortion, legal or illegal, is unsafe for the child, and all is fraught with negative health consequences, including emotional and psychological damage, for the mother.

Monies that the U.S. contributes to the Global Fund are ultimately taxpayer dollars, and polls show that 61 percent of U.S. tax-

payers do not want government funding paying for abortions. Our U.S. delegation should keep this in mind as it takes up this question with the rest of the Board at the next meeting in December.

And finally, one final concern is the importance of not only including but also reaching out to faith-based organizations in all of our global health programming. Given studies that show up to 70 percent of health care in Africa—and that is a WHO number—is provided by faith-based hospitals, clinics and organizations, it is imperative for the continued success of PEPFAR to have them as a primary partner. Thus I would hope that the administration is assisting local governments in developing strategies that include faith-based networks as an integral part of their health system. Their effort also necessitates respect for the conscience clause provisions contained in the Leadership Act and reaffirmed and strengthened by this committee and by this House and the Senate in the 2008 reauthorization.

Mr. Chairman, I look forward to our distinguished panelists' comments, and I thank you for yielding.

The gentleman has yielded back his remaining time, and for 1-minute opening statements any members of the committee?

Ambassador Watson, are you——

Ms. WATSON. I was going to defer to Barbara Lee.

Chairman BERMAN. The gentlelady from California has deferred to the gentlelady from California.

Ms. LEE. Thank you again, Congresswoman Watson.

Thank you again, Chairman Berman, for this hearing. Thank all of you for being here and specifically for the work that you do each and every day to save lives.

I, of course, as you know, helped write the initial PEPFAR with Chairman Hyde, and we sorted through many of these issues that have been raised by Congressman Smith, and believe you me, I believed then as I believe now the countries should be able to determine their own plan. However, we didn't win that one, and we know for a fact that PEPFAR funds are not used for abortions. I have been out many times, as have members of this committee, so I thought we had settled that, not to my satisfaction, but I thought we had settled it.

Secondly, let me just say I did participate recently at the International AIDS Conference in Vienna, and I know there is a lot of concern about the extent of our commitment to fighting this disease. The global economic crisis has seemed to have dried up in many quarters, the political will and the resources. Yet here in our own country we know that the drive for military spending to build new and even more deadly weapons systems, this debate continues to go unabated.

And so I think we need to really focus on how we can move forward with PEPFAR, with the International AIDS Conference coming to Washington, D.C., in 2012. I hope we can show the world that the United States is seriously committed to fighting this pandemic, and to setting our goal of an AIDS-free generation, and to use PEPFAR as an example for our own domestic strategy here in America.

Thank you again, Mr. Chairman.

Chairman BERMAN. Thank you. And just before that I do want to—Ms. Lee's opening comments reminded me that in the very beginning of all this back in 2001, 2002, she was a driving force to the initial legislation.

Ambassador Watson.

Ms. WATSON. Yes. Good morning, Mr. Chairman, and I want to thank you for holding this timely hearing on PEPFAR and the advances against HIV/AIDS. I concur with the two of you, Ms. Lee and the chair.

Currently 33.4 million people are living with HIV and AIDS worldwide, with 2.7 million new infections in the year 2008. Through President Bush's PEPFAR initiative, it has made great strides in responding to the emergency of the global pandemic, and we must now look to create a substantial approach to confronting HIV/AIDS.

President Obama's 5-year strategy aims to achieve just that. Unfortunately, it is unclear how we will transition to a country-owned, sustainable health system in struggling nations that will be able to respond to the plethora of diseases that plague the developing world. I look forward to hearing from the administration about how this transition will take place.

So I want to yield back and thank you, Mr. Chairman.

Chairman BERMAN. The time of the gentlelady is expired.

Anyone else seek recognition for an opening statement? The gentlelady from California.

Ms. WOOLSEY. What would you do without us, Mr. Chairman?

Chairman BERMAN. I wouldn't be here.

Mr. WOOLSEY. The women from California. That is true.

Thank you all for being here, and I am looking forward to your testimony.

I have to apologize. We will be in and out because of other things. But I am really interested in hearing how you are integrating HIV/AIDS treatment and prevention with a larger role of women's health and maternal health. I think that pulling all of this together into one conversation is very, very important. Are we getting more bang for our buck with PEPFAR by doing this? And are women getting health care in a one-stop shop style?

So I am just looking forward to hearing all of that from you, and I thank you for all you know and all you do for PEPFAR. Thank you very much.

Chairman BERMAN. The time of the gentlelady has expired. Any other members seeking recognition for an opening statement? If not, it is my pleasure now to introduce our first panel.

It is an amazing logistical feat that the three of you could actually get together in terms of your calendars and ours to be here, and we are very grateful that you are.

Ambassador Eric Goosby serves as United States Global AIDS Coordinator. In this capacity Ambassador Goosby oversees implementation of the U.S. President's Emergency Plan for AIDS Relief—that is the PEPFAR program—and leads all U.S. Government international HIV/AIDS efforts, including engagement with the Global Fund to fight AIDS, tuberculosis and malaria. Ambassador Goosby has over 25 years of experience developing health care delivery systems, served as the first director of the Ryan White Care

Act at the U.S. Department of Health and Human Services, and I believe has a California connection.

Dr. Thomas Frieden became director of the Centers for Disease Control and Prevention and administrator of the Agency for Toxic Substances and Disease Registry in June 2009. From 2002 to 2009, he served as a commissioner of the New York City Health Department, one of the world's largest public health agencies. Dr. Frieden previously worked for CDC from 1990 to 2002, where he began his career as an epidemiologic intelligence service officer.

Dr. Anthony Fauci was appointed director of the National Institute for Allergy and Infectious Diseases in 1984. He oversees an extensive research portfolio of basic and applied research to prevent, diagnose and treat infectious diseases such as HIV/AIDS and other sexually transmitted infections, influenza, tuberculosis, malaria, and potential agents of bioterrorism. Dr. Fauci is the recipient of numerous prestigious awards for his scientific accomplishments, including the Presidential Medal of Freedom and the National Medal of Science.

Gentlemen, we are honored to have you here.

Ambassador Goosby, why don't you start? All of your prepared statement will be included in the record, and we will be grateful for you summarizing your main points.

STATEMENT OF THE HONORABLE ERIC GOOSBY, UNITED STATES GLOBAL AIDS COORDINATOR, U.S. DEPARTMENT OF STATE

Ambassador GOOSBY. Thank you very much, Chairman Berman, Ranking Member Ros-Lehtinen and members of the committee. Thank you for this opportunity to discuss the progress we have made under PEPFAR with your long-standing bipartisan support.

I am pleased to be here with my friends and colleagues Dr. Tom Frieden and Dr. Tony Fauci. All of the agencies involved in PEPFAR contribute their strengths to a unified interagency effort that has maximized our impact.

I serve with Dr. Frieden and Dr. Shah of USAID as the operations committee for President Obama's Global Health Initiative. GHI builds on our shared interagency experience, and I appreciate the committee allowing us to speak to it and the commitment on all agencies' parts to collaboration.

I have been working on HIV/AIDS for almost 30 years. Five to six years ago those of us who engaged in HIV work in Africa saw daily tragedies on a vast scale. Yet today with American leadership, PEPFAR has brought about a dramatic transformation.

I have outlined the results to date in my written testimony. With PEPFAR as its cornerstone, GHI will support coordinated interventions to increase our ability to save lives from AIDS and other challenges. With the support of this Congress and the Obama administration, the number of people receiving HIV prevention, treatment and care will continue to grow. In addition to doubling the number of babies born HIV-free, the United States will support the prevention of more than 12 million new HIV infections, HIV treatment for more than 4 million, and care for more than 12 million, including 5 million orphans and vulnerable children.

Our prevention, care and treatment programs are integrally linked. We have led the world in rapidly scaling up biomedical prevention, such as male circumcision and prevention of mother-to-child transmission.

PEPFAR has also worked to reduce treatment costs and to expand service delivery. Reflecting a key GHI principle, we support operations research to identify innovations and best practices to save more lives.

Simply put, our work has been and continues to be about saving lives as part of our shared global responsibility to make smart investments. Partnerships are an overarching principle for the Global Health Initiative. The United States provides nearly 60 percent of donor government funding for HIV/AIDS, a leadership role we are proud of and which, thanks to Congress' reauthorization of PEPFAR, will continue.

Yet the global need is a global responsibility and all have roles to play. An important mechanism for this is the Global Fund. The United States has been its largest donor, providing more than $5.1 billion, and providing support for grant implementation at the country level that has proven crucial to ensuring the grants can deliver.

As we implement PEPFAR's 5-year strategy, let me highlight three priorities that reflect the GHI principles. First, saving more lives through PEPFAR activates our ability to focus on and be part of the Global Health Initiative. During its first phase PEPFAR focused on meeting ambitious goals for delivery of prevention, care and treatment. Moving forward, make no mistake, we will support expansion of these core services.

Yet people affected by HIV are not defined by the virus alone. Like everyone else, they have a change and range of other health needs. That is why integration is a core GHI principle, and GHI will help to holistically address these needs. At the same time we also want to reach the clients of other programs, such as maternal and child health, with HIV interventions. For example, women who come to antenatal clinics are an ideal population for PMTCT programs. Integration under GHI offers the real opportunity of increasing our impact on health and, again, saving more lives.

A second priority is addressing gender issues with HIV programming. GHI recognizes that focusing on women, girls and gender equity is a force multiplier benefiting women, their families and the communities. AIDS is the leading cause of death of women of reproductive age worldwide, and in Africa nearly 60 percent of those living with HIV are women. During its first phase PEPFAR began a five-point gender strategy seeding countries with small initiatives. We are now expanding them with a focus on PMTCT and country-led projects.

One risk factor for HIV is the tragedy of gender-based violence. We are investing $30 million to combat it in three severely burdened countries, and in all countries we are supporting post-rape care, while also seeking to prevent sexual violence in the first place. Last week at the Clinton Global Initiative, we joined the Together for Girls public-private partnership to combat violence against girls.

Lastly, we are focused on the GHI principle of expanding country ownership and local capacity to build a sustainable program. As we responded to the HIV emergency in the first phase of PEPFAR, we worked largely through international partners. A major priority we have now added is increasing the capacity of countries to manage, oversee and operate their health-delivery systems.

Moving forward we will increasingly emphasize a third dimension, community empowerment. As we pursue support for health systems under GHI, we know local communities can ensure accountability in a way that outsiders never can. That feedback dialogue is essential for true sustainability.

In conclusion, we are making great strides, but much work remains. We must keep our eyes on the prize, and that is to save more lives. I remain grateful for your ongoing support for this effort and look forward to the questioning.

[The prepared statement of Ambassador Goosby follows:]

The President's Emergency Plan for AIDS Relief

Statement of Ambassador Eric Goosby, M.D.
U.S. Global AIDS Coordinator, U.S. Department of State
Before the U.S. House of Representatives
Committee on Foreign Affairs
Washington, DC
September 29, 2010

Chairman Berman, Ranking Member Ros-Lehtinen and members of the Committee: thank you for this opportunity to discuss the President's Emergency Plan for AIDS Relief (PEPFAR) with you. I appreciate not only the attention you are bringing to global AIDS today, but your enduring focus on this issue. All Americans can be proud of the strong support global health efforts have received from Members from both sides of the aisle.

I am pleased to be here today with my friend and colleague, Dr. Tom Frieden. The Centers for Disease Control and Prevention (CDC) and the U.S. Agency for International Development (USAID) are the two largest PEPFAR implementing agencies. The populations we serve benefit immensely from these agencies, and our other implementing agencies such as the Department of Defense and Peace Corps, contributing their distinctive strengths to a unified, interagency effort.

I'm also pleased that Dr. Tony Fauci is with us today. Under his leadership, the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) continues to build our understanding of this virus, and potential approaches to reversing its spread. NIH is a critical partner in the PEPFAR effort, and we rely heavily on the research that NIH supports.

I'm honored to serve with Dr. Frieden and Dr. Rajiv Shah, Administrator of USAID, as the Operations Committee for President Obama's Global Health Initiative, or GHI. GHI is a signature initiative of the President and a concrete manifestation of the new approach to international development he announced last week at the United Nations High-Level Plenary on the Millennium Development Goals..

A key principle of the GHI focuses on strengthening health systems to save lives and achieve sustainable outcomes. It builds on the remarkable success of efforts to date with an operational model designed to integrate health programs for greater efficiency, evaluate new and innovative approaches, and make better use of taxpayer funding. It also leverages efforts of multilateral partners, other donors, and partner countries by working within a common national framework, which will allow us to better identify gaps where the U.S. should focus its contribution to achieve broader impact.

We've seen unprecedented progress through past health investments, and we can build on this success through an integrated and holistic approach that binds individual health programs together in a coordinated, sustainable way, with the countries themselves in the lead.

GHI builds on the deep experience of PEPFAR and other health programs, and PEPFAR is the cornerstone and largest component of GHI. I deeply appreciate the commitment of my

colleagues and their agencies to our collaborative, interagency effort, in PEPFAR and GHI more broadly.

The reason we're here today is because of the significant progress that has been made on global health over the past decade. Congress, with this Committee in a central role, and the Bush Administration responded to the crisis of HIV/AIDS by creating, and then reauthorizing, PEPFAR. This program has continued and expanded with the strong support of President Barack Obama and Secretary of State Hillary Rodham Clinton.

I am grateful for this Committee's partnership in this effort, and am honored to have the responsibility to lead it today. In my 15 months as Global AIDS Coordinator, I have been privileged to make 16 visits to our partner countries, to see the impact of our work and meet the people who are carrying it out. I have also participated in three Global Fund Board meetings and two meetings of the UNAIDS Programme Coordinating Board. These activities, and many more, are in furtherance of our shared vision of HIV/AIDS programs that save lives effectively today and are sustainable for the long haul.

A foundation of success

Let me offer some perspective on how this investment has worked, and how far we've come. As a clinician, I've been working on HIV/AIDS issues both domestically and internationally for almost 30 years. A decade ago, those of us engaged in HIV work in sub-Saharan Africa were witnesses to daily tragedies on a huge scale. Hospitals were not just full of people dying of AIDS, they were overflowing with multiple patients to a bed, spilling out onto the floors and in the hallways – any place where they could rest while waiting for some care.

While antiretroviral treatment had become widely available here in the United States, fewer than 50,000 people in all of sub-Saharan Africa were receiving it at the beginning of 2003. Even to those of us who had been responding to HIV/AIDS for decades, the scope and inequity of this emergency were overwhelming. Many people thought treatment could never be scaled up because of weak health systems, the need for doctors and nurses, and the lack of resources in these countries.

Today, with American leadership, the task few thought was possible is well under way. Through Fiscal Year 2009, we directly supported almost 2.5 million individuals on treatment, the vast majority in Africa. And millions more are benefiting from prevention and care programs. In FY 2009 alone, PEPFAR supported HIV counseling and testing for nearly **29 million people**, providing a critical entry point to prevention, treatment, and care. The program also supported care for **nearly 11 million** people affected by HIV/AIDS, including **3.6 million** orphans and vulnerable children, through FY 2009. And it supported essential prevention of mother-to-child transmission services to millions of women, allowing **nearly 100,000 babies of HIV-positive mothers to be born HIV-free** in FY 2009 alone**.**

Of course, those results are as of 364 days ago -- tomorrow marks the end of another fiscal year. In the coming weeks, our country programs will be doing the hard work of reviewing and reporting the progress they made during FY 2010. Based on the remarkable efforts of our country teams and partners, we believe these latest results will show continued impressive progress. We look forward to sharing them with you as soon as they are ready.

There is much more work yet to be done, and a large, continuing unmet need. But when I visit African countries now, I see the dramatic transformation PEPFAR has brought about – not only for individuals, but for their families, communities, and nations. This change is not just reflected in hospitals and clinics, which are no longer overwhelmed by people dying of AIDS. It's reflected in the day-to-day lives of people in so many ways, large and small.

Mr. Chairman and Ranking Member Ros-Lehtinen, this work is about saving lives, by meeting our shared, global responsibility to make smart investments. In our conversation today, I hope that we can maintain a focus on the human impact of this effort. It is always a challenge to make it real for people when those we serve are so far away, but we must do so, because the reality is truly inspiring.

It is the human impact of this effort to date that tells us much more is possible as we move forward. It is a strong foundation upon which we are building the next phase of PEPFAR, and a new phase of global health assistance.

My testimony today is far from an exhaustive catalogue of our efforts, and there is much more that can be said on all of these topics. I look forward to our conversation.

Areas of recent action

From my perspective, in this second phase of PEPFAR, we are realizing the vision and building on the remarkably successful foundation of its first phase. In the past year, we have released a Five-Year Strategy, outlining how we plan to do that in the next phase of PEPFAR.

We have also contributed to the rollout and implementation of GHI, and started to advance policies and programs that not only expand service delivery, but create the long-term partnerships needed for a sustainable program.

I'd like to highlight two broad categories of steps we have taken.

Saving lives through wise investments. The metric that PEPFAR and all GHI programs use to measure success is not dollars spent, but lives saved. In order to save as many lives as possible, we have focused on making smart investments that maximize the human impact of each dollar. PEPFAR has made encouraging progress in ensuring that investments are evidence-based, and in pursuing innovation to create efficiency gains in our programs.

In 15 countries, we have mapped our prevention programs, allowing us to evaluate our investments and adjust them based on the data. We have led the world in rapidly scaling up high-impact biomedical interventions for prevention such as male circumcision and prevention-of-mother-to-child transmission – in FY 2009 alone, PEPFAR programs averted nearly 100,000 infant infections. We've worked to ensure that activities target populations where new infections are concentrated, including marginalized populations such as injecting drug users, men who have sex with men, and people engaged in sex work.

PEPFAR has also increased expenditure reporting and cost-modeling efforts to identify significant reductions in treatment costs and identify how the program can expand service delivery through reinvestment of these savings. Building on this, we are developing a PEPFAR

impact and efficiency acceleration strategy, and fostering a culture of explicit value consideration and efficiency at all levels of our operations.

New clinical data have made it clear that treatment has a clear prevention effect, by sharply reducing the infectivity of people on antiretroviral drugs (ARVs). Multiple mathematical models demonstrate that continued expansion of the treatment response could begin to have a substantial impact on the incidence of new infections. So it is more important than ever that our prevention, treatment and care programs be integrally linked. The choice between treatment and prevention is a false one.

Responding to feedback from our country teams, PEPFAR has moved to a two-year planning cycle, which will reduce the paperwork burden and allow the field to increase support for service delivery. We have also launched an effort to streamline our budget execution processes so the money moves as quickly as possible – from the appropriated account to the implementing agency headquarters, and then to the field, and finally to partners to be expended. I have made it a high priority to clear balances and reduce pipelines, and we are making significant progress.

Reflecting the GHI principle of support for research and innovation, another priority is operations research, which helps us quickly determine what is working and disseminate it widely. We are working intensively to identify innovations and best practices so that all of us can do more with each available dollar – and ultimately save more lives. In the difficult economic climate we face, this is an absolute obligation.

Building the long-term response by strengthening engagement with the Global Fund and other multilateral partners. A major theme of the Obama Administration's new approach to health and development has been the shared responsibility of the U.S., partner countries, and other donors to ensure that we can build a sustained program that will result in more lives saved. Last year, the U.S. provided nearly 60 percent of donor government funding for HIV/AIDS. In many countries, our contribution to the total response is even higher.

The global need for HIV/AIDS prevention, treatment and care is a global responsibility, and all have roles to play in meeting it. Under the GHI principle of working through partnerships, the U.S. will remain strong in its commitment and seek to leverage heightened commitments from all sources -- including partner governments, donor nations, the private sector, civil society, philanthropic organizations, and others.

Building on the core strength of the State Department, we are also raising the profile of development in our diplomatic engagement with strategic allies, further engaging the global community in our shared responsibility.

A particularly important mechanism for this increased global commitment is the Global Fund to Fight AIDS, Tuberculosis, and Malaria (Global Fund). The U.S. strongly supports the Fund's collaborative, country-driven, performance-based approach to fighting HIV/AIDS, TB, and malaria.

Since the Global Fund was created, the U.S. has been its largest donor, providing more than $5.1 billion to date. We also provide key on-the-ground support for grant implementation through bilateral technical assistance, capacity-building, and procurement support. Such support has proven crucial to ensuring grants deliver on their potential. Given the size of the Global Fund grant portfolio and the global unmet need, it is essential that Fund resources are used as effectively and efficiently as possible.

We have also worked to expand collaboration with UNAIDS and the United Nations family, including UNICEF and the World Health Organization, around a common theme of shared, global responsibility and action to reverse the course of this epidemic.

Simply put, our bilateral programs and our multilateral engagement share a common purpose: saving lives, both now and into the future, through wise investments.

Plans for moving forward

As we continue implementation of PEPFAR's Five-Year Strategy and the broader GHI, let me highlight three areas that reflect GHI principles and are among our top priorities going forward.

Leveraging the foundation established by PEPFAR programs in order to save more lives through the Global Health Initiative. During its first phase, PEPFAR focused on delivery of health care services and meeting ambitious goals for prevention, care, and treatment. Its success has largely been built on the ability to meet those goals. As PEPFAR now moves from an emergency to a sustainable response as part of the President's GHI, make no mistake: we will maintain and support expansion of these core prevention, care, and treatment services that are at the heart of the program.

Part of the President's GHI commitment included specific, ambitious PEPFAR goals: direct support of treatment for at least 4 million people, prevention of at least 12 million new infections, and care for at least 12 million people, including at least 5 million orphans and vulnerable children.

Despite these clear commitments, in some quarters, there has been a perception that GHI will diffuse the focus of PEPFAR and limit our ability to deliver on our core work. I want to address this head on. I firmly believe the approach the GHI implements is critical to the future success of PEPFAR.

As I have mentioned, I have been working with people living with, or at high risk of, HIV for my entire career. These people are not defined by the virus alone. Like everyone else, they have a range of health needs. That's why integration of programs is a core GHI principle, and the GHI will make it easier for us, working with the partner country and other partners, to holistically address that range of needs. We'll align our U.S. programs so they address people the same way our field staff have always seen them -- not just as a person with HIV, but as a person, period.

The reach and impact of PEPFAR are enormous, with programs in over 80 countries. In the 30 countries where we are most heavily invested, there are many other U.S. government health initiatives that span the majority of the population. Building additional services onto the

PEPFAR platform – such as maternal and child health, tuberculosis, and nutrition support – not only expands the ability to provide care without building additional infrastructure, but also helps to create a basic package of health care services.

So on a concrete level, GHI means leveraging the systems we have built to ensure that a person with HIV has access to other U.S. programs that will improve his or her health outcome.

At the same time, PEPFAR is also eager to reach the clients of other U.S.-supported programs – such as maternal and child health (MCH) – with HIV interventions. For example, women who come to antenatal clinics in areas with high HIV burden are an ideal population for programs to prevent of mother-to-child transmission (PMTCT) of HIV to target.

So integrating MCH and PMTCT programs probably sounds like a no-brainer. But if it were already happening everywhere we wouldn't be having this conversation. Integration under GHI offers us the possibility of increasing our impact on health, and making each dollar we spend go farther. And as we integrate programs like PMTCT and MCH and increase our effectiveness and efficiency, we'll also seek through GHI to target additional investments to these high-impact activities.

Dr. Shah, Dr. Frieden and I all recognize that the mission is not program integration for integration's sake, but smart integration to improve and save lives, focusing on the areas where we can add value by collaborating. So those opportunities are what we are working to identify, in all countries with U.S. global health programs and especially in eight initial "GHI Plus" countries. For people living with or affected by HIV, I am confident that this effort will achieve our ultimate goal of saving lives.

Addressing the impact of broader gender issues with HIV programming. The President's GHI recognizes that focusing on women, girls, and gender equality is a force multiplier: it improves the health status of women, and in turn that of their families and communities.

For PEPFAR, this focus is essential. AIDS is the leading cause of death of women of reproductive age worldwide, and nearly 60% of those living with HIV in sub-Saharan Africa are women. In the countries where PEPFAR works, HIV is a women's health issue, and prevention, care and treatment services must be tailored to the gender realities within a country.

During its first phase, PEPFAR began a five-point gender strategy, through which we seeded country programs with multiple small initiatives. To build on this important foundation, in the next phase we are working to improve implementation of our gender strategy, and scale up efforts and heighten impact with a focus on PMTCT and country-led gender projects.

One risk factor for HIV infection for women is the tragic epidemic of gender-based violence. Earlier this year we launched an initiative to invest $30 million in activities to combat gender-based violence in three countries severely burdened by it. We're supporting post-exposure prophylaxis and other care for women victimized by rape, but also seeking to prevent sexual violence in the first place.

And last week, we joined with Ambassador Melanne Verveer to partner with the Together for Girls public-private partnership. This is a groundbreaking effort to address the epidemic of

violence against girls, and we are pleased to be partnering with CDC, members of the United Nations family and the private sector to help end this global scourge.

Innovation to provide women with prevention interventions they can control is a critical priority. With PEPFAR funding in 2007-2010, USAID supported two trials with specific antiviral agents and unique delivery regimens which might increase user acceptability and compliance as well as product effectiveness.

In July 2010, the landmark results of the CAPRISA trial of 1% Tenofovir Vaginal Gel were announced, providing the first-ever proof of concept that a microbicide can significantly reduce the risk of HIV infection in women. Volunteers using it had an overall reduction in HIV infection of 39%, and in volunteers who were most compliant in using the gel, the reduction was even higher, at 54%. With continued U.S. technical and financial leadership, this breakthrough in development of a woman-controlled method of HIV prevention has the potential to reduce the spread of HIV and empower women to protect their health and lives.

The U.S. is supporting further research on -- and appropriate preparations for the future introduction, distribution, and use of -- these new technologies in developing countries. Country teams are already addressing the multiple social, cultural, economic, and political factors that will influence the acceptance and use of these new products at the individual and community levels.

All of these efforts support the GHI principle of implementing a woman- and girl-centered approach to health. In the HIV context, these are smart investments that will save lives.

Expanding country ownership and local capacity to build sustainable health care delivery systems. As we responded to the HIV emergency in the first phase of PEPFAR, we tended to work through international implementing partners with existing capacity, in order to save as many lives as possible. While successful, this had the by-product of establishing or strengthening systems of care and delivery parallel to country public health systems, which are typically weak.

Reflecting the GHI principle of support for country ownership, a major priority of PEPFAR's second phase is to increase the capacity of countries at both the government and civil society level, so that countries are better able to manage, oversee, and operate their health systems – and increasingly to finance them, based on their available resources.

We are approaching countries in a spirit of true partnership to identify, prioritize and meet health needs. PEPFAR's support for country ownership is demonstrated through Partnership Frameworks, 15 of which have been signed to date. These are five-year, high-level agreements between the U.S. and partner governments that leverage our investments to obtain measurable financial, programmatic, and policy commitments to HIV and health systems.

Through Partnership Frameworks, we are demonstrating by our actions that we see governments as partners, rather than recipients or obstacles. An important recent Partnership Framework is the one we have entered into with Nigeria, which includes the first public affirmation by that country's government that they expect to self-fund 50 percent of the response to HIV by the end of the 5-year implementation period.

In addition, the U.S. has worked with specific governments, including the Government of South Africa, to establish responses that leverage initial U.S. investments for long-term increases in commitment and capacity by the partner government.

Another example of country ownership in action is the transition of treatment programs in 13 countries to the leadership of government structures and indigenous organizations. This transition is challenging but critical to ensure that these programs are deeply embedded in the national response and can be sustained for the long term.

Let me offer a template for thinking about the evolution of PEPFAR that may be helpful. During the initial, emergency phase of the program, we relied heavily on international NGOs, because they had the capacity to save lives quickly. In this second phase we have added to that activity a focus on sustainability and country ownership, which includes building the commitment and capacity of governments. As we move forward with that task, we will increasingly emphasize a third dimension of activity -- community empowerment. As we pursue the GHI principle of support for health systems for sustainability, it is local community and civil society organizations that can play the critical role of ensuring accountability for country structures in a way that outsiders never can. PEPFAR planners at the country level and at headquarters want to empower communities – including those directly affected by programs, such as people living with HIV – to have the ability to provide that feedback to government ministries, Global Fund Country Coordinating Mechanisms, and other country structures. That dialogue is essential for true sustainability.

Conclusion

In conclusion, I believe we are at a key moment in the global response to this disease.

In the last two months, there were two major international events at which HIV/AIDS played a significant part – the International AIDS Society meeting in Vienna, and the U.N. Millennium Development Goals Summit in New York.

While all acknowledge that there are significant challenges before us, both events provided many reasons to be hopeful. In Vienna we learned about the CAPRISA success and heard encouraging reports about the potential for innovation and increased efficiency to help us do much more to save lives. In New York, we heard from President Obama, the U.N. Secretary General and many others the continued strong commitment to meet the Goals – including the three health-related goals, in which effective HIV/AIDS responses play a central role.

Mr. Chairman and Ranking Member Ros-Lehtinen, under the President's approach to health and development, I believe we are well-positioned for major strides forward in the fight against HIV/AIDS. As always, I remain grateful for your strong support.

Thank you. I look forward to your questions.

Chairman BERMAN. Dr. Frieden.

STATEMENT OF THOMAS R. FRIEDEN, M.D., M.P.H., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, AND, ADMINISTRATOR, AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY

Dr. FRIEDEN. Thank you very much. Good morning, Chairman Berman and Ranking Member Smith. It is a pleasure and an honor to be here along with my friends and colleagues, Dr. Goosby and Dr. Fauci.

Over the past year I have had the great privilege of visiting PEPFAR services in Ethiopia, Tanzania, Mozambique, Nigeria and other countries. I have been inspired by the proof that there is a critical impact of the leadership and support of this committee of the wonderful work of our staff and our partners on the ground and of the effectiveness of the PEPFAR model as a true whole-of-government approach.

The CDC deeply appreciates the leadership provided by OGAC and the important work of NIH, as well as USAID and other implementing partners.

CDC has a unique role and history in global health. It is essentially in CDC's DNA, going back to the 1960s and 1970s when, with WHO, CDC led the global smallpox eradication program. Among other initiatives today we detect and stop outbreaks, support epidemiologic and laboratory systems, help prevent and control malaria, support progress in the control of measles and the eradication of polio.

We also fundamentally improved the capacity of partner governments to plan, implement and monitor their own programs. We have a unique role supporting international organizations, providing consultations, training and embedded staff.

Today more than 2.5 million people are alive, productive and healthy who would otherwise have been dead or dying without PEPFAR. Last year 100,000 babies who would otherwise have been infected were born HIV free because of PEPFAR.

The first slide shows the dramatic expansion in the proportion of met need for treatment in countries, the original PEPFAR countries, in the southern cone of Africa. The second slide shows the dramatic scale-up in treatment in recent years.

In short, not only are communities and systems throughout the world dealing with HIV better, but they are better prepared to deal with other health problems. PEPFAR, with OGAC's whole-of-government leadership, is working.

We face two key challenges going forward. First we need to scale up treatment sustainably and cost-effectively to reach even more people; and second, we need to take prevention to the next level.

When Congress had the wisdom to authorize PEPFAR and OGAC's whole-of-government model, CDC was well poised to contribute because of our work globally and in this country, and their involvement in HIV since the first days of the epidemic. We were already on the ground in sub-Saharan Africa, monitoring and directing efforts to understand the nature of the epidemic, and developing and disseminating the latest science, an effective tool to control HIV.

CDC and HHS is the counterpart of ministries of health, and we work in a peer-to-peer relationship. To implement programs effectively and sustainably, it is essential that they be inextricably linked with rigorous evaluation, capacity development, systematic laboratory and capacity tracking, and practical research. We have unique expertise evaluating whether investments are working, and doing cutting-edge research to drive improved service delivery, and to make more effective use of scarce resources.

The committee has recognized that sustainable systems and country ownership are essential components in PEPFAR, and that is our commitment at CDC as well. To further scale up effectively, PEPFAR is transitioning to more local, sustainable and cost-effective programs. Already nearly half of CDC's funding is implemented thorough cooperative agreements with health ministries or other local in-country partners, including, very importantly, faith-based organizations resident in their country, which are very important service delivery partners for us.

Treatment costs continue to decrease as we decentralize care. And the next slide shows that steady decrease in unit costs as we transition management to local partners, streamline monitoring, realize cost savings through generics, and ensure treatment at the most high-prevalent sites for pregnant women and TB/HIV co-infected people.

Prevention is critical. We can drive incidence down with a comprehensive package of interventions as shown on the next slide, including a series of proven and some potential but high—potentially high-impact interventions. Prevention of maternal-to-child transmission, HIV screening link to care and treatment, safe blood, male circumcisions, condoms and other proven interventions can make a big difference not only individually, but, as the next slide shows, in combination. We anticipate that there can be synergistic decreases in incidence.

As we think of multicomponent prevention, we make the analogy to multidrug treatment for HIV. The breakthrough in HIV treatment came when we were able to use multiple drugs to stop replication of the virus in multiple pathways. In the same way we hope to have multiple ways of stopping transmission in a community to drive incidence down.

PEPFAR is a critical platform to build the Global Health Initiative, and the whole-of-government process overseen by Ambassador Goosby is a model of effective collaboration. This gains efficiencies by using existing infrastructure of various agencies and funding programs based on comparative advantage.

PEPFAR embodies the principles of GHI to achieve specific health outcomes, strengthen systems for sustainable improvements, maximize impact of all dollars, encourage country ownership, improve monitoring and evaluation, and accelerate research and innovation.

In conclusion, PEPFAR is a tremendous success. The confidence this committee has had in us all is paying off in lives saved, infections prevented and systems strengthening. The interagency, OGAC-led model that Congress has been so supportive of is working. We are proud of the important role CDC is having in this success and will amplify PEPFAR's success as we move forward with

GHI by implementing programs which reach more people and stretch our dollars even further.

We are optimistic about the future, about the ability to reach more people, drive down incidence, reduce costs, and build sustainable capacity.

Thanks you very much for the opportunity to be here today, and I look forward to answering your questions.

Chairman BERMAN. Thank you.

[The prepared statement of Dr. Frieden follows:]

Testimony before the
House Committee on Foreign Affairs
U.S. House of Representatives

PEPFAR: From Emergency to Sustainability and Advances Against HIV/AIDS

Thomas R. Frieden, M.D., M.P.H.
Director, Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

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Good morning, Chairman Berman, Ranking Member Ros-Lehtinen, and other distinguished members of the Committee. I am Dr. Tom Frieden, Director of the Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services (HHS) and an implementing agency of the President's Emergency Plan for AIDS Relief (PEPFAR). I appreciate the opportunity to be here today alongside my colleagues Dr. Goosby and Dr. Fauci to discuss CDC's role in implementing and strengthening this critical, life-saving program.

HHS as a Department contributes to PEPFAR in many ways. In addition to CDC and NIH, significant contributions are being made every day by the Food and Drug Administration through expedited drug approval, the Health Resources and Services Administration, through delivery of medications and services, the Substance Abuse and Mental Health Administration in relation to substance abuse prevention, care and treatment, and the Secretary of HHS through the Office of Global Health Affairs, providing leadership and policy coordination.

Today, I would like to discuss: 1) the unique strengths that CDC contributes to PEPFAR and the Global Health Initiative; 2) some specific PEPFAR accomplishments; and, 3) some of the most promising tools on the horizon of the fight against HIV/AIDS.

GLOBAL HEALTH INITIATIVE

The Administration's Global Health Initiative (GHI) is a comprehensive, whole-of-government approach to global health that builds on the successes of existing programs to both achieve specific health outcomes and strengthen health systems to increase the sustainability of those improvements. This approach will maximize the health impact of every dollar the U.S. government (USG) spends on global health programs. GHI will, among other principles, encourage country ownership and invest in country-led planning; build sustainability through stronger health systems; improve metrics, monitoring, and evaluation, and accelerate research and innovation. To accomplish this, we will build

on the successful foundation of programs such as PEPFAR, which is a significant and successful platform for GHI. Through Partnership Frameworks with PEPFAR countries, the USG is already a leader in transitioning health programs to ownership and leadership by partner countries, building sustainable capacity in laboratory, workforce, and other critical elements of strong health systems, and conducting groundbreaking operations research in countries with the world's most significant health burdens.

Over the past few months, it has been my privilege to visit PEPFAR programs in several countries and see first-hand the dramatic results this program is achieving: nearly 2.5 million people alive and healthy today receiving life-saving treatment, and more than 100,000 infants born HIV-free last year who would otherwise have been infected. The success of PEPFAR is also measured by stronger health systems that can better support progress in years to come. GHI will build on PEPFAR's successes and encompass other areas of global health, as the USG continues to be a leader in the fight against HIV/AIDS around the world. Together, we are confident that our continued achievements in the fight against global HIV will reduce more infections and save more lives around the world.

GLOBAL HIV/AIDS CONTEXT

Substantial progress has been made in HIV prevention, care and treatment worldwide, under the leadership and coordination of the Office of the Global AIDS Coordinator (OGAC) and through USG implementing agencies. New HIV infections have been reduced by 17% over the past eight years[1], and at the end of 2009, more than 5 million adults and children were receiving antiretroviral therapy (ART) in low- and middle-income countries.[2] This ART expansion represents a 25% increase in one year and a 10-fold increase in 5 years, with the greatest expansions in sub-Saharan Africa where the need is greatest. In FY 2009 alone, PEPFAR supported HIV testing and counseling for nearly 29 million people and provided services to millions of women.

[1] Data from the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) 2009 AIDS epidemic update. http://data.unaids.org/pub/Report/2009/JC1700_Epi_Update_2009_en.pdf
[2] World Health Organization.
http://www.who.int/mediacentre/news/releases/2010/hiv_treament_20100719/en/index.html

Despite these tremendous achievements, AIDS remains a leading cause of death in many countries and the leading cause of mortality worldwide among women of reproductive age. According to UNAIDS, 33.4 million people are living with HIV worldwide, and approximately 2.7 million new infections occurred in 2008. It is estimated that more than 7,000 new HIV infections still occur every day. The vast majority of these new infections (97%) are in low- and middle-income countries, and women and girls are disproportionately impacted. Adding to the problem is the fact that most-at-risk populations - including men who have sex with men, sex workers, and injecting drug users - continue to face stigma that limit their ability to obtain treatment and prevention services, contributing to the wider transmission of HIV.

CDC'S UNIQUE ROLE IN GLOBAL HEALTH

CDC is a science-based public health agency that uses a government-to-government approach, both domestically and globally, to maximize public health impact. Here at home, CDC provides technical, financial, and programmatic service delivery support to State, tribal, local, and territorial health departments. Building upon this model globally, CDC has long-standing relationships with Ministries of Health in partner countries. Through these partnerships, we apply our expertise in translating and adapting scientific breakthroughs and research into program implementation. Directly funding Ministries of Health through cooperative agreements for specific projects and defined capacity-building, providing them with direct technical assistance, and embedding personnel within their offices for peer-to-peer mentoring and knowledge transfer has resulted in increased government performance, capacity development, country ownership and public health impact. CDC has for more than 50 years extended the impact of our technical assistance by also placing staff in multilateral agencies such as WHO, the World Health Organization (WHO), UNICEF and UNAIDS to apply CDC scientific and program implementation to help these agencies maximize the health impact of their programs.

Still, we can increase our global health impact by embracing more efficient and effective models of operation. We've recently created CDC's Center for Global Health (CGH), which consolidates many

of our global health programs, including our Division of Global HIV/AIDS, our Division of Parasitic Diseases & Malaria, our Division of Global Disease Detection & Emergency Response, and our Division of Public Health Systems & Workforce Development. Outside of the Center, there are still global activities in more than 100 branches throughout CDC, with more than 10,000 health professionals available to assist as needed. The new Center serves as a focal point for leveraging expertise from our domestic programs in infectious disease, chronic disease, injury prevention, prevention of birth defects, and other areas as needed in the global context, and will allow us to more efficiently achieve evidence-based global public health impact, global health security, and global capacity development.

CDC's guiding principles for our global health work are to: strengthen public health capacity; better use data to improve program performance and policy; and maximize sustainable health impact through the use of existing and new systems, cost-efficiencies, partner investments, and scale-up of the highest impact interventions with a focus on populations with the greatest need.

A SHARED APPROACH TO GLOBAL HIV/AIDS PREVENTION, CARE AND TREATMENT

CDC is dedicated to enhancing America's leadership in the fight against global HIV/AIDS. PEPFAR is the cornerstone of the Global Health Initiative, and the platform upon which many of our future health successes will be built. Under the coordination of Dr. Goosby and the Office of the Global AIDS Coordinator, CDC is committed to collaborative and complementary programming with other PEPFAR implementing agencies to achieve our common goals. Through these partnerships, we build on each other's unique strengths, and use research to constantly improve our effectiveness and efficiency. Some of the areas in which CDC provides key technical assistance to partner countries include surveillance, laboratory science, HIV/TB service delivery integration, capacity development, training, Prevention of Mother-to-Child Transmission (PMTCT) of HIV programs, and program evaluation and the development of standardized measures.

CDC's unique strengths include our historical partnerships with Ministries of Health and other local partners, our scientists and public health specialists in Atlanta and field offices in 41 PEPFAR-supported countries (including HIV clinicians, prevention specialists, epidemiologists, laboratory scientists, and public health advisors), our expertise in epidemiology, surveillance, laboratory systems, and facility-based health services, and our connection with other global health and domestic public health programs.

Build sustainable public health capacity, infrastructures, and systems

Our approach to strengthening public health systems is integrated, comprehensive and systems-wide. CDC works to build and strengthen information systems to support disease surveillance, program monitoring and evaluation, and management systems necessary for data-driven programming. In addition, CDC supports workforce capacity building through our Field Epidemiology and Laboratory Training Program, and the development of laboratory networks in collaboration with Ministries of Health and their facilities.

The impact of quality laboratory systems cultivated by PEPFAR is significant. CDC has supported the development of more than 1,900 full and integrated, non-disease specific, clinical laboratories and more than 16,500 HIV testing sites throughout the world. These public health laboratory networks build the efficiency and augment the ability of countries to respond effectively to HIV and other diseases, including emerging health issues, such as H1N1. Further, we support the quality of laboratories through a novel accreditation program and a regional training facility and the development of innovative public health laboratory approaches such as HIV testing of infants.

Expand quality HIV/AIDS care and treatment services and transition these services to local host government ownership

PEPFAR's success in expanding the reach of antiretroviral therapy in resource-constrained countries is well documented. Through FY 2009, PEPFAR directly supported life-saving antiretroviral therapy for nearly 2.5 million people. CDC works with our country programs, partners, and Ministries of Health

to plan, implement, and evaluate strategies for HIV care and treatment services. A highly integrated approach is used to link these services with HIV prevention services and other mainstream health care services to leverage resources and promote universal access. This integrated approach strengthens a country's entire health care system and HIV service delivery effectiveness, efficiency and sustainability.

Two key focus areas are the transition of adult care and treatment services from USG agency implementation to country ownership and the integration of tuberculosis and HIV services.

PEPFAR's Antiretroviral Therapy Program – CDC has a central role in program service delivery for the care and treatment of people with HIV. CDC in collaboration with the Health Resources & Services Administration (HRSA) manage a substantial part of the Antiretroviral Therapy Program, which funds US-based implementing partners, including the Elizabeth Glaser Pediatric AIDS Foundation and Columbia University's International Center for AIDS Care and Treatment Programs (ICAP), Catholic Relief Services (CRS) and Harvard School of Public Health to rapidly scale-up treatment in PEPFAR countries. Through these partners, CDC and HRSA distributes funds and technical support to about half of all patients receiving PEPFAR-funded HIV care and treatment (with USAID supporting approximately the same number). Together, CDC and HRSA support more than 1.1 million patients at 1,250 facilities in 13 countries. CDC and other USG agencies work with Ministries of Health and other local partners including Faith Based Organizations, to increase care and treatment capacity, and to work toward the goal of transferring administrative and clinical responsibilities for ART services to host governments and other local partners, while ensuring quality care. As a concrete example of transitioning to greater country ownership, PEPFAR U.S.-based implementing partners are shifting their emphasis from direct service delivery to strengthening capacity at national, provincial, and district levels to deliver these same services.

TB/HIV integrated care and treatment – The prevention and control of HIV and tuberculosis (TB) are inextricably linked, particularly in sub-Saharan Africa, home to about 80% of the world's cases of HIV/TB co-infection. Among people living with HIV, TB is the most common opportunistic infection and one of the leading causes of death. CDC staff work closely with Ministries of Health to integrate TB and HIV programs. As a result of the combined efforts of CDC, other USG agencies, multi-lateral agencies, and partner countries, the majority of TB patients are now being tested for HIV in TB clinics in Botswana, Kenya, Malawi, Mozambique, Rwanda, Tanzania, Uganda, and Zambia.

Additionally, CDC helped to establish and continues to advise the African Centre for Integrated Laboratory Training (ACILT) in partnership with USAID, WHO, the Government of South Africa, and private sector partners. The partnership improves the quality and availability of laboratory diagnostics for integrated control of TB, HIV, malaria, and other diseases. In addition, in support of multi-drug resistant TB surveillance and patient management, CDC has, through PEPFAR, strengthened TB laboratory capacity to diagnose drug-resistant TB by introducing rapid and more sensitive diagnostic methods.

CDC also plays a lead role in linking US government strategy and WHO policy to TB/HIV integration. In 2009, CDC scientists helped develop WHO's new ART guidelines which recommend immediate HIV treatment for all HIV-positive TB patients. CDC has also provided technical input to WHO's "Three I's Strategy" for global TB control - Intensified case finding, Infection control, and Isoniazid preventive therapy. Moving forward, the Global Health Initiative presents an opportunity for CDC and other USG agencies to further accelerate TB/HIV integration.

Implement effective and evidence-based HIV/AIDS prevention programs that build synergies between prevention and care and treatment programs

CDC supports the Office OGAC's vision of strengthening prevention programs through implementation of behavioral, biomedical, and structural interventions with known efficacy at a scale,

quality, and intensity to impact the epidemic. In the absence of an HIV vaccine, we believe that an aggressive, comprehensive package of prevention interventions at scale could approach moderate vaccine efficacy.

Such a comprehensive approach relies on the synergies between prevention and care and treatment programs and includes: 1) HIV testing and counseling of all adults; 2) Counseling and repeat testing of discordant couples (where one person is HIV-infected, and the other is not); 3) Circumcision of adult HIV-negative males; 4) ART for eligible HIV-infected persons and pregnant women; 5) PMTCT for pregnant women; 6) Condom promotion, distribution, and education (including female condoms); 7) Enhanced linkages among HIV testing and counseling, male circumcision, PMTCT, and HIV treatment services; 8) Availability of safe blood through strengthened, sustainable systems; 9) Availability of safe needles; and 10) Information platforms to monitor and evaluate interventions. A modeling exercise conducted by the Futures Group has looked at the impact of combination interventions on HIV infection rates, applying sophisticated modeling techniques to a generalized, high-prevalence context, and found that infections could be cut by more than half.[3] Such impact could alter the course of this epidemic.

In addition to these proven strategies, we need to study promising practices, including promoting partner reduction and delay of sexual debut, interventions to decrease intergenerational (often forced) sex, antiretroviral microbicides, and oral pre-exposure prophylaxis (PrEP). For all of these strategies, even those proven to be effective, we must conduct thorough and aggressive monitoring and evaluations and improve how we implement these interventions. Together we are committed to optimizing all proven prevention modalities while continuing our promising search for an effective vaccine.

CDC's work in program monitoring and evaluation, surveillance and epidemiology and in building the capacity of Ministries of Health in these areas has been essential to PEPFAR's effective prevention

[3] Unpublished modeling data from the Futures Group

programming. By tailoring prevention interventions to the country context and characteristics of the localized epidemic and through on-going surveillance, monitoring, and evaluation, these prevention strategies can remain effective through course corrections as the epidemic evolves.

One of the key prevention areas in which CDC has played a significant role is blood safety. CDC works with Ministries of Health to develop and strengthen national blood transfusion services (NBTS), especially in countries with a high burden of HIV. Since 2004, CDC has provided ongoing technical assistance support to 14 countries with NBTS programs, with the goal of ensuring an adequate supply of safe blood through screening for transfusion-transmissible infections (HIV, syphilis, Hepatitis B, Hepatitis C). In 13 of these countries, the NBTS reported a decrease in the percentage of collected blood units reactive for HIV between 2003 and 2009-- for example, in Botswana the percentage from 7.5% in 2003 to 2.1% in 2007. In Zambia, CDC has supported the shift from a fragmented hospital-based system to a regionalized system under the control of the country's NBTS. Zambia has also eliminated risky family replacement donations, where family members donate blood to each other without testing or other safety measures. The program has increased the number of voluntary non-compensated donations (which are at less risk for HIV reactivity) from 40,600 in 2003 to 104,000 in 2009. These achievements were made by building sustainable capacity within the health system, which will continue to benefit the health of Zambians long into the future.

Conduct, translate, and operationalize research on program impact and cost effectiveness

Through PEPFAR, unparalleled scientific innovations in evidence-based interventions, technologies, and practices in global HIV/AIDS have contributed significantly to preventing infection and providing effective care and treatment. Clinical, operations, and impact evaluation research have contributed to this scientific evidence base. CDC translates and operationalizes research to promote the use of data to make programmatic decisions and improve performance. For example, in 1999, CDC led landmark clinical trials in Thailand and Cote d'Ivoire that demonstrated the efficacy of short-course zidovudine-- a relatively simple, low-cost intervention-- to reduce the risk of HIV transmission from mother to baby.

Translating this science into action, CDC worked with PEPFAR implementing agencies and Ministries of Health to scale up PMTCT, allowing nearly 340,000 babies of HIV-positive mothers to be born HIV-free through FY2009.

The 2008 reauthorization of PEPFAR recognized CDC's unique contributions, and called for an enhanced role for the agency in "carrying out and expanding program monitoring, impact evaluation research and analysis, and operations research and disseminating data and findings." To this end, our research has included analyses of program impact, efficiency, and cost effectiveness to guide program planning and decision-making. Some of these key initiatives have focused on cost-efficient care and treatment, scaled-up PMTCT services, and aggressive analysis of programmatic cost efficiencies and impact:

- **The Basic Care Package** – A novel approach to integrating evidence-based interventions, the Basic Care Package was developed by CDC to prevent the most debilitating opportunistic infections among people living with HIV. The Basic Care Package bundles high-impact, low-cost interventions that are easy to implement, and that are tailored to the local epidemic. These interventions can include: cotrimoxazole (a powerful antibiotic preventing opportunistic infections in persons living with HIV); insecticide-treated bed nets to prevent malaria; services for the screening and management of sexually-transmitted infections; PMTCT services; counseling services; and safe water systems. The services included in the Basic Care Packages are selected based on multiple CDC research studies that demonstrate that these interventions significantly improved health outcomes while remaining cost-effective. The Basic Care Package was scaled-up in Uganda and has been replicated in all of the original 15 PEPFAR focus countries and elsewhere.

- **PEPFAR's Antiretroviral Therapy Costing Project** – Through PEPFAR, CDC and OGAC have led a study of ART costing to estimate the annual per-patient cost of outpatient HIV treatment and associated care. The study informed planning and resource requirements for treatment scale-up, identified the factors that drive costs, and created projection models for

use at both country and PEPFAR-wide levels. To date, this work has been conducted at 64 HIV treatment facilities across Nigeria, Uganda, Ethiopia, Botswana, Vietnam, Mozambique, and Tanzania. CDC and OGAC are currently planning to conduct similar evaluations for Kenya, Swaziland, and Guyana. Similar analyses are also being applied to other public health intervention strategies to ensure we maximize cost effectiveness in all public health efforts.

Together with OGAC, CDC also pioneered and successfully piloted routine expenditure analysis activities across all program areas, which provide PEPFAR country teams with regular, timely information on the total USG and unit costs for delivering a service, by program activity and partner. The expenditure analysis activities facilitate better program management and identification of efficient program models. Expenditure analysis has been embraced as a central component of PEPFAR's initiative to accelerate program impact and efficiency.

Using Data for Policy Change and Improved Performance

Perhaps one of the most significant examples of CDC's work with host country governments to build sustainable public health infrastructure, strengthen health systems, and use data to affect policy has been the Kenya AIDS Indicator Survey (KAIS), released last year by the Government of Kenya.

KAIS represents a significant milestone for Kenya in strategically targeting HIV resources and programming for maximum disease impact. With PEPFAR funding and technical assistance from CDC and USAID, the Government of Kenya implemented KAIS, the most comprehensive Kenyan national surveillance effort to date. The survey included serological testing for HIV, syphilis, HSV-2 infection and CD4 cell counts among HIV-infected participants, as well as direct questions about knowledge of self and partner HIV status. HIV-infected adults who knew their HIV status were also asked whether they were receiving treatment in order to assess coverage and unmet care and treatment needs. Nearly 18,000 adults aged 15-64 years completed an individual interview, 88% of whom consented to having blood drawn.

The findings of this survey emphasize the need for more comprehensive surveillance data to monitor the HIV epidemic and to inform HIV policies and resource allocation. A comparison of 2007 KAIS estimates to results from the 2003 Kenya Demographic and Health Survey found that only one in six (16.4%) of the estimated 1.4 million Kenyan adults aged 15-64 years living with HIV infection in 2007 knew their HIV status, suggesting that roughly 84% did not. A closer look at subpopulations also revealed important demographic and geographic patterns-- while urban HIV prevalence had stabilized or even declined, the burden of HIV in rural areas had increased. Additionally, young women aged 15-24 years were four times as likely to be infected compared to young men the same age, a pattern that had not changed since 2003.

As a result of such findings, Kenya's National AIDS Control Council changed their HIV/AIDS strategy emphasizing that HIV testing must be made more accessible through approaches such as provider-initiated testing and home-based testing. KAIS findings also prompted Kenyan policymakers to call for contraceptive services for women who do not desire children, the reduction of sexual partners of unknown HIV status, and primary prevention of sexually-transmitted infections known to increase the risk of HIV. In 2009, a new Kenya National HIV/AIDS Strategic Plan was released re-aligning program interventions and services in accordance with the KAIS findings and the evolution of the Kenya HIV/AIDS epidemic.

KAIS made it abundantly clear that an effective, sustainable public health system infrastructure and comprehensive national HIV surveillance system are critical to timely course correction in policy and strategy necessary to assure maximum health impact.

HIV/AIDS Science and Research - A Growing Body of Evidence

Many U.S. Government agencies continue to make significant contributions to the body of HIV/AIDS science and research. Each agency's contribution has been complementary to and has built upon the growing arsenal in the fight against global HIV/AIDS. CDC and other agencies have conducted significant research on HIV/AIDS domestically that has translated into important gains globally. This

important work continues and has recently yielded promising results on numerous fronts. In the last year alone we have seen several advances from both domestic and international clinical researchers, including results from research on antiretroviral-based prevention and HIV vaccine research.

- **Microbicide Research** – Announced at the XVIII International AIDS Conference in Vienna in July 2010, the results of the Center for the AIDS Program of Research in South Africa (CAPRISA) trial showed that a vaginal microbicide gel containing an antiretroviral drug could reduce the risk of transmission of HIV from men to women. The CAPRISA study—jointly funded by the Government of South Africa through the Technology Innovation Agency and by the U.S. through USAID—proved it is feasible to develop a microbicide that could empower women to protect themselves from infection. Should other studies confirm these results, widespread use of microbicide gels could have a significant impact in reducing new HIV infections.
- **Pre-Exposure Prophylaxis Research** – As part of its commitment to developing new HIV prevention strategies, CDC is sponsoring clinical trials of pre-exposure prophylaxis (PrEP), a potential strategy for HIV-negative individuals to reduce risk of infection through use of oral antiretroviral drugs. An ongoing Phase III study in Bangkok is testing the safety and efficacy of daily tenofovir in a population of 2,400 injection drug users uninfected by HIV. CDC supports one site in a multisite randomized, double-blind, placebo-controlled study in Kenya and Uganda that is testing the safety and efficacy of daily use of either tenofovir or tenofovir plus emtricitabine among 3,900 discordant couples. CDC just completed a PrEP safety trial among men who have sex with men and is supporting an additional safety trial in heterosexual young adults in Botswana, and is participating in planning a National Institutes of Health (NIH)-funded trial of intermittent antiretroviral dosing for PrEP in men who have sex with men. Results from PrEP trials will begin to be reported at the end of 2010 and discussions have already begun to address effective strategies for combining PrEP and current prevention strategies to provide the greatest protection to individuals at risk.

- **Treatment as Prevention Research** – Viral load is recognized as a key risk factor for HIV transmission, and a growing body of research supports the concept that ART can reduce HIV transmission from infected persons by lowering their viral load;. A study of discordant couples showed a 92% reduction in transmission when the infected person was on antiretroviral therapy. In the August 14, 2010 edition of *The Lancet*, Canadian researchers published a study indicating that higher uptake of antiretroviral therapy might reduce HIV transmission considerably in some populations. These complementary findings reflect the evolution of treatment as a prevention intervention-- over time, efficacy in lowering viral loads has improved and the initiation of treatment has begun earlier. Early and widespread treatment ("test and treat") is emerging as a potential component of a comprehensive prevention approach that demands further investigation. Together, efforts on microbicides, PrEP, and treatment for prevention are priority topics for research to clarify optimal use of antiretroviral therapy for individual as well as for public health.
- **HIV Vaccine Research** - Results from the first large-scale international HIV vaccine trial – RV 144 - has shown the first evidence of efficacy from an HIV vaccine candidate. This trial began in Thailand in 2003 as a collaborative effort among the Thai Ministry of Public Health, the U.S. Army Surgeon General, the U.S. Military HIV Research Program, NIH's National Institute of Allergy and Infectious Diseases, and the U.S. Army Medical Research and Materiel Command. This study shows low level but statistically significant results that the HIV vaccine regimen was safe and modestly effective (the rate of new HIV infections was lowered by 31.2%, compared with placebo). Two additional clinical studies are planned that involve providing a booster (to previous RV144 volunteers and new volunteers) to see if this will extend and increase the immune response, and future studies will likely involve populations in other parts of the world with different risk factors. While these studies will take much longer to plan and execute, they will provide important clinical data on how to develop a more effective vaccine that could be used globally.
- **Male Circumcision Research** - Over the past fifteen years, evidence has accumulated that demonstrates the partial protective effect of male circumcision in reducing acquisition of HIV from

an HIV-infected female sex partner. In 2005-2006, three randomized controlled trials (two NIH-led and one led by France's National Agency for AIDS and Hepatitis Research) of medically supervised male circumcision involving more than 10,000 men in sub-Saharan Africa conclusively demonstrated a 60% risk reduction for men from acquiring HIV from women. Based on the cumulative evidence, WHO and UNAIDS are promoting male circumcision as a key HIV prevention strategy in generalized epidemics. PEPFAR is playing a lead role in scaling-up male circumcision programs, with CDC contributing to the rigorous evaluation of these interventions. Similar recommendations have not been made in the United States, although evidence regarding the role of male circumcision and the prevention of HIV/AIDS is under review by researchers.

CONCLUSION

PEPFAR's critical contributions to the monumental fight against global HIV/AIDS has made a tremendous difference in the lives of millions of men, women, and children who would have otherwise suffered. CDC is proud that our unique strengths and our long experience in global health have played a critical role in these achievements. We are committed to working with our U.S. government colleagues, partner governments, and other stakeholders around the world to continue this fight. The Global Health Initiative marks the next phase in this global fight, as we use new models to effectively, efficiently, and sustainably improve health by building on the incredible successes of programs like PEPFAR.

Together with our partner governments and other leaders around the world, we have transformed communities suffering from the effects of the HIV epidemic. If we refocus our efforts, we can greatly improve HIV prevention and treatment while improving health outcomes and building sustainable health systems through the Global Health Initiative. CDC is more committed than ever to working with our partners to achieve these goals.

Thank you again for the opportunity to appear before the Committee today, and I look forward to your questions.

Chairman BERMAN. Dr. Fauci.

STATEMENT OF ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID), NATIONAL INSTITUTES OF HEALTH

Dr. FAUCI. Mr. Chairman, thank you for calling this hearing. Mr. Smith, thank you, and members of the committee. It is really a great pleasure for me to be able to testify before you today together with my close friends and colleagues Dr. Frieden and Dr. Goosby.

What I would like to present to you over the next few minutes is the role of the NIH basic and clinical research endeavor in partnership to help the PEPFAR program implement its fundamental mission.

As shown in this first slide, the advances in HIV research over the last 29 years have been really nothing short of breathtaking from the very beginning of the determination of the etiology, to the pathogenesis, rapid diagnosis, prevention modalities, treatment, and now the promising advances made in the arena of an AIDS vaccine.

On the next slide you see the four areas that I would like to address very briefly with regard to the importance of these findings to the mission of PEPFAR—importantly treatments, obviously prevention, but also a word or two on capacity building and implementation science.

On the third slide is a list of the 30 FDA-approved antiretroviral drugs that have been successfully used in combination to literally transform the lives of HIV-infected individuals. From the very beginning, in the mid-1980s, after we identified the etiologic agents, we began the basic and clinical research to develop these drugs, to prove their effectiveness in clinical trials, and to ultimately determine the optimal way to use them. This has been a great success.

On the next slide you see some interesting figures. I began taking care of HIV-infected individuals in the summer of 1981, within 2 months after the first cases were identified by the CDC. I have been doing that ever since, up to the present time. When a person would walk into my clinic in the summer of 1981, usually with advanced disease, the person had a life expectancy of approximately 26 weeks. If a 20-year-old comes into my clinic tomorrow with newly acquired HIV infection, and I start him on this drug, I can confidently tell him that if he adheres to the regimen, we mathematically predict that that person will live an additional 50 years until they are at least 70 years old.

PEPFAR is now beginning to translate those findings to the developing world, the countries in which they have a major impact. We are not exactly at those life-expectancy numbers yet, but were it not for PEPFAR, we would still be in the situation that I was in in the summer of 1981 with essentially nothing to do for these patients.

If you go to the next slide, these are the proven prevention modalities for HIV. Many of these have been proven by the work of the NIH and the work of the CDC and other agencies. I want to point out three of them that have particular applicability to PEPFAR.

The first is the prevention of mother-to-child transmission, the use of antiretroviral drugs to block the transmission from mother to child, something that is being implemented with great lifesaving effect by PEPFAR. Another is adult male circumcision, which NIH-funded studies proved beyond a doubt is an important way to prevent the acquisition of HIV infection. And the other is proving that the proper use of condoms can block the transmission of HIV. The issue is that we need to implement these, because only 20 percent of people who benefit from these preventive modalities actually have access to them. What PEPFAR is doing is bridging that gap.

If could I have the next slide. You mention treatment as prevention. This is really, in my opinion as an AIDS researcher and public health official, an important wave of the future. Some examples of success already are shown on this slide.

A very exciting study that took place in southern Africa, called the CAPRISA study, used 1 percent tenofovir, an antiviral, in a gel, to block the transmission of HIV to women who used this microbicide. We need to improve on this, and we will. And this is something that PEPFAR is very interested in implementing.

It was shown in a study in Africa that discordant couples, one of whom was infected and the other one was not, if you treated the infected person, you had a 92 percent decrease in the transmission to the uninfected partner.

And then you mentioned the issue of test and treat, which Dr. Frieden was mentioning. If you could penetrate the community and get as many people as possible on therapy, it looks now from mathematical models and as evidenced in places like Vancouver and San Francisco that you could actually, by decreasing the community viral load, prevent HIV transmission to a certain degree.

And then finally there is the development of a vaccine. We are not there yet, but the results over the past few years have been very encouraging.

I want to close by mentioning two additional issues. One is capacity-building, and that is to develop in-country leadership and strengthen the clinical and research capacity. The President mentioned this in his recent speech to the U.N., and Ambassador Goosby has stressed this from the very beginning. We want these countries and their people to be able to have the capacity to continue to do these things on their own. An example of this is the Medical Education Partnership Initiative with HRSA, which builds clinical-care capacity in sub-Saharan Africa.

In addition, on this last slide is implementation science. What we mean by that is how can we best translate the research findings that now work in the developed world to the in-the-trenches, on-the-ground situation that Dr. Goosby and his colleagues have to deal with in places like sub-Saharan Africa and the Caribbean, and we are in strong partnership with PEPFAR in this regard.

On the final slide I want to emphasize the common goal that all of us have. The NIH, the CDC, HHS, PEPFAR, USAID, all of us have the common goal of controlling and ultimately ending the HIV pandemic. PEPFAR is completely integral and essential to the accomplishment of that goal. So I strongly urge you to continue your strong support for the truly lifesaving program that is PEPFAR. Thank you.

[The prepared statement of Dr. Fauci follows:]

Testimony
Committee on Foreign Affairs
United States House of Representatives

The Role of NIH Research in the Implementation of the PEPFAR Mission

Statement of
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U.S. Department of Health and Human Services

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Mr. Chairman and members of the Committee, thank you for the opportunity to discuss the critical role of research supported by the National Institutes of Health (NIH), part of the Department of Health and Human Services (HHS), in advancing the mission of the President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Health Initiative (GHI). I am the Director of the National Institute of Allergy and Infectious Diseases (NIAID), the component of the NIH that conducts and supports a substantial proportion of the research on the human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS). NIH is devoted to better understanding HIV and how it causes disease; developing new and more effective treatments for people with HIV/AIDS; discovering new tools to prevent HIV infection, such as a preventive vaccine; and continuing the ongoing search for a cure for HIV disease.

Twenty-nine years ago, a handful of cases of what is now known as AIDS were first identified here in the United States.[1,2] Since that time, an estimated 597,499 people in the United States have lost their lives to AIDS.[3] More than 56,000 individuals in the United States become infected with HIV each year, and more than 1.1 million Americans currently are living with HIV, according to estimates

[1] Centers for Disease Control and Prevention (CDC). Pneumocystis pneumonia: Los Angeles. *MMWR*. 1981;30(21):250-252.
[2] Centers for Disease Control and Prevention (CDC). Kaposi's Sarcoma and Pneumocystis pneumonia among Homosexual Men: New York City and California. *MMWR*. 1981;30(25): 305-308.
[3] Centers for Disease Control and Prevention (CDC). *HIV Surveillance Report, 2008*; vol 20. June, 2010. Available at http://www.cdc.gov/hiv/surveillance/resources/reports/2008report/.

from the Centers for Disease Control and Prevention (CDC).[4] Globally, the challenges are even greater. Approximately 33.4 million people worldwide are currently living with HIV, and in 2008 alone an estimated 2.7 million people became newly infected with HIV; 2 million died from HIV disease.[5] The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimates that approximately 60 percent of HIV-infected people worldwide do not know their infection status, precluding them from seeking care and significantly increasing the risk that they will unwittingly transmit the virus to someone else.[6]

The public health response to the HIV/AIDS pandemic involves a variety of approaches that you will hear about today. Biomedical research, both basic and clinical, is a major component of this response and is the primary responsibility of the NIH. The goal of HIV/AIDS research is to provide the tools necessary to diagnose, prevent, and treat HIV disease. Several of these tools are directly applicable to the goals of PEPFAR in the developing world. In this testimony, I will first briefly describe for you the accomplishments resulting from basic, applied, and clinical research supported by NIH that have led to interventions implemented by PEPFAR, contributing to the fulfillment of its mission. Then I will

[4] Hall H, et al. Estimation of HIV Incidence in the United States. *JAMA*. 2008;300(5): 520-529; Centers for Disease Control and Prevention (CDC). HIV Prevalence Estimates – 2006. *MMWR*. 2008;57(39):1073-1076.
[5] UNAIDS, WHO. *2009 AIDS Epidemic Update*. November 2009; 6. Available at http://www.unaids.org/en/KnowledgeCentre/HIVData/EpiUpdate/EpiUpdArchive/2009/default.asp.
[6] UNAIDS. *UNAIDS Outlook 2010*. July 2010;12. Available at http://www.unaids.org/OUTLOOK/OutlookReport.aspx.

describe NIH HIV/AIDS research endeavors that will complement the PEPFAR mission in the future

NIH HIV/AIDS RESEARCH RESULTS THAT HAVE ADVANCED THE PEPFAR MISSION

Treatment of HIV Infection

For nearly three decades, NIH has supported much of the basic and clinical research that has led to the development and optimal clinical use of nearly 30 antiretroviral drugs, or ARVs; these medications have transformed the medical management of HIV/AIDS. First, NIH-supported basic research on HIV biology and pathogenesis enabled the development of these ARVs. Second, studies conducted by the global clinical trial networks established and supported by NIH demonstrated that combination ARV therapy is effective and helped to optimize the use of these medications. Finally, the longstanding NIH Multicenter AIDS Cohort Study and Women's Interagency HIV Study have illuminated the clinical course of HIV/AIDS and the effects of long-term treatment with ARVs, further informing the medical management of HIV/AIDS.

Domestically, ARVs have improved and dramatically prolonged the lives of people with HIV/AIDS. When I first began caring for patients with AIDS in 1981, the survival time for these individuals was about six months; now, the life expectancy of an HIV-infected patient with access to life-saving ARVs and other state-of-the-art care approximates that of uninfected individuals, according to

mathematical models.[7] With the provision of ARVs through PEPFAR and other programs that you will hear about from Ambassador Goosby and other witnesses, these lifesaving medications have now reached more than five million HIV-infected people throughout the world.

Prevention of HIV Infection

NIH research also has led to the development of important tools for the prevention of HIV infection that have been key to PEPFAR's successes. For example, NIH-supported studies helped demonstrate that condoms, when used correctly, can prevent sexual transmission of HIV. Another contribution of NIH research is in the prevention of mother-to-child transmission (PMTCT) of HIV, notably with the provision of ARVs before, during, and after birth to mothers and, in some cases, to their newborns. Using the results from NIH-supported studies, these regimens have been refined considerably over the past few years and have been used with great success in the developing world through PEPFAR's programs, saving hundreds of thousands of infants from HIV infection.

Adult male circumcision is another scientifically proven prevention tool in our armamentarium against HIV. In studies conducted in Kenya and Uganda, NIH-supported researchers demonstrated that medically supervised circumcision of adult African men reduced by more than 50 percent the risk of acquiring HIV

[7] van Sighem AI, Gras LA, Reiss P, Brinkman K, de Wolf F; ATHENA National Observational Cohort Study. *Life expectancy of recently diagnosed asymptomatic HIV-infected patients approaches that of uninfected individuals.* AIDS. 2010; 24(10):1527-1535.

infection through heterosexual intercourse, validating many observational studies that suggested a correlation between male circumcision and a decreased rate of acquisition of HIV infection.[8,9] This protective effect has been sustained for more than three years after the procedure.[10] Adult male circumcision now is being implemented internationally as part of PEPFAR's comprehensive HIV prevention programs.

NIH has worked in close partnership with PEPFAR in the fight against HIV/AIDS since members of this Committee, including Chairmen Hyde and Lantos, first supported PEPFAR's establishment in 2003. Much has been accomplished; yet significant challenges remain in our efforts to control and ultimately end the global HIV/AIDS pandemic. Through NIH-supported research, we are addressing these challenges by exploring new and improved ways to prevent new HIV infections, to cure HIV infection, to optimize treatment regimens, to treat HIV/AIDS co-morbidities, and to support PEPFAR programs by providing innovative solutions to these challenges and through implementation science and capacity-building activities.

[8] Bailey RC, et al. Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomized controlled trial. *Lancet*. 2007; 369(9562):643-57.
[9] Gray RH, et al. Male circumcision for HIV prevention in men in Rakai, Uganda: a randomized trial. *Lancet*. 2007; 369(9562):657-66.
[10] Bailey RC, et al. The protective effect of male circumcision is sustained for at least 42 months: results from Kisumu, Kenya Trial. *XVII International AIDS Conference*, 2008.

NIH HIV/AIDS RESEARCH ENDEAVORS THAT WILL HELP THE PEPFAR MISSION IN THE FUTURE

Preventing New Infections

While PEPFAR and other programs have made great strides in providing ARVs to those who need them around the world, the stark reality is that we will not be able to contain the HIV/AIDS pandemic by treatment alone. For every person who starts ARV therapy in low- and middle-income countries, two to three individuals become newly infected with HIV.[11] While numerous tools and strategies, such as those I mentioned earlier, can prevent HIV infection, these interventions are accessible only to a minority of persons at risk of infection.[12] In addition to improving access to these proven prevention tools, we need new prevention modalities if we are to implement a truly transformative HIV prevention effort and reduce HIV infections in the United States and throughout the world. Conducting and supporting basic, applied, and clinical research to develop new tools to prevent HIV infection remains one of the highest priorities of the NIH HIV/AIDS research program.

One such approach that is being pursued by NIH, other federal agencies, and nongovernmental organizations is pre-exposure prophylaxis (PrEP), which involves providing ARVs to HIV-negative individuals who are at high risk of HIV

[11] UNAIDS. *AIDS epidemic update 2009.* http://www.who.int/hiv/pub/epidemiology/epidemic/en/index.html.
[12] UNAIDS. *AIDS epidemic update 2009.* http://www.who.int/hiv/pub/epidemiology/epidemic/en/index.html.

infection, such as the uninfected partner in an HIV-discordant couple. This approach is well-established for preventing other infectious diseases, such as prophylactic administration of antibiotics to prevent certain bacterial infections. Several large PrEP clinical trials are under way, with the earliest results on safety and efficacy expected later this year. These trials also address important questions about the development of HIV drug resistance and the potential for increased risky behavior. Should this approach be proven efficacious in preventing HIV infection, one challenge in implementing PrEP is the cost of providing ARVs to those at high risk of infection at a time when it is not yet possible to treat all those who are already infected. Nonetheless, in selected populations at high risk of infection, it may be cost-effective to implement PrEP to prevent HIV infections. NIH and its partners are committed to determining the scientific and practical feasibility of PrEP as an HIV prevention tool.

One of the compelling features of PrEP is that women and other vulnerable individuals can control its use independent of their sexual partners. Safe and effective topical microbicides, such as vaginal gels, foams, and creams, represent another potentially important method of HIV prevention for women, who now often rely on male-controlled prevention modalities such as the male condom. NIH currently supports a robust research portfolio to develop topical microbicides to prevent HIV infection, to evaluate new products and formulations, as well as to establish different routes of administration.

The early clinical trials of microbicides tested candidates that had physical properties that were thought to be potentially protective. These trials, however, were not successful. After these disappointing results, researchers shifted their focus to a new generation of candidate microbicides, which utilize ARVs formulated for topical application. The first results from a large clinical trial using such a product—the CAPRISA 004 trial in South Africa—were announced this summer at the XVIII International AIDS Conference in Vienna. The CAPRISA study found that the incorporation of an ARV drug —in this case, tenofovir—into a vaginal gel was more than 50 percent protective against HIV infection, when used as directed.[13] With women constituting the majority of new HIV infections throughout the world, this finding is an important step toward empowering an at-risk population with a safe and effective HIV prevention tool. The CAPRISA study was sponsored primarily by the U.S. Agency for International Development using the clinical trial infrastructure established with NIH support.

Now we must build upon the CAPRISA trial results and optimize a highly effective and acceptable microbicide for women and others at high risk of HIV infection which could be deployed by PEPFAR and other programs. The NIH-sponsored Vaginal and Oral Interventions to Control the Epidemic (VOICE)

[13] Center for the AIDS Programme of Research in South Africa (CAPRISA). Information site at http://www.caprisa.org/joomla/index.php/component/content/article/1/225. *See also* Karim Q et al. Effectiveness and safety of tenofovir gel, an antiretroviral microbicide, for the prevention of HIV infection in women. *Science*. 2010;329(5996): 1168-1174.

study, which began last fall and is expected to enroll 5,000 women in four African countries, will provide additional safety and effectiveness data for a tenofovir-based vaginal gel as an HIV prevention method. The study also will offer some insight as to the gel's acceptability as a product when used just once daily rather than both before and after sexual intercourse. Additionally, the VOICE study is examining oral ARVs (tenofovir alone or tenofovir plus emtricitabine) as an alternative HIV prevention method. Thus, this study also will enable us to evaluate the relative value of oral PrEP regimens versus topical microbicide regimens in women.

NIH also is assessing the feasibility of another ARV-based prevention approach, which is often referred to as "treatment as prevention." The "treatment as prevention" concept is predicated on mounting evidence that suggests that a reduction in levels of HIV in an infected individual can reduce HIV transmission from that individual to others. For example, a recent study of HIV-serodiscordant couples in Africa, supported by NIH and the Bill and Melinda Gates Foundation, found that treatment of the infected partner reduced the risk of HIV transmission to the uninfected partner by 92 percent.[14] Moreover, studies among communities in the developed world have shown that expanded ARV treatment and the use of

[14] Donnell D et al. Heterosexual HIV-1 transmission after initiation of antiretroviral therapy: a prospective cohort analysis. *Lancet.* 2010;375(9731):2092-2098.

other preventive measures to decrease the level of HIV were associated with a decrease in the number of new HIV infections.[15]

In a similar vein, NIH, CDC, and other partners are assessing the feasibility of a voluntary "seek-test-and-treat" behavioral and clinical intervention strategy to prevent HIV infection. Through this partnership, NIH is preparing a study of at-risk individuals in inner-city areas in the United States, including Washington, D.C., to evaluate the feasibility of implementing a combined strategy of expanding HIV testing, diagnosing infection early, and better linking HIV-infected patients to medical care and treatment. This strategy may be applicable to the developing world as well, although we must assess the practical challenges of implementing this approach broadly in such settings.

Finally, the most powerful prevention tool would be a safe and effective HIV vaccine. In 2009, a large Phase III efficacy trial of a "prime/boost" vaccine regimen provided the first, albeit modest, signal that a vaccine could prevent HIV infection in people.[16] This study, conducted in Thailand by the U.S. Army and the Thai Ministry of Public Health with support from NIH and other partners, has provided important new leads that we are pursuing vigorously along with other approaches in the development of a safe and effective HIV vaccine. These

[15] Wood E et al. Longitudinal community plasma HIV-1 RNA concentrations and incidence of HIV-1 among injecting drug users: prospective cohort study. *BMJ.* 2009;338:b1649; Das M et al. Decreases in community viral load are accompanied by reductions in new HIV infections in San Francisco. *PLoS One.* 2010;5(6):e11068.

[16] U.S. Military HIV Research Program. RV144 Phase III HIV Vaccine Trial information site. Available at https://www01.hjf.org/apps/internet/hivnewscenter.nsf/phase3.

efforts include basic research to identify specific components of the virus that could potentially serve as vaccine candidates, and immune system proteins—antibodies—that target these components.

For example, the recent discovery by scientists at the NIAID Vaccine Research Center of two broadly neutralizing antibodies against HIV is especially promising.[17] Laboratory studies indicate that the newly identified antibodies can potently neutralize a larger number of HIV strains than did previously identified antibodies. The identification of these exceptionally broadly neutralizing antibodies to HIV and the structural analysis that explains how they work will contribute to efforts to find a preventive HIV vaccine for global use. Since the development of a safe and effective vaccine to prevent HIV infection would not only be an important scientific accomplishment but also would be a "game-changer" for the future of PEPFAR, we are encouraged by the potential of such research findings in this vaccine development effort.

Curing Existing HIV Infections

As mentioned above, in 2008 alone there were an estimated 2.7 million new HIV infections, most of them occurring in PEPFAR-associated and other low-income

[17] Wu X *et al.* Rational design of envelope surface identifies broadly neutralizing human monoclonal antibodies to HIV-1. *Science.* DOI: 10.1126/science.1187659 (2010); Zhou T *et al.* Structural basis for broad and potent neutralization of HIV-1 by antibody VRC01. *Science.* DOI: 10.1126/science.1192819 (2010).

countries.[18] Despite the enormous progress made by PEPFAR in providing ARVs to HIV-infected individuals in the developing world, in low- and middle-income countries, only 30 to 40 percent of people in need of such therapy are receiving it.[19] While ARV regimens have been dramatically successful at saving lives and restoring health, these drugs must be given for the remainder of a patient's life.

This situation is unsustainable both financially and operationally. One way to address the problem is to prevent new HIV infections. Another way is to cure existing HIV infections, allowing cured individuals to discontinue ARV therapy. While it may not be possible to cure all infected individuals worldwide, a cure for HIV in some proportion of HIV-infected individuals would ultimately have a dramatic impact on controlling the pandemic.

Despite our substantial progress in understanding HIV/AIDS and treating it with ARV medications, a cure for HIV/AIDS that would induce permanent remission in the absence of drug therapy has remained frustratingly out of reach. Research aimed at eliminating HIV from the body has been unsuccessful, largely because HIV is unlike virtually any other pathogen in its singular ability to hide from the body's immune system. HIV evades ARV therapy by shielding itself in latent cellular "reservoirs" that are rapidly established after initial infection. Even in

[18] UNAIDS, WHO. *2009 AIDS Epidemic Update.* November 2009; 6. Available at http://www.unaids.org/en/KnowledgeCentre/HIVData/EpiUpdate/EpiUpdArchive/2009/default.asp.
[19] WHO. *Antiretroviral therapy.* http://who.int/hiv/topics/treatment/en.

patients who have received ARV medications for a decade or more, we cannot fully purge the virus from these hiding places. If therapy is discontinued or interrupted, the virus invariably re-emerges from its reservoirs and begins replicating vigorously.

A cure for HIV infection might take one of two approaches. First, we may be able to completely eradicate the HIV reservoirs in the body; this is referred to as a "sterilizing" cure. Second, and more likely, we may be able to shrink HIV reservoirs to the point that a rebound of virus replication and the appearance of virus in the bloodstream do not occur, even after the withdrawal of ARV medications. This is a so-called "functional" cure, or permanent suppression of viral replication without eradication. A functional cure is probably most feasible in patients who are treated early and aggressively after the onset of HIV infection—in these individuals, the HIV-specific immune response is likely to still be intact. NIH is actively supporting research to find a cure for HIV disease. Much of this research, both fundamental and clinical, is aimed at better understanding where reservoirs of HIV are located, how they are established and maintained, and how to eliminate them.

Optimizing Treatment Regimens and Treating Co-morbidities

Tens of millions of HIV-infected individuals likely will depend on antiretroviral medications and other therapies for many years. To help these people, NIH is committed to research to optimize treatment of HIV/AIDS and its associated

infections and co-morbidities. For example, NIH supports studies to evaluate strategies for the best use of existing ARVs in combination with other drugs, including ways to minimize drug-related complications. Many new and improved HIV treatment strategies, as well as preventive strategies, are tested through the longstanding NIH HIV/AIDS Clinical Trial Networks, which have led to many of the medical advances that are being successfully implemented by PEPFAR today. The awards supporting the six current clinical trial networks will expire in 2013 and 2014. Building on the success of the current infrastructure, NIH is looking to expand the scope of the networks' activities to include studies of other infectious diseases of significance to people who are infected with HIV or are at risk for infection, especially tuberculosis (TB).

TB is a very serious co-morbidity for HIV-infected individuals and accounted for nearly a quarter of HIV-related deaths worldwide in 2008.[20] Improving the effectiveness of the standard therapeutic protocol for HIV-TB co-infection and developing more sensitive TB diagnostics will help programs such as PEPFAR save lives and improve clinical outcomes. Promising results from the recent Cambodian Early versus Late Introduction of Antiretroviral Drugs (CAMELIA) trial, funded by NIH and the French National Agency for Research on AIDS and Viral Hepatitis, indicate that it is possible to prolong the lives of untreated HIV-infected adults with very weak immune systems and newly diagnosed TB by

[20] World Health Organization. Tuberculosis and HIV factsheet. Available at http://www.who.int/hiv/topics/tb/en/index.html.

starting HIV therapy two weeks after beginning TB treatment, rather than waiting eight weeks, which had been the standard of care.[21] This finding brings physicians closer to optimizing the treatment of severely immunocompromised individuals co-infected with HIV-TB.

Implementation Science

Implementation science is the translation of evidence-based findings from efficacy trials, such as those routinely supported by NIH, into at-scale population-level practices. While implementation science is not our primary mandate, NIH is collaborating with PEPFAR and its partners to conduct studies that address the "research-to-practice" gap. For example, with support from PEPFAR, NIH is sponsoring a number of implementation research projects through supplemental awards to NIH grantees who already are conducting research at PEPFAR sites. These studies will assess the efficiency, effectiveness, and impact of PEPFAR programs such as PMTCT and adult male circumcision and provide insights into how proven interventions can be brought to scale.

Capacity Building and Training

In addition to the research and development of new and improved tools and strategies for the prevention, diagnosis, and treatment of HIV/AIDS, NIH

[21] F.X. Blanc, T. Sok, D. Laureillard, et al. Significant enhancement in survival with early (two weeks) vs. late (eight weeks) initiation of highly active antiretroviral treatment (HAART) in severely immunosuppressed HIV-infected adults with newly diagnosed tuberculosis. *XVIII International AIDS Conference*. July 18-23, 2010. Vienna. Abstract THLBB106.

contributes to PEPFAR by building global research and clinical capacity, developing a cadre of skilled in-country partners, and expanding the ranks of skilled health personnel in PEPFAR countries. For example, NIH recently announced a new initiative to strengthen medical education in sub-Saharan Africa, in collaboration with PEPFAR. The *Medical Education Partnership Initiative* —a joint effort of the Office of the Global AIDS Coordinator, the Health Resources and Services Administration, CDC, the Department of Defense, and NIH—will support PEPFAR's goal to increase the number of new health care workers in this area. This program also will serve the related objectives of strengthening host-country medical education systems and enhancing clinical and research capacity in Africa.

Conclusion

The basic, applied, and clinical HIV/AIDS research supported by NIH has played a critical role in the response of the U.S. Government to the HIV/AIDS pandemic through PEPFAR and the GHI. The results of NIH-supported research—for example, the research, development, and optimization of ARVs; prevention of mother-to-child transmission; and the proven efficacy of medically supervised adult male circumcision—have provided the tools for global HIV/AIDS programs on the ground that have already saved millions of lives.

While we have accomplished much since those first AIDS cases nearly three decades ago, much remains to be done if we are to control and ultimately end

the global HIV/AIDS pandemic. As we endeavor to prevent new infections, cure existing infections, and optimize treatment of HIV and its co-morbidities, I firmly believe that basic, applied, and clinical research will continue to form the foundation for these efforts.

Chairman BERMAN. Thank you, and thank all of you. And I now yield myself 5 minutes to begin the questioning.

Now, Ambassador Goosby, you touched on it, but develop this a little more fully. We are trying to move from emergency to sustainability. The issue of financing, of course, is quite critical. The majority of countries receiving either PEPFAR or Global Fund resources don't have the budget to take on the full funding of these programs, yet these programs have to be integrated within their national health care system.

Could you sort of spell out PEPFAR's strategy to integrate AIDS programs into their systems and without overwhelming their budgets?

Ambassador GOOSBY. Well, thank you, Mr. Chairman.

You are correct to highlight that as a critical need in all of our program, thinking both in the past and in the future. Our ability to move from an emergency response to a sustained response is integrally related, and our ability to make sure that the programs that we have put up and established in the emergency phase do not lose their impact or their ability to expand to the changing needs of the population that use them.

Our feeling is that country ownership is critical. By country ownership we are focused really on both the government as the public sector component, but also just as importantly on the community and the civil society around it. All three are required for the appropriate establishment of a continuum of care and services, a continuum of prevention interventions that impact the community in the region and areas that they are most vulnerable. So understanding the epidemic in the context of each country's epidemic is the critical piece.

Our commitment to working with countries to continue to support programming includes both a financial commitment as well as the realization that capacity expansion within the ministries of health, the ministries' ability to play a technical assistance role for provincial ministries of health, are all part of the vision that we carry and try to align in each of the countries that we are in.

Chairman BERMAN. Thank you.

Dr. Frieden, you made reference in your testimony, you talked about your trips, and in your prepared testimony you made reference to CDC's relationship with the African Center for Integrated Laboratory Training.

Who has been trained? And does the laboratory training prepare technical personnel to work with diseases other than AIDS, TB and malaria?

Dr. FRIEDEN. Thank you very much for the question, Mr. Chairman. The African Center trains people not just from the country where it is resident, but throughout the region. We have been able to promote laboratory network strengthening, including the beginnings of an accreditation system, so that when you get a result back from a laboratory, you can be confident in its accuracy. We have trained not only the laboratorians, but the people who supervise and manage the laboratory systems to establish sustainable laboratory services not just in HIV, but also more broadly to strengthen the health systems, whether that is TB testing or basic laboratory testing.

I have been quite impressed by the systems that I have seen out there. They are very reliable. They include very complex testing, including CD4 counts and early infant diagnosis using the latest technologies, but also applied effectively within PEPFAR and to strengthen the system.

So we see laboratory strengthening as one of the core pillars of strengthening a health system, and we have been delighted to be able to that with support from PEPFAR.

Chairman BERMAN. The question—if I had time to ask and hear the answer to—I would be asking now to Dr. Fauci, is your remarkable testimony about some of the advances and connections between treatment and prevention. Unless you can say sort of in three words, but the question would be to what extent should that alter the way Congress approaches the funding of PEPFAR, or do you have the discretion within the program to make the adjustments that these conclusions might cause you to make without any particular changes in the way we are approaching the appropriations process? That is the question. We don't have time for the answer.

Mr. SMITH. I ask unanimous consent the gentleman have 2 additional minutes.

Chairman BERMAN. Could we make it at least 1 additional minute with unanimous consent, because I think it is——

Dr. FAUCI. Well, to answer it in as broad an applicable way as possible is this just underscores in my mind how important what PEPFAR doing is. I mean, people often say we put a lot of money in something; is it really worth it? Well, the fact is that if you are trying to prevent infection and treat people who are infected, you actually get two for the price of one, because what we are starting to see is the support for treatment isn't at odds or in competition with prevention, it is actually part of prevention. So when you hear people from PEPFAR say that, when you hear Tom Frieden and his colleagues from the CDC say that, it really is true.

I mean, all the data that is starting to accumulate now means that, in fact, you can, by treating people appropriately, ultimately prevent infection. So we have got to put aside the tension between treatment and prevention. They synergize with each other.

Chairman BERMAN. Thank you.

And now I am pleased to yield 5 minutes to the gentleman from New Jersey Mr. Smith.

Mr. SMITH. Thank you, Mr. Chairman.

First of all, let me thank you for the most recent addition of enrollees for Uganda. I had been very critical—I am not the only one—that there was a straight-lining, and some additional 36,000 people in Uganda will now get ARVs courtesy of the United States Government. So thank you for doing that, especially in light of the double duty that treatment is prevention, and I think that is very, very encouraging.

Dr. Frieden, if you could maybe touch on briefly the issue of safe blood. I actually held a hearing several years ago when I chaired the Africa Subcommittee, and one of the issues we learned from WHO is maternal mortality can be reduced by 44 percent, according to the witness from WHO, if safe blood were available. I know

you have 14 initiatives going. In your testimony you speak to it. Maybe you might want to touch on that.

And secondly, according to the WHO, and I said this in my opening statement, an overwhelming amount of health care is provided by faith-based entities—under the auspices of faith-based communities in Africa. Forty percent of that is delivered by the Catholic community, and worldwide the Catholic community provides 25 percent of all care and prevention for HIV/AIDS patients.

I would argue that failure to aggressively include faith-based organizations in the Global Health Initiative will seriously undermine the efficacy and sustainability of our struggle to mitigate and hopefully end this pandemic that has so ravaged Africa and other parts of the world.

I understand that the country ownership issue is central to the Global Health Initiative. Yet given the poor track record of the Global Fund, to which U.S. taxpayers donate over $5 billion and counting, in its national ownership scheme known as the Country Coordinating Mechanisms, could you tell us what the administration is doing to ensure that faith-based organizations are not discriminated against in the allocation of grants at the country level? How does that figure into our partnership framework agreements? Are we saying this is something we think is important? Why create a new infrastructure when there is a preexisting one where rollouts can occur? And how do you plan to ensure that PEPFAR's conscience clause, which I offered to the original law—and it was actually strengthened when we went through the reauthorization. And Chairman Berman, the Democrats and Republicans were of one accord in strengthening that conscience clause—so that when it gets to that country level, the conscience clause is not shredded, and these faith-based organizations are not shown the door, and they are part of delivery of services?

Dr. FRIEDEN. Thank you very much. I will start, and then perhaps Ambassador Goosby will address it as well.

The safe blood program really is a success story. It is now scaled up to all 60 countries with technical assistance, and it has been done in a way that builds local capacity. It has not been an external system imposed, but a system of helping countries establish, monitor and maintain a safe blood system, and that is critically important and a real win in HIV prevention and in confidence in the health care system.

So I think it is a great example. It is an example of prevention. It is working, and, very importantly, it is working by building systems. I met with the staff who had helped to grow that. They were essential in improving that quality.

And as we transition through the Global Health Initiative, we will be looking also at the appropriate use of blood and increasing to make sure that it is not being used when it is unnecessary, and is being used adequately, such as in the reduction of infant mortality where hemorrhage is a leading cause of death. And addressing emergency hemorrhage is something that we hope to be able to do in the Global Health Initiative as we transition from prevention of mother-to-child transmission to a broader sense of protecting mothers' lives.

In terms of faith-based organizations, I agree completely. In many countries in which we work, there are superb service delivery platforms. They provide services where there are no other service providers. They provide them with very high quality and at very low cost, and we see them as essential partners, and we continue to work with them. In fact, as I mention in my oral statement, as we transition to local partners increasingly, and we are already—45 percent of our grants are local partners rather than U.S.-based—but as we continue and expand that transition, faith-based organizations have a very essential role to play.

Mr. SMITH. Real quick.

Chairman BERMAN. We can give you unanimous consent for 1 additional minute for the full answer to this.

Mr. SMITH. I mentioned the Global Fund because I have met with the Global Fund many times and their leadership about the exclusion of faith-based organizations, especially at the country coordinating mechanism level.

In many of these countries, as we know, for years the churches collectively have been the bulwark in protecting human rights, and very often they are seen as the thorn in the side of governments, particularly as they matriculate from dictatorship to a democracy. So there is a reason to keep them at bay and look for other partners. And again, who hurts? It would be the potential patients.

Ambassador GOOSBY. Well, let me just echo Dr. Frieden's statements around the faith-based organizations. They have historically played, as you have really eloquently outlined, a critical role in the delivery of health care in sub-Saharan Africa in particular. As you move from urban to rural, their importance increases, and in many countries where PEPFAR is working, the faith-based organizations really comprise the district hospital-level capability in many of the rural areas that we are in.

That role is not going to change. Indeed, in many countries the faith-based organizations are part of the public health system. When a graph is charted of their referral, tertiary, secondary and district-level hospitals, the faith-based organization is often playing that role solely, as I said. They also have a series of clinics that reach out from that hospital base that again extend their reach and have been extensively engaged with in all of our programs in PEPFAR with completing continuums of care in services in both treatment and prevention fronts.

So we are committed to continuing that and would look, if you had examples of concern or issues where it has come to your attention that someone has been excluded, we would be very interested in engaging with that directly.

I would finally answer your Global Fund question to say that the CCM process, the country coordinating committees, are locally determined as to who sits on those seats. We do give a significant amount of resources to it. We see the Global Fund and PEPFAR as joined at the hip; our success is interdependent. Our planning together and defining unmet need and allocating resources is now getting much more sophisticated so the duplication overlap, the ability to take advantage of common procurement distribution systems, administrative oversight management, et cetera, it is all moving forward.

We believe——

Chairman BERMAN. Ambassador, the time has more than expired. So perhaps there is a way to get back to that.

The gentlelady from California Ms. Lee is recognized.

Ms. LEE. Thank you very much. And, yes, Mr. Chairman, we will get back to that.

And let me just say I am glad you mentioned that Dr. Goosby has a California connection, but I am very proud to say he is my constituent——

Ambassador GOOSBY. Absolutely.

Ms. LEE [continuing]. And has done a very fine job in this position also, as he has in previous positions.

With regard to the Global Fund, following the International AIDS Conference, of course, I sent a letter to the President along with 100 Members of Congress asking for $6 billion over 3 years to fight—well, committed to the Global Fund. Together with PEPFAR our contributions have been responsible for treatment of 5 million people worldwide. So next week in New York, of course, the Global Fund is holding its replenishment hearing, and I wanted to find out where the administration stands on this request for a $6 billion pledge. Can we reach that target? If so, great; if not, why not?

I think it is very important, because we want this announcement to be clear so that we can begin to leverage contributions from other donors who are still considering their pledge. So that is one question, Dr. Goosby.

And then my second question any member of the panel could answer as it relates to the joint United Nations program on HIV/AIDS. I have been asked to serve as a Commissioner on the Global Commission on HIV and the Law. This new international Commission, the objective is to develop actionable, evidence-informed, and human-rights-based recommendations supporting national legal environments that enable effective HIV responses and realize the human rights of those living and affected by HIV. The Commission will hold three meetings over the course of 18 months. The first meeting, of course, is next week in Brazil.

So I wanted to find out if you are aware of the Commission and its goal? Is the United States providing any direct support, whether technical or material, of the Commission? And can we count on your input, because I would like to talk to you about our input in terms of helping to overcome some of these legal barriers to providing access to services and to encouraging the research that is really necessary to fight this disease.

Ambassador GOOSBY. Well, thank you, Congresswoman Lee, and you are my Congresswoman. Thank you.

I think that the relationship between PEPFAR and the Global Fund has evolved. Our presence as a Board member on the Global Fund and our engagement with both the Executive Director and the Secretariat has given us an increasing opportunity to again lay this trackwork to merge our resources in a way that is highly efficient and increases both of our programs' impact at the country level. We are excited about that merging. We believe this will bring many more people into our care and treatment and prevention services and will save many more lives.

Our ability to have a meaningful relationship with the Global Fund has been one of iterative dialogue around strengthening mechanisms for both the Secretariat as well as the CCM process.

As the PEPFAR programs have staff in country, we are intimately aware in 80 countries in which we overlap with Global Fund of a lot of the implementation issues that come to bear, such as we saw in Uganda where our programs are connected to theirs. If Global Fund programs are performing well, we move together. If either of us fall in that ability to move patients through, to identify clients, to address and deliver services, there is a displacement of patients into the other's programs. And we have seen this in many of the other countries we are in.

In order to minimize that, to anticipate it and to prevent it, we are really moving aggressively over the next few months to a shared planning and implementation vision.

The Global Fund is part of our success and will continue to be an integral piece of how we are able to increase our ability to impact.

Ms. LEE. Bottom line is how about our pledge for 3 years?

Ambassador GOOSBY. We have been aggressively involved in a dialogue over the last few weeks. That dialogue has continued through this week. We will come to replenishment next week with a proposal that I believe is strongly supported within the administration. It has required a new vision and new commitments being made on our part——

Ms. LEE. Dr. Goosby, do you think that the 101 members that signed that letter will be strongly supportive of the recommendation?

Ambassador GOOSBY. I think that we always appreciate the input from our congressional leaders and the insight and wisdom that they bestowed on us through that letter was greatly appreciated, and all of those issues were taken into account in the discussion.

Ms. LEE. You sound like a lawyer.

Thank you very much.

Chairman BERMAN. They appreciate the 101. We don't know whether the 101 appreciate them.

Ms. LEE. Can I get a response?

Chairman BERMAN. By unanimous consent, the gentlelady has an additional minute.

Ambassador GOOSBY. We are very supportive of that effort. We are thrilled that you have committed to giving your time and thoughts to this. The connection to health and human rights is basic, fundamental, needs to be amplified and we are supportive and will be supportive of the committee.

Dr. FRIEDEN. Similarly, we would be delighted to be supportive in any way with our colleagues. I will emphasize one area in particular, which is gender-based violence, where CDC studies in multiple countries in Africa have shown this, particularly intergenerational gender-based violence to be far too common and a driving force behind the epidemic. So this is one area which is not only a terrible human rights violation but also a driver of the epidemic.

Chairman BERMAN. The gentleman from Arizona, Mr. Flake, is recognized for 5 minutes.

Mr. FLAKE. Ambassador Goosby, when the last reauthorization came in in 2008, there were several requirements put into law in terms of reporting having to do with best practices and efficiencies. It is my understanding that those reports have not been issued. If not, why not? And how can we be expected to reauthorize or appropriate more money without some of the requirements having been met?

Ambassador GOOSBY. Well, thank you, Congressman Flake. Perhaps the central emphasis since I have started this position has been to look at, especially in this economic decline, all areas that we can engage in to become more efficient, to take advantage of synergies and collapsing of resources so they are truly additive within the program as well as between the programs.

We have created a process that has canvassed every country that we are in. Thirty at a high level, but all 80 countries. And we have compiled a strategy that is focused specifically on identifying and integrating these strategies into an identification of efficiencies that become programmatic and entered into our budgetary relationships.

We have completed a document that I had thought had come to you. It has been submitted to the committee, but you obviously haven't seen it. We will work with your staff to make sure that you get that forthwith.

Mr. FLAKE. This will comply, or be responsive to the requirements in the 2008 reauthorization?

Ambassador GOOSBY. Yes, sir.

Mr. FLAKE. I will yield the rest of my time to Congressman Smith.

Mr. SMITH. I thank my good friend for yielding.

If I could just, Dr. Goosby, get an answer. In the partnership framework, is the conscience clause included there, because obviously, while we are encouraging local control, it is never absolute. Obviously, we have parameters. Is it in there?

Secondly, I was at a roundtable last week at the U.N. Development Goals Summit at the United Nation run by the Rockefeller Foundation and GAIN, and seven first ladies, led by Lady Odinga, emphasized the first 1,000 days of life from the moment of conception is a wonderful event, which obviously that will predict what happens in the next, 25,000 hopefully, days of life, if someone can live into the seventies.

But it was from the moment of conception, it was all about good nutrition and it was an affirmation of life before birth, that an unborn child is sacred and precious, and birth is just an event that happens to all of us. It's not just the beginning of life.

I would note the next day the Secretary of State was at a similar unveiling with the foreign minister of Ireland during which she wouldn't say the words "moment of conception." Okay. That is unfortunate. But it is still the same idea. Those first 1,000 days are absolutely crucial. And with PEPFAR, Don Payne was very emphatic on this, as was I, as chairman and ranking member of the Africa Subcommittee, that nutrition is crucial to PEPFAR.

It is contradictory to me that on the one hand, Global Fund is talking about reproductive health including the killing of the unborn child by way of abortion, and we are also talking about nutrition and providing protection and all the possible enforcement backstopping for that baby in the first 1,000 days.

Finally, behavior modification, and I assume that is A and B of the ABC model. Doctor Eliodo—head of the Ugandan member of parliament—has said very clearly that the B is so important—A is important—but the B is so important. When there are multiple concurrent partners, the epidemic continues to spread notwithstanding perhaps ARVs. So what about the emphasis on the B?

But if you could get into the conscience clause first.

Ambassador GOOSBY. Yes, Congressman.

The partnership framework is an attempt to engage in a new dialogue with country to establish a commitment to relative contributions from our partner country as well as the United States Government over a 5-year period. It is under the PEPFAR legislation, and the conscience clause does apply to that dialogue. In terms of the Global Fund and the chart that you mentioned——

Mr. SMITH. Is it binding or is it just part of the dialogue?

Ambassador GOOSBY. We legislatively are bound by the conscience clause legally so we cannot agree to something that is outside of the parameter.

Chairman BERMAN. The gentleman from North Carolina, Mr. Miller, is recognized for 5 minutes.

Mr. MILLER. Thank you, Mr. Chairman.

I think all of you have spoken of pediatric HIV/AIDS. And I have been stunned when I traveled in Uganda on a congressional delegation 3 years ago at how pervasive transmission from mother to child is very rarely in the United States and very common in the developing world. It certainly makes the goal of eliminating all pediatric HIV by 2015 look to be an enormous task.

And the precautions that are routine that are universal in the United States are almost unheard of in other parts of the world, and as a result, thousands of children every year begin life with HIV, either born with it or through contracting it through breast feeding. The routine precautions beginning with the testing of pregnant women with HIV is almost unheard of almost all the way through.

What are the barriers? Is it all the amount of resources? Are there other barriers? What stands between us and having the transmission of HIV to children from their mothers is as rare in other parts of the world as it is in the United States? Dr. Frieden?

Dr. FRIEDEN. Thank you very much, Congressman Miller.

It is a great question, and I think this is an area where we are poised—we have had a lot of progress in the last couple of years and we are poised to have even more progress. We have countries that now have moved to a universal screening for HIV and pregnancy. So we are seeing a substantial scale-up of effective prevention.

There are a series of barriers. First, in some countries the proportion of women who give birth in an institution or are attended is in the single digits. So when you have a service delivery gap that is that large, it shows you some of the limitations of a program

that is within the envelope of HIV only. That is one of the reasons why we think the global initiative will actually greatly strengthen not only health systems but also HIV prevention and prevention in terms of the mother-to-child transmission. But there has been tremendous progress in recent years, testing more women, getting more women on treatment, getting the children appropriately cared for.

The second key issue is the effectiveness of treatments. Some of the regiments require the women to take medications and take additional medications during delivery. But if that delivery is not attended because, for example, of co-payment charges at institutions, then the investment that we have had to protect that child is not fulfilled really and the child becomes infected.

So there are ways that we need to change the way women are cared for and focus on women getting care before, during and after pregnancy. There is also the challenge of breast feeding and reducing the risk during breast feeding. And there are some real challenges there in terms of the women's experience. The data from this comes from trials led by both CDC and NIH, and I think it is a success area, but one where I think we need more progress.

Dr. FAUCI. I agree completely with Dr. Frieden's assessment. I think it also underscores what we were saying before about the penetration into the community of getting people tested and treated. We need to think not only that we have to prevent transmission to the baby, but also that we have to treat the mother as an individual, and then you will do two things: You will prevent transmission to the child, and you will also prevent transmission through breast feeding.

As Dr. Frieden said, really the opportunity is extraordinary. The more people we test, the more people we treat. Among those will be women who either will be pregnant or are pregnant, and then you have the secondary benefit of preventing the transmission to the child.

Mr. MILLER. Similarly there have been—the other parts of the world lag well behind in early diagnosis of children with HIV. What are the barriers to earlier diagnosis and therefore earlier treatment?

Dr. FRIEDEN. We have been delighted to be able to work with a series of African countries to build up a capacity for early infant diagnosis, and I was delighted to see, for example, in Mozambique, the reference laboratory using the text messaging technologies secure through return results very rapidly so that children, infants, could get on treatment. And that kind of innovation is what we hope to see more of, getting cutting-edge laboratory services through dried blood spot and then getting the results back to the treating physician right away so that they can start treatment rapidly right away if needed. That early infant diagnosis is also very important. Has a quality assurance mechanism. We know we are treating women, testing women, but are we preventing transmission? And that is a critical mission for us.

Ambassador GOOSBY. If I could just add an anecdote to that. The remarkable moment at birth and having the child there and having to wait for antibody production over an 18-month to 2-year period has been preempted with the ability of early infant diagnosis. And

PEPFAR is committed to expanding that capability in all of our programs to allow individual children to get on both cotrimoxazole as well as antiretrovirals at birth.

Chairman BERMAN. The gentlelady from California, Ms. Woolsey, is recognized for minutes.

Ms. WOOLSEY. Thank you, Mr. Chairman, and thank you to the panel. I want to take this just one step further and then I have another question to ask also.

So when women are unable to obtain family planning information and the appropriate prevention methods, NuvaRing, shots, condoms, because of the complications that come along with the conscience clause, or maybe that doesn't happen, tell me if I am wrong. But when we make it difficult for women to prevent pregnancy in the first place, and quite often that would prevent AIDS and HIV with the appropriate prevention products, what impact does that have on HIV/AIDS and the numbers before we start treating it?

Ambassador GOOSBY. Well, I can take an attempt at that. It is a difficult question. It is a good question. We have been very aggressive at talking with our partners who we are engaged with at the country level to understand their concerns around making available a referral mechanism to family planning reproductive health services. That usually is doable. And it is a commitment on part of the institution itself who has difficulty moving forward with those services on their own site, but allowing the patient in front of them with that immediate need to be addressed and referred in a seamless way is our goal.

We have been able to engage in that in most every instance that it has come up, and will continue to honor both the conscience clause in that effort, but also being clear that our real responsibility to the patient in front of us is to respond to her needs. Thank you.

Ms. WOOLSEY. Speaking about her needs, without taking anything away from HIV/AIDS support and investment, both from the United States and internationally, what would it take for this same group of partners to invest in maternal mortality and child mortality at the same time? I mean, my goal is not to take anything away from the successful HIV programs, but to build on that and to go into the next level of maternal health.

Ambassador GOOSBY. I will take the first attempt at that. We are thinking alike. President Obama's Global Health Initiative is an attempt to do just that, to take the successful programming that we already have in place—in this instance HIV/AIDS—to use that robust medical platform to build onto, to add to, services that allow the same patient with HIV in front of us who has needs in maternal and child health, family planning, neglected tropical diseases, immunizations for the children, other family members, as well as a package of essential services for hypertension, diabetes, whatever, defined by each country, this is an attempt to do just that. Build on the platform that is already in place, to expand the services that are needed by the population that we have already captured.

Ms. WOOLSEY. Dr. Frieden, I am not suggesting that we take the same pot of money, and then expand the services and I am also

suggesting that there are women, and young women, that don't have HIV. So how do we get to them and set up—I don't want it to only be women who are already infected.

Dr. FRIEDEN. Through the PEPFAR support we have been able to strengthen health systems; we have been able to improve the quality of delivery; we have been able to increase access to emergency obstetrical care, and this is critically important for HIV prevention, and also to support women's health and child health. And I think, you can see an evolution from the PEPFAR reauthorization, which enables us to strengthen systems more comprehensively, so that we would not only have a more sustainable way of achieving the outcomes of PEPFAR, but also improve other health conditions through the Global Health Initiative, where we are saying we are going to take all of our investments we know that we are in a scarce resource environment, we know that every dollar is precious, and we are going to stretch each of them as far as we can by having the services that are available as efficiently and as close to the client as possible.

Ms. WOOLSEY. Dr. Fauci, before you answer, try to add into if this were a perfect world, and we really cared about children and their mothers, what would it take from the United States?

Chairman BERMAN. By unanimous consent, the gentlelady has 1 minute—not until we have a perfect world.

Dr. FAUCI. I can do it in less than one.

In fact, Congresswoman, that is exactly what the fundamental philosophy and strategy of the President's Global Health Initiative is—exactly what you are saying. PEPFAR is a major component of that, but within the Global Health Initiative is exactly what you are referring to, not only have both an independent as well as interdigitating approach toward women's health and child mortality but also have it something that has its own force and its own life apart from PEPFAR.

But they are so closely joined, that you can almost not separate them.

Ms. WOOLSEY. Thank you very much, Mr. Chairman.

Chairman BERMAN. Time of the gentlelady has expired. The gentleman from Minnesota, Mr. Ellison, is recognized for 5 minutes.

Mr. ELLISON. Mr. Chair, thank you for this really important hearing and thank you to our witnesses.

Could you talk about the issue about the scarcity that you mentioned a moment ago? I am curious to know how are our country partners addressing and augmenting the battle to overcome AIDS and HIV? Are we seeing legislatures from the countries that we are partnering with appropriating money to the degree that can handle some of the outyear cost associated with the ARTs and so? Could you address this?

Ambassador GOOSBY. Thank you, Congressman. It is an excellent question.

Our whole approach with the partnership framework is to engage in a different dialogue with each country around the human resources, the financial resources, the administrative resources that are needed to continue a specific outline of programs that the partner government is contributing to and the United States Government is contributing to.

Over a 5-year period, we define it explicitly and include in that an expectation and time line around commitments.

The dialogue is with country leadership. That leadership has largely been central with the Ministry of Health, but the Minister of Finance comes into it eventually always. The President frequently blesses it and/or signs it. We have had multiple, in every country that I go to, I meet with leadership, including legislative appropriators, and have had difficult discussions around relative contributions on a financial level to this effort.

Nigeria is a good example of this. Deputy Secretary Lew and myself went to Nigeria and in addition to looking at programs, we met with the President, with the Appropriations Committee, with legislative leadership on multiple party levels. We have also met at the provincial level with leadership as well.

All of it was a discussion around what can we expect in a country with an emerging economy, such as Nigeria, to assume in the monetary support of these services. Again, remaining committed to administrative and continued support on part of the United States, it was the first time we got into an explicit dialogue around what portion of that monetary allotment can you realistically begin to assume for yourself.

Nigeria came in within at the end of their 5-year period that they would assume 50 percent of the cost. That was a huge increase from where they are currently, and a sincere commitment made by both appropriators and the President.

Mr. ELLISON. I am glad you all have that conversation because I think it could have some benefits to other health challenges that a lot of other emerging countries are facing. If you can develop a system to address HIV/AIDS, you can do that, perhaps, for malaria and other things.

Let me ask you this much, too. How much input do partner countries have into how we are appropriating PEPFAR dollars in their own country? I have had a chance to spend some time in Kenya and learned they have more deaths from malaria than they do from HIV—of course, both are serious problems. But talk to me about how much input our partner countries have into directing how PEPFAR resources are allocated?

Ambassador GOOSBY. I will very quickly say that our initial response with PEPFAR was an emergency response, and we deployed largely through NGO continuums of care and services with partnered governance and civil society.

We, in the second phase of PEPFAR, looking at the emergency response, moving into now sustained responses, see the need to move more aggressively and to a different dialogue with partner countries around their relative management, ownership, oversight, defining unmet need, prioritizing unmet need, and being in and part of the allocation discussion.

This is in most of our countries a new and expanded dialogue for PEPFAR. It is a dialogue that the President and the Secretary of State feel very strongly about, I feel very strongly about, that this is the conduit through which we will really achieve sustainable, durable programming.

Mr. ELLISON. I guess my last question is the U.S. Congress is a highly political body. How is that for stating the obvious? And peo-

ple bring their agendas here. Unfortunately when it comes to foreign affairs, our agenda gets pressed on other people outside of our borders allotted. And when it comes to——

Chairman BERMAN. The gentleman has an additional minute.

Mr. ELLISON. When it comes to programs like PEPFAR and PEPFAR, for example, are there certain things that Members of Congress here think are very important to them and maybe important to their constituents but that create complications when they are translated into the work that you have to do? So, for example, well, I'll leave the example out for the moment.

Ambassador GOOSBY. It is a an astute question. But an understandable dissonance is created with our congressional bodies and the constituencies within our Congress moving forward in a Congress. We have that same dissonance set up in our country dialogue as well because each country is different, has different norms and self-expectations that must be considered and acknowledged and incorporated into the plan as we move forward.

That sensitivity and where we draw that line is much of what our dialogue becomes in the actual final partnership framework discussion. We are acutely sensitive to it, but also have frames and references that kind of define our parameters and how far we can go in both ways.

So it becomes a dialogue.

Chairman BERMAN. The time of the gentleman has expired.

The gentleman from New Jersey, the chair of the Africa and Global Health Subcommittee, Mr. Payne, is recognized for 5 minutes.

Mr. PAYNE. Thank you very much, Mr. Chairman. Let me commend you for having a full committee hearing on this very important subject. It is so good to see our panelists, Dr. Goosby and Dr. Frieden, and who has been a longtime friend from New Jersey, Dr. Fauci. We can't think of anything that is more important right now as it relates to the developing world. And I think that the program of PEPFAR was really a program that made many of us very proud, even with the first authorization of the $15 billion over 3-year period. This was a quantum leap from what we had been funding.

As you know, funding for HIV/AIDS has—even here in the U.S.—gone very slowly, and when it was first diagnosed, in the early 1980s, there was only several hundred thousand dollars that actually was appropriated over the course of 3 or 4 years in the 1980s, where we simply allowed this to fester and continue. There was very little attention given.

So we have continually commended President Bush when the notion of increasing the PEPFAR program—of course, we had the majority in the House, but we did need the cooperation from the White House and the President did agree to double it from $15 billion, and I was advocating with them. But then I thought if he was willing to go along with $30 billion, that that wasn't enough. So we pushed the $50 billion number, and we were able to get a $48 billion reauthorization, which I think was one of the greatest marks of our country's foreign assistance program in its history, and has done so much to save so many lives.

I know they have been recognized, but I understand the 24 women from Parliament, and several First Ladies from Ethiopia, and Deputy Prime Minister of Zimbabwe are here. It is great to have you here in the audience. I look forward to meeting with you later in the day.

Let me ask, Ambassador Goosby, we do know that you need to have the participation and cooperation from local people to move this program forward, and anyone can chime in.

But specifically, let me ask you, what is the role of local, national, and international nongovernmental organizations and civil society in designing and implementing the PEPFAR program? Just how much are they engaged on the ground and so forth?

Ambassador GOOSBY. Congressman Payne, let me first say thank you for your leadership, longstanding leadership in this arena, both domestically and internationally.

We have seen an emergency response in PEPFAR move to a sustained response. We are scrambling now to implement that shift from emergency to sustainable. It brings in country ownership. The country ownership aspect includes government as well as civil society. And I would include certainly the NGO community as an integral part of that civil society component.

We feel that they have and will continue to play the critical role in prioritizing and defining our implementation needs with the dialogue in our partner countries.

The final role that we seek to complete and improve the chances of sustainable durable program is to work in civil society, to establish a voice that is in and amongst those who use the services to give feedback to allocators and appropriators around the appropriateness of their allocation. When you keep that dialogue present, and when you create a safe space for that dialogue to occur, the program becomes self-correcting. When you don't, it is ephemeral and fragile. So we are committed to that third component.

Mr. PAYNE. Thank you very much.

Let me just ask this last question before my time expires.

The good news is that HIV-infected persons with either latent TB infections or active TB can be effectively treated. It would maybe be Dr. Frieden or Dr. Fauci who would want to answer. How is PEPFAR aggressively addressing the TB/HIV co-infection issue?

Chairman BERMAN. Without objection, the gentleman has 1 additional minute.

Mr. PAYNE. Thank you, Mr. Chairman.

As you may recall, about 4 or 5 years ago, we found in South Africa about 53 or 54 persons who had the virus, Bishop Desmond Tutu wrote a letter that when the infection of the TB came through, 53 of the 54 people died within several weeks. So I wonder if you could respond to that in the time that I have left.

Dr. FRIEDEN. Thank you. I will try to summarize my 10–15 years working in tuberculosis control globally in the next 30 seconds.

Fundamentally, it is a question of good management and significant PEPFAR resources are going into improving the management of tuberculosis. Many of the countries in Africa had functioning tuberculosis-control systems, but when HIV came in and tripled the number of cases they were overwhelmed.

The most effective way we can reduce TB is to scale-up treatment for HIV at this point because that drives down numbers, but often, TB comes before we treat at the current guidelines. So the challenge is to make sure that the patients are promptly treated and fully treated and we work closely with countries throughout Africa to improve their treatment systems and improve the ability to diagnose and ultimately treat the resistant forms of drug-resistant forms of tuberculosis.

What we do hope is that by scaling up effective treatment, we can prevent that in the first place.

Chairman BERMAN. The time of the gentleman has expired.

We don't often get the three of you here together so that we are going to allow Mr. Smith and then Ms. Lee to each have 1 minute for a last question and answer.

Mr. SMITH. Because of time, some of the questions were unanswered. Dr. Goosby, again, the Board of the Global Fund talks about funding abortion. Is that the administration's view? And secondly what priority is given to A and B, the abstinence and befaithful part of the ABC model?

Ambassador GOOSBY. Congressman Smith, I really have to say I need to look at that because that will be something that we would want to understand better and we will definitely get back to you on that in terms of what the Global Fund is saying.

In terms of what the commitment to our conscience clause and the abstinence and being faithful. The abstinence and being faithful, we continue to fund at high levels, and I would be very happy to go over it in great detail with you country by country, the abstinence and be faithful efforts. And as I said in the previous question, we had linked referral mechanisms so services that are needed that fall out of the abstinence and be faithful response can be addressed as well.

Chairman BERMAN. The time of the gentleman has expired. The gentlelady from California, 1 minute.

Ms. LEE. Let me just say when we were in Vienna, there was a lot of discussion about men having sex with men and how they are 19 times more likely to be living with HIV other than the general population. So what are we doing to ensure that countries are actually attempting to provide services to this vulnerable population without stigmatizing or jeopardizing the privacy and safety of these individuals?

Ambassador GOOSBY. It is a very good question, Congresswoman, in terms of in a high interest and focus for PEPFAR.

Men who have sex with men are complicated in sub-Saharan Africa. For example, in Malawi, 67 percent of the men who have sex with men are married. They have families. And they perceive themselves in the community and present themselves in the community as heterosexual. That kind of stigma that pushes that revealing oneself to family and community down is something that PEPFAR has attempted to develop unique strategies that are different in each neighborhood and each region to try to create safe spaces so an individual can indeed access services.

We also have a diplomatic component that engages in dialogue at the Presidential level and at legislative levels in country to express concern with legislative responses to behavior patterns that

are unacceptable in the country but have criminal associated consequences for them. And we are engaged in multiple countries on that front.

Chairman BERMAN. The time of the gentlelady has expired. I want to thank all of you very much for making time in your schedules to be here today, and I appreciate all you are doing in this effort and your leadership, and thank you.

We now have a second panel, people right out there in the field. If the two witnesses could come up.

Paula Akugizibwe is a citizen of Rwanda, is currently based in Cape Town as the advocacy coordinator at the AIDS and rights alliance for South Africa. ARASA conducts training and self-advocacy in the southern region to improve access to TB, HIV services and to advance a human rights base response to health.

Dr. Wafaa El-Sadr is professor of medicine and epidemiology at Columbia University, the director of the International Center for AIDS care and treatment programs, and the director of the Global Health Initiative at Columbia University's Mailman's School of Public Health. ICAP, the center she founded and currently directs, works in 14 countries in sub-Saharan Africa in partnership with governmental and nongovernmental organizations building in-country capacity for HIV prevention care and treatment.

We are delighted to have you with us this morning. And we look forward to your testimony. Your entire statements will be included in the record.

Ms. Akugizibwe.

STATEMENT OF MS. PAULA AKUGIZIBWE, ADVOCACY COORDINATOR, AIDS AND RIGHTS ALLIANCE FOR SOUTHERN AFRICA (ARASA)

Ms. AKUGIZBWE. Mr. Chairman, committee members and distinguished guests, good morning and thank you for this invitation to testify before one of the most historically significant committees on global policy on what is probably the most significant issue on global health.

The establishment of PEPFAR in 2003 represented an unprecedented response by the United States to a global health problem which had far-reaching implications with development. The founder of the U.N. AIDS wrote that PEPFAR changed the landscape elevating AIDS issues to one of the big political themes of our time.

In 2008, under the leadership of this committee, you enhanced that commitment with the visionary Lantos-Hyde Act which set forth a ground-breaking direction for the future of global HIV funding and helped to significantly strengthen our resolve to fight HIV in African countries. As the Lantos Foundation previously stated, to some, HIV treatment and prevention is seen as a burden on the U.S. taxpayer. Instead, it should be seen as an investment that has already paid for itself many times over in goodwill toward our country and hope restored in African communities.

There is no question that PEPFAR has great erased the stigma in the African region and rightly so. It remains an initiative for which millions of people across the continent are grateful, an unquestionable investment in public perception of the U.S. enhancing global security.

It is critical to acknowledge from the outset that the value of PEPFAR is not limited to dollars, cents, and public health statistics, but extends to significant political impact.

The political world resources that were mobilized by the U.S. for the fight against HIV reverberates across the world at a time when AIDS was estimated to be decreasing the TDB of high-prevalence countries in Africa by an average of 1.5 percent per year. Increased investment in HIV gave us an opportunity to bend these economic and epidemic curves which has led us to where we are today—at a tipping point for global health, balancing precariously between the good news and the bad news.

The good news, which we have heard this morning, is that we are not fighting a losing battle. There is ample evidence that we are bending the curves, that the once illusive dream of an HIV-free generation is eminently achievable changing the question from "can we?" to "do we want to?"

The bad news is that without increased resources now, our chance to defeat HIV must slip from our grasp and the climate of AIDS could return. It would be tragic for this to happen in the context of some of the most encouraging leaders in the history of the HIV epidemic, which we have heard in the past couple of years and we have heard this morning as well that AIDS deaths are declining globally for the first time since 2007. The HIV incidents is declining especially in sub-Saharan Africa, and that treatment has turned out to be a most effective biomedical prevention tool.

A U.S.-funded study as was cited earlier showed that treatment reduces the transmission of HIV by approximately 90 percent with incredible long-term cost saving potential.

Modeling studies presented at the Vienna Conference indicated that universal access in South Africa, if fully funded today, would result in a 17 percent reduction of transmission over 3 years achieving cost break even in the same space of time.

In the time of economic crisis, it is politically and financially expedient to look to short-term savings, but long-term social economic rationale tells us that greater investment now will mean smaller expenditure down the line. This has already been retrospectively validated by data released this month from one of the largest PEPFAR-funded treatment sites in South Africa, which demonstrated even further cost savings associated with an incredible impact of ARV therapy on boosting our response to other health challenges such as TB and maternal and child health.

On maternal and child health, earlier this year HIV was described by The Lancet, the world's leading medical journal, as the greatest cause of paralysis in efforts to address maternal and child mortality in sub-Saharan Africa, a paralysis that has been alleviated by PEPFAR's provision of ARV services to at least 1.7 million women and children in the region, as well as a provision of prevention and testing services to millions more.

An analysis that I got from the Journal of AIDS last year, which I will be happy to share with you, also demonstrated the scale-up of ARC has increased access to reproductive health services across the board—not just women living with HIV.

President's Obama's Global Health Initiative is welcome in its recognition of the need for comprehensive package of health serv-

ices and an increased focus in maternal and child health. However, the lack of a sufficient correlating increase in funding to support this expansion, such as the fulfillment that will come at the cost of HIV, TB, and malaria programs. Any slackening of efforts to scale-up HIV treatment will scale back progress in all other areas of health and development identified as a priority by the GHI and will push us toward a loss at a time when we are more poised than ever to win.

Unfortunately, the trend toward flatlining PEPFAR funding has already begun to do this. The Global Fund rotation requested by President Obama was $50 million less than what was given last year, and even with the current known level of $1.1 billion, still falls far short of the $2 billion per year that was authorized by the Lantos-Hyde legislation.

We are not worried about money for its own sake but the impact of these financing decisions on our communities. We are worried that given these trends of flatlining, the 2009 directive to Uganda PEPFAR centers is namely that new patients could only be enrolled when others died or lost a follow-up might be repeated elsewhere in the future and wreak similar havoc.

Doctors Without Borders has already reported increasing treatment of migrants at many of its sites in Mozambique where it notes that PEPFAR has warned of an annual 10–15 percent reduction in the ARV supplies over the next 4 years. Similar concerns have been reported in other countries.

These developments seriously threaten to undo our progress in the fight against HIV. I would like to emphasize that we, of course, appreciate that the U.S. cannot do it alone. Advocacy and increased funding has been directed to a wide variety of governments. However, we do have to recognize that much like the establishment of PEPFAR changed the landscape of global AIDS response for the better, so the current slackening of U.S. Government efforts on scaling up HIV treatment is leading a regression back to the landscape where HIV was a death sentence because the price tag of life was deemed too high by governments.

But the longer-term price tag will be even greater. The World Bank warned us last year that responding to immediate fiscal pressure by reducing spending on HIV treatment and prevention will reverse recent gains and require costly offsetting measures over the long term. It would be sad to see this come at a time when we are poised to turn the tide and when advocacy to hold national governments accountable for their contribution to the fight against AIDS is rapidly gaining momentum.

In the African region over the past 15 months, civil society organizations have intensified efforts to scrutinize government budgets and expenditure and advocate for increased transparency and accountability.

Yesterday, more than a dozen countries across the region took part in the first ever regional day of action on health funding. Thousands of people took to the streets in public demonstrations, health press conferences and public meetings all geared as calling on our governments to increase the domestic investment in helping, including HIV treatment, and as global leaders to fully replenish the Global Fund.

This advocacy drew in a remarkable variety of partners under the leadership of NGOs working on HIV, thus demonstrating that the extensive community networks and movements that have been created through the HIV response present extraordinary platforms for mobilization and national government accountability, which will be severely undercut if funding retreat persists.

We also note that we have seen positive government response from countries around the region. For example, in Kenya the 2010–2011 budget for HIV treatment has doubled compared to the previous year due in large part to the Kenya PEPFAR partnership framework. In South Africa, the HIV budget showed a 3 percent increase this year. Following advocacy in Swaziland earlier this year, the government exempted the Ministry of Health from a sweeping budget that affected all other sectors. And we have heard earlier from Ambassador Goosby about the positive developments in Nigeria.

Some of the poorest countries in the regions, such as Rwanda, Malawi, and Tanzania are leading the region when it comes to the domestic investment in health. Rwanda and Botswana are two of only eight countries in the world where universal access to treatment has been achieved.

All of this goes to show that the vision originally embraced by this committee with establishment of PEPFAR and the Lantos-Hyde legislation is entirely attainable but the key to determine success as we move ahead is political will.

The crucial bottlenecks that we face with the future progress in the fight against HIV are not related to economics or to science but to political priorities. When the Lantos-Hyde Act was passed 2 years ago, you took a very definitive landmark step toward realigning these political priorities and gave people living with HIV all around the world, as well as the communities, great hope that finally, a lasting precedent had been set for an energized global response to HIV, which would set the tone for a much broader response from all countries, and influence responses to other health needs as well. This has already been seen.

Next week as mentioned earlier, donors will meet in New York to determine the fate of the Global Fund which requires a minimum of $20 billion U.S. dollars over the next 20 years. The United States could transform the replenishment with a promise of a bold 3-year pledge at the levels authorized through Lantos-Hyde of up to $2 billion per year.

I am here today to urge you to make this happen or to help make this happen, and best meet global efforts to making history by winning the fight against AIDS.

Third, as you move toward a more long-term strategy for PEPFAR, it is my hope that you will recognize that sustainability will be achieved not by relaxation, but rather by intensification of efforts and investment because while this might cost us more today, evidence clearly shows that it will save us much more tomorrow. And that is the true basis of sustainable development.

So I hope this committee will help us make a decision for tomorrow.

Thank you.

[The prepared statement of Ms. Akugizbwe follows:]

House Committee on Foreign Affairs

Testimony – PEPFAR: From Emergency to Sustainability and Advances Against HIV/AIDS

Paula Akugizibwe
Advocacy Coordinator, AIDS and Rights Alliance for Southern Africa
29 September 2010

25 million: number of people who have died of AIDS since 1981. That's three quarters of the total number of military deaths for the whole of the 20th century – taking place in a quarter of the time. The comparison is staggering, and highlights a sad truth: that the greatest political hindrance to overcoming disease is the convenient passivity of not overcoming it. We don't have to lift a gun or drop a bomb to kill 25,000 infants in a day, as preventable diseases do. All we have to do is nothing at all.

For as far back as scientific literature goes, this peculiar violence of apathy has, for the large part, characterized public health responses at various levels. From maternal mortality to tuberculosis to child health, United Nations institutions and prominent academics speak reproachfully of "disquieting stagnation", of "time bombs", of "inexcusable neglect" – all references to the political tradition of public health neglect that, despite all this criticism, more often than not is tacitly excused.

HIV bucked this tradition, due in part to the unprecedented devastation that it wreaked on health and socio-economic systems, as well as to persistent advocacy that generated major global initiatives to combat HIV – leading to the establishment of PEPFAR in 2003, which represented an unprecedented response by the United States to a global health problem. Peter Piot, the founder of UNAIDS, wrote at the time that

> *"[PEPFAR] changed the landscape... elevated AIDS issues to one of the big political themes of our time."*

In 2008, under the leadership of this committee, you renewed and enhanced that commitment with the Lantos-Hyde act, which strengthened our resolve to fight HIV in African countries. The Lantos Foundation recently stated, and I wholeheartedly agree, that:

> *"To some, scaling up HIV treatment and prevention is seen as a burden on the U.S. taxpayer. Instead, it should be seen as an investment that has already paid for itself many times over in goodwill towards our country and hope restored in African communities."*

There is no question that PEPFAR has greatly raised the standing of the US in Africa and rightly so – it remains an initiative for which millions of people across the continent, such as myself, are grateful. It is

thus critical to recognize that when we assess the value of PEPFAR, as well as other instruments in the global HIV response such as the Global Fund, we need to do so not only in terms of dollars, cents and public health statistics – but also in terms of their political impact.

The scale and scope of political will – and correspondingly, the resources – that have been mobilized for the fight against HIV reverberated across the world, bringing hope that world leaders were finally responding to the ancient news that human realities such as disease cannot bend to economics; and so sustainable development necessarily requires that economics bend to human realities, or break – as many in sub-Saharan Africa had begun to do due to AIDS. In high prevalence countries AIDS is estimated to decrease GDP by an average of 1.5% per year, and is cited by UNDP as having played a more significant role in the reversal of human development than any other single factor. This apparent realization by governments led us to the hope that if we were long-sighted enough to make the necessary investment, we could bend the epidemic curves and undo what was then a relentlessly bleak reality; ultimately achieving the dream of an HIV-free generation – and finally, an AIDS-free world.

Which brings us to where we are today: on the brink of a watershed decision for global health, balancing precariously between the good news and the bad news. The good news is that we are not fighting a losing battle – there is evidence we are bending the curves, that the once-elusive dream of an HIV-free generation is eminently achievable. The bad news is that without increased resources now, our chance to defeat HIV may slip from our grasp and the carnage of AIDS will return.

> **The dream of an AIDS-free world is now so concretely achievable that it comes with a concrete bill , and the concrete bill comes with many, many concrete zeroes – changing the critical question from "can we?" to "do we *want* to?" – and that is the watershed decision that rests in part in your hands today.**

Let us first briefly examine the key arguments for "can we?" In the past few months, we have heard some of the most encouraging news in the history of the HIV epidemic. Following on from the first-ever global decline in AIDS deaths in 2007, we now know that there is also a global decline in HIV incidence – a decline that is being led by sub-Saharan African countries, once the spiraling hotbed of the epidemic. We know that, in an incredible stroke of public health serendipity, treatment has turned out to be our most effective biomedical tool against the transmission of HIV: a US-funded study of over 3,000 sero-discordant couples that was released this year found a 92% reduction in HIV transmission associated with the use of ARVs.

Extrapolating on this, some experts have suggested that in the absence of a vaccine, immediate treatment of all people living with HIV is our best hope for eliminating the epidemic. Mathematical models

have demonstrated that universal access to treatment for all people with CD4s under 350 *(an evidence-based and WHO-recommended threshold for initiation that is currently disallowed by PEPFAR with the exception of pregnant women and people co-infected with TB)* would result in a 17% decrease in HIV transmission over three years in the South African context, achieving cost breakeven within the same period of time.

There is also an abundance of retrospective good news. PEPFAR's investments over the past 7 years have resulted in incredible gains not just for people living with HIV, but for health systems across the board. In Rwanda, where I worked with the Clinton Foundation on supply chain management systems in close partnership with PEPFAR implementers, this was clearly demonstrated through the PEPFAR-funded revamp of national drug management systems, which improved supply of ARVs as well as other medical commodities; ultimately leading to long-term health systems strengthening.

This systems-wide impact has not only been infrastructural, but is also extremely well-documented with regards to challenges posed by co-morbidities such as TB; and maternal and child health. Studies have shown that that the use of ARVs is associated with up to 80% decrease in TB incidence in high-prevalence countries.

HIV continues to be the leading cause of death in children under 5 in several southern African countries, as well as the major contributor to maternal mortality in high prevalence countries such as South Africa, where 43% of maternal deaths are due to HIV. A region-wide analysis of maternal mortality data that was published by the Lancet earlier this year described HIV as a "major source of paralysis in improving maternal mortality" in sub-Saharan Africa: making it clear that PEPFAR's contribution to treatment scale-up in sub-Saharan Africa, from which at least 1.7 million women and children in the region have benefitted, has had a substantial impact on reducing maternal and child mortality; and needs to be sustained and increased if we are to achieve millennium development goals 4 and 5.

Now is not the time to slacken our efforts. The AIDS emergency is not over – only one third of the universal access target has been reached – and the future of socio-economic development in sub-Saharan Africa depends to a large extent on sustained progress in the fight against HIV. Even in low-prevalence countries that are now held up by HIV funding critics as examples of over-investment in HIV – such as Rwanda, where HIV has been infamously pitted against diarrhea in recent global policy debates on funding priorities – data from public hospitals in the capital city of Kigali, prior to the introduction of ART showed that 94% of chronic diarrhea cases were HIV-related.

No health need has been overcome, or can be overcome, in isolation. We should not let progress in the fight against HIV erase the lessons of the past; nor distract us into complacency. Far from being

evidence-based, the political pitting of various health needs against each other in competition for scarce resources, as has happened increasingly in the policy arena over the past year often with an underlying resistance to increased HIV funding, is neither evidence-based nor constructive.

President Obama's announcement of a Global Health Initiative is welcome in its recognition of the need for a comprehensive package of health services – including maternal and child health, reproductive health, neglected tropical disease and others. However, the lack of a sufficient increase in funding to support this expansion suggests that fulfillment of this broader mandate will happen at the cost of HIV, TB and malaria programmes. This is irrational and self-defeating. While health priorities may exist separately in policy, in reality they co-exist within the same individuals. As emphasised in a statement issued by close to 100 civil society organizations from around the world in November 2009:

> *"HIV is not over-funded: rather, health is under-funded... Shifting funding from HIV will not fill the yawning gaps in resources for health – this move is a cheap diversionary tactic that offers no genuine or long-lasting solutions for health systems. What is required is a shift in political will to prioritize and invest vigorously in health. Until this happens, neglect and dysfunction will continue to pervade health systems irrespective of what specific health needs we focus upon."*

The slackening of efforts to scale up HIV treatment take us one step further from this vision of adequate prioritization of health by governments around the world. While the USG has not decreased its overall HIV-dedicated funding in absolute terms, it is not meeting the plan set out by this committee in the landmark Lantos Hyde Act; which set forth a groundbreaking visionary direction for the future of US global HIV funding. That vision would help set the world on the path to defeating HIV.

Unfortunately, the marginal increases in the PEPFAR budget – estimated to be 2% in 2010 – have barely been adequate to sustain treatment programmes given current inflation rates. PEPFAR reduced its budget for treatment for the first time in 2009, from $1.56 billion in 2008 to $1.4 billion in 2009. Additionally, the Global Fund allocation requested by President Obama for 2011 was US$50 million less than what was given last year – and at current levels approximating US$1,1 billion, still falls far short of the US$2 billion per year that was authorised in the Lantos-Hyde legislation.

Communities, however, are worried not about money for its own sake, but about the impact that these financing decisions has on lives saved. A leaked 2009 memo from PEPFAR to Ugandan implementers warned them to expect "Flat-lined budget for ARV procurement" and directed that new patients could only be enrolled with outside funding or when others died or were lost to follow up. This combined with other challenges wreaked havoc on treatment scale-up efforts in Uganda. We are told this has been reversed after significant attention, but we worry that Uganda is only the highest profile example.

In Mozambique, Doctors Without Borders (MSF) has reported increasing treatment migrants at many of its sites—and noted that PEPFAR announced it will reduce its ARV supplies by 10-15% each year over the next four years. In the DRC, MSF's analysis shows that the U.S. ceased the purchase of any drugs for Opportunisitc Infections or renewable laboratory supplies. Simultaneously other donors also pulled out of supporting treatment and the Global Fund had to pick up the slack, reducing scale up from 1,000 new patients accessing treatment per month to 2,000 per year: which represents an 83% decrease in scale-up rate.

These developments pose immediate as well as imminent threats to accessing HIV treatment, and cast doubt on the future of the HIV response and hence the stability of socio-economic systems, particularly in sub Saharan Africa. We appreciate that the US cannot do it alone – earlier this year Ambassador Goosby wrote in a letter to civil society organizations that:

> *"one country alone cannot respond to the unmet needs that are present, either globally or in any particular country. In certain countries, the PEPFAR investment represents something on the order of three-quarters of all funding for HIV/AIDS. That is not a sustainable situation, either for a particular country or for the program worldwide. Every country must take a leadership role, including providing resources to the extent of its ability."*

We could not agree more. According to the Kaiser Family Foundation, the U.S. contributes 27% of the global investment in HIV when contributions by national governments and by patients themselves are included. This shows the US has undoubtedly taken on a considerable leadership role – one that needs to be increasingly shared among all countries – but requires continued strong leadership in that direction; not evasion of pre-existing commitments.

Much like the establishment of PEPFAR changed the landscape of the global AIDS response in the direction of universal access, so the current slackening of US government financial commitment to HIV, rather than encouraging an invigorated response from other countries, is instead leading a regression back to the landscape where HIV was a death sentence because the price tag of life was deemed too high by governments. However, the longer-term price tag will be even greater. The World Bank warned in a 2009 report about the impact of the economic crisis on HIV that "responding to immediate fiscal pressure by reducing spending on HIV treatment and prevention will reverse recent gains and require costly offsetting measures over the longer term."

Even more disappointingly, this reduced spending on HIV comes at a time when the fight against AIDS is showing encouraging signs of success; and when advocacy to hold national governments accountable –

both for adequate investment in health as well as responsible usage of health funds – is rapidly gaining momentum. The extensive community networks and movements that have been created through the HIV response have presented extraordinary platforms for mobilization around the broader challenge of holding national governments accountable for their action on resource allocation for health, including HIV treatment; on optimal use of these resources through improved policy and programming; and on intensified efforts to fight corruption. Decreasing funding will contribute to dismantling these platforms and undo the momentum that has begun to build up – at a time when we need it most.

The issue of national ownership that has increasingly become prominent in talk of PEPFAR phase II, while it entails a valid challenge to national governments, also serves as a defensive refrain for dwindling funding if its implications are not scrutinized beneath the surface of the overarching rhetoric. While almost everyone would likely support the essential concept of national ownership, it does not justify abdication of responsibility to uphold prior commitments; and further, it is requires a carefully and inclusively thought-out process, not a simple policy decision based on which substantial budget changes can reasonably be made, and support withdrawn. We would do well to reflect back on the United Nations Millennium Declaration (2000), in which heads of States and governments acknowledged that:

> *"in addition to [their] separate responsibilities to [their] individual societies, [they] have a collective responsibility to uphold the principles of human dignity, equality and equity at the global level"*

Yesterday, Tuesday the 28th of September, HIV NGOs mobilized civil society in a dozen countries across the African region to unite in a day of action for increased health funding; and through demonstrations, press conferences and public meetings called on global leaders to fully replenish the GF, and on AFrcan governments to meet the 2001 Abuja pledge to spend at least 15% of their national budgets on health. Some took action even in the context of repressive political circumstances, as in Swaziland where a memorandum was delivered, through a mass march, to the Ministry of Finance and the European Commission but unfortunately, was refused by the American embassy. Activists took this action recognizing that addressing the potentially devastating impact of a weakening HIV response necessitates courageous action even in adverse circumstances, and I call on you today to do the same.

This call is not directed at the US government alone: over the past few months, civil society organizations across the world have targeted Global Fund donors from several countries including Italy, Germany, France, UK and Japan – to name a few. In the African region, ARASA and others have led the mobilization of civil society organizations under the banner of the slogan "we are watching" – a slogan that symbolizes our commitment to sustained scrutiny of government budgets to ensure responsible allocation to health, tracking of expenditure, and improved transparency and accountability. This advocacy, although young, has already began to pay off in countries around the region – in Kenya, the

2010/2011 budget for HIV treatment doubled compared to previous years; in South Africa, the HIV budget increased by 33% over the past year. An increasing number of private African enterprises, such as Access Bank, have begun to make pledges to the Global Fund.

Our governments are beginning to realize themselves that increased investment in health is a socio-economic necessity – the IMF reported in April 2010 that African countries had sustained social spending, particularly on health and education, despite the economic recession – and further, that this social spending contributed significantly to cushioning the blow of the recession on countries in the region, ultimately allowing for better overall economic recovery. However, we still have a long way to go, and we are committed to intensifying our advocacy in the months to come: yesterday's day of multiple-country action merely was a starting point.

It is interesting to note that income status of countries in the African region is not the key predictor of their allocation to health budgets. Some of the best performing countries with regards to health expenditure in the region – such as Rwanda, Malawi, Tanzania – are also among the poorest. Some of the worst performing countries on health expenditure are among the richest. But regardless of geography and demography – the need for health, life, and human dignity remains the same, and the struggle for universal access to HIV services is ultimately about the fight for universal recognition and prioritization of these needs.

It is, quite simply, a question of political prioritization. We have heard from governments that there is restricted money for health and particularly, universal access to HIV treatment, in these times of economic difficulty. We hear these words with a sense of outrage and ironic bewilderment, coming as they do from the podiums of lavish conferences whose bills cost far more than the development funding pledges that emanate from these expensive discussions. People of the world are scrambling for crumbs from the high table, while more and more loaves are put aside for military expenditure, for corporate interests, for political extravagance, for the global web of complicity on corruption – for let us be honest: no corrupt man or woman is an island – be they in Uganda, Switzerland, or the United States of America.

We see billions and billions being wasted on these things that do nothing to advance human development, and are forced to ask ourselves how our priorities have become so skewed that we are willing to spend more on talking than we are on doing – the G8 summit this year cost more than the pledges that it generated for maternal and child health; willing to spend more on breaking down than we are on building up – expenditure on wars never seems to be diminished by economic crises; willing to

spend more on cushioning the rich than we are on supporting the poor. There is a striking and inevitably self-destructive obscenity in this.

I want to end this testimony with an optimistic outlook, but I cannot do so without acknowledging the pessimistic prognosis of the current approach to public health by most governments around the world, as has been demonstrated by the retreat from HIV funding. I do this because in order to make real, lasting progress we have to recognize that the real crises that we face are not of economics or microbes, but of priorities. I referred to this earlier as the peculiar violence of apathy, the death of millions of people annually that are very easily accomplished simply by us doing nothing at all.

When the Lantos-Hyde Act was passed in 2008, reauthorizing PEPFAR and the US contribution to the Global Fund, you took a very definitive landmark step away from that apathy; giving people living with HIV all around the world and their communities great hope that finally, a lasting precedent had been set for an energized global response to HIV, which would influence responses to other health needs as well. This impact has already been witnessed. AIDS programs have been not only the most effective public health programs of our time, but a hugely significant political tool. As has been shared by witnesses at this hearing, with adequate resources we stand to win on the public health front; but we also stand to make great strides on the political front and can continue to move the world in the right direction so as to ultimately overcome this epidemic. With adequate investment now, AIDS could be history in a few decades, making it the greatest public health success story of our time – but with inadequate investment, it could be a historical lesson in the danger of making decisions based on short-term fiscal convenience rather than on long-term socio-economic rationale. The choice between these two outcomes is not beyond our control – it is a choice.

Next week, donors will meet in New York to decide the fate of the Global Fund and the U.S. could transform the replenishment with the promise of a bold, 3-year pledge at the levels authorized by Lantos-Hyde, of up to US$2 billion per year. I have travelled here today to urge you to help make this happen and thus send the strong, trend-setting signal that the U.S. is committed to making history by winning the fight against AIDS. And as you move towards a more long-term strategy for PEPFAR, it is my hope that you will recognize that sustainability cannot be achieved by relaxation, but rather by intensification, of efforts – because while this might cost us more today, it will save us much more tomorrow – and that is true sustainable development. I hope that you will make a decision for tomorrow.

Chairman BERMAN. Thank you for reminding us of the dangers of backsliding.

Dr. El-Sadr.

STATEMENT OF WAFAA EL–SADR, M.D., M.P.H., DIRECTOR, INTERNATIONAL CENTER FOR AIDS CARE AND TREATMENT PROGRAMS (ICAP), MAILMAN SCHOOL OF PUBLIC HEALTH, COLUMBIA UNIVERSITY

Dr. EL-SADR. Good morning, and thank you for the opportunity to testify today at this very important hearing.

I have personally been working in the field of HIV medicine since the very beginning of the epidemic when I was working at Harlem Hospital in New York City. And over the past decade, I have spent a great deal of my time working on PEPFAR-supported HIV and related capacity building, program development, and implementation in sub-Saharan Africa.

As mentioned, I serve as director of ICAP, which is situated at Columbia's Mailman School of Public Health, an institution with a long history of work, not just in HIV, but also in maternal mortality and child health.

ICAP is a PEPFAR-implementing partner that supports more than 1,200 health systems in 15 countries in Africa today, and to date, it has supported services for over one million HIV-infected adults and children in a family-focused, women-centered approach. Roughly half of these individuals have initiated treatment. More than a million pregnant women with HIV have received HIV care for their own health, as well as prevention of transmission to their babies. Other supports include integration of TB/HIV services, HIV testing counseling, laboratory support, amongst many others. It has also supported the dynamic evaluation methods to inform programs and to ensure quality of the programs.

We have witnessed firsthand the impact of PEPFAR on individuals, families, and communities, the rapid expansion of host country capacity, and the remarkable goodwill generated by PEPFAR for the U.S. and its people. Yet the work is far from done. The success of PEPFAR is widely acknowledged by the millions who have benefited from its program. Thus it is sometimes puzzling when one hears some misunderstandings regarding PEPFAR. I will briefly address these through the lense of my own experience and observations.

First, some claim that PEPFAR works in isolation disconnected from country ownership. My experience says otherwise. PEPFAR is demand-driven at the community and host government levels. The work has been planned and implemented in partnership with Ministries of Health, regional district and facility health teams, as well as nongovernmental organizations, including faith-based organizations and with the affected communities.

PEPFAR implementers play important and complementary roles in the scale-up of these programs, all contributing to the national AIDS control programs developed within the countries themselves. U.S. agencies, such as CDC and USAID, play key roles in forming these efforts under other coordination and guidance.

Second, some claim that PEPFAR-supported programs have been developed as separate and distinct services in silos that are not in-

tegrated and linked to established services within the countries. Again, my own experience differs from this perception. The majority of health facilities deliver integrated HIV and primary care services right where these services are provided, including linkages to other key services such as reproductive health.

In Nigeria, for example, ICAP supports PMTCT services for pregnant women within existing antenatal clinics. In Rwanda, ICAP in collaboration with the Rwandan Government, has supported integration of TB and HIV services and synergies between these two programs.

In Ethiopia, in collaboration with the regional health bureaus, ICAP supports scale-up of routine HIV screening for all in-patients and out-patients at health facilities, including testing of mothers and babies integrated in immunization clinics. And there are many, many other examples.

Fundamentally on the ground, there is no distinction between Global Fund and PEPFAR funding. The inputs are all integrated at the delivery site.

Third, some claim that PEPFAR has had limited contributions to the country's health systems, but the evidence says otherwise. In many of the countries where ICAP works, it has supported the development of tiered laboratory systems as we heard before. Good national regional local laboratories provide training and mentorship to staff. Health work toward innovations have also built up on the skills and morale of tens of thousands of existing health care workers in new countries through training and mentorship.

Pharmacies across the continent have been supported through the provision of infrastructure, training, mentorship, capacity building for stock management and many, many other inputs—all of them contributing to stronger health systems that can respond to HIV as well as to all other health threats.

A fourth misconception is that evidence of PEPFAR's impact is difficult to discern. In reality, a key attribute of PEPFAR is its focus on concrete measurable outcomes, an approach that should serve as a model for other health and development programs. Without a doubt, PEPFAR has saved millions of lives and has preserved families and communities through access to HIV treatment. More than 7 million pregnant women have received counseling and treatment to prevent HIV transmission.

Expansion of prevention counseling programs for male circumcision for HIV prevention are taking off in several countries. Overall, there is encouraging information indicating a 25 percent decrease in new HIV infections.

Remarkably, with the expansion of HIV treatment, we are now witnessing a decrease in death rates in the most severely affected countries, including South Africa and Botswana. Different contributions to other health outcomes beyond HIV can also be noted. ICAP-supported programs in Nigeria offer pregnant women insecticide-treated bed nets for malaria prevention, water purification systems and "mama packs" to encourage safe pregnancy and facility-based deliveries thus impacting maternal and child health.

Renovation of antenatal clinics, labor and delivery wards in support of orphans and vulnerable children are just a few examples of the broad impact of PEPFAR on the health of children.

Encouraging evidence from South Africa shows a decrease in under five child deaths with expansion of HIV treatment to women in one community.

But we are at a critical point in the response to the HIV epidemic. Scale-up of HIV treatment in PEPFAR-focused countries has been phenomenal, but it has only reached about a third of those in urgent need. Desperately ill men, women, and children living in communities near and far continue to line up at clinics in urgent need of services. For these individuals, the emergency is far from over.

In addition, the more we learn about HIV, the clearer it becomes that earlier diagnosis and earlier treatment is more successful, and most importantly, more cost effective.

New WHO guidelines support earlier treatment for adults, and it is now recommended that all children with HIV receive treatment. Similarly, a global consensus has arisen that all pregnant HIV-infected women must be reached if we are to eliminate HIV.

There is also evidence that treatment for persons with HIV can prevent them from developing tuberculosis, a leading complication. Here is a chance to impact the TB epidemic in countries hit hard by the dual epidemics of HIV and TB. However, despite the scientific evidence, some national programs are reluctant to expand HIV treatments and the achievements of all of these benefits are outdone due to resource constraints.

Another critical need is to scale-up evidence-based prevention programs, as well as to engage marginalized groups like men who have sex with men, injection drug users and commercial sex workers in both care and prevention services. Recent guidance from OGAC in terms of emphasis on addressing gender equity and support for harm reduction, including syringe exchange programs, go a long way to reinvigorating HIV prevention efforts.

Thus, we are poised now with many of the new tools that you heard about earlier today to have a profound impact on stemming the epidemic and preventing new infections.

There is little doubt that PEPFAR can and does provide a platform for addressing some of the key priorities of President Obama's Global Health Initiative. Rather than reinventing the wheel or starting from zero, we can build on the platform established by PEPFAR at the tens of thousands of health facilities and under partnerships already established within the many communities.

However, if we stall the expansion of PEPFAR in the name of a greater balance in global health spending, then we risk limiting advances in maternal and child survival as well as many other advances that go beyond HIV/AIDS per se.

This committee envisioned a scale-up of resources when it reauthorized PEPFAR and set bold targets and new policies that would move us toward a world without an AIDS crisis. But the potential to truly turn the tide against the HIV epidemic and to achieving the durable impact, we all desire will not be realized if current funding crisis is not addressed. People will be turned away from clinics, services will be rationed, women and children and their

families will suffer. The optimism we have witnessed will evaporate and this remarkable potential will be squandered.

Time is of the essence. The sooner we continue the scale-1up of HIV treatment and prevention, the more lives will be saved, the more tuberculosis cases can be prevented, the more families, communities and livelihoods will be preserved. Greater investments aiming at universal access, continued commitment to research in conjunction with an emphasis on building capacity and meaningful partnerships can change the trajectory of the HIV epidemic in the most severely-affected countries. It can also contribute substantially to the overall health and well-being of women and children and communities.

Strong U.S. leadership and partnership with the affected countries and communities, as well as other donor nations can bring this goal within our reach.

Thank you.

[The prepared statement of Dr. El-Sadr follows:]

House Committee on Foreign Affairs
Public Witness Hearing
September 29, 2010
9:30 AM

Dr. Wafaa El-Sadr, MD, MPH, MPA
Director of International Center for AIDS Care and Treatment Programs
Director of Center for Infectious Disease Epidemiologic Research
Professor Mailman School of Public Health, Columbia University
Testimony Concerning the President's Emergency Plan for AIDS Relief (PEPFAR)

Testimony of Wafaa El-Sadr, MD, MPH, MPA
U.S. House of Representatives Committee on Foreign Affairs Hearing
PEPFAR: From Emergency to Sustainability and Advances against HIV/AIDS
Wednesday, September 29, 2010

Thank you for affording me the opportunity to testify about the transformative and life-saving PEPFAR program, its remarkable achievements, and the numerous opportunities it has created in our fight against the AIDS epidemic and other global health threats.

I have been working in the field of HIV medicine since the very beginning of the epidemic when the first cases were noted at the hospital I was working at in Harlem, New York. I have spent a great deal of my time over the last decade working on HIV research, training, and service delivery and related capacity building, program development and implementation in sub-Saharan Africa.

I currently serve as Director of the International Center for AIDS Care and Treatment Programs (ICAP), an interdisciplinary center which is situated at Columbia University's Mailman School of Public Health. ICAP has been a PEPFAR implementing partner since 2004, and now supports more than 1,200 health facilities in 15 countries in sub-Saharan Africa. To date, ICAP support has enabled the provision of HIV prevention, care and treatment services to more than a million HIV-infected adults and children, roughly half of whom have initiated antiretroviral treatment (ART). In partnership with local Ministries of Health and other stakeholders, ICAP provides nearly 10% of all antiretroviral therapy in sub-Saharan Africa. The ICAP model of multidisciplinary, family-focused HIV prevention, care, and treatment includes support for prevention of mother to child transmission (PMTCT) of HIV, and this effort has enabled more than a million pregnant HIV-infected women to receive care for their own HIV infection and interventions to prevent their babies from becoming HIV infected. ICAP-supported programs also provide HIV testing and counseling services to millions, as well as a wide range of prevention interventions, specialized services for infants and children with HIV, integrated tuberculosis (TB) and HIV services, laboratory support, training and mentorship, all in the context of health system strengthening.

The transformative impact of ICAP's work is made possible by PEPFAR, and by our partnerships with Ministries of Health, local universities, non-governmental organizations, faith-based organizations, civil society, and associations of people living with HIV (PLWH). My colleagues and I have been privileged to witness first-hand the unprecedented scale-up of life-saving services, the impact of PEPFAR on individuals, families, and communities, the rapid expansion of host country capacity, and the remarkable goodwill generated by PEPFAR towards the US government and its people.

PEPFAR's success is widely acknowledged. Millions of lives have been saved, communities have been restored, overburdened health systems have been buttressed, and while much remains to be done, significant progress against the scourge of HIV has been made. Despite these historic

achievements, however, some myths and misunderstandings regarding PEPFAR have gained surprising credibility. Some of these inaccurate ideas are the result of misinformation or genuine confusion, while others are harder to understand. I will highlight a few in my testimony today and address them through my own experience and observations.

First, some claim that PEPFAR works in isolation, disconnected from country ownership and country systems. My experience says otherwise. PEPFAR is demand driven, at the community *and* the host government levels. The work has not been done in isolation or in "silos," but rather in partnership with ministries of health, regional health bureaus, district health teams and non-governmental organizations. PEPFAR operates within the established health structures in the countries where we work, supporting national plans and protocols. All PEPFAR implementers, whether they be international organizations, indigenous governmental or local non-governmental organizations, faith-based organizations, community based organizations or academic institutions play complementary roles in the scale-up of prevention, care and treatment programs—all contributing to national AIDS control programs developed within the countries themselves.

Second, some claim that PEPFAR supported programs have been developed as separate and distinct services that are not integrated and linked to ongoing services within countries. Again, my experience differs from this perception. Those not familiar with HIV programs may envision stand-alone HIV clinics while in reality, the majority of sites that ICAP supports are rural or semi-urban. These health facilities deliver integrated HIV and primary care services right where other services are provided. In Nigeria, for example, ICAP supports PMTCT services for pregnant women within existing antenatal clinics. In Rwanda, ICAP has led efforts in collaboration with the Rwandan government to integrate HIV and TB services, and these innovations have now been taken to scale nationwide. In Ethiopia, in collaboration with regional health bureaus, ICAP supports scale-up of routine HIV screening for TB patients and to all patients and their families whether they are seen in a clinic or on an inpatient ward. In other countries, HIV testing for mothers and babies has been integrated into immunization clinics.

Third, some claim that PEPFAR has had limited benefits to the countries' health systems. The evidence says otherwise. For example, in Tanzania, Ethiopia, Rwanda, Nigeria, Kenya, Mozambique and other countries, ICAP has supported the development of tiered laboratory systems; equipping national, regional and local laboratories; providing training and mentorship to staff; developing effective specimen tracking and transport system; introducing novel interventions, such as early infant diagnosis; and supporting quality assurance. This work strengthens lab systems overall, not HIV systems. At pharmacies across the continent, ICAP has provided infrastructure support, training, mentoring, and supervision, building capacity for stock management, patient counseling, and adherence support that reaches far beyond HIV treatments. Another major contribution has been in the realm of health workforce innovations. In addition to training tens of thousands of health care workers, ICAP and other PEPFAR partners have worked to build skills and morale, and to identify and treat HIV-infected health workers. ICAP programs have also supported new health worker cadres, from adherence counselors and outreach workers to advanced physician-assistant equivalents, such as the *technicos* in Mozambique—efforts aimed at addressing the severe shortage of health care

workers. These models, systems, and investments position the health system to respond to other threats.

A fourth misconception is that the evidence of PEPFAR's impact is lacking. In reality, a key attribute of PEPFAR is its focus on concrete measurable targets, updated quarterly, such as the number of individuals receiving HIV testing and counseling services, the number enrolled in care and the number on ART among other goals and objectives. This approach should serve as a model for other health and development programs. Without a doubt, PEPFAR has saved millions of lives, prevented tens of thousands of new infections, preserved families and communities, and enabled thousands to return to work, and unburdened health systems staggering under the weight of sick and dying populations. More than 7.3 million pregnant women have received counseling and treatment to prevent transmission of the virus to their babies, and we know that with ART we have a real chance to end the HIV/AIDS epidemic in children. Expansion of prevention counseling and campaigns for male circumcision are taking off in several countries. There is also encouraging new information from UNAIDS indicating that twenty-two of the most affected countries in sub-Saharan Africa have reduced new HIV infections by more than 25% between 2001 and 2009. Remarkably, we are now also witnessing a decrease in death rates in the most severely affected countries like South Africa and Botswana with the expansion of HIV treatment. Other evidence from South Africa showed a decrease in under 5 child mortality with expansion of HIV treatment to women in one community.

PEPFAR's contributions to other outcomes beyond strictly HIV targets, are a major achievement. As an example, ICAP-supported programs in Nigeria offer pregnant women insecticide-treated bed nets for malaria prevention, water purifying systems and "mama packs" to encourage safe pregnancy and facility-based delivery—thus impacting maternal and child health. Laboratories supported by PEPFAR serve all within a community, not just people living with HIV. Support and expansion of the healthcare workforce benefits all those needing services within a community. Renovation of antenatal care setting, labor and delivery wards and support of orphans and vulnerable children are just a few examples of the broad impact of PEPFAR. All of these achievements cause great apprehension that if we stall the expansion of PEPFAR, in the name of "greater balance" in global health spending, then we will also be stalling advances in maternal and child survival, as well as many other advances that go far beyond AIDS *per se*.

While so much has been accomplished, there is so much more that needs to be done. Scale up of HIV treatment in PEPFAR focus countries has been phenomenal, but it has only reached about a third of those in urgent need with many more in need of this lifeline today and many more will require treatment in the coming years. Desperately ill men, women and children living in communities near and far continue to line up at clinics with advanced HIV disease in need of urgent services, including HIV treatment. For these individuals with advanced AIDS, the emergency is far from over. In addition, the more we learn about HIV, the clearer it becomes that earlier diagnosis and treatment is more successful and more cost-effective. Reaching individuals at early stages of HIV and linking them to care and appropriate treatment is critical to the achievement of optimal treatment and prevention outcomes – and an entirely different

challenge than providing services to those with advanced or symptomatic illness. As new data have emerged, treatment guidelines have changed. New World Health Organization (WHO) guidelines support earlier treatment for adults, and it is now recommended that *all* children with HIV receive treatment. Similarly, a global consensus has emerged on the need to reach *all* pregnant HIV-infected women in a concerted effort towards the elimination of pediatric HIV. However, despite the evidence, national programs in some PEPFAR focus countries are reluctant to expand treatment eligibility due to resource constraints.

Resources are also critically needed to scale up evidence-based prevention programs, as well as engaging marginalized groups like men who have sex with men (MSM), injection drug users and commercial sex workers. Ground-breaking new research suggests that HIV treatment itself may not only benefit the individual receiving ART, but may also prevent transmission of the virus to their partners. The promise of treatment as part of the prevention armamentarium is terribly exciting. In one recent study, providing treatment to an HIV-infected partner in a discordant couple lowered the chance of infecting the HIV-negative partner by 92 percent. Remarkably, UNAIDS estimates that treating everyone in need of treatment according to current treatment guidelines could result in a one third reduction in new infections globally. Let me emphasize this point – providing treatment to those patients already eligible and in need of ART *for their own health* could have a stunning secondary benefit on the global epidemic. If we continue to scale-up and decentralize access to HIV services, we may very well be able to "treat our way out of the epidemic." But, for now, results from research studies are needed to confirm the value of HIV treatment as a prevention strategy in populations. Encouragingly, recent studies offer promising microbicide and vaccine candidates and efforts are ongoing to study combination prevention strategies that include behavioral, biomedical and structural interventions. Recent guidance from OGAC in terms of an emphasis on addressing gender inequity and support for harm reduction including syringe exchange programs will go a long way to re-invigorating HIV prevention efforts.

Despite enormous progress in the form of lives saved, infections averted and the promise of major scientific breakthroughs, it is a sobering time. The worldwide economic recession has taken its toll on the global response to HIV/AIDS, both in donor nations and in developing countries. PEPFAR has been nearly flat-funded for several years now and the Global Fund will be greatly challenged to respond to continuing needs as it embarks on its replenishment conference this coming week.

This committee envisioned a scale up of resources when it reauthorized the PEPFAR program and set bold targets and new policies that would move us toward a world without an AIDS crisis and with an empowered and enabled health system in the most severely affected countries. We and other PEPFAR implementers are working hard towards this worthy goal. But the potential to truly turn the tide against the HIV/AIDS epidemic and to achieving the durable impact we all desire will be squandered if this funding crisis is not addressed.

While scaling up of treatment and prevention calls for a significant infusion of resources in the short run, there are remarkable benefits to be garnered. There is little doubt that PEPFAR can and does provide a platform for addressing some of the key priorities of President Obama's

Global Health Initiative, such as building health systems for the provision of critical health care services not only for those living with HIV but to others in their communities including women and children. PEPFAR supports tens of thousands of programs and sites embedded within antenatal care programs and primary care settings at health centers, district and referral hospitals. Rather than reinventing the wheel, or starting from zero, we can build on this platform, on the partnerships already established within the many communities, and on the lessons learned from the scale-up of HIV programs. Much can be achieved to advance the health of women and children through smart use of resources and by searching for synergies and economies of scale.

I have witnessed in my own career the worst of times and the best of times in relation to the HIV epidemic. In the early 1980s in Harlem, New York, we watched helplessly as our patients died and their families mourned. This was the worst of times. We then lived through the miracle of newly-discovered HIV treatments, reviving those close to death. In Africa, for years we watched helplessly as communities were decimated, despairing from the ravages of this epidemic. Here too, we witnessed a remarkable transformation, a transformation that you and every American citizen can take great pride in. So much has been accomplished through PEPFAR, so much remains to be done.

Time is of the essence. The sooner we scale up HIV treatment and prevention, the more lives we will save, the more deadly tuberculosis infections can be prevented, the more families, communities and livelihoods we will preserve. Aggressive investment in HIV prevention and treatment scale-up with universal access, combined with continued investment in research, in conjunction with a commitment to building capacity and the strengthening health systems, can change the trajectory of the HIV epidemic in sub-Saharan Africa. It can also contribute substantially to the overall welfare of women and children. Strong US leadership in partnership with affected countries and other donor nations can bring this goal within our reach.

Thank you

Chairman BERMAN. Thank you for that testimony.

I am now going to recognize Ambassador Watson for 5 minutes. We are told there will be votes on the House floor in the next 10 or 15 minutes. So I think this will be our last shot.

Ms. WATSON. Thank you so very much. You did mention in your testimony, and I missed the other witnesses, but our administration really would like to now focus on women and girls. They tend to be victimized more so in many different ways you mentioned. What is the common treatments and thinking in terms of securing the health and reducing the risk for women and girls?

Dr. EL-SADR. There are many, many opportunities to do that, and some of them are ongoing. There clearly is the effort to prioritize the needs of women in the context of PEPFAR. For example, in the expansion of treatment, almost 60 percent of individuals receiving treatment through PEPFAR are women. In addition, the expansion of reach for prevention of mother-to-child transmission in enhancing the potential for a safe pregnancy and safe delivery is actually very profound in terms of trying to address the needs of these women.

Lastly, I think the engagement of women in the context, of course, of taking care of their own families by providing them with all the resources that they need, recognizing that women are the central fulcrum for the health of the families themselves is also a very important contribution of what—the ongoing work of PEPFAR.

Ms. WATSON. I understand that myths are flying all over the place, and there are certain beliefs in certain areas of Africa, in particular South Africa. And I go often to South Africa, but I heard that there is a belief in the southern tip that if men had sex with babies, it would relieve them of AIDS.

What do we have to do—and, you know, women cannot refuse their men when they want to have sex. That is a belief in some areas. How do we go about changing the way, the old customary ways, of believing when it comes to women and girls? And I am just wondering what we can do to enhance the obliteration of those kinds of cultural mythical beliefs.

Ms. AKUGIZIBWE. Well, you know. I think one of the reasons why HIV—the HIV epidemic was exceptional is because it has highlighted a lot of these long-standing cultural challenges. And it has really brought in to bear the public health context, but underlying that are much more deep-rooted social issues.

And speaking from my experience in working with an NGO that does community training and community advocacy, issues such as this are a fundamental component of all the training that we do related to HIV, because unless we can address underlying dynamics, we can't actually overcome the HIV epidemic.

And I think that possibly one of the most valuable things that the HIV response has brought us is the creation of these extensive, far-reaching, community-based networks that give us space to start discussing a lot of otherwise issues that would otherwise never have had the opportunity to explore.

But to also touch on the earlier point about women and girls and how they fit into this, one of the things that I had mentioned is that HIV in South Africa, for example, is the cause of more than

40 percent of maternal mortality. And so for us to separate these two things can get a bit misleading sometimes. And I think what we need to be doing is seeing how we can strengthen the value that HIV response has brought to efforts to advance women's health while adding resources to us to expand, to address a wider range of issues that don't necessarily fall within HIV.

Ms. WATSON. The most successful programs that I saw in areas of South Africa were the programs where we gave them the resources and let them, through their own techniques, deal, and they can talk a small amount of money and stretch it. And so I believe that we can better serve the people we are targeting with our resources by going through the structure that is already it socially and culturally.

I yield back. You have got 30 seconds, Mr. Chairman, to give to someone else.

Chairman BERMAN. The gentlelady has yielded back. The votes have just been called, so we have about 10 more minutes here.

Can I just arbitrarily say let us take 4 minutes a witness rather than 5?

Mr. Smith, 4 minutes.

Mr. SMITH. Thank you very much.

Chairman BERMAN. 4 minutes.

Mr. SMITH. Sorry I missed our distinguished witnesses. I was at a press conference with Jim Moran on a child abduction case. The chairman was kind enough to place on the calendar yesterday a very important resolution that calls for the release of American children who have been abducted to Japan. So I do apologize for missing that.

I would ask unanimous consent that the ranking member's statement, Ileana Ros-Lehtinen, be included in the record.

Chairman BERMAN. Without objection.

[The prepared statement of Ms. Ros-Lehtinen follows:]

THE HON. ILEANA ROS-LEHTINEN
REMARKS FOR HEARING ON
"PEPFAR REAUTHORIZATION: FROM EMERGENCY TO SUSTAINABILITY"
SEPTEMBER 29, 2010

When the Committee last held a hearing three years ago on the President's Emergency Plan for AIDS Relief, PEPFAR, attention largely was focused on the accomplishments to date.

It is appropriate to reflect on those accomplishments again today.

Through PEPFAR, the American people have provided over 2.4 million people with life-saving treatment.

We have provided compassionate care for 11 million people, including 3.6 million orphans and vulnerable children.

We have saved 340,000 newborn children from infection.

And we have supported the development of promising new prevention technologies, including microbicides.

These accomplishments are a testament to the generosity of the American people and the tireless dedication of our implementing partners on the front lines of this pandemic.

Still, we are losing the war.

While an estimated 5 million people worldwide now have access to treatment, more than 33.4 million people are infected with HIV/AIDS.

For every two people who start treatment, five more become infected.

At this rate, the cost of achieving 80% coverage for treatment would require an average of $21 billion annually for the next 40 years.

For the United States, supporting universal access to treatment in just the original 15 PEPFAR focus countries would absorb more than half of the entire foreign assistance budget by 2016---just a little over five years from now.

Meanwhile, here at home, domestic funding deficits have forced states, including Florida, to create waiting lists and cut benefits for Americans who rely on AIDS Drug Assistance Programs (ADAPs).

Obviously, the global economic crisis and our crushing national debt are underminingthe ability of the American taxpayer to continue to shoulder over 58% of the entire, global response to the HIV/AIDS crisis.

Nevertheless, we simply cannot turn the tide of this pandemic if we fail to prevent new infections from occurring.

So, we need to do better.

Consistent with Congressional directives, the administration's new five-year strategy reportedly seeks to transition PEPFAR from an emergency program to a sustainable response.

As a result, PEPFAR funds are being used to address [quote] "complementary" [end quote] development challenges.

Many of these goals are commendable.

However, we must not lose the focus that made PEPFAR successful.

The apparent preference to reorient PEPFAR toward the same old ambiguous, inefficient, and ineffective development programs that have failed for the past 20 years, is therefore deeply troubling.

To succeed, PEPFAR must remain focused on its core objectives: providing care and treatment to those affected by HIV/AIDS, while expanding efforts to prevent new infections from occurring.

Funds must not be diverted for other purposes, particularly those which the majority of American people regard as morally repugnant.

I also am concerned by the inclination of some – in the name of sustainability – to shift increasing amounts of United States assistance toward the Global Fund.

While increased burden-sharing to fight HIV/AIDS is desirable, the Global Fund is fraught with structural challenges that must be addressed if we are going to continue our support.

For example, the amount of funds that middle-income countries have drawn from the Fund – at the expense of less developed nations with higher prevalence rates – is shocking.

China, with the world's second largest economy and over $2.5 trillion in foreign reserves, is the fourth largest recipient of Global Fund grants.

Additionally, massive fraud and the outright theft of Global Fund grants continually rob intended beneficiaries of life-saving support.

The unwillingness of the Global Fund's Secretariat and Board to press for greater accountability from its implementing partners, particularly the UN Development Program, is disgraceful.

As the single largest donor to the Fund, the United States owes a duty of care to the intended beneficiaries.

As we prepare for the Fund's "replenishment" in October, we must remember that success can't be measured by the amount of money raised, but rather by the lives saved.

Mr. Chairman, the PEPFAR program is emblematic of what can be accomplished through a serious, bipartisan commitment to resolve one of the world's most pressing challenges.

But that effort must remain focused, efficient, and accountable.

Success will be measured in human lives. Failure is not an option.

Mr. SMITH. As well as that of Joseph O'Neill and Michael Miller, who have transcripts of testimony that——

Chairman BERMAN. Will be included.

Mr. SMITH [continuing]. An op-ed that I wrote for the Washington Post, and the African First Lady's declaration.

Chairman BERMAN. It will all be in there.

Mr. SMITH. I appreciate that.

Let me just very briefly raise for all my colleagues, I am sure our distinguished witnesses know all about this as well, the Call for Action at the Millennium Development Summit last week. The First Ladies of Africa—there were nine in total, and I believe there were seven in the room—I was at the roundtable discussion—they made a very, very important contribution, as they always do. Part of their statement was good nutrition is a requirement, a way to advance the Millennium Development Goals. There is a direct link between malnutrition, hunger and poverty, MDG 1; child mortality, MDG number 4; maternal health, MDG 5; and AIDS and other infectious diseases, MDG number 6. Equally important, poor nutrition has a causal effect in eliminating achievement of education, MDG 2, and gender equality, MGD number 3.

They went on to say in their declaration, we now know how to reduce malnutrition through the life cycle by a number of simple, targeted and cost-effective solutions. The critical window of opportunity is the 1,000-day period from conception to 2 years old. Fortified staples; good infant-feeding practices; more nutritious, complementary foods are some of the tools available to help permanently break the intergenerational cycle of malnutrition. New ways to mobilize business, develop agriculture and food security, improved feeding and health practices are available. And then they go on in their declaration to make a number of very important mutually reinforcing statements.

I am wondering from our distinguished witnesses how you see this playing out, because as we did in the last PEPFAR reauthorization, we made sure that nutrition was included. I mean, I recall once when I was taking antibiotics, and I wasn't eating as much, it causes a backlash even from something as simple as doxycycline or some other antibiotic. I can only imagine with ARVs, on an

empty stomach, in a malnourished person, how that could not only be difficult, but also counterproductive.

Obviously nutrition is important. But this idea of the first 1,000 days from the moment of conception, could you speak to that, if you would?

Dr. EL-SADR. I will start.

I think from day 1 in terms of implementation of PEPFAR-supported programs, there had been attention given to nutrition and clearly integration of and provision of nutritional supplements to individuals who need it, as well as often to families of these individuals. So that has been part and parcel of the work on the ground.

In addition, there has also been very innovative programs to try to enable people living with HIV and their families to support themselves and to grow their own foods. There are some very—programs that I am aware of and some of them we have supported in terms of income generation and generating food and nutrition for the families and for the communities.

I think that the third point I want to make in terms of nutrition is the importance of, obviously, within the PMTCT programs, programs for prevention of mother-to-child transmission, there are situated right in antenatal care to provide counseling to these women regarding nutrition in terms of their own health as well as also in terms of feeding of their babies after their babies are born.

So there is a package that includes—that focuses on nutrition that is part and parcel of several components of the work that we do, whether it be in the PMTCT antenatal setting, in the postnatal setting, or just in terms of the ongoing care and treatment activities.

Ms. AKUGIZIBWE. Your question reminds me of a conversation we had with the Canadian national AIDS coordinator and someone living in a low-income part of Nairobi.

Chairman BERMAN. Our problem is the 4 minutes has expired. I am sorry to do this, but maybe you can worm it into the next answer here.

The gentlelady from California, Ms. Lee, is recognized for 4 minutes.

Ms. LEE. Thank you, Mr. Chairman.

Let me just say the importance of women's voices and the work of women, the empowerment of women is so key to stamping HIV and AIDS from the face of the Earth. You both are really wonderful examples of why women have to be at the lead in this effort, so thank you very much.

I just wanted to ask you one question about—and I mentioned earlier that I was appointed as a Commissioner on the Global Commission on HIV and the Law. We will be meeting next week in Brazil. I wanted to find out from you in terms of—and part of our job is to look at some of the legal impediments for vulnerable populations: Gender violence, men having sex with men, commercial sex workers. What you would say should be some of your top priorities that we should consider?

Ms. AKUGIZIBWE. I think the issues that you have highlighted around vulnerable groups and the way that legal frameworks present the ability to access health services, such as sex workers,

such as men who have sex with men, are some of the biggest challenges we are facing in the African region.

Additionally, the introduction of laws that give punitive sanctions for what is called willful HIV transmission, which is often interpreted in many ways. For example, a woman who cannot negotiate safe sex with her husband and never had sex without a condom, but is HIV positive could then be prosecuted under these laws for willful transmission, and that has happened in several countries. I would be happy to provide you with more detail on some of the work that is highlighting these issues.

I think another, much bigger challenge is also around the way that legal systems recognize other socioeconomic rights, such as nutrition, and it affects the success of HIV programs. And I think the failure by many countries to recognize basic socioeconomic rights is impacting our ability to successfully implement HIV programs, especially when it is compounded by the flatlining of budgets that we are seeing in many HIV programs as a result of global declines and funding. You have situations where people are willing to take treatment that is readily available, an anecdote I referred to earlier, but are not able to start it because they don't have food, because the HIV program, because of its reduced budget, has cut food packages out of the overall package of services, and the government hasn't stepped in to fill that gap.

So those are the social challenges.

Chairman BERMAN. The gentlelady has yielded back her time.

All right. In that case I recognize for a couple of minutes—we do have to leave for vote—but for 3 minutes the gentlelady from Texas Ms. Sheila Jackson Lee.

Ms. JACKSON LEE. Thank you very much, Mr. Chairman, and I thank the witnesses.

If I understand, the earlier testimony by Dr. Goosby and other—Ambassador Goosby, rather, and a number of the witnesses on the first panel was to affirm the importance of PEPFAR, Global Health Initiative. I want to affirm the importance of sustainability and to comment that when we have made progress, but still see sub-Sahara Africa with 67 percent of worldwide HIV infections and infections still occurring in 2008, it means that we still have work to do. And I would like to make our program focus itself more clearly on sustainability and a combined effort as I know we are with malaria and tuberculosis.

So I would like to ask Ms. Akugizibwe, if I could, about the point that you just made about more funding and the lack of food packages, because at one time there was some dialogue that it was a nutrition issue. We know that we have dispelled that myth, but there is no doubt that you need to have nutrition, and you need to have a basis of healthiness, diet, so that you can continue to have people live longer if they are already HIV-infected.

Would you just highlight and emphasize how we need to use our monies for sustainability in this fight against HIV/AIDS?

Ms. AKUGIZIBWE. I think, as I mentioned in my testimony, that sustainability, a key component of that is recognizing that investments now are beginning to pay off and will continue to do so at a greater scale if they are sustained. Although we are still seeing infections, we are also seeing for the first time a decline in the rate

of new infections, especially in sub-Saharan Africa, and this is due in large part to the investment that has been made into treatment.

And I can mention this investment in HIV programs and treatment has highlighted a lot of other social issues, such as gender violence, such as nutrition. And what is more interesting is that the HIV response and the civil society mobilization that just happened around that has been probably the most effective vehicle for mobilizing advocacy around our own Government's accountability in addressing these other challenges.

So when we talk about government's investment in HIV treatment, it also gives us an opportunity to raise the investment in food and other——

Ms. JACKSON LEE. Can I ask Dr. El-Sadr to give a comment in my remaining short seconds? Can you just comment very quickly on that question, sustainability?

Dr. EL-SADR. I think that we have had remarkable success, and I think, again—and it should be recognized even in the hardest hit countries. So the effect has been profound.

There are investments today by the countries themselves in terms of the response to HIV/AIDS. So it is not a unilateral U.S.-supported response or largely from donors, but it is joint investment from the countries and from the external resources.

The conversations that are happening within the countries now are to identify and recognize the national—the country contributions as well as the external investments.

I think an investment today—what we need to do today will absolutely ensure the durability of this response and the ability to actually sustain it beyond the next 5 years. So stalling on the commitment today can have far-reaching impact on the ability to actually have a durable and sustainable response.

Ms. JACKSON LEE. Thank you very much.

Thank you, Mr. Chairman.

Chairman BERMAN. The time of the gentlelady has expired.

You were great witnesses. Thank you very much for coming, and, without objection, the opening statement of the gentleman from New Jersey Mr. Payne will be included in the record.

The committee is now adjourned. Thank you.

[Whereupon, at 11:55 a.m., the committee was adjourned.]

APPENDIX

Material Submitted for the Hearing Record

FULL COMMITTEE HEARING NOTICE
COMMITTEE ON FOREIGN AFFAIRS
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, D.C. 20515-0128

Howard L. Berman (D-CA), Chairman

September 24, 2010

TO: MEMBERS OF THE COMMITTEE ON FOREIGN AFFAIRS

You are respectfully requested to attend an OPEN hearing of the Committee on Foreign Affairs, to be held in **Room 2172 of the Rayburn House Office Building (and available live, via the WEBCAST link on the Committee website at http://www.hcfa.house.gov)**:

DATE: Wednesday, September 29, 2010

TIME: 9:30 a.m.

SUBJECT: PEPFAR: From Emergency to Sustainability and Advances Against HIV/AIDS

WITNESSES: **Panel I**
The Honorable Eric Goosby
United States Global AIDS Coordinator
U.S. Department of State

Anthony S. Fauci, M.D.
Director, National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health

Thomas R. Frieden, M.D., M.P.H.
Director, Centers for Disease Control and Prevention, and
Administrator, Agency for Toxic Substances & Disease Registry

Panel II
Ms. Paula Akugizibwe
Advocacy Coordinator
AIDS and Rights Alliance for Southern Africa (ARASA)

Wafaa El-Sadr, M.D., M.P.H.
Director, International Center for AIDS Care and Treatment Programs (ICAP)
Mailman School of Public Health
Columbia University

By Direction of the Chairman

The Committee on Foreign Affairs seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202/225-5021 at least four business days in advance of the event, whenever practicable. Questions with regard to special accommodations in general (including availability of Committee materials in alternative formats and assistive listening devices) may be directed to the Committee.

COMMITTEE ON FOREIGN AFFAIRS

MINUTES OF FULL COMMITTEE HEARING

Day Wednesday **Date** 9/29/10 **Room** 2172 RHOB

Starting Time 9:40 A.M. **Ending Time** 11:55 A.M.

Recesses - (to)

Presiding Member(s)

Howard L. Berman (CA), Chairman

CHECK ALL OF THE FOLLOWING THAT APPLY:

Open Session ✓
Executive (closed) Session
Televised ✓
Electronically Recorded (taped) ✓
Stenographic Record ✓

TITLE OF HEARING or BILLS FOR MARKUP: *(Include bill number(s) and title(s) of legislation.)*

PEPFAR: From Emergency to Sustainability and Advances Against HIV/AIDS

COMMITTEE MEMBERS PRESENT:

Howard L. Berman, Chris Smith, Diane Watson, Jeff Flake, Albio Sires, Bob Inglis, Lynn Woolsey, Sheila Jackson Lee, Barbara Lee, Brad Miller, David Scott and Keith Ellison

NON-COMMITTEE MEMBERS PRESENT:

n/a

HEARING WITNESSES: Same as meeting notice attached? Yes ✓ **No**
(If "no", please list below and include title, agency, department, or organization.)

STATEMENTS FOR THE RECORD: *(List any statements submitted for the record.)*

- Statement from Joseph F. O'Neill; Statement from Michael W. Miller, Navigator Strategies LLC; Statement by Africa First Ladies to the United Nations General Assembly; and Article dated 9/19/10 entitled Abortion does not further children's health - submitted by Chris Smith

ACTIONS TAKEN DURING THE MARKUP: *(Attach copies of legislation and amendments.)*

n/a

RECORDED VOTES TAKEN (FOR MARKUP): *(Attach final vote tally sheet listing each member.)*

Subject	Yeas	Nays	Present	Not Voting

TIME SCHEDULED TO RECONVENE _____
or
TIME ADJOURNED 11:55 A.M.

Doug Campbell

Doug Campbell, Deputy Staff Director

HFCA: Full Committee Hearing:
"PEPFAR: From Emergency to Sustainability and Advances Against HIV/AIDS"
Opening remarks:
Rep. Donald M. Payne
SAGH Subcommittee Chairman
Wednesday, September 29, 2010
9:30 AM in 2172 RHOB

Remarks

Good morning. Thank you, Chairman Berman for calling this full committee hearing on PEPFAR. As Chair of the Subcommittee on Africa and Global Health, and someone that has worked on this issue for many years, I want to recognize and commend your commitment to PEPFAR and to global health as a whole.

The United States has been a strong leader in the fight against HIV/AIDS, TB and Malaria. In 2003, under President Bush, Congress passed the U.S. Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act authorizing an unprecedented $15 billion for global HIV/AIDS, TB and malaria programs. With courageous bipartisan leadership, PEPFAR quickly became the world's largest effort to combat a single disease.

Then in 2008, Congress extended the program for another five years and authorized $48 billion for U.S. global HIV/AIDS, TB, and malaria efforts over the next five years, to prevent 12 million new infections, treat 3 million people living with HIV/AIDS and care for 5 million orphans and vulnerable children. Included in the $48 billion PEPFAR reauthorization was $4 billion for international TB programs, $5 billion for international malaria programs, and $2 billion towards the Global Fund in FY2009, with such sums as necessary for FY2010 through FY2013. I want to again thank you Chairman Berman for recognizing the importance of proper nutrition as an element of PEPFAR by including my global nutrition bill in the 2008 PEPFAR reauthorization.

As we know, Sub-Saharan Africa remains the area hardest hit by HIV/AIDS, accounting for 67% of worldwide HIV infections in 2008. Women and girls are disproportionately affected in the region, making up approximately 60% of all people living with the virus. While the HIV/AIDS crisis presents a tremendous global challenge, in the seven years since Congress passed PEPFAR I, it has become a historic program, yielding remarkable results. The Office of the U.S. Global AIDS Coordinator (OGAC), headed by our first witness Ambassador Goosby, reports that as of September 30, 2009 PEPFAR directly provided over 7,300,000 pregnant women with HIV counseling and testing services, and over 500,000 pregnant women with antiretroviral therapy (A.R.T.). In total, an estimated 97,000 infant HIV infections were prevented. PEPFAR has directly supported A.R.T. for 2.5 million individuals, just over half of individuals on treatment in low and middle-income countries; and cared for over 7 million adults affected by HIV/AIDS and 3.6 million infants and vulnerable children. Indeed, great progress has been made, but the challenges require a forward looking, comprehensive, and sustainable approach.

I commend the Chairman for raising this critical question of how to move towards sustainability in our global HIV/AIDS, TB, and malaria strategy. In order to move towards sustainability, we must take an integrated approach to our global health policy to ensure that we are meeting our goals with respect to HIV/AIDS, while also adequately addressing critical issues such as maternal and child health, neglected tropical diseases, and health system capacity building in focus countries.

As we examine the promising advances in scientific research on HIV/AIDS treatment that we will hear about later today, we must look to strengthen health systems in focus countries to help prepare those countries for the next global pandemic. Again, PEPFAR is the largest commitment by any nation in history to combat a single disease. One thing that we can learn from both history and science is that it is only a matter of time before another health epidemic hits our globe. We must help the focus countries to: improve service delivery, better educate and retain health care workers, gain access to adequate products, vaccines, and technologies, and better administer health care services to their citizens. In order to move towards sustainability, focus countries must be able to take ownership over their health programs, so our investments should provide the sort of technical assistance and capacity building necessary to facilitate country ownership.

I applaud President Obama's Global Health Initiative (GHI) which will invest $63 billion over six years to strengthen health systems, with a particular focus on maternal and child health and on building capacity of health systems. GHI adds $3 billion to PEPFAR and includes $11 billion for health systems, maternal and child health, and NTDs. The US commitment to the Global Fund also supports these goals and we must ensure that we strike the right balance to get the best use of critical global health funds. And of course we must recognize that PEPFAR is critical to the 1.4 billion individuals who continue to be infected with malaria, TB, and NTDs. In a time of crucial discussions for U.S. foreign assistance reform, malaria and NTD control represent some of the strongest returns on investment for foreign assistance dollars.

As PEPFAR has been a bipartisan program since its inception, I must close by recognizing my colleagues on both sides of the aisle who have been true champions of PEPFAR, including my subcommittee's Ranking Member Mr. Smith and Mr. Boozman, my co-chair of the Malaria and NTD Caucus for his leadership on Malaria, TB and NTDs, and, of course, former President George W. Bush. I look forward to hearing from the witnesses today.

OPENING STATEMENT OF
THE HONORABLE RUSS CARNAHAN (MO-03)
COMMITTEE ON FOREIGN AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

Hearing on
PEPFAR: From Emergency to Sustainability and Advances Against HIV/AIDS
Wednesday September 29, 2010, 9:30 a.m.
2172 Rayburn House Office Building

Chairman Berman and Ranking Member Ros-Lehtinen, thank you for holding this hearing regarding PEPFAR's progress on reversing the global AIDS pandemic. I appreciate the attention that is being given to this topic and hope that we can work toward achieving sustainability in the advancements made to fighting HIV/AIDS.

Despite barriers like weak health delivery systems, poor infrastructure, and powerful social stigmas, PEPFAR has made significant steps forward in its first five years of implementation, with the overall rate of new HIV infections having slowed and prevalence rates having leveled off. In addition to the efforts of the United States, the international community has made a priority of combating this epidemic with the inclusion of reversing the spread of HIV/AIDS in the United Nations Millennium Development Goals (MDGs). Recently, I participated in the MDG Summit at the UN headquarters in New York, which concluded with an announcement of major new commitments for women's and children's health.

Moreover, investment in scientific research continues to yield promising progress on new, innovative, and increasingly successful antiretroviral and preventative measures. Development of these new technologies is vital to the battle against HIV/AIDS. In my district, St. Louis is at the forefront of the scientific and medical research community. Leading in HIV/AIDS research, Washington University in St. Louis – named third best research medical school in the country – contributes extensive work on methods to prevent the transmission of HIV and reducing human suffering as a result of this disease. We must ensure that this type of innovative research is part of our overall strategy to address HIV/AIDS.

The strides we've made in reducing the spread of this disease will not be fully realized until we effectively counter social stigmas, especially those impacting at-risk populations. Women and girls are disproportionately affected by HIV/AIDS in Sub-Saharan Africa, composing 60% of all people living with the virus. Violence against women and girls is both a cause and a consequence of HIV/AIDS and an integral component in the fight to end the pandemic. PEPFAR's new gender-based violence (GBV) initiative that seeks to prevent and respond to gender-based violence is therefore a commendable addition to the program. The empowerment of women and girls is essential not only to combating HIV/AIDS, but also to promoting stability in the region. I am additionally optimistic that the Obama Administration's Global Health Initiative (GHI) has a "woman-and-girl-centered approach." I look forward to hearing from our

In closing, I'd like to thank the panelists for their testimonies and presence here today. I hope that your answers and opinions will further our understanding of the challenges to reversing the global AIDS pandemic and ensuring long-term sustainability in PEPFAR's initiatives abroad.

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CONGRESSWOMAN SHEILA JACKSON LEE, OF TEXAS

STATEMENT BEFORE THE COMMITTEE ON FOREIGN AFFAIRS

FULL COMMITTEE HEARING

"PEPFAR: FROM EMERGENCY TO SUSTAINABILITY AND ADVANCES AGAINST HIV/AIDS"

SEPTEMBER 29, 2010

Thank you, Mr. Chairman, for convening this hearing on this ongoing global health crisis. I would also like to thank the Ranking Member, and to welcome our witnesses, The Honorable Eric Goosby, U.S. Global AIDS Coordinator, Department of State;

Anthony Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health; Dr. Thomas R. Frieden, MPH, Director, Centers for Disease Control and Prevention, Administrator, Agency for Toxic Substances and Disease Registry; Ms. Paula Akugizibwe, Advocacy Coordinator, AIDS and Rights Alliance for Southern Africa (ARASA); Dr. Wafaa El-Sadr, MD, MPH, MPA, Director of International Center for AIDS Care and Treatment Programs (ICAP), Director of Center for Infectious Disease Epidemiologic Research Professor Mailman School of Public Health, Columbia University; I look forward to all of your testimonies.

Some thirty years after the first cases were diagnosed, AIDS remains the most relentless and indiscriminate killer of our time, with 33.4 million people worldwide now living with HIV or AIDS. Despite pouring billions and billions of private and federal dollars into drug research and development to treat and "manage" infections, HIV strains persist as a global health threat by virtue of their complex life cycle and mutation rates. 22.4 million of those

infected, or about 67%, live in Sub-Saharan Africa, a region with just 11% of the world's population. 60% of those infected in this region are women. 1.4 million Africans died from AIDS in a single year. Though Africa, and even more specifically African women, bear the brunt of the AIDS pandemic, Americans should be reminded that HIV/AIDS does not discriminate, with well over a million people in our own country currently living with HIV or AIDS and more than 25 million people have died from AIDS since 1981.

Africa's astronomical rate of HIV infection can be attributed to a range of different factors. Poverty, women's frequent lack of empowerment, and high rates of male worker migration combined with the limited resources, facilities, and expertise of many national health systems have left this region particularly vulnerable to the disease. Sub-Saharan Africa also faces a wide range of social and economic consequences as a result of its high HIV/AIDS rates, including a decline in economic productivity due to sharp life expectancy reductions, the loss of skilled workers, and

an estimated 11 million AIDS orphans facing increased risks of malnutrition and a lack of access to education.

Throughout my time in Congress, I have fully and eagerly supported legislation giving increased attention to this disease, both domestically and globally. I have worked to declare HIV/AIDS a state of emergency among the African American community, which faces an infection rate nearly eleven times that of white Americans. Internationally, I have worked to support PEPFAR in all they have done and continue to do to help those who struggle to combat the brutal HIV/AIDS virus.

Furthermore, the past Administration's commitment of $15 billion dollars from 2004-2008 to this matter and the U.S. government's current 6 year commitment of $63 billion to the Global Health Initiative has great promise to make substantial headway in fighting this worldwide crisis if it is fully funded. Top scientists from around the world are committed to vaccine development, which remains one of the greatest hopes the world has for preventing transmission of the virus. Clinical trials are now

ongoing in several countries, including the United States. Still, more work must be done.

Though the drugs we currently have are effective in managing infections and reducing mortality by slowing the progression to AIDS in an individual, they do not do enough to reduce disease prevalence and prevent new infections. The situation has remained rather bleak, until now with the recent discovery and use of microbicides that have been effective in arming women with greater control in shielding themselves from contracting the HIV/AIDS virus. For this reason, the prevention programs are perhaps the most critical aspect of any initiative to combat global HIV/AIDS. Though AIDS is clearly a global problem, it does not affect every nation equally or in the same manner. By moving towards sustainability, Congress allows PEPFAR to better address the requirements of each country, making more efficient and effective use of taxpayer dollars in serving the millions affected by this virus.

AIDS has proven an adamant and relentless health crisis. Numbered among our tasks here must be to work towards a long-term and sustainable approach to this ongoing threat. There is an ongoing need for continued coordination between US and international agencies and multilateral engagements. In addition, local health infrastructure must be strengthened, and every effort must be made to increase numbers of qualified health workers in Sub-Saharan Africa.

If we are to turn the tide of turmoil and tragedy that HIV/AIDS causes to millions around the world, and hundreds of thousands right here in our backyard, it is imperative that we continue to fund and expand medical research and education and outreach programs. However, the only cure we currently have for HIV/AIDS is prevention. While we must continue efforts to develop advanced treatment options, it is crucial that those efforts are accompanied by dramatic increases in public health education and prevention measures. Investments in education, research and

outreach programs continue to be a crucial part of tackling and eliminating this devastating disease.

As Americans, we have a strong history, through science and innovation, of detecting, conquering and defeating many illnesses. We must and we will continue to fight HIV/AIDS until the battle is won. Thank you again, Mr. Chairman, for convening this important hearing.

MATERIAL SUBMITTED FOR THE RECRORD BY THE HONORABLE CHRISTOPHER H. SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Testimony of Joseph F. O'Neill, MD, MS, MPH

Submitted, September 29, 2010

US House of Representatives Committee on Foreign Affairs Hearing: PEPFAR From Emergency to Sustainability and advances against HIV/AIDS

It is an honor to submit this testimony regarding the President's Emergency Plan for AIDS Relief.

As the director of the office of HIV/AIDS policy in White House during the time that the PEPFAR program was conceived and as the first acting director of OGAC during the critical initial months of its launch I can offer some particular insights into the rationale underpinning this very successful initiative.

I have been an HIV physician since before we knew that AIDS was an infectious disease and have worked clinically in a wide variety of settings and in a broad range of communities. Now as a visiting professor of medicine and the director of global initiatives at the University of Maryland, Baltimore, I coordinate a large portfolio of international programs including two very important efforts in Africa and the Caribbean funded by PEPFAR, one of which is managed in partnership with Catholic Relief Services and is providing anti-retroviral treatments to about one quarter of a million people living with HIV.

I directed the national Ryan White CARE Act program for many years as the first HIV Bureau Director at HRSA in the Department of Health and Human Services, have been the President and CEO of a publically traded biotechnology corporation developing vaccine therapies for HIV and autoimmune diseases, and serve on the boards of a number of global non governmental organizations focused on the HIV epidemic.

Global health is becoming increasingly central to our country's security and diplomatic agendas. To be sure, there are compelling ethical and humanitarian rationales for supporting global health agendas but these alone, while necessary, are insufficient to explain why we did what we did to create PEPFAR.

Dr. Bob Redfield has noted that just as the physical sciences formed an essential partnership with defense and diplomatic policy institutions in the post World War II era to further US national interests so to must these same public institutions now engage the biologic health sciences in the post 9/11 era. An effective global health investment, well deployed against a smart strategy is, I believe, key to projecting American values around the world and, hence, essential to our national security in an increasingly globalized and dangerous world.

It is in this context that I wish to place the PEPFAR discussion.

PEPFAR was conceived as a medical and public health initiative that, if successful, would deliver significant diplomatic and national security benefits. It was not conceived as a diplomatic initiative with secondary health consequences.

This is not to contradict the importance of PEPFAR to diplomatic and security goals. It simply makes the point that quality and effectiveness matter. The mother whose child comes into the world uninfected with HIV is likely to have a much more positive view of the political system that made such a miracle happen than a system that tried but failed in its fundamental technical objective. An ineffective health program on PEPFAR's scale would be, from public health, national security, and advocacy perspectives, a disaster.

It was clear from the outset that PEPFAR could not be effective if it were constructed or managed as a "business as usual" development project. This is why time-framed, defined targets were incorporated into the crescendo moment of President Bush's 2003 announcement of the initiative, and why we did not place the management of PEPFAR squarely into the heart of any of our implementing agencies; rather, we created a new structure capable of marshalling all of our bureaucratic apparatus and leading the American people and our private sector in this fight.

Promulgation of clear objectives and quality standards provided a critical means of managing PEPFAR's implementing agencies, contractors and partners. The absence of ambiguous and vague objectives gave us a powerful yardstick by which to guide funding decisions, find the quickest path to our objectives and, importantly, hold ourselves accountable to the American taxpayers who were, after all, financing the effort.

What did this mean in practical terms?

It meant that, despite making the founding contribution and ongoing generous donations to the Global Fund, we made our major investment in a bilateral, rather than a multilateral, structure. We intended to actively manage and guide our investment along a path to reach concrete objectives, not to merely support a funding mechanism that would not be directly accountable to Congress and the American public.

It meant that we did not allow our embassies and missions to have a free hand in determining how the funds were spent. We asked our field offices to develop, in concert with indigenous organizations, ministries of health and governments, operating plans that were time-framed, measurable and reflective of PEPFAR priorities. There were to be no "walking around" funds for diplomats or blind eyes turned to corruption. We wanted results.

It meant that we created a central funding mechanism that put resources into the hands of faith-based and academic organizations capable of rapidly mobilizing care, treatment and prevention services on the ground that would have been unlikely to be selected by a field driven process.

It meant that we instigated FDA review of generic drugs purchased by PEPFAR. A study published in the peer reviewed Journal of Pharmaceutical Sciences last year demonstrated that some generic copies of important antiretrovirals used in Africa had bioequivalence less than 5% compared to the branded versions – making them the effective equivalent of placebo[1]. We

[1] Journal of Pharmaceutical Sciences

acted to make sure that no American tax dollars would be expended for these types of inferior medications.

It meant that, among the range of laudable things that could have been done to better the status of women in our target countries, PEPFAR's strategy was preferentially centered on keeping as many women alive as possible by providing them treatment. We saw good health as the ultimate empowerment.

Above all, it meant that we didn't try to "boil the ocean" - to chase an ever-expanding list of goals and ideas across the globe with limited resources. Rather, we focused on a highly ambitious, but focused, set of targets in a limited number of countries selected on the basis of need, political stability and ability to form the kind of effective bilateral partnerships we envisioned as being necessary for success.

Second, we viewed PEPFAR as a tool of global leadership on health:

- Leadership to other donor nations to match us and contribute their fair share to the fight against HIV/AIDS;
- Leadership to heavily impacted countries like China and India that had sufficient economic resources at hand but were not spending them sufficiently on their HIV problem;
- Leadership to potential recipient countries to encourage adoption of standards of transparency, integrity, rule of law and democracy; and
- Most importantly, leadership to the American people and our private sector institutions upon whose good will, talent and support global health expansion would ultimately depend.

The development community is fond of discussing the "sustainability" of a program in the field - meaning, "To what degree is this program able to stand on its own if donor funds disappear?" Given the magnitude of the task facing global health, however, it was clear that we needed to think about the "sustainability" of PEPFAR itself within the political system from which it sprung.

American taxpayers have demonstrated their generosity time and time again when faced with human suffering around the globe. They have also, however, proved themselves to be practical and results-oriented in their attitude toward development programs. They want to see results from their investments and to know that their recourses are being used in ways consistent with deeply held values.

PEPFAR has been the largest and boldest development undertaking since the Marshall plan and a critical first step along a path for much broader US global health engagement.

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Had it enmeshed itself into an intractable political and moral debate by attempting to fund, either consciously or carelessly, abortion, it would have certainly lost the goodwill of a large segment of the public who do not want their tax contributions to global health to be used in that way and who, in fact, saw to it that such funding would be illegal.

So, by incorporating respect for the diversity of American values along with, bold, focused, and accountable leadership into the design and management of PEPFAR President Bush delivered to the world arguably the most successful global health program in history. Millions of lives have been saved, goodwill toward America has been strengthened, and countless minds have been changed as to the feasibility of providing high quality care, treatment and prevention in the most vulnerable communities in the world.

Now, sadly, we are facing pressure to back away from this success. We are being told that HIV care is too expensive, that we can save more lives doing other things and that multilateral efforts are somehow superior, more responsive to local needs or a better value than a bilateral approach. There is interest in moving funds from PEPFAR to other accounts, to back away from FDA review of medications, to adopt broader, less focused targets and to increase funding of other global health concerns at the expense of HIV/AIDS.

In our own AIDSRelief clinics we have patients we have cared for six or seven years who we promised we would start on life saving HAART therapy when their immune system became badly compromised whom we now can't enroll in therapy because of flattened funding and shifting budget priorities.

The US Congress passed PEPFAR with near unanimous support. In doing so it made serious commitments to people living with, and at risk for, HIV – commitments upon which millions of people, men and women living with HIV, their doctors, nurses, families, children and governments relied.

To transmit the message to these people that "America is with you....until we decide to pursue some other initiative" is bad diplomacy, bad national security, bad public health and bad medicine. No calculus of lives saved per dollar spent can answer the fundamental problem of loosing our focus, weakening our commitments to people living with HIV and their families, and loosing an historic chance to prove the value of global health expenditures.

Clearly, no one program can meet all the global needs for HIV/AIDS – that is why we tried to keep a sharp focus on well-defined goals and did not try to "boil the ocean" by adding more and more agendas and countries onto the strategy.

That is why strong and careful management oversight of the PEPFAR funds to focus on treatment, care and prevention is morally and politically essential.

That is why heeding the lessons from PEPFAR's success, doing the hard work necessary to find new resources for other global health concerns and then expending them with focus on results and conscious of the importance of building a broad based support among American taxpayers

is a better option than balancing new health agendas on the backs of people living with HIV/AIDS.

That is why we Americans should be proud to be the only donor country in the world that provides the same level of consumer protection to the poorest person living with HIV in the developing world as we do for the most privileged of our own citizens.

That is why those wishing to roll back stringent regulatory review in favor of World Health Organization prequalification or, worse, to purchase medications without any review in times of shortages should explain why we should use US tax dollars to provide a demonstrably lower standard for the world's poor than for our own people.

In summary, we designed PEPFAR with both practical and process outcomes in mind. The practical outcome is the lives saved, diseases prevented, care provided and national security enhanced.

The process outcome is the clear demonstration that a health development program could hold itself accountable, be managed in a business-like manner and succeed in a way that would encourage and inspire us to do more and yield national security benefits.

It will become increasingly problematic from both a moral and national security perspective for America to exist in a world marked by massive disparities in health. The 21st century will increasingly demand that we find ways of approaching global health problems in serious and effective ways. The PEPFAR program is well on its way to show how this might be done.

If, however, the US government weakens the commitment is has made in PEPFAR; if we dilute our effort against HIV/AIDS by draining resources into other concerns; if we blunt the management and leadership tools that have made the program a success or dissolve this bilateral effort into a multilateral one; if we encumber it with activities that a significant portion of the American public find morally repugnant; if we spread scarce resources too thinly over too many different issues --we will fail.

We cannot afford to fail. Thank you.

Michael W. Miller
President, Navigator Strategies LLC and Adjunct Associate Professor of Global Health
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Written Testimony to the House of Representatives Committee on Foreign Affairs
PEPFAR: From Emergency to Sustainability and Advances Against HIV/AIDS
September 29, 2010

Chairman Berman, Ranking Member Ros-Lehtinen, Members of the Committee, I am grateful for the opportunity to provide testimony on the subject of the transition of the President's Emergency Plan for AIDS Relief (PEPFAR), from its success as an emergency response to its future as a sustainable and life-saving act of generosity on the part of the American people.

President Obama has indicated his intention is to build on the successes of President Bush's initiatives, but to shape and direct that effort toward his own vision and goals, as he is doing under the rubric of his Global Health Initiative (GHI). Clearly, he and his Administration also recognize the critical point we have reached in PEPFAR, where it has surpassed the ambitious goals set out by President Bush in 2003, and the Administration and Congress must determine its course and funding for the future. Just as PEPFAR has saved the lives of millions of people who would otherwise have little or no hope, decisions on how to alter the program's growth, mission, and vision will also affect millions of lives.

At hand are fundamental questions of mission and vision. Perhaps the most weighty and challenging question is whether PEPFAR's provision of anti-retroviral treatment (ART) to millions of patients, mostly the poor in Africa, is an appropriate and sustainable mission in the face of other funding needs and in a epidemic where the rate of new infections far exceeds the number of people who can be treated.

These questions around ART and the future mission of PEPFAR are critical, but they are not the only issues on which the Administration and Congress must focus their energies if we are to truly preserve and build on the success of PEPFAR.

In addition to these questions of "mission" and sustainability is the challenge of preserving and building on PEPFAR's (and the President's Malaria Initiative's (PMI)) successes in the realm of what I would call "architecture" – how the programs are structured and the modes by which they pursue their objectives.

Questions of Mission

Two questions of mission are now clearly at the forefront of decision-making in the Administration.

First is this question of shifting our efforts away from single-disease-focused programs (so-called "vertical" or "stovepipe" programs) like PEPFAR, and toward programs that are by design more integrated across diseases (sometimes referred to as "horizontal" programs), with health systems strengthening (HSS) being the most important program focus in this category.

In many respects, turning now to HSS is a logical, evolutionary shift: AIDS and malaria hardly exist in isolation, nor do they have a monopoly on death and suffering. Moreover, it can be practically and ethically difficult to run well-funded programs for two diseases simultaneously with acutely underfunded programs for others.

But I am worried by what I see in global health circles as a reflexive and un-methodical endorsement of HSS as inherently more effective and necessarily more sustainable than single-disease programs. More to the point, HSS in and of itself does not provide solutions to the difficulties of PEPFAR implementation and sustainability. Nor can a HSS program be expected to produce the same results as a program that focuses on a single disease. As Peter Piot, Michel Kazatchkine, Mark Dybul, and Julian Lob-Levyt point out in their seminal article in *The Lancet* on lessons learned in the global fight against HIV/AIDS, a myth has emerged that strengthening health services alone will solve the world's health problems. Our expectations of what HSS can achieve must be realistic.

In reality, both "vertical" and "horizontal" programs are needed, and the distinction between the two is often overstated. Jeffrey Sachs decries such a black-and-white distinction and observes that in development we should do both, just as we do here domestically. We already have a strong basis to do so. PEPFAR and PMI provide significant benefits to health systems as a whole – if nothing else than by lowering the burden overall of what are the two, single-biggest killers in much of Africa. Also, I believe these two "vertical" programs have laid the necessary groundwork for effective HSS that would not be achievable without the accomplishments of the clear focus and mission of a single-disease program leading the way.

In making such consequential decisions of mission and focus, we cannot ignore the obvious fact that it is very hard to do more with the same amount of money, and we cannot rely on unproven efficiencies or an assumed multiplier effect to hasten such a significant policy shift. With a discrete amount of funding for the GHI overall, many observers rightly worry that an ambitious shift could come at the expense of PEPFAR and PMI. PEPFAR would be at greatest risk, especially its ART programs, with resentment toward the huge amount of funding for HIV/AIDS generally, and ART specifically, quite out in the open in global health circles.

I should be clear that I am not saying that the United States should not provide leadership in HSS programming in the same way we have in HIV/AIDS and malaria globally. We should. The ingenuity and hard work we brought to the AIDS and malaria fights, truly revolutionizing them, can be brought to bear in equal measure in favor of strengthening health systems globally; that is a good and worthy cause. However, the risk of compelling our agencies to cannibalize PEPFAR and PMI in order to feed an appetite for HSS is very real and it should be at the forefront of Congress's oversight and funding decisions. Millions of real, vulnerable human beings are counting on these programs; the cost of imprudence would be high.

The second question of mission is that of PEPFAR's significant focus on treatment of those already infected with HIV, whether that focus is appropriate in light of the losing battle against new infections, and whether that focus is sustainable. Many argue that instead of spending so much money on treatment of those already infected, we must shift our focus and money

significantly toward prevention measures; that the math is simply against us as new HIV infections greatly outpace the number of people we can put on ART; and that lifelong, expensive commitment is simply unsustainable. Some take this argument a step further and apply it to HIV/AIDS programming as a whole, arguing that seven billion dollars a year could be applied to other diseases and save many, many more lives.

I do not doubt the underlying assumption of either of these arguments. Clearly, if we had seven billion dollars each year to spend on simple, highly-cost-effective child survival programs that adopted the same rigor as is applied to AIDS by PEPFAR, we would save more lives. It is a sobering conclusion, but it does not provide an obvious path forward.

So, what is the United States to do?

Surely, the answer is not to prematurely push the responsibility for the treatment programs to country ministries under the pretense of the legitimate goal of "country ownership." We cannot expect to quickly get expensive, long-term treatment "off our books" with a shift from bilateral financing to Global Fund financing, allowing us to direct our bilateral funds toward prevention. Such attempts at short-cuts to "sustainability" would have devastating disruptive effects and, in the end, wouldn't be any more sustainable than our funding the programs directly – perhaps even less so.

We must keep in mind how we came to have such a robust and generous treatment program in PEPFAR in the first place. AIDS strikes the most vigorous and productive in society, on who so many others depend – effectively the opposite of many other infectious diseases, which hit the youngest and weakest. PEPFAR was envisioned to stabilize societies that were under threat of collapse and especially to provide the great intangible element of hope. We know that available treatment provides a strong invitation to seek testing and counseling for people who would never do so otherwise, risking virtually everything to stigmatization and exclusion and still realize no benefit. Access to treatment thus plays a significant role in prevention.

A program that provides an effective mix of prevention, treatment, and care was the goal for PEPFAR. A significant treatment element was essential, but treatment was then and still is the most expensive part of the equation. While the rate of new infections raises important questions about prioritization of prevention within the large but limited budget, the assumptions about the importance of ART and a program that integrates prevention, treatment, and care are just as valid today as they were in 2003. There was never any illusion that we could treat our way out of the pandemic. A strong treatment focus in PEPFAR now should not be confused with such a misguided notion, and we must recognize that a robust treatment program cannot be kicked overboard if we are to have an effective PEPFAR in the future.

Finally, the United States made a commitment to these countries and people that we simply cannot back away from. This commitment to the original commitment, if you will, is of great moral significance and great political consequence. PEPFAR was conceived as an act of generosity and compassion, but its diplomatic value is truly remarkable and far in excess of anything envisioned, especially in Africa. (The PMI is viewed similarly.) The Administration has rightly recognized the power and importance of health diplomacy. But I would caution that

such generosity and compassion embodied in PEPFAR are inherently awkward – even risky – diplomatic tools to try to wield with precision, and that great intangible element of hope they can produce is fragile. The accounts in the press of the devastating effect on hope of even a limited or rumored curtailment of that commitment are anecdotal, perhaps, but certainly are real bellwethers of possible trouble to come. The potential for a perception of betrayal to take root and grow seems real. Such an outcome would have great, negative consequences for the United States.

An easy solution to this problem of an international "entitlement" does not exist. We do know that such burdens should not be borne indefinitely by donors, and that country "ownership" is a universally-accepted goal. Such a transition will take significant time and discipline, even in the best cases.

Questions of Architecture

Less recognized than the on-the-ground success of PEPFAR is how it has forever changed global health programs – and perhaps development assistance overall – by structuring the program around ambitious, numerical public health targets, clearly defined authorities, and direct accountability to the President, Congress, and taxpayers. These qualities of PEPFAR (and PMI) make them highly-effective and cost-effective. That effectiveness and cost-effectiveness translates directly into greater coverage, more service, and better services. Certainly, the dramatic increase in funding financed the revolution and still provides unprecedented power to our implementing agencies. But it is the unambiguous measures of success or failure and the rigorous accountability that keeps implementers and country programs motivated, focused, and always mindful of priorities. In short, these qualities ensured that the programs saved many more lives than would have been saved had we taken a conventional approach.

These real innovations of the Bush-era programs should not be mistaken for Republican ideological artifacts, excessive central planning, or a misapplication of corporate culture. The leadership and accountability structures of PEPFAR and PMI frequently chafe because they are so often at odds with decades of established practice and cut against the grain of a professional culture that values collective decision-making. Numerical targets determining success or failure are often viewed as inappropriate for activities and outcomes whose "goodness" is obvious. Adding to the antagonism are reporting and policy oversight requirements in PEPAR that are viewed as excessive and designed to allow political appointees in Washington to second-guess professional judgments in the field.

Unfortunately, for some, a shift away from single-disease-focused programs and toward HSS stands as an antidote to PEPFAR's demanding architecture. As PEPFAR evolves, the Administration should make common-sense adjustments to how it operates, but they must take great care to preserve the architecture of the programs and not throw the proverbial baby out with the bathwater. Additionally, they should apply the same architecture and rigor to any new mission, especially HSS.

In particular, I would recommend that Congress work with the Administration to ensure the centrality of four elements of PEPFAR's architecture are preserved in PEPFAR and applied to

HSS: focus on clear and ambitious targets; scientific and methodical measurement of progress toward those targets (and demonstrating success); accountability up and down the line for meeting those targets; and a leadership structure that ensures accountability and that provides necessary authorities along with responsibility.

Clear and ambitious targets; measuring success: The Administration has in PEPFAR continued to work toward clear and ambitious targets. But HSS is by definition more diffuse than a single-disease program and, as a consequence, I believe it will be more difficult to determine appropriate targets and achieve them. Part of the problem here is that the definition of health systems is not so well-understood or agreed-upon. The World Health Organization has a good, high-level conceptual definition, but the level of detail needed for an effective and practical application to program design is not clear. Still, the application of ambitious targets to HSS is essential. The Administration has a remarkable level of world-class talent and know-how to bring to bear here. They should seek to do so and seek to be a leader in this effort globally as we have been in HIV/AIDS and malaria.

Measuring and demonstrating success: Measuring your success toward your goal can be burdensome, but the rewards are great. Measuring outcomes allows implementers to make adjustments and decisions on real-world information, not just on educated guesses or episodic observations. In the case of PEPFAR, being able to demonstrate with real data how the program performs has contributed significantly to the broad support it enjoys here in Congress. Real world outcomes – in this case a clear demonstration of lives saved – also has the virtue of salience with the public and broad conceptual accessibility that is absolutely essential for sustaining political support. This is not to suggest the President or Congress should make global health policy decisions on the basis of politics, but for those of us who worry that the current popularity of global health funding will be increasingly hard to sustain, political popularity is a virtue that can be translated into lives saved.

Accountability and leadership structure: Accountability has been a virtue of PEPFAR at all levels. The first level of accountability is that of those implementing the programs to the President and to Congress – and in turn to the American public. The second is accountability to those who we intend to help with these programs. The power of accountability to focus any organization is remarkable; in the case of PEPFAR, it provides clear objectives, clear distinction of roles and responsibilities, and incentivizes dedication to real outcomes.

A leadership and decision-making structure that supports and exercises that accountability effectively is essential for success. Congress was wise in the design of leadership and accountability structure outlined in the original authorization for PEPFAR. It provides the Global AIDS Coordinator (and later the PMI Coordinator) with the responsibility to lead the programs and achieve results, as well as the necessary authority to do so. That accountability extends up and down the chain. This link of responsibility with authority is absolutely essential, and the question of who is accountable to whom must remain unambiguous.

On these issues of accountability and leadership structure, the current GHI structure should be of the source of some concern for Congress. Congress put into law clear accountability of the Coordinator for PEPFAR and for PMI to implement these programs. They were, in turn, given

commensurate authorities to carry out those missions. How the legally-defined responsibilities and authorities for implementation for PEPFAR and PMI are reconciled with the decision-making structure of the GHI is not entirely clear.

The Administration has inherited a remarkable and historic success in the form of PEPFAR – as well as very difficult policy decisions. I am heartened that they have not pursued radical changes in mission in order to distinguish themselves from the previous Administration, but instead seek to build on that successful legacy. The most difficult decisions are still ahead, it seems. The course the Administration and Congress chart for the future of PEPFAR and how we seek to achieve sustainability has immediate and profound implications for the lives of millions of people. It also has great implications for the United States' standing in the world, especially in Africa, and for the future of global health programming and all of foreign assistance. Preserving the innovations in programming and architecture of PEPFAR into the future will itself go a long way toward effectiveness and sustainability; it's hard to image success without them.

Abortion does not further children's health

By Chris Smith
Sunday, September 19, 2010

An army of health activists and world leaders will gather at the United Nations this week to review the eight Millennium Development Goals agreed to at the start of the century and to recalibrate and recommit to more effectively achieve them by 2015. The overarching and noble goal is reducing global poverty. But the most compelling and achievable objectives -- huge reductions in maternal and child mortality worldwide -- will be severely undermined if the Obama administration either directly or covertly integrates abortion into the final outcome document.

If the summit is sidetracked by abortion activists, the robust resolve required at national levels to deploy the funds needed to achieve the internationally agreed targets will be compromised. The risk is real. Secretary of State Hillary Clinton has said publicly that she believes access to abortion is part of maternal and reproductive health, thinking that runs contrary to the understanding of the more than 125 U.N. member states that prohibit or otherwise restrict abortion in their sovereign laws and constitutions. Moreover, speaking before the House International Relations Committee in 2005, Mark Malloch Brown, chief of staff for then-Secretary General Kofi Annan, said concerning reproductive health, "we do not interpret it as including abortion." Clinton also calls pro-abortion nongovernmental organizations "partners."

At the Group of Eight meetings in Canada this year, Prime Minister Stephen Harper rebuffed Clinton's attempt to integrate abortion with initiatives to reduce maternal mortality. He stated his opposition to funding abortions by saying: "We want to make sure our funds are used to save the lives of women and children and are used on the many things that are available to us, and, frankly, do not divide the Canadian population."

Millennium Development Goal No. 4 is reducing child mortality rates two-thirds from 1990 levels. It is clear that myriad cost-effective interventions need to be expanded to save children's lives. These include treatment and prevention of disease, as well as greater access to adequate food and nutrition, clean water, childhood vaccinations, oral rehydration packets, antibiotics, and drugs to inhibit mother-to-child HIV transmission.

Similarly, unborn children desperately need care to optimize their health before and after birth. Healthy children start in the womb.

Abortion is, by definition, infant mortality, and it undermines the achievement of the fourth Millennium Development Goal. There is nothing benign or compassionate about procedures that dismember, poison, induce premature labor or starve a child to death. Indeed, the misleading term "safe abortion" misses the point that no abortion -- legal or illegal -- is safe for the child and that all are fraught with negative health consequences, including emotional and psychological damage, for the mother.

Talk of "unwanted children" reduces children to mere objects, without inherent human dignity and whose worth depends on their perceived utility or how much they're wanted. One merely has

to look at the scourge of human trafficking and the exploitation of children for forced labor or child soldiering to see where such disregard for the value of life leads.

The long-neglected health of mothers is prioritized by Millennium Development Goal No. 5, which rallies the world to cut maternal mortality rates 75 percent from 1990 levels.

We have known for more than 60 years what actually saves women's lives: skilled attendance at birth, treatment to stop hemorrhages, access to safe blood, emergency obstetric care, antibiotics, repair of fistulas, adequate nutrition, and pre- and post-natal care. The goal of the upcoming summit should be a world free of abortion, not free abortion to the world.

A recent landmark study funded by the Bill and Melinda Gates Foundation and published in the British journal the Lancet in April is a great encouragement to governments that have been seriously addressing maternal mortality in their countries. The study, confirmed by similar numbers in a World Health Organization report released just this month, shows progress in the fight against maternal mortality; the number of maternal deaths per year as of 2008 has been reduced to 342,900 -- or 281,500 in the absence of HIV deaths -- some 40 percent lower than in 1980. And contrary to prevailing myths, the study underscored that many nations that have laws prohibiting abortion also have some of the lowest maternal mortality rates in the world -- Ireland, Chile and Poland among them.

Implementation of the Millennium Development Goals will cost tens of billions of dollars. Credible polls from CNN and Gallup show that huge majorities of Americans don't want their tax dollars used to pay for abortions.

Including abortion in the U.N. Outcome Document or in its implementation will undermine the Millennium Development Goals. Actions and programs to achieve the latter must embrace all of the world's citizens, especially the weakest and most vulnerable. We must affirm, respect and tangibly assist the precious lives of women and all children, including the unborn.

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CALL FOR ACTION

Putting Nutrition at the Heart of Development

Statement by African First Ladies to the United Nations General Assembly

On the occasion of the opening of the Summit on the Millennium Development Goals in New York, we as African First Ladies, commit ourselves as champions of one of the most critical human development issues of the 21st century: the growing burden of malnutrition.

Malnutrition kills 3.5 million children annually and contributes to more than a third of all deaths in children under the age of five. In Africa, twenty five percent of children are undernourished and forty percent are stunted. Sixty percent of the world's chronically hungry are women. Fifty three percent of pregnant women in Africa are anemic, itself a public health crisis.

Good nutrition is a requirement if we are to achieve the Millennium Development Goals. There is a direct link between malnutrition, hunger and poverty (MDG 1), child mortality (MDG 4), maternal health (MDG 5) and AIDS and other infectious diseases (MDG 6). Equally important, poor nutrition has a causal effect in limiting achievement of education (MDG 2) and gender equality (MDG 3).

Malnutrition destroys young bodies, creating vulnerability to disease and illness. It also damages young minds, harming educational and work performance in later life, damaging individuals, their families, communities and nations. It has a particularly harmful effect on women's health. It saps strength and can reduce national GDP by up to 3%.

We know how to reduce malnutrition throughout the life-cycle by a number of simple, targeted and cost-effective solutions. The critical window of opportunity is the 1000 day period from conception to two years old. Fortified staples, good infant feeding practices, more nutritious complementary foods are some of the tools available to help permanently break this intergenerational cycle of malnutrition. New ways to mobilize business, develop agriculture and food security, and improve feeding and health practices are available.

Leadership in mobilizing these different elements of the solution into comprehensive national plans is essential.

Therefore, we as African First ladies:

1. Commit ourselves to work closely with our Heads of State, ministries of health and agriculture, the private sector, international organizations and civil society leaders to champion greater awareness about improving nutrition for the most at risk of malnutrition. A national plan is required in each of our countries which we will actively support.

2. We urge Africa's leaders and the African Union to improve food and nutrition security within the context of the Comprehensive Africa Agriculture Development Programme (CAADP), and to speed up efforts to develop and coordinate the implementation of a strategy to create a food secure Africa.

3. We give our personal support to the annual Africa Food and Nutrition Security Day on 30 October, the proposal adopted by the African Union at its last meeting in July in Kampala, Uganda. This day can serve as a rallying point to share experiences and report progress made towards a fifty percent reduction of stunting and other nutrition disorder in the next five years and beyond, to ensure that Africa is free of malnutrition.

4. We pledge to mobilize our societies and support advocacy in our countries and globally for the implementation of specific plans to end the scourge of malnutrition. The involvement of grassroots stakeholders, nutritionists, health care experts, researchers, legislators, and farmers can together create a social movement to create broad based societal consciousness and accountability to overcome food insecurity and malnutrition at the national and continental level.

5. We call on leaders across the world to put improved nutrition at the heart of development, to recognize that if the MDGs are to be achieved, nutrition must be given greater political and development priority by governments, donors and food producers alike. In particular, we call for greater investment and more priority within donor budgets to stimulate and support national actions against malnutrition.

6. We invite our peers from other regions to join this campaign, and invite cultural, sports, social and political leaders in every country to join public campaign efforts to raise awareness and action to end malnutrition.

Signed:

Mrs. Simone Gbagbo, First Lady of Côte d'Ivoire

Mrs. Azed Mesfin, First Lady of Ethiopia,

Mrs. Ernestina Naadu Mills, First Lady of Ghana

Mrs. Ida Odinga, First Lady of Kenya

Mrs. Mathato Mosisili, First Lady Lesotho

Mrs. Callista Chimombo, First Lady of Malawi

Mrs. Penehupifo Pohamba, First Lady of Namibia.

Mrs. Viviane WADE, First Lady of Senegal

Mrs. Sia Nyama Koroma, First lady of Sierra Leone

Questions for the Record Submitted to
U.S. Global AIDS Coordinator Eric Goosby, M.D.; Director of the Centers for Disease Control and Prevention, Thomas Frieden, M.D.; and Director of the National Institutes of Allergies and Infectious Diseases, Anthony Fauci, M.D. by
Representative Russ Carnahan
House Committee on Foreign Affairs
September 29, 2010

Question 1:

PEPFAR's new gender-based violence (GBV) initiative is critical to helping prevent and responding to gender-based violence. How does PEPFAR intend to preserve the multisectoral focus of its new GBV initiative, and how are other agencies supporting the success of this initiative?

Answer:

Addressing gender inequality is a key cross-cutting element of PEPFAR's delivery of prevention, care and treatment. PEPFAR has implemented a gender strategy for its interagency programs that focuses on five cross-cutting or multisectoral areas. The areas are:

- Increasing gender equity in HIV/AIDS activities and services, including maternal and reproductive health
- Addressing male norms and behavior
- Reducing violence and coercion
- Increasing women's and girls' access to income and productive resources and education
- Increasing women's and girls' legal rights and protection.

In May of 2010, PEPFAR launched a special initiative to significantly scale up the response to gender-based (GBV) violence in three countries: Democratic Republic of Congo, Mozambique, and Tanzania. This initiative supports comprehensive GBV response packages for survivors of violence (including post exposure prophylaxis, legal services, security, psychological support, and social services) as well as GBV prevention programs to address the underlying causes of violence.

PEPFAR's multisectoral and interagency model is critical to the success of our GBV work. USAID, HHS, DOD and Peace Corps are all engaged as is the Department of State's Office of Global Women's Issues. In DRC for example PEPFAR hopes to expand models and intervention supported by the United States Government in conflict areas to other parts of the country where PEFPAR's HIV programs are targeted.

Multisectoral efforts are essential to address this rampant human rights violation. The first phase of PEPFAR supported high level policy reform efforts along with community mobilization to change social norms that enable GBV. This involves working across health, education and

economic strengthening sectors. Also PEPFAR is working to ensure access to post-rape care health services.

Finally, PEPFAR is also a partner in an innovative public-private partnership, Together for Girls, which brings U.S. government institutions already involved with PEPFAR, four UN Agencies and the private sector together to measure, prevent and respond to sexual violence against girls. The partnership is developing an action framework to coordinate evidenced-based interventions. Partner governments, donors, civil society and the private sector will use this action framework as the basis to develop locally-relevant, comprehensive plans for addressing the epidemic of sexual violence. Plans will explicitly link key sectors such as child protective services, social welfare and psychosocial services, health services, education, and police, legal and legislative branches, and will ensure partners report on common indicators as appropriate.

Question 2:

The first successful trial of an ARV-based microbicide was announced at the Vienna AIDS Conference. In a landmark in HIV prevention, recent data from a USAID supported study has demonstrated that an anti-retroviral based microbicide can prevent HIV in women. In general, what is PEPFAR doing to support clinical studies to advance microbicide development? Does PEPFAR have plans for eventual product roll out if the early data on tenofovir gel is confirmed by other studies? If so, please elaborate on what these plans look like and FDA's role.

Answer:

In July 2010, the results of the CAPRISA trial of 1% Tenofovir Vaginal Gel, were announced, providing the first-ever proof of concept that a microbicide can significantly reduce the risk of HIV infection in women. PEPFAR, through USAID, is proactively collaborating with other partners, agencies, and donors to confirm these results through replication, collaborate with regulatory authorities for the approval of use of CAPRISA, and introduce this new technology where it is needed most. PEPFAR, through USAID, will continue to advance this specific ARV-based approach, as well as additional microbicide research on:

- Novel delivery methods (such as vaginal rings, tablets, or films)
- Combination products including multi-mechanism and multi-purpose agents (to also prevent pregnancy or other STIs)
- Understanding and preventing the risk of viral resistance
- Optimized trial design and coordination; and
- Ensuring post-trial availability of new prevention products.

As with other emerging technologies and interventions, the U.S. is supporting appropriate preparations for the future introduction, distribution, and use of these new technologies in developing countries. Country teams are already addressing the multiple social, cultural, economic, and political factors that will influence the acceptance and use of these new products at the individual and community levels.

The NIH convenes the US Microbicide Working Group which involves all the relevant agencies in the US to guide our efforts, answer the questions and ensure we have a safe and effective microbicide as a powerful prevention intervention.

In addition to the research supported directly by PEPFAR to advance microbicide development overseas, the National Institutes of Health (NIH) through its National Institute of Allergy and Infectious Diseases (NIAID), and coordinated by the NIH Office of AIDS Research (OAR), is also conducting important basic and applied research that will increase our understanding of ARV-based microbicides and evaluate potential usage in populations most likely to benefit from these products.
The NIH/NIAID microbicide strategy following the relative success of the CAPRISA 004 trial continues to be the creation of a sustainable pipeline of microbicide products and filling the scientific gaps needed to move a tenofovir-based microbicide to FDA approval. Our efforts can be divided into three areas:

- **Basic and Preclinical Research:** Since 2006, NIAID has sponsored the Microbicide Innovation Program (MIP). The MIP has supported 54 national and international investigators studying microbicide science in the following areas: (1) basic research; (2) preclinical characterization of new microbicides; and (3) emerging or new technologies or models.

- **Translational Research:** Since 2003, NIAID has sponsored the Integrated Preclinical/Clinical Program for HIV Topical Microbicides (IPCP-HTM). This program has supported over 23 national and international investigators. The goal of the IPCP-HTM is to advance microbicide candidates into Phase I clinical trials. This program has been instrumental in developing new formulation approaches for microbicides, including intravaginal rings, and supported the first development of tenofovir gel as a rectal microbicide.

- **Clinical Research:** In 2006, the Microbicide Trials Network (MTN) was established with support from NIAID, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, and the National Institute of Mental Health.. The goal of the MTN is to prevent or reduce the sexual transmission of HIV through the development and evaluation of products applied topically to mucosal surfaces or administered orally.

Currently, through the MTN, NIAID is supporting the ongoing Vaginal and Oral Interventions to Control the Epidemic (VOICE) study. VOICE is a Phase IIb microbicide study examining daily use of tenofovir 1% vaginal gel (regardless of when women have sex) to prevent HIV transmission. In addition, VOICE is testing daily use of oral ARV tablets, tenofovir and tenofovir plus emtricitibine (Truvada®). The study is expected to enroll 4,200 women in Africa. The results of this study will build on the results of CAPRISA 004. VOICE is powered so that it can provide the strength of evidence needed to support approval of tenofovir gel. It will also significantly extend the safety data available on tenofovir gel. Other MTN clinical studies also are underway.

Questions for the Record Submitted to:
U.S. Global AIDS Coordinator Eric Goosby, M.D.; Director of the Centers for Disease Control and Prevention, Thomas Frieden, M.D.; and Director of the National Institutes of Allergies and Infectious Diseases, Anthony Fauci, M.D. by Representative Barbara Lee
House Committee on Foreign Affairs
September 29, 2010

Question 1:

Funding for the Global Fund to Fight AIDS, Tuberculosis, and Malaria

Following the International AIDS Conference in Vienna, I sent a letter to the President – along with 100 other members of Congress (though not one Republican mind you) calling on the President to pledge a total of $6 billion over three years to the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Together with PEPFAR, our contribution to the Global Fund is responsible for providing AIDS treatment to an overwhelming amount of the 5 million people around the world now receiving AIDS treatment.

Next week in New York the Global Fund is holding its replenishment hearing for countries to make new three year commitments to the Fund. Where does the Administration stand on a $6 billion pledge? Can we reach this target and if not, why not?

The Global Fund has laid out three future funding scenarios of $13, $17 and $20 billion over the next three years- what is the overall US position on what the Fund's goals should be over that three years? Can we expect an announcement soon so that the Fund can leverage contributions from other donors still considering their pledge?

Answer:

On October 5th, the Obama Administration announced the first-ever multi-year pledge to the Global Fund of $4 billion for FYs 2011-2013. During times of economic constraints this unprecedented pledge represents a 38% increase in U.S. support for the Global Fund and demonstrates our strong commitment to the success of the Global Fund as part of our shared goal to save lives devastated by HIV/AIDS, malaria and TB.
The Administration is committed to making smart investments to save lives. PEPFAR considers both multilateral and bilateral efforts to be essential in achieving ongoing success in the fight against HIV/AIDS. The funding for the U.S. contribution to the Global Fund is a part of the funding under the Global Health Initiative and will help our bilateral programs reach their ambitious yet achievable program targets. The Global Fund is structured as a financing mechanism – not an implementing entity – and in order for Global Fund grants to succeed, there is a critical need for bilateral technical support to

address gaps in national capacity related to grant oversight and implementation. Through our bilateral programs and central resources, the U.S. provides country-level technical assistance, capacity-building, and emergency support to Global Fund grant recipients, sub-recipients, and Country Coordinating Mechanisms. This support is essential to the effective functioning of Global Fund grants at the country level.
PEPFAR will continue to work with our donor colleagues to support increased contributions. At the Global Fund Replenishment, donors pledged $11.7 billion. Moving forward, PEPFAR's unprecedented commitment serves as a challenge to other donors. Several donors have not pledged, or may increase their contributions, and resource mobilization for the Global Fund is an on-going process, with new and existing donors able to make commitments at any time. The allocation of resources and the scope of the Global Fund-financed activities will be determined through the Global Fund Board, and the U.S. will continue to participate in these conversations.

PEPFAR's highest priority is that Global Fund resources – and the American taxpayer dollars invested in the Global Fund – are used efficiently and effectively to save more lives, increase life expectancies, and alleviate suffering. It is for this reason that our first multi-year pledge was tied to a call to action for reforms to improve the impact of the Global Fund. PEPFAR is committed to working through the Global Fund Board and with all stakeholders to advance this process of reform.

Question 2:

Support for the Global Commission on HIV and the Law

Earlier this year I was invited by the United Nation's Development Programme, in conjunction with the Joint United Nation's Programme on HIV/AIDS, to serve as a Commissioner on the Global Commission on HIV and the Law. This new international commission's objective is "to develop actionable, evidence-informed and human rights-based recommendations supporting national legal environments that enable effective HIV responses and realize the human rights of those living and affected by HIV."

In many respects, the goals of the commission fall in line with the objectives of the partnership frameworks we have developed with countries to encourage the removal of barriers to accessing prevention, care, and treatment services and removing stigma for people living with HIV/AIDS.

The Commission will hold three meetings over the course of 18 months, beginning with this initial meeting next week in São Paulo, to develop and identify a set of recommendations to remove legal impediments to accessing HIV/AIDS services that will then be presented in a written report to the United Nations General Assembly.

I was honored to receive the invitation and to represent the United States among a distinguished group of Commissioners including former presidents, ministers, members of parliament, judges, and journalists from around the world.

Are you aware of the new commission and its goals? Is the United States providing any direct support, whether technical or material to the commission? Can we count on you to provide your input, both in terms of helping to overcome legal barriers to providing, and access services and to encouraging the kind of research that is necessary to fight this disease?

Answer:

PEPFAR is aware of the Global Commission on HIV and the Law and its goals, and we appreciate your willingness to participate in its very important work. The Commission's efforts are consistent with our programmatic efforts to ensure that prevention, treatment and care services are accessible to those who need them.

PEPFAR staff are in communication with their counterparts at UNDP to stay abreast of the activity of the Commission and support its work in any way that is helpful. Representatives from UNDP are coming to meet with senior level staff in my office in early November to discuss a variety of issues, including the Commission's work.

Question 3:

AIDS Treatment Targets

As you know there are mounting concerns about the commitment of the US government to supporting the continued rapid scale up of AIDS treatment. Earlier this year we heard and read a number of stories which suggested that the US was actively making decisions to stop new enrollment for HIV/AIDS treatment at facilities that we fund.

Compounded with recent requests for funding that are not keeping pace with the demonstrated global need there is concern that in the near term we could be facing potentially serious treatment problems in the field – including drug shortages, the emergence of drug resistance, and an overall decrease in the effectiveness of HIV prevention, counseling, and testing efforts.

As articulated in the PEPFAR five year strategy, the US will support HIV treatment for over 4 million people by the end of fiscal year 2013.

Can you provide some clarification on the Administration's overall treatment strategy for reaching the goal of providing AIDS treatment to 4 million people?

What is the overall budget for treatment in 2011 and approximately how many new patients will this allow PEPFAR to add? Can you tell us what the treatment target is for 2012? How about 2013?

UNAIDS has released a new proposal to scale up treatment, called Treatment 2.0. It promises to substantially strengthen and improve the global response to the AIDS pandemic. In brief it proposes to: simplify the treatment regimen, get people on treatment

early, reduce non-drug related treatment costs, expand testing and links to care, and get the community involved.

What are we doing to support UNAIDS new Treatment 2.0 proposal?

Mounting new evidence now shows that HIV treatment is an effective prevention tool--and that reaching Universal Access to AIDS treatment could bend the curve of both infections and costs. It seems we face a choice of investing the resources now to reach at least 80% coverage or see escalating costs into the future without end.

How will we provide support to scale up treatment as prevention, and what's sorts of research questions, if any are still left to ask about this promising intervention?

Answer:

PEPFAR supports an integrated approach to HIV prevention, care, and treatment and is working towards ambitious targets in each of these areas. PEPFAR is deeply committed to combating AIDS through both bilateral and multilateral efforts. The rapid expansion of access to antiretroviral therapy (ART) under PEPFAR is one of the program's most significant achievements; contrary to some erroneous reports, PEPFAR is not stopping the enrollment of new patients and is, instead, continuing to scale up treatment services. As you have noted in your question, PEPFAR's five year strategy articulates that the US government will support HIV treatment for over 4 million people by the end of FY 2013. We are on track to meet this goal. PEPFAR has increased the number of patients receiving ART from 1.7 million in 2008 to 2.5 million in 2009. We will have further clarity on the number of patients supported on treatment as of the end of FY 2010 when the process of analyzing the data provided by our field missions is complete. This information will be provided to Congress. Treatment targets are developed at the country level as part of our country operational plan process. Because this process is decentralized and developed in the field, PEPFAR is not currently able to provide reliable worldwide or country-specific treatment projections for FY 2011 or FY 2012. Beginning in FY 2011, however, we will work on an individualized basis with country teams to develop country-specific projections of annual treatment scale-up and associated budgets. Plans for each year will be finalized as part of the Country Operating Plan review and approval process.

PEPFAR agrees that the goals you noted for the UNAIDS Treatment 2.0 concept are important ones. We are promoting an efficiency agenda that is consistent with these key ideas, and welcome the insights generated by the UNAIDS effort as we work to strengthen our programs. As part of our contribution to this dialogue, PEPFAR recently published a piece in the Journal of the American Medical Association, *"Use of Generic Antiretroviral Agents and Cost Savings in PEPFAR Programs,"* which describes one key element of efforts to improve treatment program effectiveness and efficiency.

NIH is assessing the feasibility of an ARV-based prevention approach, which is often referred to as "treatment as prevention" or "test and treat." The "test and treat"

concept is predicated on mounting evidence that suggests that a reduction in levels of HIV in an infected individual can reduce HIV transmission from that individual to others. For example, a recent study of HIV-serodiscordant couples in Africa, supported by NIH and the Bill and Melinda Gates Foundation, found that treatment of the infected partner reduced the risk of HIV transmission to the uninfected partner by 92 percent.[1] Moreover, studies among communities in the developed world have shown that expanded ARV treatment and the use of other preventive measures to decrease the level of HIV were associated with a decrease in the number of new HIV infections.[2]

A number of important research questions must still be answered in order to fully evaluate this HIV prevention strategy, including research to define the contribution of each stage of infection, with specific emphasis on acute HIV infection, to the maintenance and growth of the HIV epidemic. Additionally, research leading to rapid, accurate, and inexpensive diagnostics for each stage of infection, with particular attention to acute HIV infection, needs to be accelerated. Additional data on the efficacy of ARV in preventing infection in multiple risk groups and populations will help determine the feasibility of a test-and-treat strategy. ARV resistance and the transmissibility of drug-resistant strains must also be considered. New strategies must be developed to foster adherence to ARV in a culturally specific context, to improve monitoring of patient responses to ARV, and to determine the optimal frequency of follow-up. Behavioral issues, including the effects of testing or treatment on disinhibition and new approaches to promote reduced risk-taking, must also be evaluated. Finally, issues of importance to the individual infected with HIV must also be considered, including whether early treatment confers long-term benefits not overcome by drug toxicities and the long-term complications of the therapies given to reduce viremia.

In order to begin to address some of these research questions on an integrated and comprehensive basis, NIAID is supporting the multi-stakeholder TLC-Plus study that will evaluate the feasibility of an enhanced test, linkage-to-care, and treatment strategy for HIV prevention in the United States.[3] The study, which was recently initiated at sites in the Bronx and Washington, D.C., is composed of the following components: 1) expanded HIV testing, focused on high risk populations and settings; 2) linkage-to-care for individuals newly diagnosed with HIV, and additional outreach for those lost to follow-up; 3) clinical focus on achieving well controlled viral suppression; 4) prevention counseling for those testing positive; 5) evaluation of the viability of financial incentives to increase adherence to treatment; and 6) patient and provider surveys to improve service quality and responsiveness across trial settings. The study is expected to last for three years.

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[1] Donnell D et al. Heterosexual HIV-1 transmission after initiation of antiretroviral therapy: a prospective cohort analysis. *Lancet*. 2010;375(9731):2092-2098.

[2] Wood E et al. Longitudinal community plasma HIV-1 RNA concentrations and incidence of HIV-1 among injecting drug users: prospective cohort study. *BMJ*. 2009;338:b1649; Das M et al. Decreases in community viral load are accompanied by reductions in new HIV infections in San Francisco. *PLoS One*. 2010;5(6):e11068.

[3] HPTN 065: TLC-Plus: A Study to Evaluate the Feasibility of an Enhanced Test, Link to Care, Plus Treat Approach for HIV Prevention in the U.S.

Two ongoing studies supported by NIAID are expected to inform TLC-Plus. This includes a feasibility study of a community-level, multi-component intervention for black MSMs in Atlanta; Boston; Decatur, GA; Los Angeles; New York; San Francisco; and Washington, DC.[4] The study is currently enrolling participants and will assess uptake and acceptance of the intervention components by black MSM, including the proportion of enrolled participants who: a) agree to HIV testing and counseling; b) agree to sexually transmitted infection (STI) testing; and c) utilize peer health navigation. In addition, a multi-site prospective observational cohort study with a retrospective component will estimate the overall HIV-1 incidence rate among 2,000 women in the United States from areas with high HIV prevalence and poverty (Atlanta; Baltimore; the Bronx; Chapel Hill, NC; Decatur, GA; Raleigh, NC; New York; Newark,; and Washington, DC) and evaluate the use of innovative recruitment and retention methods which will help to inform future interventional trials in high-risk women.[5] This study is currently nearing completion and results are expected in 2011.

Question 4:

Addressing sexual minorities – particularly men who have sex with men:

We know that men who have sex with men (MSM) are disproportionately impacted by the HIV epidemic. And some studies indicate that they are 19 times more likely to be living with HIV than the general population in low- and middle-income countries.

With PEPFAR and the Global Health Initiative moving toward "country-led approaches", how will PEPFAR ensure that MSM are reached even in country contexts where MSM are criminalized and/or aren't prioritized within a country's National AIDS Strategy?

While in Vienna to attend the AIDS Conference, I participated in a pre-conference event sponsored by the Global Forum on MSM and HIV where new data was presented by researchers at Johns Hopkins in collaboration with the World Bank which revealed that effectively addressing HIV among men who have sex with men (MSM) also reduces overall HIV prevalence in the general population.

Targeting resources at MSM should therefore be a key priority for PEPFAR.
What percentage of funding does PEPFAR currently target toward MSM?
What steps will be taken to ensure that PEPFAR programs for MSM are not only prioritized, but fully funded?
What are we doing to ensure that countries are actually attempting to provide services to this vulnerable population – without stigmatizing or jeopardizing the privacy and safety of these individuals?

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[4] HPTN 061: Feasibility of a community-level, multi-component intervention for Black MSM in preparation for a Phase IIB community-level randomized trial to test the efficacy of the intervention in reducing HIV incidence among Black MSM.
[5] HPTN 064: the Women's HIV Seroincidence Study (ISIS).

Answer:

I strongly agree that targeting resources at MSM and other most at-risk populations (MARPs) should be a priority for PEPFAR – and I am pleased to report that it is. PEPFAR has worked with partner governments and civil society to address the imbalance between the currently high level of burden of HIV risk and diseases for MARPs and the low coverage of a comprehensive package of prevention, treatment and care services. PEPFAR's new Five Year Strategy seeks to continue to expand prevention, treatment and care services in countries with concentrated epidemics of HIV among MSM and other MARPs, as well as in generalized epidemics.

I have identified a need for additional guidance for the field on comprehensive HIV prevention for MSM. A new guidance document is under development, and we plan to consult our Congressional colleagues to solicit feedback and guidance prior to new guidance being finalized.
This document would represent PEPFAR's first implementation guidance focused on this population. It will respond to the urgent need to strengthen and expand HIV prevention for MSM and their partners and to improve MSM's ability to access HIV care and treatment.

MARPs are often marginalized, stigmatized and discriminated against and subject to arrest and harassment. They are often hard to reach and hidden; yet there is a need for credible estimates of the size of the populations for planning an effective public health response to increase coverage of services, advocacy and program evaluation. In terms of PEPFAR's spending on MSM activities, PEPFAR does not disaggregate MSM activities from other sexual prevention activities for budget purposes.

To cite one example of our current efforts, research shows that 67% of men who have sex with men in Malawi are married. Given this fact and the high risk associated with MSM activities, the U.S. team in Malawi has prioritized work with MSM on the risks associated with multiple concurrent partnerships -- both within the MSM network and outside the MSM network into the heterosexual population. Working through local implementing partners, the team is developing and pretesting appropriate messages and interventions for this target group to promote adoption of safer sexual behaviors, including partner reduction. We are engaging with existing MSM networks to disseminate information on the risks faced by MSM and adoption of safer sexual behaviors, including condom use. Our partners are working on peer education activities and development of MSM-specific HIV counseling and testing programs. In all countries, including Malawi, careful program planning, taking into account the local context; ethical considerations; cultural traditions; economic circumstances; and technical, human and fiscal resources and capacities is applied in order to ensure that activities do not put MSM at increased risk of violence or stigma and incarceration.

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