

The President's Emergency Plan for AIDS Relief
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Committee on Foreign Relations
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Chairman Coons, Ranking Member Isakson: thank you for inviting me to discuss the President's Emergency Plan for AIDS Relief, or PEPFAR, and our activities on the African continent.

From the day it was first announced nearly eight years ago, the story of PEPFAR has demonstrated the remarkable good will and generosity of the American people. Congress' ongoing bipartisan support for PEPFAR, and President Barack Obama's continuing stewardship of a landmark program launched by President George W. Bush, have shown the world that this is a vital, effective and durable element of our foreign policy.

All across Africa, I have been struck by the deep gratitude of governments and ordinary people for PEPFAR's lifesaving mission. This effort has provided a positive and powerful message in our public diplomacy. Actions speak louder than words, and the people of Africa clearly understand that this support comes from the American people, providing them with a window into who we are as a people.

The Foreign Relations Committee has been a key partner in the success that we have been able to achieve through the years. You played a central role in both our 2003 authorization, and our 2008 reauthorization. Pursuant to our reauthorization, despite challenging economic and budget times, President Obama's Fiscal Year (FY) 2012 request for this program reflects the Administration's strong, continuing commitment on HIV/AIDS. We are deeply appreciative of your partnership in this work.

Saving Lives

When I talk about HIV/AIDS, I bring the perspective of one who has been involved in the response for 30 years. And I believe that 2010 was a crucial chapter in the global response, providing many reasons for hope about the future. As has been true throughout the past decade, the commitment of the American people was central to virtually all of the year's breakthroughs. America is truly leading the world in this effort.

We must always remember that numbers are not the whole story of PEPFAR, but when those numbers represent children, women and men whose lives are being saved, they are critical. The people implementing PEPFAR in the field continued to expand life-saving programs this year, as shown by our 2010 program results – the vast majority of which were achieved in Africa. At the end of the fiscal year, PEPFAR supported over 3.2 million people on treatment through bilateral programs worldwide, an increase of more than 700,000 over the previous year. PEPFAR and the U.S.-supported Global Fund to Fight AIDS, Tuberculosis and Malaria continue to be the leading

engines of the dramatic increase in availability of treatment. UNAIDS estimates that at least 5.2 million people in low- and middle-income countries are now receiving treatment, predominantly in Africa. Most of these people were already quite ill when they accessed treatment, and would have died in the near future without it. This is truly an extraordinary global achievement.

PEPFAR programs provided more than 600,000 pregnant women with drugs to prevent mother-to-child transmission of HIV (PMTCT), reflecting one of my top priorities. As a result, it is estimated that over 114,000 babies were born free of HIV in 2010 – representing continued sharp acceleration of PMTCT efforts relative to earlier years. PEPFAR also provided care and support for over 11 million people in FY 2010, including over 3.8 million orphans and vulnerable children.

When I reflect that each of the numbers represents a real person -- with a story, a family, a community -- the impact of this work is too vast to comprehend through numbers alone. I am fortunate to have frequent opportunities to hear the stories of our real people in Africa and around the world, which provide a window into the human impact of America's effort. In Nigeria, I heard from a man who told me of his fear that the U.S. government would cut support for the drugs that kept him alive. In Mali, I met with a young woman who was born with HIV and has been facing stigma and discrimination for most of her life, but has not let that keep her from pursuing her dreams of becoming a writer.

In short, much has been accomplished and much more remains to be done. With this in mind, we will push on toward the ambitious goals in our Five-Year Strategy – using all that we have learned, to do more and to do better.

Smart Investments

One encouraging aspect of these life-saving results is that they were achieved despite the difficult economic environment. A key element has been a heightened commitment to smart investments – that is, stretching each dollar as far as we can to save as many lives as we can. Let me briefly highlight areas we have identified for focus:

- We are strengthening use of economic and financial data to ensure efficient use of resources.
- We are incorporating innovations that promote efficiency and allocate resources based on impact.
- We are increasing collaboration with governments, the Global Fund and other stakeholders to align programs and target investments.
- We are reducing costs by streamlining our U.S. Government operations and supporting increased country ownership.
- We are achieving the best available, all-inclusive commodity pricing.
- We are leveraging creative mechanisms for healthcare financing, in order to bring additional resources to bear.
- And finally, we are developing an evaluation and research agenda that will show all global health how to improve efficiency and impact.

Through all of these smart investments, we are supporting countries as they try to build an effective, durable *continuum of care* that meets the needs of their people. The more impactful and

efficient our investments, the greater the country's ability to create a sustainable response. Here are just a few examples of the impact of this focus on smart investments to date.

Treatment and Care

Antiretroviral treatment saves lives, but it is a significant component of our overall costs. In July, we reported on treatment costs, based on groundbreaking studies of PEPFAR-supported treatment sites across 12 countries. This data, indicating an estimated mean cost to PEPFAR of \$436 for each patient supported, provides a baseline for efforts to identify treatment efficiencies.

South Africa has the world's largest number of people living with HIV, and the world's largest treatment program. The South African Government identified the need for additional funding that would help to fill urgent short-term gaps in drug availability and drive changes in procurement policies, while greater South African investments could be marshaled. I personally joined our country team in working with the Ministry of Health, and we concluded there was a need for an additional one-time \$120 million dollar investment over 2 years. With this money, PEPFAR was able to buy drugs at 50% of their previous prices in South Africa. This investment, along with substantial work by the Government, led to an historic change in South Africa's policies that enabled the Government to do what we had done, and purchase medicines at 50% of its previous costs. This allowed the country to save an estimated \$600 million dollars over the next two years alone. In short, the PEPFAR investment had a remarkable multiplier effect. It will immediately allow hundreds of thousands to receive lifesaving treatment that they would not otherwise have received, preventing the vertical transmission of HIV to thousands of additional infants and keeping their mothers alive and their families intact, while remaining a South African Government investment.

Other compelling examples drawn from the treatment program area reflect the work of the Supply Chain Management System, which PEPFAR created and manages through USAID. Antiretroviral drugs purchased through that mechanism are now over 98 percent generic – an amazing achievement that saved us over \$380 million dollars in 2010 alone. Our progress toward reliance on generics was described in a recent paper in the Journal of the American Medical Association.

And through our supply chain strengthening efforts, we're increasingly moving those drugs and other commodities in more cost-effective ways. SCMS estimates we've saved almost \$40 million dollars to date just by using sea rather than air freight, for example. Through SCMS, we've also set up three state-of-the-art regional distribution centers in Ghana, Kenya, and South Africa, helping to make us more efficient in moving products. All of these commodity savings lead directly to being able to serve more people, and save more lives.

Prevention

In HIV prevention, smart investments are equally essential, and this year brought much encouraging news. UNAIDS reported significant declines in new HIV infections in over 30 countries, including 22 in Africa – a remarkable turnaround from the trends of a few years ago. In the past, we've used the phrase 'combination treatment' to suggest the need to rely on several antiretroviral drugs, not just one. Now we also talk about 'combination prevention' to demonstrate the importance of relying on multiple prevention tools for a given population –

including biomedical, behavioral, and structural approaches. It is essential for each country to know its epidemic, and PEPFAR is seeing the payoff from heavy investments in high-impact prevention activities tailored to the needs of specific countries. Evidence on the epidemiology of HIV within each country helps answer questions such as need for relative emphasis on youth or older population groups to find the right mix of programs that promote, for example, delay of sexual debut and partner reduction. Country epidemiology also helps us identify and focus on most-at-risk populations, where comprehensive prevention efforts play a critical role in halting the advance of the epidemic, including among men who have sex with men, sex workers, migrant workers, and those who inject drugs. We have also strengthened efforts to rigorously evaluate the impact of prevention activities, in order to target investments to save more lives. Two key examples of smart prevention investments I'd like to highlight are PMTCT and male circumcision.

Prevention of mother-to-child transmission. Vertical transmission is a significant cause of new HIV infections worldwide – causing one in every seven new infections. Yet PMTCT interventions are extraordinarily effective. Without PMTCT, 25-40 percent of babies of HIV-positive mothers will be born infected; with PMTCT that number can be reduced to below 5 percent, as Botswana has demonstrated. PMTCT has a triple life-saving benefit: saving the life of the woman, protecting her newborn from HIV infection, and protecting the family from orphanhood. Because it works so well and touches so many lives, PMTCT is a smart investment for PEPFAR -- high-impact and cost-effective. In FY 2010 alone:

- PEPFAR directly supported HIV counseling and testing for nearly 8.4 million pregnant women;
- More than 600,000 HIV-positive pregnant women received antiretroviral prophylaxis to prevent mother-to-child transmission; and
- Through these PMTCT efforts in 2010, more than 114,000 children are estimated to have been born HIV-free (adding to the nearly 340,000 from earlier years of PEPFAR).

We are leading the global effort on PMTCT, and I'm proud to note these are the highest PMTCT results of any year in PEPFAR's seven-year history. We are working to ensure that every partner country affected by the HIV epidemic has at least 80 percent coverage of testing for pregnant women at the national level, and 85 percent coverage of antiretroviral drug prophylaxis and treatment, as indicated, of women found to be HIV-infected.

In 2010, PEPFAR established "PMTCT Acceleration Plans" for six countries with high burdens of vertical transmission – all located in Africa. PMTCT Acceleration Plans provided \$100 million in additional FY 2010 PEPFAR funding -- above the more than \$956 million spent on PMTCT from FY 2004-2009 -- to fund plans targeting bottlenecks to expanding services. Based on the encouraging early results of this effort, PEPFAR has continued this funding in FY 2011. With the help of Congress, I was proud to oversee the “virtual elimination” of pediatric AIDS here in America during my tenure at HHS, and I believe PEPFAR can be instrumental in helping to end pediatric AIDS worldwide and laying a foundation for an AIDS-free generation.

These PMTCT efforts have benefits for overall health care for women. Linking HIV testing with antenatal care helps to identify women who are in need of care. In addition, counseling and

testing can help women who are HIV-negative remain HIV-free. The availability of these additional services also provide an incentive for women to seek antenatal care. In Kenya, Uganda, South Africa and other countries, strong linkages among PMTCT, maternal and child health and other programs dramatically increased program coverage, allowing programs to focus on the needs of each woman and family in a more holistic way.

Male circumcision and other innovations in prevention. PEPFAR is leading the world in support for rapid scale-up of male circumcision, which was scientifically validated in recent years as a highly protective intervention against HIV infection. Studies show that if we rapidly scale up circumcision to 80 percent coverage over 5 years in Eastern and Southern Africa, we can prevent 20 percent of all new HIV infections in that region – an incredible 4 million infections averted. And doing so would save over \$20 billion dollars over a 16-year period. Our experience shows that there is strong demand for this service when men are made aware of its prevention benefits. In Kenya’s Nyanza province, PEPFAR supported the Government in an intensive effort that performed more than 30,000 male circumcisions in a 30 working days, coupling this effort with other prevention messaging and support.

Looking to the future, we have new hope of adding much-needed new tools to the global prevention toolkit. Especially encouraging have been proof of concept of a woman-controlled microbicide, based on a study funded by PEPFAR through USAID, and highly positive research findings on pre-exposure prophylaxis, funded by the National Institutes of Health. As we previously did with male circumcision, PEPFAR will continue to aggressively pursue formative work that prepares for implementation of these new tools as they become available, based upon scientific and regulatory guidance. As the world seeks a vaccine against HIV infection, it is also important to note the significant U.S. Government support for the Global Alliance for Vaccines and Immunization.

Gender

Across all programs, PEPFAR recognizes that gender inequalities fuel the spread of HIV and supports programs that respond to this challenge. Gender-based violence (GBV), in particular, limits women's ability to negotiate sexual practices, disclose HIV status, and access medical services and counseling. We have intensified our focus on GBV with a \$30 million commitment that builds on PEPFAR platforms in all countries, with a particular focus on Mozambique, Tanzania, and the Democratic Republic of Congo – and with strong governmental and civil society engagement in all three countries. We have also created a Gender Challenge Fund to stimulate our country teams to identify and seize new opportunities. As part of a strong and growing portfolio of innovative partnerships with the private sector, PEPFAR also joined the Together for Girls public-private partnership to work with countries to inform and implement a coordinated approach to surveillance, policy and programs for ending sexual violence against girls.

Program Evaluation and Research

After seven years of implementation, PEPFAR is generating a growing body of evidence and lessons learned and redoubling its efforts to apply and disseminate these. We have reformed our Public Health Evaluation process to better allow for both U.S. Government- and externally-generated studies that will provide timely operations research on urgent questions, and instituted a Scientific Advisory Board to ensure that programs reflect the latest science. As described in a

recent paper in the Journal of AIDS, PEPFAR has adopted an innovative framework for implementation science, defined as “methods to improve the uptake, implementation, and translation of research findings into routine and common practices,” to improve the development and effectiveness of our programs.

Broader Context of Health and Development

Like all others engaged in this work, PEPFAR has encountered the reality that HIV/AIDS is linked to a wide range of global challenges. In her recent testimony before this Subcommittee, Secretary Clinton noted that global health programs not only stabilize societies devastated by HIV, malaria, tuberculosis, and other illnesses, they save the lives of mothers and children and halt the spread of deadly disease toward our own country.

In September, President Obama announced a new global development policy to raise the importance of development in our national security policy decision-making and generate greater coherence across the U.S. Government. The policy is the guiding framework for U.S. development initiatives including the Global Health Initiative, of which PEPFAR is the largest component.

All of our global health efforts reflect a vision of better coordinated and linked U.S. development investments. This emphasis is great news for PEPFAR, because better coordination can save both money and lives, and help us expand the reach of our development dollars. Since its inception, PEPFAR has used coordination as a tool to maximize impact. Our implementers have long known that people affected by HIV face a range of broader health and development challenges, and have seen the opportunities to ensure that our other programs are meeting their needs. At the same time, the health systems platforms established under PEPFAR have much to contribute in meeting the broader health and development challenges of partner nations. By meeting the HIV challenge, we have naturally created significant health care systems improvements that are important in the struggle against other threats, and we have done so without diluting our focus on our own mission of combating HIV/AIDS.

Country Ownership

An area of striking progress has been movement toward country ownership, with developing countries increasingly taking the lead in responding to HIV/AIDS, while the U.S. and other external partners play key supportive roles. We have used every opportunity to promote the centrality of country ownership principles, including both governments and civil society. PEPFAR country teams initiated processes to assess and support countries, across many sectors and functions, in defining their needs for health systems capacity development and targeted technical support. For governments, key areas of focus included surveillance, planning, analysis, management, monitoring and evaluation, and budgeting, at key national ministries as well as other levels of government.

To address one central facet of the multifaceted health systems challenge – severe shortages of well-trained health workers recognized in the reauthorization -- PEPFAR and NIH teamed up to launch Medical and Nursing Education Partnership Initiatives. Fostering partnerships between African and other universities to enhance the quality of training of health professionals and increase the numbers trained as we work to meet the goal Congress established, these initiatives

are a key part of wide-ranging U.S. support for health systems prepared to meet the needs of their populations.

In another example of support for African institutions, PEPFAR recently helped launch the African Society for Laboratory Medicine (ASLM), which will advance laboratory medicine practice, science, systems, and networks on the continent and foster South-to-South sharing of best practices. Laboratory services are vital to support quality medical care with correct diagnoses and monitoring, preventive medicine, surveillance and disease control. As part of our health systems strengthening work, PEPFAR is committed to supporting African leadership to build strong laboratories that perform to international standards and provide prompt diagnoses and clinical management support for patients.

Through the mechanism of Partnership Frameworks, encouraged by Congress in our reauthorization to promote accountability, PEPFAR and 21 partner governments have documented mutual commitments for the next five years, with still more to follow. Our Framework with South Africa deserves special note in light of that nation's central role in the global HIV/AIDS challenge. Turning a decisive page, the South African Government has assumed increasing leadership, including a dramatically heightened financial contribution to HIV/AIDS and an intention to approach full financial responsibility for its program by 2016. Secretary Clinton personally signed PEPFAR Partnership Frameworks with South Africa, Angola and Vietnam, signaling commitment to country ownership as part of U.S. foreign policy at the highest level.

One thing we've tried to do with these Frameworks is to secure commitments to ensure participation of the full range of civil society partners needed for countries to respond effectively – including faith-based partners. In many countries, faith-based organizations play a critical role as part of national health systems, and it is vital for that role to be acknowledged and strengthened.

Shared Responsibility

The global HIV challenge cannot be met by any one country alone – nor should it be. In addressing this complex epidemic, all have a part to play. In addition to the contributions of the U.S. and partner nations, a truly global response requires commitment by other donor nations and the private sector.

The Global Fund is a critical vehicle for this full range of stakeholders to contribute and heighten their commitment to the fight, as the U.S. has done over the past decade. Through our contribution to the Global Fund, the United States is able to support the delivery of significant and concrete health results; expand the geographic reach of and enhance bilateral efforts; catalyze international investment in AIDS, TB, and malaria; build capacity, country ownership, and sustainability; and demonstrate political commitment to international cooperation. The U.S. remains by far the largest contributor to the Fund, and last year, the Obama Administration made its first-ever multi-year pledge to request \$4 billion for contribution to the Fund over 2011 to 2013. This strong U.S. support for the Fund's work is vital to generating increased commitments by others. Equally as important, we issued a Call to Action for reform, launching a process to improve the Fund's operations, especially at the country level. This statement has been embraced

by the Global Fund Board, which has established a Reform Working Group, to push this reform agenda forward as a top priority. The U.S. is actively advancing this work through our seat on the Global Fund Board and leadership roles in its key committees and working groups. We are also working to support and strengthen the Fund's efforts to root out corruption in its grants, supporting a strong and independent Inspector General and working to protect both U.S. taxpayers and the people who rely upon the health programs financed through the Fund.

The Global Fund is an essential partner in the fight against AIDS, TB, and malaria, supporting significant health results, building country capacity, and attracting continued investments from other donors. Simply put, the world needs a highly effective, efficient Global Fund.

The U.S. has promoted the theme of shared global responsibility in its dialogues with other international partners. Through deepened participation in global fora, the U.S. has used its opportunities to leverage more engagement by others. PEPFAR is working with partners throughout the world to ensure that this message is featured prominently at the United Nations General Assembly High Level Meeting on HIV/AIDS in June.

Conclusion

The driving force behind all of PEPFAR's efforts has been a desire to maximize the life-saving impact of each dollar entrusted to PEPFAR by Congress and the American people. As we move forward, I want this Subcommittee to know that PEPFAR will maintain this focus on the people we serve, in Africa and around the world.

Thank you very much. I look forward to our dialogue.