Testimony
Before the Committee on Health, Education, Labor, and Pensions
United States Senate

Meeting the Global Challenge of AIDS, Tuberculosis, and Malaria

Statement of
Julie L. Gerberding, MD, MPH
Director
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00am
Tuesday, December 11, 2007

The HHS COMMITMENT TO GLOBAL HEALTH

Mr. Chairman and Members of the Committee, I am pleased to be here to discuss with you the role of the U.S. Department of Health and Human Services (HHS) in the implementation of the President's Emergency Plan for AIDS Relief. I will cover a number of our Department's recent accomplishments under the Emergency Plan, as well as provide some considerations for the future. We at HHS are proud to be one of the main implementing agencies of the Emergency Plan, under the leadership of Ambassador Mark Dybul, M.D., and I am pleased to join him to represent the Department and Secretary Mike Leavitt at this hearing today. I had the privilege of traveling with Secretary Leavitt and Ambassador Dybul in August of this year to four Emergency Plan focus countries in Africa, and saw first-hand the programs' results and challenges.

HHS has a long history in global health, and all of us appreciate this Committee's bipartisan support for our international work. The Department, through the Centers for Disease Control and Prevention (CDC), played a leadership role in the eradication of smallpox, and is currently working to eradicate polio and guinea worm, and eliminate measles. Over the years, the scope of HHS' global efforts has expanded to strengthen the capacity of other countries to conduct critical public-health activities. Today, we have made global health a central part of our mission, and HHS continues to be on the frontlines of international disease eradication, health promotion and, increasingly in the 21st century, global health preparedness—focused on protecting the United States and the world from emerging, and re-emerging, worldwide threats.

HHS has been proud to play a seminal role in the early development of The Emergency Plan and its precursors. A number of our Operating and Staff Divisions have been involved in the design and scale-up of the U.S. Government's expanded battle against HIV/AIDS since the beginning of the Administration, and indeed, since the early days of the HIV/AIDS pandemic. Work at HHS also led to the ideas the President endorsed when he called in 2001 for the creation of what became the Global Fund to Fight AIDS, Tuberculosis and Malaria and made the founding contribution to the Fund. We at the Department have stayed closely involved in the governance structure of the Fund, and in the creation and implementation of many of its projects around the world.

The Department received a total of more than $1 billion in Fiscal Year (FY) 2007 to carry out activities under the Emergency Plan in the treatment, care and prevention of HIV/AIDS, and we are active in more than 30 countries, and support an additional 30 countries through regional programs and headquarters. Everything we do on behalf of the Emergency Plan is part of a well-coordinated, cross-Government team, both here in Washington and Atlanta, and in the field. We believe in a "One U.S. Government" approach. We participate in the inter-agency technical working groups that oversee the implementation of the Emergency Plan, provide scientific counsel to Ambassador Dybul, review proposals for public-health evaluations or operational research on aspects of the Plan's work, and provide a network of technical staff of medical and public-health experts who do the day-to-day work of the Plan on the ground. HHS staff scientists, medical officers and public-health experts serve on nearly all the Technical Working

Groups and inter-agency committees that give policy advice to Ambassador Dybul and review the yearly Country Operational Plans that U.S. Embassies around the world develop with local partners. Finally, the Department has detailed staff members to the Office of the Global AIDS Coordinator in leadership and expert advisory roles since the inception of the program.

In the same way each Federal partner brings a well-defined contribution to our bilateral programs in global health, under the Emergency Plan, each HHS agency contributes its expertise to tackle the many facets of the HIV/AIDS pandemic. As of May 2007, HHS has approximately *120* direct-hire staff assigned to *26* countries around the world to work on the Emergency Plan, part of a total complement of nearly *270* staff overseas, who represent a range of scientific expertise in environmental health, infectious disease, chronic disease, and injury prevention and control. The vast majority of these personnel come from HHS/CDC. The Department also employs approximately 1,400 local staff in host countries to support its global programs, and has approximately 40 U.S. experts detailed to work with international organizations, especially the World Health Organization (WHO) and the United Nations Children's Fund. Supporting these in-country staff are teams in Atlanta and at other HHS Operating Divisions, who facilitate the sharing of best practices, provide technical assistance, and who, in addition to being renowned experts in their own right, draw on the capacities of the Department's domestic efforts.

HHS's main role in the Emergency Plan is to provide scientific and technical expertise to build the capacity of host-country health-care institutions to respond to HIV/AIDS. We work in collaboration with the U.S. Agency for International Development (USAID), the U.S. Department of State, and other Federal Departments and agencies; national Ministries of Health (MOH) and their sub-components; and international partners such as the WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS). HHS provides the scientific and medical evidence base for implementing treatment, care, and laboratory support within the Emergency Plan, and plays a critical role in gathering strategic information, including through disease surveillance, epidemiology, evaluation, research, and health informatics. I would like to highlight a few areas that demonstrate our Department's critical and substantial contributions:

Prevention of New HIV Infections

The prevention of new infections represents the only long-term, sustainable means to stem the global HIV/AIDS pandemic. As Ambassador Dybul has said, we cannot defeat the HIV/AIDS pandemic through treatment alone. To support the Emergency Plan's prevention activities, HHS/CDC assists with the development of comprehensive, evidence-based programs to prevent the spread of HIV/AIDS through sexual and non-sexual transmission. In addition, in collaboration with the HHS National Institutes of Health (NIH), HHS/CDC supports research internationally to identify new prevention interventions, such as microbicides, vaccines, and the prophylactic use of anti-retroviral (ARV) medications. HHS/CDC also collaborates with the WHO Secretariat and UNAIDS to develop guidelines, protocols, and training curricula to support nations in

their efforts to prevent new HIV infections. The following are some of the Department's recent activities and accomplishments in support of prevention under the President's Emergency Plan:

Prevention with HIV-positive individuals: "Prevention with positives" (PwP) involves working with HIV-positive individuals and their partners to prevent further HIV transmission. HHS/CDC spearheaded a new, provider-initiated intervention for HIV-infected individuals in Kenya, and we are now implementing it in countries throughout Africa under the guidance of the Office of the U.S. Global AIDS Coordinator. This technique gives providers the tools and skills to deliver tailored prevention messages to HIV-infected persons at the end of every routine clinic visit. Messages focus on the disclosure of HIV status, partner testing, the reduction of transmission to others, and the prevention of other sexually transmitted infections.

Addressing drug and alcohol abuse as drivers of the epidemic: The Substance Abuse and Mental Health Services Administration (SAMHSA) within HHS is engaging with U.S. Government Emergency Plan country teams to address the role abuse of alcohol and injectable drugs are playing to spread HIV in focus countries. As part of this work, under the Emergency Plan HHS/SAMHSA has assigned an expert to work in the field overseas for the first time, to help design HIV-prevention and drug-treatment programs in Viet Nam, which has a concentrated epidemic driven in many places by heroin abuse.

Provider-initiated voluntary testing and counseling: Assuring access to quality HIV testing is a necessary step in preventing transmission and treating HIV-infected persons. HHS/CDC is taking a lead role to help make provider-initiated voluntary testing and counseling routine in medical facilities in Emergency Plan focus countries through training, the development of curricula, and pediatric counseling and testing. HHS/CDC is also collaborating with the WHO Secretariat in the development of normative guidance on provider-initiated testing and counseling, to encourage host Governments in high-prevalence countries to assure everyone has an opportunity to get an HIV test during all medical encounters. This summer, Secretary Leavitt and I saw the power of testing in action as he participated in "know-your-status" events in several countries, but we will never reach the number of people we need to unless more individuals have a chance to receive an HIV test every time they come in contact with the health-care system.

Preventing HIV infection in children: Through the Emergency Plan, HHS supports a wide range of activities, including support to countries in the rapid scale-up of the prevention of mother-to-child transmission (PMTCT), such as counseling and testing and ART for pregnant women, and the expansion of polymerase chain reaction (PCR) testing for early infant diagnosis. In addition to the prevention of pediatric HIV/AIDS, HHS is committed to building national capacity and policy regarding formulations for and access to appropriate long-term combination anti-retrovirals for HIV-infected children. HHS also supports the

international scale-up of comprehensive, quality PMTCT and pediatric programs by providing leadership and technical expertise for country programs, Emergency Plan Technical Working Groups (TWGs) and public-health evaluation (PHE) teams, U.S. Government partners, and international organizations.

Male circumcision: As a result of research funded by the HHS National Institutes of Health (NIH), evidence from several African countries has now shown medically provided adult male circumcision can decrease the rate of heterosexual HIV acquisition in men. Under the guidance of the Office of the Global AIDS Coordinator and local legislation, HHS is providing support and technical assistance to many Ministries of Health, including the South Africa National Department of Health, to formulate policies and guidelines in this area. In FY 2008, the Emergency Plan's specific activities will include working with local health officials on the development and dissemination of policies related to safe male circumcision, working with traditional healers regarding safe circumcision, and incorporating HIV-prevention messaging into circumcision activities.

Clinical and Behavioral Research, Public-Health Evaluation, and Disease Surveillance

Research conducted over the past 26 years with funding from the HHS/NIH National Institute of Allergy and Infectious Diseases and other HHS/NIH Institutes and Centers, and to a lesser extent HHS/CDC, has provided the scientific and clinical tools to allow

the Emergency Plan to provide HIV/AIDS care to millions. HHS/NIH's role in the Emergency Plan has been a specific and defined one in providing expertise to the Office of the Global AIDS Coordinator to assure it reviews and implements service-provision programs that are in keeping with the most current scientific findings. Grantees funded by HHS/NIH in the United States and elsewhere have the opportunity to seek financial support from the Emergency Plan for partnerships that can help improve individual survival and quality of life, while also helping to strengthen the Plan's programs. Also, by studying populations served by the Emergency Plan, researchers can address key questions important to the countries most severely affected by HIV/AIDS, tuberculosis (TB) and associated co-infections.

Through CDC and NIH, HHS provides critical support to public-health evaluations (PHE) under the Emergency Plan, which ensures all interventions are scientifically sound and delivered as effectively and efficiently as possible. PHEs are necessary to understand the outcomes and effects of Emergency Plan activities, to inform the design of current and future programs, as well as to optimize allocation of human and financial resources. HHS also contributes to the Emergency Plan a wide range of scientific and technical resources that inform practice in the field, such as scientific and operational research, technical guidelines, standard operating procedures for laboratories, curricula and other training materials. A partial list of PHE activities supported by HHS in support of the Emergency Plan includes the following:

Anti-retroviral costing studies: Efficient scale-up of ARV treatment requires an accurate estimation of resource needs and an understanding of how these needs change over time as a result of changes in the epidemic. HHS/CDC is providing technical support on ARV costing/budgeting in five countries - Nigeria, Uganda, Ethiopia, Botswana and Viet Nam. Preliminary analysis of data indicates treatment costs vary widely across facilities, and that the composition of spending changes markedly as programs mature. This ongoing study will strengthen knowledge about the costs of comprehensive HIV treatment to inform efficient and cost-effective policy and planning.

Evaluating barriers to care and treatment: HHS/NIH is helping enable the Office of the Global AIDS Coordinator to investigate the biological and behavioral predictors of adult and pediatric treatment compliance and success, while HHS/CDC is supporting studies in Mozambique and Tanzania to evaluate the key enabling factors and barriers within the community and the health system that affect children's access to and use of HIV care and treatment. This evaluation will include examining the beliefs, attitudes and experiences of clients, health-care providers and community members associated with providing or seeking access to care and treatment for children. Identifying reasons for the poor access to and use of HIV care and treatment will help to identify policies and specific interventions that can improve the identification of more effective strategies and best practices. It will also help reduce loss to follow up of HIV-exposed and infected children, and thus improve their survival.

Disease surveillance: HHS/CDC is at the forefront in developing new surveillance and reporting tools to help track and fight the global HIV/AIDS epidemic. Working with Ministries of Health and international partners, HHS/CDC is helping to build capacity in focus countries to design and implement HIV/AIDS surveillance systems and surveys, and to monitor and evaluate the process, outcomes, and impact of HIV programs. The recent estimates of the scale of the HIV/AIDS epidemic released by the WHO Secretariat and UNAIDS are, in part, the fruits of this investment.

Capacity-Building

A good public-health laboratory network is a cornerstone of a strong response to HIV/AIDS in any country. Without laboratory support, it is difficult to diagnose HIV infection and provide high-quality care and treatment for people who are living with HIV/AIDS. Under the Emergency Plan, HHS/CDC is building capacity for high-quality laboratory services to assist with the rapid expansion of HIV treatment, and the accompanying need for HIV diagnosis and associated care. This year, HHS/CDC's Global AIDS Program (GAP) laboratory in Atlanta received the internationally recognized accreditation of the College of American Pathologists (CAP), and provides critical, external quality-control and quality-assurance programs for partner laboratories that are helping to implement the Emergency Plan throughout the world.

Similarly, heath-care workers who have participated in training and research-capacity programs funded by HHS/NIH have used the expertise gained through this training to become the core personnel who are helping to implement in-country treatment programs under the Emergency Plan, and are also serving as trainers of other health-care providers. As part of HHS/NIH-funded research training supported by the Fogarty International Center and other HHS/NIH Institutes/Centers, scores of clinicians have learned how to optimally treat HIV/AIDS by using anti-retroviral therapy, and how best to manage co-infections. In addition, these scientists have learned how to evaluate and analyze health outcomes in clinical settings, and to incorporate these new findings into the design of prevention and treatment programs.

In an innovative partnership through a "Twinning Center" managed by the American International Health Alliance, the HHS Health Resources and Services Administration (HRSA) is helping to match U.S. institutions with indigenous groups in Emergency Plan focus countries to transfer skills and train local professionals. These peer-to-peer, collaborative relationships between American universities and other organizations with partners in seven of the Emergency Plan focus countries are proving an effective way to share best practices and create sustainability.

HHS/HRSA supports the International AIDS Education and Training Center (I-TECH), the American International Health Alliance, the Georgetown Nursing School and numerous other partners to provide training to HIV professionals and paraprofessionals in nine African countries, as well as in India, the Caribbean, and Viet Nam. This

multiple-agency effort was responsible for training 8,783 health-care workers across 25 countries during FY 2007.

Care and Treatment

As President Bush announced on November 30, 2007, the Emergency Plan is supporting anti-retroviral (ARV) treatment to more than 1,445,500 individuals throughout the world, approximately 1,358,500 of whom are men, women and children in the 15 focus countries in sub-Saharan Africa, Asia and the Caribbean. Complementing the work of USAID and in conjunction with local partners, HHS has made strong contributions to the success of the Emergency Plan in this area. We supervise treatment grants at the field level in the focus countries, and manage four, large, multi-country grants through HHS/CDC and HHS/HRSA that deliver anti-retroviral treatment to 300,000 people among the total above. We also provide direct technical assistance to help host countries integrate HIV prevention, care and treatment with TB care; help teach medical professionals to prevent, diagnose, and treat opportunistic infections, including TB; and support the prevention of mother-to-child transmission (PMTCT) of HIV. HHS also works with the Ministry of Health in each Emergency Plan focus country to develop guidelines for HIV care and treatment that address first- and second-line drug regimens, as well as how to apply WHO guidelines for beginning treatment and changing regimens. Recent examples of successes by HHS in care and treatment in support of the Emergency Plan include the following:

Basic Care Package: HHS/CDC led groundbreaking research conducted in rural Uganda and elsewhere that used an integrated package of interventions to minimize the susceptibility of HIV-positive persons to common opportunistic infections and illnesses spread by unsanitary water. This research demonstrated the Basic Care Package is a low-cost, evidence-based way to reduce deaths, hospital visits, and illnesses, including malaria and diarrhea, among HIV-positive people and their families. The package includes insecticide-treated mosquito nets; a safe-water vessel, filter cloth, and bleach solution to disinfect water; information on how to obtain HIV family counseling, HIV testing; and cotrimoxazole -- an antibiotic that reduces opportunistic infections among HIV-positive persons. Armed with the evidence we gathered in Uganda, the Emergency Plan is now rolling out the Basic Care Package in a number of focus countries.

Quality improvement: To answer the need for the systematic measurement of quality improvement and to promote consistent quality standards for care and treatment in Emergency Plan programs, HHS/HRSA works in partnership with the International HIV and AIDS Quality Center to support the expansion of the New York AIDS Institute's HIVQUAL initiative, which has already implemented quality-management programs in Thailand, Uganda, and Mozambique, and this year initiated programs in Namibia and Nigeria.

The review and use of safe and effective anti-retroviral drugs: Since 2004, the HHS Food and Drug Administration (FDA) has ensured the availability of safe and effective anti-retrovirals to meet the President's treatment goals through 1) an intensive process to help generic manufacturers from developing countries that are not familiar with HHS/FDA procedures to prepare high-quality applications and prepare for inspections; 2) an expedited review of generic ARVs, including combination products and pediatric formulations; and, 3) tentative approval for generic ARVs that meet U.S. safety and efficacy standards, but for which existing patents and/or market exclusivity prevent their immediate approval for marketing in this country. Through this fast-track process, HHS/FDA has approved or tentatively approved 56 low-cost, high-quality, generic anti-retroviral therapies since December 2004, and, in August 2007, tentatively approved the first fixed-dose anti-HIV product designed to treat children under the age of 12 years. All of these products are now available for purchase by the Emergency Plan. Also, through a confidentiality arrangement with the Quality Assurance and Safety: Medicines Unit of the WHO that allows the exchange of sensitive data, HHS/FDA tentatively approved products move quickly onto the WHO pre-qualification list that many Governments use as the basis for their national drug-registration and procurement decisions. More than 90 percent of ARV purchases under the Emergency Plan are now generic products given approval or tentative approval by HHS/FDA, which is saving lives while also reducing the cost of treatment by millions of dollars.

HIV/TB integration: TB is the leading cause of death among HIV-infected individuals, and one of their most common opportunistic infections. The prevalence of HIV infection among patients in TB clinical settings is high-- up to 80 percent in some countries. In many countries, including Botswana, Ethiopia, Kenya, Rwanda and Tanzania, HHS has worked with partners to support the expansion of provider-initiated testing and counseling among TB patients, and collaborated with international partners to develop and disseminate protocols, training and policy to improve the integration of HIV and TB service care.

HIV/Malaria integration: In sub-Saharan Africa, co-infection with malaria and HIV is common. The President's Malaria Initiative (PMI) presents us with a perfect opportunity for collaboration to reduce the dual burden of HIV/AIDS and malaria and to create synergies between two major international initiatives in the eight focus countries they share. Examples of successful collaborations between PMI and the Emergency Plan in the field include the following: 1) distributing long-lasting, insecticide-treated mosquito bed nets through a home-based-care network funded by the Emergency Plan in Zambia; 2) streamlining supply-chain coordination for malaria and HIV/AIDS commodities under one manager in Mozambique; and 3) integrating Emergency Plan PMTCT program activities, such as testing, counseling and treatment, with general maternal and child health care, and including malaria prevention in these activities by providing bed nets to expectant and new mothers.

THE ROAD AHEAD

HHS is proud of our role in helping to design and implement the President's Emergency Plan, and we look forward to our continued participation in this important initiative. Mr. Chairman, I would like to share with you and your colleagues some observations for the road ahead, based on my recent travels in Emergency Plan focus countries.

Preventing New Infections is Key

Prevention of HIV is the single most critical factor for turning the tide against the global HIV/AIDS epidemic. We must work intensively with Governments and the private and not-for-profit sectors to ensure they put HIV prevention at the top of their agendas. In the coming years, the Emergency Plan should place additional emphasis on the following approaches: (1) carefully defining current and emerging risk groups who are contributing to new infections so our field teams and partners can appropriately target prevention interventions**;** (2) intensively rolling out prevention for discordant couples and concurrent partners; (3) assuring maximum coverage of proven prevention interventions -- including male circumcision, consonant with local laws and regulations -- and ensuring prevention of HIV transmission for all infants; 4) exploring the potential of pre-exposure prophylaxis; (5) maximizing behavior-change interventions with all infected persons to decrease the rate of HIV transmission, such as the evidenced-based, balanced "ABC" approach – abstinence, being faithful, and correct and consistent use of condoms; and (6) making provider-initiated testing routine in all health-care settings.

Infrastructure and Human Capacity

Another key challenge for the Emergency Plan is sustainability, which will largely depend on strengthening indigenous infrastructure and local human capacity. Additional laboratory infrastructure is necessary to provide adequate geographic coverage across Africa and Asia. In addition to continuing to provide focus countries the technical expertise to establish regional training and reference laboratories, we also need to make sure we can leverage our investments in labs through other programs, such as pandemic-influenza preparedness and HHS/NIH grants, and avoid duplication.

In the area of human resources, the Emergency Plan should continue to increase our efforts to train local health-care workers and public-health specialists; the so-called "task-shifting" Secretary Leavitt and I saw in Africa that has increased the use and skills of community health workers is one answer. To the greatest extent possible, we should increasingly rely on local service providers to assure sustainability and to lower per-person costs.

We should also expand appropriate training programs by HHS/CDC and HHS/NIH to help produce more skilled health professionals who can investigate disease outbreaks, strengthen surveillance and laboratory systems, conduct cutting-edge research studies and serve as mentors for future public-health officers in their countries.

Better Data

The increased scale-up of HIV/AIDS prevention, care, and treatment activities has increased the demand for accurate, sophisticated data on the epidemic. The

Emergency Plan has successfully supported Ministries of Health to implement innovative surveillance and data-collection systems. The result has been better, more informed programming. Still, many countries have collected data that sit unused, and we need to help our partners analyze and use these data for decision-making.

Public Health Research and Translation

Increased focus on Public Health Research and Translation is also critical to our success in fighting the HIV/AIDS epidemic through the Emergency Plan. As we move from emergency responses to sustainable strategies, and from individual-, project- or activity-focused effectiveness to community or population-wide impact, we need to be asking ourselves questions such as: (1) Is what we thought would work—based on best evidence and principles—actually working?; (2) How do we best move beyond the basics, to enhancing quality and complexity of interventions?; and (3) What needs to be done to expand prevention, care, and treatment to more difficult-to-reach populations? HHS-supported research and translation is critical for the scale-up and sustainability of Emergency Plan programs. Research should be undertaken strategically to answer questions critical to improving the quality, scope, effectiveness, and impact of our programs. When effective interventions are identified, HHS should support the translation into practice, as well as the scale-up and roll out of these interventions by HHS and other U.S. Government agencies.

Integration of the Emergency Plan with Other Programs

While the Emergency Plan is the largest investment the American people are making in health in the developing world, it is not the only one. An important emphasis for the coming years should be cross-program collaboration on key global initiatives, such as pandemic influenza, global disease detection, neglected tropical diseases, and the President's Malaria Initiative. Increasingly, HIV and malaria programs are conducting joint planning and program execution. Linking our HIV and TB investments will bring more care and treatment to the large numbers of co-infected people. Comprehensive and integrated service delivery is key to the sustainability of the Emergency Plan, and can increase its impact and reach. To ensure our own U.S. Government complement of experts in our focus countries has the right mix of skills, we should expand the "Staffing for Results" exercise that Ambassador Dybul has begun, so we can place the right experts in the right places, regardless of their home-agency affiliation.

Better Branding of Our Assistance

Finally, we should work to maximize the public-diplomacy impact of our investments under the Emergency Plan. Secretary Leavitt and I toured more than a dozen sites funded by the Emergency Plan in four countries, from rural clinics to urban hospitals to schools and universities. We noticed that we need to pay even more attention to assuring that the generosity of the American people is evident where we are working in partnership with health-care providers around the world. To this end, HHS will enhance our efforts to assure the programs implemented with Emergency Plan support make the commitment of the American people more evident. Furthermore, we will continue to work with our colleagues in other U.S. Government agencies to promote a "One-U.S.

Government" approach to branding and communicating about the Emergency Plan, so both Americans and the people we are serving overseas have a clearer understanding of what we are doing together to fight this pandemic.

CONCLUSION

HHS has contributed significantly to the Emergency Plan's remarkable achievements in HIV prevention, care, treatment and training of local health professionals. We look forward to continued collaboration with our sister Federal Departments and agencies to implement the President's vision for this life-saving program. Secretary Leavitt and I, and our colleagues across HHS, greatly appreciate the Committee's interest in these important issues, and I am happy to answer questions from you on their behalf.

I would be happy to answer any questions.