

The President's Emergency Plan for AIDS Relief

U.S. Five-Year Global HIV/AIDS Strategy





This report was prepared by the Office of the United States Global AIDS Coordinator in collaboration with the United States Departments of State (including the United States Agency for International Development), Defense, Commerce, Labor, Health and Human Services (including the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the National Institutes of Health, and the Office of Global Health Affairs); and the Peace Corps.

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United States Department of State

Washington, D.C. 20520

February 23, 2004

Dear Senator/Representative:

On behalf of the President of the United States, it is my pleasure to submit to you a comprehensive five-year global strategy for President Bush's Emergency Plan for AIDS Relief, as required by Section 101 of PL. 108-25, The United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003.

I am encouraged by the progress achieved in the four and a half months since I assumed the position of U.S. Global AIDS Coordinator – by those working with me to create and launch the new Office of the U.S. Global AIDS Coordinator, by my colleagues across the government, many of whom will play key roles in implementing this plan, and by those across a wide spectrum outside the U.S. Government who have already provided valuable input and advice, including those in countries in which we are working. This global strategy is an important part of that progress. It is intended to address key questions raised by the legislation, as well as to define the strategic direction of our activities – in the focus countries and around the world.

The foundation for this effort is President Bush's commitment to provide \$15 billion over five years to fund the Emergency Plan for AIDS Relief. Our strategy takes into account the pragmatic necessity that annual funding requests within that commitment will ramp up as effective implementation capabilities are put in place and expanded. It outlines our work through bilateral programs as well as the significant role that will be played by multilateral partners such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria. And finally, it recognizes that national leadership is one of the critical factors in achieving success in the battle against HIV/AIDS. Our priorities in carrying out this extraordinary humanitarian effort ultimately draw on that leadership and will follow closely the strategies and priorities of the host countries we seek to assist. After all, their needs are what this effort is all about.

This strategy has been carefully, thoughtfully, yet urgently developed with the knowledge that each day, 8,000 lives are lost to AIDS. Clearly, we do not have answers to every question we have identified. Working closely with host governments, U.S. Government teams in the field, our various partners, and those living with AIDS, we will continue to learn and to develop new or more comprehensive approaches. Our intent is to move ahead without delay. At the same time, our strategy will evolve as we engage new partners and respond to innovation, input, experience, and outcomes. It must be a living document – always a work in progress. We must maintain flexibility and remain responsive to the ever-changing nature of the HIV/AIDS pandemic.

This plan reflects our current best thinking about what needs to be done and what we believe it is possible to do. We have not tempered our aspirations with our knowledge of the magnitude of the challenges ahead. Yet we do not underestimate the implementation difficulties the Emergency Plan will face. Addressing HIV/AIDS in the developing world requires confronting overstressed and struggling health care systems with limited capacity to provide treatment and care; social inequalities such as those involving the status of women, girls, and the poor; and the varied economic and political circumstances (as well as diverse and deeply ingrained cultural patterns) of each country. In addition, the sheer magnitude of the crisis, and its effect on present and future populations, brings about consequences that reverberate from the individual to the international community, many of which we are only beginning to understand. The challenges inherent in combating HIV/AIDS are very real, but if the battle is not won – if instead citizens, many in their most productive years, die in greater and greater numbers – opportunities for broad-based economic and social development will be set back for decades.

In carrying out President Bush's intent, our strategy is built on four cornerstones: (1) rapidly expanding services by building on existing successful programs that are consistent with the principles of the Emergency Plan;

(2) identifying new partners and building capacity for sustainable, effective, and widespread HIV/AIDS responses; (3) encouraging bold leadership and fostering a sound enabling policy environment for combating HIV/AIDS and mitigating its consequences; and (4) implementing strong strategic information systems that will contribute to continued learning and identification of best practices. We will pursue these strategies through collaborative and coordinated processes that ensure programming that is responsive to local needs, is supportive of and integrated with national strategies, and enlists the strengths and expertise of the many U.S. agencies and departments, nongovernmental organizations including faith-based organizations, the private sector, and multilateral institutions that have made vital contributions to combating HIV/AIDS. This strategy will ensure that the President's unprecedented commitment is a success. The Emergency Plan is the single largest up-front commitment in history for an international public health initiative involving a specific disease.

In the short time I have held this position, I have been privileged to see firsthand the success that can be achieved in fighting HIV/AIDS, even in some of the most under-resourced communities in the world. This success is measured in lives saved, families held intact, and nations moving forward with development. I look forward to working with you as we embark on transforming despair into hope worldwide.



Ambassador Randall L. Tobias

U.S. Global AIDS Coordinator

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I. EXECUTIVE SUMMARY

“Human dignity has been a part of our history for a long time. We fed the hungry after World War I. This country carried out the Marshall Plan and the Berlin airlift . . . It’s nothing new for our country. But there’s a pandemic which we must address now, before it is too late.”

President George W. Bush, January 31, 2003

1. Strategic Guidance

The President’s Vision Statement describes our aspiration for the future. Our Mission Statement describes our overarching approach to achieve the vision. Our Goals identify the actions we will take, then measuring the results to determine our progress toward achieving our mission. Our Strategic Principles describe many, but certainly not all, of the principles that have driven our deeper thinking.

Our Vision:

President Bush’s Emergency Plan for AIDS Relief will turn the tide of this global pandemic.

Our Mission:

To work with leaders throughout the world to combat HIV/AIDS, promoting integrated prevention, treatment, and care interventions, with an urgent focus on countries that are among the most afflicted nations of the world.

Our Goals:

Across the world, we will:

- Encourage bold leadership at every level to fight HIV/AIDS;
- Apply best practices within our bilateral HIV/AIDS prevention, treatment, and care programs, in concert with the objectives and policies of host governments’ national HIV/AIDS strategies; and
- Encourage partners, including multilateral organizations and other host governments, to coordinate at all levels to strengthen response efforts, to embrace best practices, to adhere to principles of sound management, and to harmonize monitoring



and evaluation efforts to ensure the most effective and efficient use of resources.

In the Emergency Plan’s 15 focus countries,¹ we will:

- Provide treatment to 2 million HIV-infected people;
- Prevent 7 million new HIV infections; and
- Provide care to 10 million people infected and affected by HIV/AIDS, including orphans and vulnerable children.

Our Strategic Principles:

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

Recognizing that HIV/AIDS is a global emergency, we will rapidly mobilize resources. We do not underestimate the implementation challenges the Emergency Plan will face. The task is daunting. Nonetheless, we are determined to reverse the momentum of increasing HIV/AIDS infections and stem suffering through

¹ Botswana, Côte d’Ivoire, Ethiopia, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, and Zambia in Africa; Guyana and Haiti in the Caribbean; and a 15th country to be determined.

prevention, treatment, and care. Our strategic plan lays the cornerstone of our approach. At the same time, we must maintain flexibility and remain responsive to the ever-changing nature of the HIV/AIDS pandemic. Our strategy will evolve as we seek new partners and respond to innovation, input, experience, and outcomes.

We will fight HIV/AIDS worldwide.

The United States has been and will continue to be a world leader in combating HIV/AIDS. The President's Emergency Plan reinforces U.S. global leadership in three key areas:

- ▶ Focusing significant new resources in 15 of the most afflicted countries in the world;
- ▶ Consolidating our leadership, renewing our commitment, and harmonizing our policy in the more than 100 countries where we currently have bilateral programs; and
- ▶ Amplifying the worldwide response to HIV/AIDS through international partners, including the Global Fund To Fight AIDS, Tuberculosis, and Malaria.

We will actively seek new approaches.

Global HIV/AIDS is an unprecedented crisis requiring an unprecedented response. The President's Emergency Plan for AIDS Relief is the boldest international health initiative ever undertaken by a single country. It not only brings hope through the commitment of extraordinary resources, but, as important, the opportunity to find new and more effective ways to fight the HIV/AIDS pandemic. Our approach will not be "business as usual."

We will use a new leadership model.

The United States Global AIDS Coordinator will oversee and direct all U.S. Government (USG) international HIV/AIDS activities in all departments and all agencies of the Federal Government. This new approach for the coordination and deployment of resources from across the U.S. Government will result in more effective and efficient programs that capitalize on the skills and expertise of staff from across the U.S. Government.

We will make policy decisions that are evidence-based.

We will build on the best practices established in the fight against HIV/AIDS and bring the resources of sound science to bear in selecting and developing interventions that achieve real results.

We will demand accountability for results.

The President's Emergency Plan will establish measurable goals for which we will hold ourselves and our partners accountable. In the focus countries and throughout the world, effective monitoring and evaluation systems will identify successful models for scale-up and poorly performing programs for revision or termination.

We will implement programs suited to local needs and host government policies and strategies.

We will implement programs that are coordinated with the policies and strategies of host governments and are responsive to local needs. Countries and communities are at different stages of HIV/AIDS response and have unique drivers of HIV, distinctive social and cultural patterns (particularly with regard to the status of women), and different political and economic conditions. Effective interventions must be informed by local circumstances and coordinated with local efforts. The U.S. Global AIDS Coordinator will provide the strategic direction, the "what" for USG programs. Each U.S. Chief of Mission will lead a coordinated U.S. Government country team to identify the "how," through program implementation that is directed by a USG country plan, responsive to local needs and circumstances, and coordinated with the host government's national HIV/AIDS strategy.

We will develop and strengthen integrated HIV/AIDS prevention, treatment, and care services.

The President's Emergency Plan is unmatched in its commitment to provide prevention *and* treatment and care services, with the knowledge that these efforts are enhanced through their integration. In the absence of treatment and care, HIV infection is perceived as a death sentence, hindering prevention efforts as fear inhibits people from seeking testing services and internalizing prevention messages. The availability of treatment and care, in addition to prolonging life and easing the suffering of the infected and affected, amplifies prevention efforts by offering incentives to seek HIV/AIDS information, get tested, and declare HIV status.

We will develop sustainable HIV/AIDS health care networks.

We recognize the limits of health resources and capacity in many, particularly rural, communities. To more effectively address that shortfall, we will build on and strengthen systems of HIV/AIDS health care based on the "network" model. Prevention, treatment, and care protocols will be developed, enhanced, and promoted in concert with local governments and ministries of health. With interventions emphasizing technical

assistance and training of health care professionals, health care workers, community-based groups, and faith-based organizations, we will build local capacity to provide long-term, widespread, essential HIV/AIDS services to the maximum number of those in need.

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

Uganda’s success has identified the “ABC” model (Abstinence, Be faithful, and, as appropriate, correctly and consistently use Condoms) as an effective HIV/AIDS prevention tool. We will promote the proper application of the ABC approach, through population-specific interventions that emphasize abstinence for youth, including the delay of sexual debut and abstinence until marriage; HIV/AIDS testing and fidelity in marriage and monogamous relationships; and correct and consistent use of condoms for those who practice high-risk behaviors.

We will combat stigma and denial.

Stigma remains a primary barrier to combating HIV/AIDS. Fear of disease and discrimination inhibits people from seeking and offering information, testing, treatment, and care. HIV travels swiftly and surely under cover of silence and denial. We will take leadership, and encourage leadership, in promoting the message that HIV is a virus that knows no borders, discriminates against no race, no gender, and no class. We will encourage people to fight the disease, not the people who live with it, and to treat people infected and affected by AIDS not with cruelty and discrimination but with dignity and compassion.

We will seek new strategies to encourage HIV/AIDS testing.

The war against HIV/AIDS begins with prevention. The disease cannot be conquered unless new infections are eliminated. Forty million people worldwide are already infected with HIV, and each day 14,000 more are added to their ranks. Alarming, the vast majority do not know they are infected and unknowingly pass the virus to others. People have not wanted to be tested, in part because a positive result was a death sentence. Knowledge about the President’s commitment to antiretroviral treatment and care will encourage testing. Knowledge of HIV status is a vital tool for helping individuals avoid behaviors that place them at risk of HIV infection, leading people to protect themselves and others from HIV infection. We will seek and promote new strategies to dramatically increase HIV testing.

We will encourage bold national leadership.

Where national leaders have taken early and effective action to publicly acknowledge HIV/AIDS as a prob-

lem in their country, raised and devoted appropriate resources, and demanded broad involvement, the battle against HIV/AIDS is meeting success. Through effective diplomacy and communication, we will engender new leadership at every level – from national statesmen to village elders – in the fight against HIV/AIDS.

We will seek the involvement of people infected with and affected by HIV/AIDS.

People infected with and affected by HIV/AIDS have unique contributions to make in identifying their needs, testifying to program effectiveness, advocating for an improved response, and combating stigma and discrimination. We will encourage the input of these individuals so that we respond more effectively to the needs of these people, who are among those the Emergency Plan seeks to serve.

We will encourage and strengthen faith-based and community-based nongovernmental organizations.

Faith-based and community-based organizations were among the first responders to HIV/AIDS, caring for fellow human beings in need. Their reach, authority, and legitimacy identify them as crucial partners in the fight against HIV/AIDS. We will encourage their involvement, and, in particular, we will welcome new partners with innovative ideas.

We will maintain our own focus while coordinating with other partners.

Our focus, worldwide, is on achieving targeted goals within HIV/AIDS prevention, treatment, and care. Other entities contribute vital efforts to these goals and to combating the drivers and consequences of HIV/AIDS. This pandemic is one of the most complex crises the world has encountered, and all of these efforts are necessary and important. Each of our efforts is amplified when we work in concert toward the overarching shared goal of eradicating HIV/AIDS and the devastation it wreaks.

2. Summary

The Global HIV/AIDS Emergency and the U.S. Response

The global HIV/AIDS pandemic is one of the greatest challenges of our time. Worldwide, over 40 million people are now infected, and each day 14,000 more are added to their ranks. In claiming the lives of societies’ most productive populations – adults ages 15 to 45 – HIV/AIDS threatens a basic principle of development, that each generation does better than the one before.

Four months after his inauguration, President George W. Bush began an historic expansion of the U.S. Government's commitment to global HIV/AIDS when he announced the founding donation of \$200 million that established the Global Fund to Fight AIDS, Tuberculosis, and Malaria. Shortly thereafter he initiated his International Mother and Child HIV Prevention Initiative and, in his 2003 State of the Union address, he announced his historic Emergency Plan for AIDS Relief – the largest and boldest assault on the global AIDS pandemic in history. Other global leaders have also taken action against the crisis of HIV/AIDS, and there are many successes to build upon. Nonetheless, significant challenges remain. Treatment remains out of reach for the vast majority of those who need it. The lack of basic care and support services leaves millions in daily pain and suffering. The ever-growing orphan population is straining community support mechanisms, with little to fill the gaps. Inadequate leadership and enduring stigma keep HIV spreading swiftly and surely under cover of silence. Combined, these challenges necessitate a complex response to delivering prevention, treatment, and care services to the many who are in need.

President Bush has responded to the challenge of global HIV/AIDS with his Emergency Plan for AIDS Relief. The Emergency Plan targets \$9 billion in new funding to dramatically ramp up prevention, treatment, and care services in 15 of the most affected countries of the world representing at least 50 percent of HIV infections worldwide. The Emergency Plan also devotes \$5 billion over five years to ongoing bilateral programs in more than 100 countries and increases our pledge to the Global Fund to Fight AIDS, Tuberculosis, and Malaria by \$1 billion over five years.

President Bush's Emergency Plan also demands a new way of doing business that will transform U.S. Government HIV/AIDS activities worldwide. It makes a revolutionary commitment to providing integrated prevention, treatment, and care services to those infected with and affected by HIV/AIDS, and establishes measurable goals against which progress will be tracked and evaluated. Policy and program decisions will be evidence-based and results-driven. New partners and innovations will be actively sought and rigorously evaluated. The President's Emergency Plan will be implemented under new leadership from the U.S. Global AIDS Coordinator, coordinating, in the United States and in the field, the work of all U.S. agencies fighting HIV/AIDS globally.

President Bush has demanded that the U.S. Government's approach to global HIV/AIDS be

focused, coordinated, and accountable for results. It capitalizes on specialized expertise and the strengths of partnerships with host governments, multilateral institutions, nongovernmental organizations, and the private sector.

Engendering Bold Leadership

As President Bush has demonstrated, leadership is an essential enabler for HIV/AIDS efforts, spurring action and magnifying its effects. In highly impacted countries and those experiencing emerging epidemics, leadership is required from the statehouse to the village to combat stigma, denial, and misinformation; influence cultural patterns; and mobilize new partners, action, and resources. For those countries with the means to be international donors, national leaders are in a position to increase public and private international HIV/AIDS assistance. The U.S. Government, under President Bush's leadership, will use its position and influence to encourage others to demonstrate similar bold leadership that is necessary to win the war against AIDS. Through proactive diplomacy and communications, the United States will engender greater leadership at every level in the fight against HIV/AIDS.

Critical Interventions in the Focus Countries

Within prevention, treatment, and care interventions, activities will focus on rapidly scaling up existing successful programs to immediately stem the tide and halt suffering attributable to HIV/AIDS. They will also focus on expanding partnerships; building capacity for effective, innovative, and sustainable services; creating a supportive and enabling policy environment for combating HIV/AIDS; implementing strong monitoring and evaluation systems to identify best practices; evaluating progress toward goals; and ensuring compliance with Emergency Plan policies and strategies.

Prevention

Prevention remains the primary strategy to combat HIV/AIDS. Despite two decades of focused attention on prevention, however, we have yet to achieve widespread success. Inappropriate and inconsistent prevention messages, stigma, gender inequality, poor knowledge of HIV status, limited testing strategies, medical transmission of HIV through unsafe injections and blood supply, and HIV transmission from mother to child continue to fuel the spread of HIV. President Bush's Emergency Plan is specifically designed to address these challenges by using evidence-based prevention programs such as the "ABC" approach of Abstinence, Be faithful, and as appropriate, the correct and consistent use of Condoms. Other identified best practices to achieve real results

in reducing the number of new infections include increased testing; appropriately tailored interventions for specific populations including women, men, and high-risk groups; the involvement of people living with HIV/AIDS, parents, and leaders from all sectors of society; and stigma reduction.

Treatment

Fewer than 8 percent of the 6 million people in resource-limited settings in immediate need of antiretroviral treatment currently receive it. A strong focus on treatment underlies the Emergency Plan. President Bush's vision that each human life has dignity and that the most vulnerable people in the world living with HIV/AIDS should have access to anti retroviral treatment guides the U.S. Global AIDS Coordinator's implementation activities. Providing treatment may be our best hope against the disease and the devastation it wreaks. Availability of treatment provides an incentive to get tested; reduces stigma; and, in restoring health, mitigates consequences of the disease such as loss of productivity, dramatically increased poverty, and growing orphan populations. The Emergency Plan will build on established clinical programs and develop the necessary infrastructure, staff, and technical capacity to provide long-term, widespread, high-quality, safe, and essential HIV/AIDS services to the maximum number of people in need. In addition, it will contribute to the development of appropriate treatment protocols and policies to ensure safe and effective treatment services, drug supply, and equitable distribution of health resources.

Care

Care services under President Bush's Emergency Plan include both palliative care for people living with HIV/AIDS and care for orphans and other vulnerable children affected by HIV/AIDS. HIV/AIDS and associated opportunistic infections cause severe pain and debilitating symptoms for many with advanced disease. Poor health contributes to reduced productivity and diverts meager resources, leading to myriad consequences including diminished food security. At the same time, millions of orphans growing up without the support of their parents face increased vulnerability to HIV, violence, sexual coercion, and reduced access to essential services such as health care and education.

The President's Emergency Plan seeks to mitigate these consequences by building the capacity of professional and family- and community-based health care providers to provide palliative care, by strengthening health care referral networks, and by ensuring necessary supplies. For orphans and vulnerable children,

the Emergency Plan seeks to strengthen the capacity of extended families and communities to care for orphans and to advance policy and legal reforms related to inheritance, access to basic social and protective services in order to enable supportive environments for children's growth and development.

Strengthening Bilateral HIV/AIDS Programs

President Bush has called upon political leaders around the world to address the HIV/AIDS crisis and to partner with the United States under a shared vision of human dignity and access to treatment, prevention, and care. His Emergency Plan offers a fresh opportunity to develop and implement consistent HIV/AIDS policies and programs across our existing bilateral prevention, treatment, and care programs. By drawing on the body of evidence collected over 20 years, new evidence-based lessons and insights from Emergency Plan initiatives in focus countries, and the U.S. Government's strong field presence and technical expertise, the Office of the U.S. Global AIDS Coordinator will work to harmonize in policy and management our bilateral programs worldwide.

Strengthening Multilateral Actions

The Bush Administration has recognized the importance of multilateral approaches to fighting the global HIV/AIDS pandemic. The President's early and aggressive support of the Global Fund to Fight AIDS, Tuberculosis, and Malaria has enabled this important mechanism of funding HIV/AIDS programs to begin to fulfill its potential. The contributions of other multilateral institutions and international organizations working with great dedication to combat HIV/AIDS provide a vital opportunity for a comprehensive response. The diverse drivers and consequences of HIV/AIDS, and its many complicated interactions with a variety of other social, political, and economic circumstances, demand an equal number of diverse actors with varied expertise. The President's Emergency Plan commits a significant proportion of its resources to the Global Fund to Fight AIDS, Tuberculosis, and Malaria in recognition of the fact that the Global Fund is a promising global force in the fight against AIDS, tuberculosis, and malaria, and offers important opportunities to address needs complementary to other elements of the Emergency Plan. Other multilateral institutions and international organizations, such as the Joint United Nations Program on HIV/AIDS, the World Health Organization, and the World Bank, have also provided essential global leadership, expertise, and resources. The U.S. Government will strengthen its relationships with multilateral institutions and international organizations to amplify global action against HIV/AIDS by encouraging coordination, based on

comparative strengths, to fill gaps in current activities, avoid duplication of efforts, and ensure efficient and effective use of resources.

Implementation and Management

Meeting the challenge of the global AIDS crisis is a monumental task that will require – along with strong leadership and vision – robust and flexible administrative structures. President Bush has set clear goals for his Emergency Plan and has insisted that the U.S. Global AIDS Coordinator’s response be rapid, effective, and evidence-based, and make efficient and focused use of all relevant government capabilities through coordination, collaboration, and cooperation across U.S. Government agencies. It must also reflect administration policy and statute; respond to the diverse needs of the various communities around the world in which the U.S. Government works; and account for progress toward achieving these goals. Four primary processes underlie this approach:

- **Coordination.** President Bush created the position of the U.S. Global AIDS Coordinator, who shall have primary responsibility for the oversight and coordination of all resources and international activities of the U.S. Government to combat the HIV/AIDS pandemic. The U.S. Global AIDS Coordinator is thus responsible for both internal and external coordination of HIV/AIDS activities. Internal coordination is carried out by country-specific response teams comprising staff from the implementing agencies and the Office of the U.S. Global AIDS Coordinator. In Washington, coordination between various federal agencies is achieved through multiple methods of communication, joint project planning, and policy development. External coordination with non-U.S. Government stakeholders, including host-country governments and multilateral institutions, is carried out both through in-country coordination led by field staff and through proactive liaising on the part of the U.S. Global AIDS Coordinator.
- **Planning.** At the core of the implementation strategy is an ongoing in-country planning effort, beginning with the focus countries. Chiefs of Mission in each country will lead a strategic planning process, aided by the Office of the U.S. Global AIDS Coordinator and involving all relevant U.S. Government entities, host-country governments, nongovernmental organizations, the corporate sector, multilateral institutions, and other in-country stakeholders. This process will result in individual-five-year country strategies and annual operational plans for strengthening the quality, availability, and sustainability of prevention, treatment, and care

services. Plans will be submitted to the U.S. Global AIDS Coordinator for review. Final approval by the Coordinator will ensure consistency with Congressional intent, Administration policy, and the Coordinator’s strategic objectives.

- **Allocation of Funding.** The President’s Emergency Plan relies on a variety of funding allocation mechanisms in order to maximize flexibility and encourage innovation while responding to specific country needs:
 - ▶ Funding levels by country will be allocated on the basis of the country’s five-year strategic plan, and funds will be released upon approval of annual country operational plans by the U.S. Global AIDS Coordinator.
 - ▶ Central funding mechanisms developed and approved by the Office of the U.S. Global AIDS Coordinator will fund regional initiatives serving more than one country, such as professional training or twinning for which organizations will provide technical assistance on a regional basis.
 - ▶ Funding decisions will be based upon performance in reaching annual prevention, treatment, and care targets. Strategic information will guide allocation of resources for maximum impact and ensure accountability to American taxpayers.
- **Communications.** President Bush has insisted that implementation be transparent and accountable. The U.S. Global AIDS Coordinator will ensure that the public is given timely, accurate, and complete information regarding the President’s Emergency Plan for AIDS Relief. A variety of mechanisms, including Web technology, reports to Congress, and media outreach will serve this purpose.

Supportive Interventions for U.S. Government Programs

Interventions that support implementation of the President’s Emergency Plan include an effective and accountable supply chain; a strong research program to provide the evidence base necessary to guide policies and programs, including a coordinated strategic information system; and enhanced public-private partnerships.

- **Supply chain management** is critical to ensure a secure and sustainable supply of quality essential drugs, materials, and equipment for HIV/AIDS programs. Supply chain management systems will be coordinated with complementary programs and will reduce and eliminate diversion, counterfeiting,

and the sale of HIV/AIDS products and supplies on the black market.

- ***A strong evidence base*** will provide new knowledge and give direction to policy and program decisions. Strategic information systems will track programs to ensure they are meeting targets and having measurable impact. Best practices for HIV/AIDS treatment, prevention, and care will be identified through both of these processes.
- ***Public-private partnerships*** will mobilize the private sector to leverage resources and capabilities across all sectors, including contributions to building sustainable systems of HIV/AIDS treatment, prevention, and care. The comparative advantages of these partnerships will be maximized to complement services provided by the public and non-governmental/faith-based organization sectors.

II. THE GLOBAL HIV/AIDS EMERGENCY AND THE U.S. RESPONSE

“The legislation [P. L. 108-25] that I sign today launches an emergency effort that will provide \$15 billion over the next five years to fight AIDS abroad. This is the largest single up-front commitment in history for an international public health initiative involving a specific disease. America makes this commitment for a clear reason, directly rooted in our founding. We believe in the value and dignity of every human life.”

President George W. Bush, May 27, 2003

1. The Global HIV/AIDS Emergency: A Severe and Urgent Crisis

President Bush has recognized that the global HIV/AIDS pandemic is one of the greatest health challenges of our time. Worldwide, over 40 million people are now infected, and each day 14,000 more are added to their ranks. Over 25 million have lost their lives to the disease, leaving behind anguished loved ones, orphaned children, and ravaged communities. The burden of disease, pain, and suffering is immense and growing every day. More than 13 million children have been orphaned by AIDS, leaving families and communities to face the challenges of providing guidance, health care, education, love, and hope. These children are often vulnerable to the worst forms of child labor and risk dropping out of school.

The disease has turned back many of the hard-won development gains of the 20th century, reducing life expectancy, increasing child mortality, and threatening fragile democracies as nations are overcome by political, social, and economic instability. AIDS strikes at the heart of hope, progress, and potential by claiming lives and causing untold suffering. Some of the most affected are societies' most productive populations – parents and teachers, police officers and government workers, farmers and health care providers. In robbing societies of these individuals, AIDS threatens a basic principle of development, that each generation does better than the one before it.

The greatest burdens of disease are concentrated in developing countries least able to cope. The countries of sub-Saharan Africa and the Caribbean are home to nearly 30 million people with HIV/AIDS, nearly 70 percent of the world's total. HIV/AIDS has deepened poverty and diverted state resources in regions already struggling with overburdened health systems and populations living on less than \$2 per day. It has fueled a



White House Photo Office

resurgence of the tuberculosis epidemic, further exacerbating strained health resources and compounding the suffering of those infected and affected by HIV/AIDS.

Emerging epidemics in India, China, and Eastern Europe threaten to become new epicenters of the disease. Given current infection rates and limited health services, these regions may compete with central and southern Africa as home to the greatest number of HIV-infected individuals by the end of the decade.

Like President Bush, the international community and many national leaders have taken action against the crisis of HIV/AIDS, and there are many successes to build upon. The United Nations General Assembly Special Session on HIV/AIDS affirmed the international community's commitment to progress against HIV/AIDS and provided the foundation for mobilizing significant resources to fight it. The Global Fund to Fight AIDS, Tuberculosis, and Malaria and other multilateral institutions, such as the Joint United Nations Program on HIV/AIDS (UNAIDS) and various other U.N. agencies, have made vital contributions.

We now have proven methods for combating HIV/AIDS, including effective strategies that highlight abstinence and fidelity, fight stigma and denial, and partner government with civil society. We know that leadership is essential and that early and effective action can contain and even roll back epidemics. Most importantly, where there used to be a “prevention versus treatment” debate, today few dispute that we must do both.

However, significant challenges face all nations, donors, institutions, and individuals attempting to respond to the global AIDS pandemic. Treatment continues to be out of reach for the vast majority of those who need it. The lack of basic care and support services leaves millions in daily pain and suffering. Limited infrastructure and human resource capacity in affected countries constrain their ability to respond to the HIV/AIDS crisis overtaking their communities. The ever-growing orphan population is straining community support mechanisms, with little to fill the gaps. Inadequate leadership and enduring stigma keep HIV spreading swiftly and surely under cover of silence. Insufficient coordination and evaluation of programs contribute to the inefficient use of funds and ineffective interventions. Combined, these challenges necessitate an extremely complex response to delivering HIV/AIDS prevention, treatment, and care services to the many who are in need.

Without intervention, experts predict that over 100 million people will be infected worldwide by 2010, with a cumulative loss of human life to AIDS totaling 100 million by 2020. We cannot let that happen. With our partners worldwide, we will turn the tide against HIV/AIDS and release its stranglehold on the future.

2. President Bush’s Emergency Plan for AIDS Relief: The Hope of a New Approach

President Bush has responded to the challenge of global HIV/AIDS with the his Emergency Plan for AIDS Relief. The Emergency Plan brings unprecedented resources to bear against the disease. Committing \$15 billion over five years, the President’s initiative is the largest commitment in history by a single nation for an international health initiative. The Emergency Plan makes a revolutionary commitment

to providing resources for treatment for HIV-infected individuals, a vital intervention that many have thought could not be offered in developing-country environments. President Bush has asserted that “in the face of preventable death and suffering, the United States has the power and moral duty to act,” and the Emergency Plan will focus on bringing life-extending HIV/AIDS treatment to some of the most afflicted and under-resourced countries in the world.

The Emergency Plan strongly supports integrated prevention, treatment, and care with the knowledge that the availability of each enhances the effect of all. Prior interventions have focused on preventing HIV transmission, correctly acknowledging that the war against the disease cannot be won unless new infections are prevented. But prevention efforts have been hindered by the limited availability of treatment and care. Lack of treatment has contributed to fear of and stigma against the disease, discouraging people from seeking testing and disclosing their status to partners, a necessary step for preventing HIV transmission.

The priorities defined above – providing treatment in some of the most afflicted nations, and integrating prevention, treatment, and care – are reflected in the breakdown of the initiative’s funding. The Emergency Plan targets \$9 billion in new funding to dramatically ramp up prevention, treatment, and care services in 15 of the most affected countries of the world,² representing at least 50 percent of HIV infections worldwide. At the same time, President Bush’s Emergency Plan devotes \$5 billion over five years to existing bilateral efforts to support HIV/AIDS, tuberculosis, and malaria programs and research, and pledges \$1 billion over five years to the Global Fund to Fight AIDS, Tuberculosis, and Malaria. Through intensive intervention in areas with the highest concentration of disease and strengthened programs worldwide, the United States and its partners will defeat AIDS.

The Emergency Plan is defined by more than the unprecedented commitment of resources. Through his Emergency Plan, President Bush has also demanded a new way of doing business that will transform our HIV/AIDS activities worldwide. His Emergency Plan will demand high levels of accountability and will establish measurable goals against which progress will be tracked and evaluated, with funding decisions based on performance toward these goals. Policy and program decisions will be evidence-based and results-

²Through President Bush’s Emergency Plan for AIDS Relief, the United States will continue to work throughout the world to combat HIV/AIDS, tuberculosis, and malaria through bilateral programs, providing \$5 billion in baseline funds over five years. Bilateral programs will also be harmonized to incorporate new best practices. New funding of \$9 billion over five years will focus on countries that are among the most afflicted in Africa and the Caribbean: Botswana, Côte d’Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, and Zambia. These 14 countries are also the focus of the President’s International Mother and Child HIV Prevention Initiative. Per the requirement in P.L. 108-199 (FY 2004 Consolidated Appropriations bill), a 15th country will be named shortly as a focus country not located in Africa or the Caribbean region.

driven. The Emergency Plan will be implemented under new leadership from the U.S. Global AIDS Coordinator, reporting directly to the Secretary of State and coordinating, in the United States and in the field, the work of all U.S. agencies fighting HIV/AIDS globally. With the core expertise of various U.S. agencies reoriented and redirected toward a coordinated, focused mission to achieve measurable goals, our progress against HIV/AIDS will be greatly amplified.

The President's Emergency Plan dramatically expands upon two decades of the United States' global leadership in the fight against HIV/AIDS. The United States has been the primary contributor to HIV/AIDS research, instrumental to the development of tools rang-

The Integrated HIV/AIDS Prevention, Treatment, and Care Model

President Bush's Emergency Plan is based on the established best practice of providing a continuum of care consisting of a full range of integrated HIV/AIDS services. The availability of each of the continuum's activities – prevention, treatment, and care – strengthens and reinforces the effect of each intervention. Prevention activities such as HIV/AIDS education and awareness, behavior change, and testing are thus more effective when combined with treatment and restorative or curative care, including such services as routine follow-up of HIV-infected individuals prior to receiving antiretroviral therapy, control of symptoms, end-of-life care, and bereavement support. All three interventions are mutually supportive, so that over time, as the availability of treatment (e.g., antiretroviral drugs) grows under the Emergency Plan, the need for palliative care will decrease.

Care for orphans and vulnerable children is another critical component of the Emergency Plan. The strategy emphasizes mitigating the consequences of disease to this population and reducing their risk and vulnerability to HIV. The difficulties faced by children orphaned by HIV/AIDS represent some of its greatest short- and long-term consequences. In providing prevention, treatment, care, bereavement, and other support services to children, orphan care further reinforces the synergies of integrated service delivery. Wherever appropriate, services for orphans and vulnerable children will be linked to the health care and human services network.

ing from testing to treatment, as well as projects that provide hope for the future, such as vaccines and microbicides. Under President Bush's leadership, the United States currently provides over 50 percent of all bilateral funding to combat global AIDS; was a founding member of the Global Fund to Fight AIDS, Tuberculosis, and Malaria; and is the Fund's largest donor, responsible for over 37 percent of all pledges to it. The Secretary of Health and Human Services is lending additional U.S. leadership and support to the Fund as Chair of its Board through 2005.

Through their field presence in over 100 countries, U.S. agencies have provided essential technical assistance and training to strengthen HIV/AIDS programs worldwide. The President's International Mother and Child HIV Prevention Initiative, established in 2002 to reduce mother-to-child HIV transmission by 40 percent within five years in the Emergency Plan's 14 focus countries, has laid the groundwork for the strategies that the Emergency Plan will pursue. It has also provided additional evidence and knowledge on the feasibility – and necessity – of integrated prevention, treatment, and care programs.

Following President Bush's lead, we embark on this new phase of our global leadership in the fight against HIV/AIDS with hope and humility, knowing that our efforts must be grounded in partnership, collaboration, and compassion. The world is poised to halt and reverse the devastation wrought by HIV/AIDS, with the historic opportunity to confront the challenges and achieve dramatic results. With a fundamental belief in the value and dignity of every human life, as articulated by President Bush, the United States is capitalizing on its expertise and the strengths of its partnerships with host governments, multilateral institutions, nongovernmental organizations, and the private sector to take bold action against HIV/AIDS.

3. Structure of the Strategic Plan

Critical interventions to reach the goals of President Bush's Emergency Plan are presented in the following chapters. Chapter III emphasizes the need for bold leadership from all sectors, and in all nations, and describes strategies the United States will pursue to bring voice and additional resources to the fight against global AIDS. Chapters IV, V, and VI describe strategies for integrating and strengthening prevention, treatment, and care activities in the focus countries. Chapter VII illustrates how the Emergency Plan will direct U.S. Government HIV/AIDS activities in countries beyond the focus countries where today we have existing bilateral programs. Chapter VIII identifies methodologies for engagement with multilateral institutions and joint

ventures for an amplified global HIV/AIDS response. Implementation and management strategies are presented in chapter IX. Interventions that support strengthened programming and accountability in USG initiatives, including issues related to supply chain management and the role of research and strategic information, are presented in chapter X. Chapter XI presents special topics of congressional interest and other appendices.

III. ENGENDERING BOLD LEADERSHIP

“There are only two possible responses to suffering on this scale. We can turn our eyes away in resignation and despair, or we can take decisive, historic action to turn the tide against this disease and give the hope of life to millions who need our help now. The United States of America chooses the path of action and the path of hope.”

President George W. Bush, April 29, 2003

President Bush’s bold and aggressive attack on global HIV/AIDS has made it clear – leadership is essential to battling HIV/AIDS. Early and effective action by high-level political leaders can contain and even roll back epidemics, as evidenced in Uganda, Thailand, and Senegal. Where leaders have been silent, inactive, or worse – combative, or propagating incorrect or stigmatizing messages – HIV continues to spread despite the best efforts of communities and contributors. Leadership is an essential enabler for HIV/AIDS efforts, spurring action and magnifying its effects. Heads of state wield enormous power, authority, and legitimacy. They can combat stigma, denial, and misinformation through forthright discussion of the nature of the disease and thus lead citizens to change their behavior. They can influence cultural patterns that contribute to the spread of disease, including gender inequity. By demonstrating that all sectors of society must contribute to the battle against AIDS and applying appropriate levels of human and financial resources to prevention, control, and treatment activities, they are powerful mobilizers of new partners, action, and resources. It is political leadership that ensures a multisectoral response, proven crucial to combating HIV/AIDS effectively.

The need for leadership is not limited to heads of state. At both the national and community levels, wide-ranging leadership is needed in civilian government, the military, medical institutions, ethnic and cultural groups, corporations, labor unions, schools and universities, religious institutions, nongovernmental organizations (NGOs), and the media. Those who lead and influence people and organizations have the capacity, and the duty, to make a dramatic difference in stemming the spread of the epidemic and supporting the necessary treatment and care for those infected and affected by AIDS.

The need for leadership is also not limited to highly impacted countries. Every country has a starting point for the epidemic. Early leadership can determine the



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difference between societies that experience low incidence of disease and those held hostage by raging epidemics. In many countries, low overall prevalence rates often mask firmly entrenched epidemics in high-risk groups, such as injection drug users, sex workers, and men who have sex with men. Epidemics among these often disenfranchised communities must be addressed to conquer the disease. Too often, patterns of official denial and stigmatization have led to widespread epidemics.

President Bush has called for leadership against AIDS from every nation. For those countries with the means to be international donors, national leaders are in a position to increase public and private international HIV/AIDS assistance. The United States is continuing to show unprecedented global leadership and commitment in funding the global AIDS response. In 2002 and 2003, the U.S. Government gave international contributions greater than those of all other donor governments combined. Assuming level funding by other donors, U.S. international contributions in 2004 will be approximately twice those of the rest of the world’s donor governments combined. Given that HIV/AIDS is a crisis of unprecedented global

proportions, there is a role for every leader to play in defeating it.

President Bush has stepped up to this challenge with his Emergency Plan for AIDS Relief. His Administration will use its leadership position and influence to encourage others to demonstrate the bold leadership that is necessary to win the war against AIDS. Through proactive diplomacy and communication, the U.S. Government will stimulate greater leadership at every level – from national statesmen to village elders – in the fight against HIV/AIDS.

Leadership Objective:

Engender bold leadership and additional resources from other countries for the fight against global AIDS

Leadership Strategies:

1. Engaging heads of state and other government officials through bilateral diplomatic interventions and multilateral forums
2. Reaching out to a broad range of community and religious leaders and private institutions to generate multisectoral leadership and responses to HIV/AIDS
3. Using the tools of public diplomacy and communications to inform and engage new partners, including media, in the fight against HIV/AIDS
4. Using diplomatic interventions in bilateral and multilateral forums with donor nations, and communications tools with the public and private institutions, to raise additional resources for global AIDS

1. Engaging heads of state and other government officials through bilateral diplomatic interventions and multilateral forums

Heads of state have a particular role to play, and particular responsibility to bear, in engendering an appropriate response to HIV/AIDS. In countries facing current or emerging epidemics, leadership from heads of state can generate early and effective action by publicly acknowledging HIV/AIDS as a problem in their country, raising and devoting appropriate resources, and demanding broad involvement. In many countries, budgetary resources need to be focused on prevention, care, and treatment programs to stem the epidemic. The engagement of heads of state contributes greatly to a coordinated response, offering such tools as national HIV/AIDS strategies and dedicated funding streams through which to allocate and track resource distribution.

HIV/AIDS adversely affects health care systems, education in schools and universities, economic development, and, more broadly, peace and security. All ministries have a role to play in the fight against the pandemic. Military leaders and other sectoral leadership such as ministers of education and labor can strengthen the HIV/AIDS response by capitalizing on their access to specific populations that have specific needs.

Under President Bush's leadership in fighting global HIV/AIDS, the U.S. Government has an opportunity to encourage leadership from heads of state and other government officials. The United States will:

- Employ diplomatic interventions by high-level officials based in Washington and American ambassadors abroad to engage directly with and encourage strong leadership from heads of state and counterparts in government such as ministers of health, education, defense, and foreign affairs;
- Ensure that American embassy staffs abroad are informed and engaged on the issue of HIV/AIDS as it relates to their host countries and raise HIV/AIDS issues in host-country forums; and
- Advocate for greater leadership through multilateral forums such as UNAIDS, international HIV/AIDS events and conferences, and multilateral actions such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria.

2. Reaching out to a broad range of community leaders and private institutions to generate multisectoral leadership and responses to HIV/AIDS

Some of the most intractable problems in achieving an effective HIV/AIDS response have been combating stigma, reaching individuals with HIV/AIDS messages to bring about behavior change, and addressing issues of culture and traditional roles that contribute to increased vulnerability, especially for women and girls. HIV/AIDS messages need to reach people where they live, learn, work, and worship. Trusted community leaders have reach, authority, and legitimacy to carry forward vital messages about HIV/AIDS and combat stigma, denial, and negative cultural practices. In addition, where government has not responded adequately to HIV/AIDS, bottom-up leadership can help mobilize appropriate responses, including resources, from government.

The U.S. Government will use public-private partnerships at local, national, regional, and world-

wide levels to strengthen global and in-country responses to HIV/AIDS. These partnerships will be fostered by the Office of the U.S. Global AIDS Coordinator and U.S. ambassadors in all regions. In countries where the United States has existing HIV/AIDS programs (see appendix F), these efforts will be closely linked to the programs. In countries where the U.S. Government has HIV/AIDS activities, such as public diplomacy efforts, but no assistance programs, these efforts will serve as a catalyst for action by local officials.

The United States will:

- Engage with community leaders such as mayors, tribal authorities, elders, and traditional healers to promote correct and consistent information about HIV/AIDS and combat stigma and harmful cultural practices. Even in an environment of strong government leadership and good policy, failure to involve community leaders can undermine efforts to implement sound policies and programs. Conversely, community leaders can reinforce messages and engender cultural change that is difficult to achieve via program or policy means.
- Engage with faith-based leaders on international, national, and local levels. Religious leaders have enormous reach and authority. In many countries, as many as 80 percent of citizens participate regularly in religious life, and the pulpits of religious leaders are a powerful platform from which to promote correct and consistent information, encourage behavior change, combat stigma, and strengthen community responses to HIV/AIDS. The United States will identify, train, and partner with faith-based leaders.
- Work with national and international business coalitions and labor organizations to facilitate their efforts to improve and greatly expand programs in the workplace, particularly at companies in heavily impacted countries. Through close collaboration with business and labor, the U.S. Government will serve as a catalyst for developing and implementing prevention, treatment, and care programs for employees and immediate communities. The strategy will take advantage of marketing, communications, and logistical skills in the business sector to improve the reach and effectiveness of AIDS programs.

3. Using the tools of communications to inform and engage new partners, including media, in the fight against HIV/AIDS

In many countries of the world, there is great unrealized potential in using the media as a positive force for discussion of AIDS and for overcoming stigma and denial, promoting information based on best practices, and expanding the reach of correct and consistent HIV/AIDS messages. The United States will:

- Inform the public of the extent and nature of the AIDS epidemic and the need for action through international media channels and through print and electronic media in the 162 countries where the United States is represented, including placement of public service announcements on radio and television and publication of op-ed pieces by the American ambassador and others;
- Assist journalists in promoting responsible reporting on HIV/AIDS; and
- Use exchange programs to provide key people with participatory involvement in a range of activities that serve to enhance their skills and knowledge related to HIV/AIDS. These exchanges will be customized for specific sub-groups of people who are in a position to demonstrate leadership in their home countries, including health care workers, journalists, and others.

4. Using diplomatic interventions in bilateral and multilateral forums with donor nations, and communications tools with the public and private institutions, to raise additional resources for global AIDS

Worldwide resources to combat global HIV/AIDS remain far short of what is necessary to win the war against the disease. Wealthy nations, corporations such as the Coca-Cola Company, and private institutions such as the Bill & Melinda Gates Foundation have made vital contributions to the fight against HIV/AIDS, and the U.S. Government will continue to seek their partnership and support. Under President Bush's lead, the U.S. Global AIDS Coordinator will work with the Secretary of State, the Secretary of Health and Human Services, and others in this high-level effort to generate greater bilateral and multilateral contributions from donor governments and private institutions. In addition, the Office of the U.S. Global AIDS Coordinator will use public communications tools to inform and engage citizens worldwide in the battle against HIV/AIDS and develop a constituency that will ensure a long-term global response.

IV. CRITICAL INTERVENTIONS IN THE FOCUS COUNTRIES: Prevention

“We will train doctors and nurses and other health care professionals so they can treat HIV/AIDS patients. Our efforts will ensure that clinics and laboratories will be built or renovated and then equipped. Child care workers will be hired and trained to care for AIDS orphans, and people living with AIDS will get home-based care to ease their suffering . . . And we’re developing a system to monitor and evaluate this entire program, so we can be sure we’re getting the job done.”

President George W. Bush, July 2, 2003

The 2003 UNAIDS *AIDS Epidemic Update* offered a set of stunning statistics – last year, 3 million people died of AIDS. At the same time, 5 million more were infected with HIV. Despite two decades of focused attention on prevention, we have yet to achieve widespread success, as evidenced by the 14,000 people who each day join the ranks of those infected. Clearly, HIV/AIDS cannot be defeated unless the number of new infections is dramatically reduced and eventually eliminated.

It is time, however for new thinking and approaches. Past and current prevention messages have often failed to achieve the widespread behavior change that is necessary to end the pandemic. Prevention efforts are further hampered by the stigma surrounding HIV/AIDS and gender inequality that increases the vulnerability of women and girls.

Of the approximately 40 million people infected with HIV worldwide, it is estimated that as many as 95 percent do not know their status. Without knowledge of their status, people continue to spread the disease unwittingly and do not seek treatment. Given the sheer numbers of people who do not know their status, this factor alone represents an enormous challenge to turning the tide against HIV/AIDS. Limited testing strategies, insufficient testing services, and a lack of enabling policies have thus far proven inadequate for making sufficient progress against the disease.

Overstressed and poorly functioning health care systems also contribute to the spread of disease. Medical transmission of HIV continues to be a problem, spread through unsafe injections, unnecessary medical procedures, and use of unscreened blood supplies. Rates of sexually transmitted infections (STIs) remain high, and, when untreated, contribute to the spread of HIV. Health care systems, understaffed and inadequately supplied, have been unable to close this entry point for HIV infection.



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In 2001, an estimated 720,000 children globally were infected via mother-to-child HIV transmission. U.S. Government programs such as the President’s International Mother and Child HIV Prevention Initiative, as well as those implemented by other partners, have proven that the administration of a short course of antiretroviral (ARV) drugs and improved breastfeeding practices can dramatically reduce the number of mother-to-child infections and thus the number of new infections overall. Such programs also provide a critical link to HIV/AIDS treatment programs that offer ARV and other treatment to HIV-infected women and their families, thus helping to preserve the family unit.

Finally, the limited availability of treatment and care, and its effects of extinguishing hope and fueling fear and stigma, presents its own barriers to prevention efforts, as denial continues to bolster inaction.

The President’s Emergency Plan is specifically designed to address these challenges and capitalize on the opportunities outlined above in achieving its goal of preventing 7 million new HIV infections. In its use of evidence-based prevention programs such as the “ABC” – Abstinence, Be faithful, and as appropriate,

correct and consistent use of Condoms – approach, proven successful in Uganda, Zambia, Senegal, and elsewhere, the Emergency Plan will target prevention funds to methodologies that are effective in helping people avoid behaviors that place them at risk of contracting HIV. Identified best practices such as increased testing; appropriately tailored interventions for specific populations including women, men, and high-risk groups; the involvement of people living with HIV/AIDS, parents, and leaders from all sectors of society; and stigma reduction will be aggressively promoted to achieve real results in reducing the number of new infections. At the same time, these interventions must strengthen existing indigenous responses to the epidemic, be discerning and responsive to the culture, and build on community structures that influence social and community norms in order to reduce risk behaviors.

Furthermore, in keeping with the Emergency Plan’s health care approach, specific interventions to strengthen health care services to reduce HIV transmission are another cornerstone of prevention activities. The President’s Emergency Plan will help build the health infrastructure necessary to strengthen infection control programs, reduce medical transmission of HIV, and build the capacity of health care workers to treat STIs and prevent mother-to-child infection. Last, the fundamental principle of the President’s Emergency Plan – to integrate prevention, treatment, and care – is intended to stimulate a cycle that will reduce stigma and fear, create incentives for testing, and thus amplify prevention efforts.

Prevention Objective:

Prevent 7 million HIV infections in the focus countries

Prevention Strategies:

1. Rapidly scale up existing prevention services
2. Build capacity for effective long-term prevention programs
3. Advance policy initiatives that support prevention of HIV infection
4. Collect strategic information to monitor and evaluate progress and ensure compliance with Emergency Plan policies and strategies

1. Rapidly scale up existing prevention services

It is estimated that immediate action to implement comprehensive prevention programs could avert 60 percent of new HIV infections in resource-limited set-

tings by 2010. A delay of only three years could reduce efficacy by nearly 50 percent. Thus, rapid scale-up of existing prevention services is an urgent priority of President Bush’s Emergency Plan. Much has been learned about effective strategies for prevention over the past two decades. While the President’s Emergency Plan seeks in the long term to develop sustainable national programs in each country, in the short term it will move quickly through the expansion of current activities. Faith-based and community-based groups, as well as many ministries of health, have established excellent prevention programs in the areas of abstinence promotion, behavior change, prevention of HIV infection from mother to child, and technical assistance for improved medical practices. These organizations offer innovative, effective, and accountable local programs, and have established relationships with national organizations and local communities. Such organizations provide the optimal foundation to build on best practices toward the development of comprehensive national prevention programs.

Organizations are poised to rapidly and accountably scale up programs in the following priority areas:

- Prevention of HIV infection through abstinence and behavior change for youth;
- Prevention of HIV infection through HIV testing, targeted outreach, and condom distribution to high-risk populations;
- Prevention of HIV infection from mother to child; and
- Prevention of HIV infection through safe blood, improved medical practices, and post-exposure prophylaxis.

Prevention of HIV infection through abstinence and behavior change for youth

In many of the countries hardest hit by HIV/AIDS, sexual activity begins early and prior to marriage. Surveys show that, on average, slightly more than 40 percent of women in sub-Saharan Africa have had premarital sex before age 20; among young men, sex before marriage is even more common. Moreover, a significant minority of youth experience first sex before age 15. Abstinence until marriage programs are particularly important for young people, as fully half of all new infections occur in the 15- to 24-year-old age group. Delaying first sexual intercourse by even a year can have significant impact on the health and well-being of adolescents and on the progress of the epidemic in communities.

Adolescent girls in high HIV-prevalence countries in Africa are at significantly higher risk of acquiring HIV. In some communities, as many as 20 percent of girls aged 15 to 19 are infected compared to 5 percent of boys the same age. These age differentials in HIV prevalence reflect a pattern of older men having sex with younger women. Young women involved in exchange relationships with older men are disadvantaged by gender, age, and economic power. Moreover, a substantial proportion of girls in Africa and the Caribbean experience coerced sex, including forced first sex.

Youth are subject to a variety of conflicting social messages and influences related to sex. Although many traditional social norms emphasize abstinence for youth, extramarital sexual activity is common among adults, especially men. While virginity is emphasized for girls, sexual activity is often seen as a sign of manhood for young men. Parents, religious leaders, teachers, and the media may each provide different information related to HIV/AIDS, adding to confusion in decision-making.

Comprehensive and effective prevention approaches reflect the complex influences on young people's decision-making and the need to address the broader social factors that shape their behaviors. Internationally, a number of programs have proven successful in increasing abstinence until marriage, delaying first sex, reducing the number of partners, and even achieving "secondary abstinence" among sexually experienced youth.

President Bush's Emergency Plan recognizes the diversity of countries and the need to harmonize prevention messages at the community level. Correct and consistent information is vital to effective HIV prevention, and program partners thus should not disseminate incorrect information about any health intervention or device. In addition, national governments may appropriately seek to coordinate information or referral links to other services designed for high-risk populations.

The Emergency Plan supports the following categories of activities as part of its rapid scale-up of prevention programs for youth:

Scale up skills-based HIV education, especially for younger youth and girls. Young people need to be reached early, before they begin having sex, with skills-based HIV education that provides focused messages about the benefits of abstinence until marriage and other safe behaviors. Activities should help young people develop the self-esteem to delay sex until mar-

Risk Elimination, Risk Reduction

Basic public health approaches to disease prevention rely on both risk elimination and risk reduction. Risk elimination strategies are those that reduce exposure to disease, such as abstinence in the case of STIs. Risk reduction strategies are those that reduce the likelihood of transmission during any given exposure, such as the use of condoms or the provision of prophylactic ARV treatment for exposed newborns or health care workers.

Risk elimination is a cornerstone of the President's Emergency Plan. Approaches that are directed to behavior change, such as encouraging abstinence, testing, and faithfulness in sexual relationships, have proven to be successful and will be expanded. Knowledge of HIV status, fidelity in marriage, and monogamy for the sexually active are equally important goals of prevention programs.

Evidence from Thailand suggests condom use is an important means of reducing, but not eliminating, risk. Working closely with local governments, nongovernmental organizations, and prevention experts, condom programs targeted to at-risk populations will be supported. In doing this, it will be important to disseminate clear messages that support, rather than confound, a core risk elimination approach.

riage, make informed choices, and develop the communication skills to say "no" to sex (as well as to alcohol and drugs, which increase vulnerability to sexual pressure). Best practices suggest that communication skills and the ability to personalize risk can be achieved through curricula that use interactive methods to target specific risk factors for early sexual activity in the local context and help young people define values. Ideally, programs should go beyond sexuality to build on young people's assets and encourage them to stay in school and plan for their futures. While these programs are most relevant to younger adolescents aged 10 to 14 years, especially girls, they are also appropriate for older adolescents. Suggested activities include:

- ▶ Developing and disseminating age-appropriate curricula that include clear messages about abstinence until marriage and other safe behaviors, and that address risk factors in the local context;

- ▶ Expanding skills-based HIV education through schools, working both at the national level with ministries of education and local schools at the community level;
- ▶ Strengthening HIV education delivered through after-school programs run by youth services networks, including faith-based networks; and
- ▶ Strengthening programs in HIV education for children who are not in school.

Promote healthy norms and behaviors. Communities need to mobilize to address the norms, attitudes, values, and behaviors that increase vulnerability to HIV, including multiple casual sex partners and cross-generational and transactional sex. To stimulate such mobilization, there is an urgent need to help communities identify and recognize the ways in which they contribute to establishing and reinforcing norms that may contribute to youth risk, vulnerability, and stigma. President Bush's Emergency Plan will support groups that discourage harmful norms through a variety of media and other activities at both the community and national levels. Suggested activities include:

- ▶ Training local religious and other traditional leaders in HIV concerns and supporting them in publicizing the risks of early sexual activity, multiple partners, and cross-generational sex;
- ▶ Supporting youth-led community media to help youth, their parents, and the broader community personalize the risks involved in these behaviors; and
- ▶ Supporting media campaigns that reinforce and make abstinence until marriage, fidelity, partner reduction, and other safer behaviors legitimate options and standards of behavior for both youth and adults.

Reinforce the role of parents and other protective factors. Parents are potentially the most powerful protective factors in young people's lives; they have great potential to guide youth toward healthy and responsible decision-making and safer behaviors. In Emergency Plan countries, where many youth have lost their parents to AIDS, other adult caregivers and mentors also have an important role to play in providing guidance to youth. Many adults, however, find it difficult to communicate with teens, both on broader issues of regulation and discipline and in discussing sexuality and their own expectations and values about sex. The Emergency Plan will support efforts to reach out to parents and other adult caregivers to educate

and involve them in issues relating to youth and HIV and to empower them by improving their communication skills in the areas of sexuality as well as broader limit-setting and mentoring. Suggested activities include:

- ▶ Holding parenting education workshops to improve parent-child communication on HIV, sexuality, and broader issues such as limit-setting, through parent-teacher associations, local social and civic clubs, and faith-based groups;
- ▶ Organizing special school and community events jointly for parents and teens to promote mutual communication about HIV and healthy behaviors; and
- ▶ Developing and training a cadre of volunteer mentors for youth who lack sufficient parental or other adult supervision, including training in messages for HIV prevention.

Address sexual coercion and exploitation of young people. Adolescents need a safe environment where they can grow and develop without fear of forced or unwanted sex, which often precludes the option of abstinence. The Emergency Plan supports psychosocial and other assistance for victims of sexual abuse. Efforts to target men with messages that challenge norms about masculinity and that emphasize the need to stop sexual violence and coercion will also be important. Suggested activities include:

- ▶ Organizing campaigns and events to educate local communities about sexual violence against youth and strengthen community sanctions against such behaviors;
- ▶ Implementing workplace programs for older men and school-based programs for young boys to provide education about preventing sexual violence, with a special focus on men who have a higher propensity to become perpetrators;
- ▶ Training health care providers, teachers, and peer educators to identify, counsel, and refer young victims of sexual abuse for other health services; and
- ▶ Working with governments and NGOs to eliminate gender inequalities in the civil and criminal code.

Violence Against Women and HIV/AIDS

Evidence from Rwanda, Uganda, Tanzania, and Zambia shows that violence against women is both a cause and consequence of rising rates of HIV infection – a cause because rape and sexual violence pose a major risk factor for women and a consequence because studies have shown that HIV-positive women are more likely to suffer violence at the hands of a partner than those who are not infected. For many women, fear of sexual coercion and violence often precludes the option of abstinence or holds them hostage to their husband's infidelity. Through President Bush's Emergency Plan, the U.S. Government will work closely with communities, donors, and other stakeholders to reduce stigma, protect women from sexual violence related to HIV, promote gender equality, and build family skills in conflict resolution. The Emergency Plan will also support interventions to eradicate prostitution, sexual trafficking, rape, assault, and sexual exploitation of women and children.

Prevention of HIV infection through HIV testing, targeted outreach, and condom distribution to high-risk populations

Following the "ABC" model, and recognizing that condoms are an essential means of HIV prevention for populations who engage in risky behavior, rapid scale-up of activities that target specific at-risk populations with outreach, prevention messages, testing, and condoms will be undertaken. These groups include prostitutes, sexually active discordant couples, substance abusers, and others. In doing this, care will be taken to adhere to local guidelines and standards and to ensure that the key behavioral messages of abstinence, faithfulness, and partner reduction are not confounded.

Prevention of HIV infection from mother to child

The technology now exists to substantially reduce mother-to-child transmission (MTCT) using simplified interventions that international clinical trials have demonstrated can reduce risk of HIV transmission from mother to child by 30 to 50 percent. The interventions involve providing routine HIV testing for pregnant women, administering short-course ARV prophylaxis to HIV-infected mothers in the last weeks of pregnancy or during labor or delivery, and administering ARV drugs by droplet to infants within 72 hours of birth. The interventions also call for less invasive medical procedures during childbirth,

improved breastfeeding practices, and prevention and treatment of malaria.

The President's Emergency Plan will build on the significant work already accomplished under the President's 2002 International Mother and Child HIV Prevention Initiative (now integrated into the Emergency Plan). President Bush's Emergency Plan will support rapid expansion of these programs through the following suggested activities:

- ▶ Scaling up existing prevention of mother-to-child transmission (PMTCT) programs by rapidly mobilizing resources;
- ▶ Providing technical assistance and expanded training for health care providers (including family planning providers, traditional birth attendants, and others) on appropriate antenatal care, safe labor and delivery practices, breastfeeding, malaria prevention and treatment, and family planning;
- ▶ Strengthening the referral links among health care providers;
- ▶ Ensuring effective supply chain management of the range of PMTCT-related products and equipment; and
- ▶ Expanding PMTCT programs to include HIV treatment for HIV-infected mothers and other members of the child's immediate family.

Prevention of HIV infection through safe blood, improved medical practices, and post-exposure prophylaxis

HIV transmission in medical settings, including through blood transfusions, is a significant contributor to the HIV pandemic. Thus, the rapid implementation of safe blood programs and precautions against medical transmission of HIV is a priority area for the President's Emergency Plan. The World Health Organization (WHO) estimates that 5 to 10 percent of all HIV transmissions are attributable to unsafe blood transfusions. Transmission of HIV and other bloodborne pathogens via blood transfusion is preventable by establishing an adequate supply of safe blood through a systematized blood transfusion service and by minimizing unnecessary transfusions. According to WHO, however, in 2002 only 90 percent of blood donations in Africa were screened for HIV, only 40 percent for hepatitis C, and 55 percent for hepatitis B.

Much can be done to reduce the likelihood of transmission, improve infection control, and increase the quality of health care services overall. President Bush's Emergency Plan will provide technical assistance and training to prevent medical transmission of HIV and improve the quality of services through the network model. Support will be provided to improve blood safety, increase the use of safe injection practices, ensure the practice of universal precautions, and increase the availability of post-exposure prophylaxis. Specifically, expert guidance, support, and assistance from organizations currently providing training and technical assistance will be provided to ministries of health and national transfusion services to develop and implement comprehensive national safe blood programs. Suggested activities include:



John E. Lange

- ▶ Providing technical assistance for developing effective national, generic, and site-specific policies, protocols, guidelines, and practices related to blood donation; safe injections; obtaining, handling, storing, testing, transporting, distributing, and disposing of blood, sharps, other injection equipment, and medical wastes; and universal precautions for infection control and prevention and management of occupational exposure to HIV;
- ▶ Training health care staff in the use of protocols and guidelines – the Emergency Plan will support training, supervision, and other performance improvement measures for health care professionals in the areas listed above as well as education about alternatives to injection in primary care practice;
- ▶ Ensuring effective supply chain management of the range of products and equipment needed to prevent medical transmission of HIV; and

- ▶ Providing technical assistance, training, and products for post-exposure prophylaxis in health care settings and for other types of potential exposure (such as sexual violence) once protocols have been established and trained personnel and supplies are in place.

2. Build capacity for effective long-term prevention programs

At the same time that President Bush's Emergency Plan is mobilizing the rapid scale-up of behavior change interventions and other prevention services, it will also be laying the foundation for sustainable and effective long-term local and national prevention programs. The President's initiative will help build, strengthen, and improve the quality and sustainability of prevention programs by promoting evidence-based best practices, encouraging innovation and evaluation to identify effective new approaches, and improving program planning, implementation, management, and monitoring. The development of such comprehensive and sustainable programming will be accomplished through the following key operational strategies:

- Promoting the "ABC" model;
- Innovatively expanding HIV testing;
- Supporting interventions for those at high risk of infection;
- Reaching and engaging mobile male populations;
- Improving diagnosis and treatment of STIs; and
- Developing and strengthening institutional capacity of implementing organizations.

Promoting the "ABC" model

Evidence from Uganda, Senegal, and Zambia demonstrates the effectiveness of a balanced approach to behavior change that encourages the adoption of "ABC" behaviors – A for abstinence, B for being faithful, and C for correct and consistent use of condoms as appropriate.

The application of A, B, and C interventions will be balanced and targeted according to the needs and specific circumstances of different at-risk populations. Expanding the human resources necessary to implement this bold new prevention strategy will require engaging a wide range of partners, from women's associations to faith-based organizations (FBOs), sports clubs to workplaces, parents to schools, and health workers to traditional healers. President Bush's

Emergency Plan will support efforts to build the capacity of local and national partners to strengthen ABC prevention messages and link them in their application to ongoing treatment and care programs.

The application of the ABC model will emphasize:

Abstinence for youth. The strategies for youth described in detail above encourage abstinence until marriage for those who have not yet initiated sexual activity and “secondary abstinence” for unmarried youth who have already engaged in intercourse. FBOs are in a strong position to help young people see the benefits of abstinence until marriage and support them in choosing to postpone sexual activity. Programs will help youth develop the knowledge, confidence, and communication skills necessary to make informed choices and avoid risky behavior. President Bush’s Emergency Plan will also support programs that reinforce parental involvement, as parents are the primary caregivers and have the responsibility of overseeing the upbringing of their children.

Being faithful. Some of the most significant results from Uganda resulted from changes in behavior related to fidelity in marriage, monogamous relationships, and reducing the number of sexual partners among sexually active unmarried persons. President Bush’s Emergency Plan will build on this success by supporting counseling, peer education, and community-based interventions to address social norms that increase vulnerability to HIV, such as the acceptance of men having multiple sexual partners outside of marriage, cross-generational sex, and transactional sex. Working through the media and community-based and faith-based institutions, interventions will deliver messages that promote abstinence until marriage and fidelity to one partner, encourage men to refrain from sexual promiscuity and to respect women, and encourage testing. Knowledge of HIV serostatus is especially important, and counseling and HIV testing of couples can be an effective strategy. Despite the fact that sero-discordant couples – couples in which one partner is HIV-positive and the other HIV-negative – may remain monogamous, the risk still remains high for the uninfected partner.

Correct and consistent use of condoms as appropriate. For those who are infected or who are unable to avoid high-risk behaviors (such as discordant couples), condom use is a critical risk-reduction intervention. The Emergency Plan will make condoms available to reduce the risk of the spread of HIV infection among those who engage in high-risk activity by strengthening public and private sector programs to create demand among those at high risk and by expanding

the number of condom distribution outlets near areas where high-risk behavior takes place. Improved condom forecasting and supply chain management will be necessary to ensure condoms are available in these high-risk settings. Use of condoms will also be promoted for sexually active discordant couples. In doing this, every effort will be made to deliver a consistent “ABC” message so that the general population receives a clear message that the best means of preventing HIV/AIDS is to avoid risk all together.

Innovatively expanding HIV testing

Estimates indicate that at many as 95 percent of people living with HIV/AIDS do not know their status. Without knowing their status, individuals can neither access appropriate care service for themselves nor take steps to prevent transmission to others. HIV testing is a critical intervention that serves as a linchpin connecting prevention to care and treatment. When combined with counseling, testing can also be a powerful means of educating individuals and communities about HIV and preventing infection. Those who know their HIV-negative status can avoid future infection and be linked to community prevention activities. Those who know their HIV-positive status can live positively and start early prevention and treatment of opportunistic infection or STIs, begin antiretroviral therapy (ART), seek psychosocial support, and plan for their futures. A strong testing and counseling program helps to reduce stigma and enhance the development of care and support services. In addition, HIV testing programs that target couples can identify sero-discordant couples and create a critical opportunity for prevention interventions.

While it is anticipated that the hope generated by access to ART will increase demand for HIV testing, this is not sufficient. Innovative solutions must be found to dramatically increase the number of individuals who are tested and know their status. The Emergency Plan will increase the availability of HIV testing services through a number of key innovative strategies:

- ▶ Integrating testing with other health services, such as family planning, antenatal care, STI, tuberculosis, and malaria programs, and improving the referral links among all of these services;
- ▶ Expanding the range of settings in which confidential testing and counseling are offered, including at times of employment, school enrollment, military enlistment, and marriage registration, and ensuring that non-discrimination policies and practices are in place;

Reducing Stigma and Denial

Stigma against HIV and AIDS, real or perceived, is one of the most difficult barriers to overcome. It strengthens existing social inequalities and prejudices, especially those related to gender, sexual orientation, economic status, and race. Fear of rejection by family, employer, or community causes many people to fear the stigma associated with the virus more than the virus itself. It may encourage people to ignore or deny their HIV status and make choices that are not in their own or society's best interest. Among health workers, negative perceptions of people living with HIV/AIDS can affect the quality of care they provide to patients suspected of HIV and cause those who need services to avoid them for fear of disclosure.

Stigma and denial create barriers to prevention, treatment, and care that must be addressed. President Bush's Emergency Plan will act boldly to address stigma and denial through three operational strategies that:

- ▶ Engage local and national political, business, community, and religious leaders and popular entertainers to speak out boldly against HIV/AIDS-related stigma and violence against women, to promote messages that address gender inequality, to encourage men to behave responsibly, to promote HIV testing, and to encourage those found to be HIV positive to seek treatment;
- ▶ Identify and build the capacity of new partners from a variety of sectors to highlight the harm of stigma and denial and promote the benefits of greater openness through community- and faith-based organizations, private sector businesses, the entertainment industry, the public health system, and the national government; and
- ▶ Promote hope by highlighting the many important contributions of people living with HIV/AIDS, by providing ARV treatment to those who are medically eligible, and by involving those who are HIV-positive in meaningful roles in all aspects of HIV/AIDS programming.

Finally, efforts to address stigma and denial will seek synergies among the prevention, treatment, and care realms. The hope offered by treatment is an effective tool to combat irrational fear of the disease and open up channels of communication within communities.

- ▶ Strengthening training of health workers, professional and lay counselors, laboratory technicians, and other support people necessary to rapidly expand services;
- ▶ Strengthening linkages between testing and counseling and post-test services;
- ▶ Focusing efforts to make HIV testing available to those at highest risk of infection;
- ▶ Strengthening of counseling and support to clients to encourage disclosure of status to others;
- ▶ Ensuring adequate supplies of HIV test kits and other essential products;
- ▶ Stimulating demand for services through innovative communications and social marketing approaches at the community and mass media levels;
- ▶ Providing support to women to mitigate potential violence or other negative outcomes of disclosing HIV-positive status to male partners; and
- ▶ Strengthening national guidelines for HIV testing and counseling, where appropriate; encouraging the adoption of routine testing policies; and ensuring regulatory support for maintaining confidentiality, service quality, and adequate procurement and supply chain management.

Supporting interventions for those at high risk of infection

Some of the populations most affected by HIV/AIDS are also the most difficult to reach through conventional health care programs. Prostitutes and their clients, men who have sex with men, and injecting drug users are among those who are most marginalized in society and have the least access to basic health care. Developing and implementing interventions with some of these groups is even more difficult because of stigma and discrimination. At the same time, these populations are generally at higher risk of infection and in greatest need of prevention services. First and foremost, the Emergency Plan will support approaches directed at ending risky behavior. In addition, the Emergency Plan supports effective new approaches to reach groups at high risk through a combination of:

- ▶ Interpersonal approaches to behavior change, such as counseling, mentoring, and peer outreach;

- ▶ Community and workplace interventions to eliminate or reduce risky behaviors;
- ▶ Initiatives to promote the use of testing and counseling services;
- ▶ Linkages through referral networks with other health services;
- ▶ Diagnosis and treatment of STIs;
- ▶ Promotion of condom use during high-risk sexual activity;
- ▶ Strengthened referral systems to link substance abuse treatment services with HIV testing and counseling;
- ▶ Promotion of substance abuse prevention and treatment services; and
- ▶ Mass media interventions with specially tailored messages.

Reaching and engaging mobile male populations

Workers engage in risky behavior, such as sexual relations with non-regular partners, more often when they are posted away from home or are required to travel for extended periods of time. Migrant workers, truck drivers, and members of uniformed services such as the armed forces and police face serious risks of HIV and other STIs and can serve as a bridge for transmitting infection to the general population. The uniformed services present unique challenges and opportunities for HIV prevention. The United States has played a leadership role in pioneering prevention approaches with the military. President Bush's Emergency Plan will build on already initiated U.S. Government activities to reach the military and other uniformed services including:

- ▶ Peer education, interpersonal and group communication strategies, and local mass media to promote faithfulness, partner reduction, avoidance of commercial sex, and condom use during high-risk sexual behavior;
- ▶ STI and HIV testing and counseling services, linked to treatment and care;
- ▶ Basic workplace and in-service training on HIV/AIDS for employees, new recruits, and existing personnel; and
- ▶ Condom promotion and distribution for those who practice high-risk sexual behavior.

Improving diagnosis and treatment of STIs

An important link exists between STIs and the sexual transmission of HIV. Untreated, STIs can significantly increase the likelihood of both acquiring and transmitting HIV. President Bush's Emergency Plan will support STI prevention, diagnosis, and treatment services, and the linking of these services through referral networks with HIV testing and counseling and other HIV services, through implementation of the following strategies:

- ▶ Increasing availability and accessibility of STI treatment services through the expansion of STI prevention and treatment services where appropriate;
- ▶ Integrating STI treatment services with other HIV/AIDS and reproductive health care services and improving the referral links between programs; and
- ▶ Improving national STI treatment protocols, training health workers in their use, and where needed, developing national evidence-based guidelines, protocols, and training curricula.

Developing and strengthening institutional capacity

Prevention programs are only as strong as the institutions that support them. Therefore, a strong organizational infrastructure is the foundation upon which the planning, implementation, and evaluation of effective behavior change interventions and prevention services are built. Many of the organizations that implement risk elimination and reduction interventions may need to enhance or develop the institutional capacity to support the rapid scale-up of prevention programs necessary to effectively address the epidemic.

The President's Emergency Plan will invest in strengthening the institutional capability of implementing organizations by providing technical assistance, training, and funding to improve and expand the organizational capability of key partners – including FBOs, other community-based organizations (CBOs), and nongovernmental organizations (NGOs) – as well as public and private facilities that deliver abstinence-until-marriage programs, HIV testing and counseling, and PMTCT and STI services. By looking at the institutional capacity building needs of partners within a network, and the linkages between them, support will be provided to:

- ▶ Equip health facilities and mobile units to provide testing and counseling and STI services;

- ▶ Strengthen public and private sector capabilities to design and produce behavior change materials;
- ▶ Upgrade routine health information systems to improve prevention services data management;
- ▶ Strengthen qualitative and quantitative research capability;
- ▶ Support effective product procurement, storage, and distribution, particularly for HIV testing and targeted condom distribution programs;
- ▶ Strengthen NGO/CBO financial and administrative systems; and
- ▶ Improve laboratory capacity to perform HIV testing.

3. Advance policy initiatives that support prevention of HIV infection

Many of the focus countries have elevated HIV/AIDS to national priority status. All promote a comprehensive approach integrating prevention, treatment, and care. Most have clear statements supporting the human rights of people living with HIV/AIDS and condemning stigma and discrimination related to HIV status. Several explicitly state the importance of greater involvement of people living with HIV/AIDS in program planning and policy. In an effort to address underlying factors that promote vulnerability to HIV, most of the focus countries have established policies to promote gender equality, improve women's socioeconomic status, and address violence against women. Application of these policies is far from complete, however, especially at the community level.

A key priority of President Bush's Emergency Plan will be to support implementation of good policies and effective legislation, particularly at the community level. Illustrative examples of policy issues that may be addressed through Emergency Plan technical assistance include:

- Protection against stigma and discrimination, particularly within key settings such as workplaces, schools, and the military;
- Use of routine testing while applying the principles of confidentiality;

- Human resources policies, including the broadening of responsibility for HIV testing and counseling to lower levels of care;
- Access to health information and care, including for traditionally underserved populations such as women, the poor, and the disabled;
- Policies to promote gender equality;
- Support for the review, revision, and enforcement of laws relating to sexual violence against minors, including strategies to more effectively protect young victims and punish perpetrators; and
- Programs that support abstinence until marriage and fidelity within marriage.

4. Collect strategic information to monitor and evaluate progress and ensure compliance with Emergency Plan policies and strategies

Measuring prevention activities and providing useful feedback to programs for accountability and quality improvement is a goal of strategic information for improved HIV prevention activities. Improved HIV sentinel clinical and population-based surveillance systems will measure the impact and outcomes of prevention programs. Program monitoring will enable the tracking of training, media, and community outreach activities, including interventions to promote abstinence. Targeted program evaluations will provide evidence-based information to improve prevention programs, and information management systems will facilitate data storage and data flow. Sets of internationally agreed upon prevention indicators developed by WHO, UNAIDS, and U.S. Government agencies will guide the Emergency Plan's strategic information system.

The prevention goal of 7 million HIV infections averted over five years will, by necessity, be based on mathematical projections. A methodology will be established that will use estimates of new infections based on assumptions of rates that would occur without the Emergency Plan, estimates of numbers of new infections under the new program, measures of program intensity (such as numbers of persons receiving prevention services, numbers of workers trained, and numbers of programs supported), and expected levels of program effectiveness.

V. CRITICAL INTERVENTIONS IN THE FOCUS COUNTRIES: Treatment

“There are whole countries in Africa where more than one-third of the adult population carries the infection. More than 4 million require immediate drug treatment. Yet across that continent, only 50,000 AIDS victims – only 50,000 – are receiving the medicine they need.”

President George W. Bush , January 28, 2003

In 2003 alone, AIDS claimed a staggering 3 million lives. The vast majority of these deaths – 2.4 million – occurred in developing nations. Access to anti-retroviral therapy (ART) and improved treatment of opportunistic infections have dramatically reduced AIDS morbidity and mortality in the industrialized world. But in developing countries, fewer than 8 percent of the 6 million people in immediate need of treatment receive it.

The United States has been a global leader in developing the tools – including ART and other treatment methodologies – that have enabled people in industrialized nations to live long and productive lives despite HIV. Driven by the President’s fundamental belief in the value and dignity of every human life, President Bush’s Emergency Plan for AIDS Relief expands this leadership role to dramatically increase access to treatment in some of the most affected and underserved countries in the world.

In the past, the provision of treatment in the developing world was considered too costly for under-resourced nations and too complicated for developing-country health infrastructures. These concerns are real but can no longer be barriers to providing treatment to the millions who need it. President Bush believes that moral duty alone is sufficient reason to act quickly to save lives. Providing treatment may be our best hope against the disease and its consequences.

In the absence of treatment, HIV is viewed as a death sentence. With no hope of survival, many refuse to be tested and thus lack information they need to protect themselves and others. Lack of hope contributes to fear of the disease and stigmatization of those who live with it, further hindering testing efforts. In contrast, the availability of treatment demystifies, and thus destigmatizes, AIDS and people who have it. The availability of treatment also provides an incen-



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tive to get tested. Treatment, then, can provide links to prevention efforts.

In addition, treatment provides a means to address the devastating consequences of AIDS-related mortality. It is the human toll of the disease that contributes to the loss of productivity, the dramatically increased poverty, the staggering numbers of orphans, and the population distortions that threaten not only the present but also the future. Treatment, in its basic ability to prolong life and reduce morbidity, allows parents to continue parenting, teachers to continue teaching, and civil servants, including health care workers, to continue serving their nations and fellow citizens for years to come. The hope for a future again appears on the horizon.

The President’s Emergency Plan establishes the aggressive goal of providing treatment over the next five years to at least 2 million people living with HIV/AIDS in countries bearing some of the greatest burdens of disease. Not everyone infected by HIV needs immediate ART, which starts when a person begins to experience symptoms or when their immune system has deteriorated. Once ART has begun, it continues for life.

Meeting this goal requires far more than providing a consistent supply of essential drugs, although this is a daunting challenge in itself. It requires addressing complex issues such as the lack of adequate infrastructure, staff, and technical capacity to provide safe, high-quality treatment programs that reach even rural communities. Further, many countries have yet to develop appropriate treatment protocols and policies to ensure safe and adequate drug supply and the equitable distribution of health resources. Other issues, such as drug resistance and patient adherence, are essential challenges that must be addressed.

The President's Emergency Plan will capitalize on decades of U.S. Government expertise in biomedical research, delivery of HIV/AIDS care and treatment, and development to address these challenges and rapidly expand ARV treatment availability while building national and local health care capacity to sustain treatment programs over the long term. Reduced drug prices, proven treatment methodologies, committed host governments, and the involvement of FBOs, CBOs, and other private sector partners have proven that it is possible to deliver this life-extending intervention in resource-poor settings.

Priorities for the distribution of resources for treatment will ultimately be based upon the strategies, needs, and existing resources of the host countries. Activities funded under the Emergency Plan will collaborate closely with other donors to ensure complementary treatment efforts and the best use of treatment dollars.

The President's Emergency Plan is fundamentally oriented to removing barriers to treatment and working to ensure that geography, gender, ethnicity, risk factors, and income no longer determine who lives and dies with AIDS. With the knowledge that 8,000 lives are lost daily to AIDS, there is no time to waste.

Treatment Objective:

Provide treatment to at least 2 million HIV-infected individuals in the focus countries

Treatment Strategies:

1. Rapidly scale up treatment availability through the network model
2. Build capacity for long-term sustainability of quality HIV/AIDS treatment programs
3. Advance policy initiatives that support treatment
4. Collect strategic information to monitor and evaluate progress and ensure compliance with

Emergency Plan and national policies and strategies

1. Rapidly scale up treatment availability through the network model

The expansion of treatment services in the focus countries at the scale and scope envisioned by President Bush's Emergency Plan is unprecedented. Pioneering new approaches are required to achieve the Emergency Plan's ambitious treatment goal. Four operational strategies will guide the rapid scale-up of treatment availability:

- Assessing network capacity for treatment expansion;
- Building on established clinical programs;
- Rapidly training and mobilizing health care personnel to provide treatment services; and
- Enhancing the capacity of supply chain management systems to respond to rapid treatment scale-up.

Assessing network capacity for treatment expansion

The Emergency Plan will move quickly within each of the focus countries to help the host government and other in-country stakeholders assess the current capacity of the HIV/AIDS network by identifying key facilities, organizations, and health providers who deliver treatment at each level of the system. Using existing data to the greatest degree possible, the rapid assessment will document:

- ▶ Current capacity (human resources, infrastructure) of key units within the network to deliver and rapidly expand treatment and related services, including public facilities, private NGOs, FBOs, and private commercial facilities;
- ▶ The strengths and weaknesses of the systems that support the delivery of treatment, such as referral systems, logistics systems, management information systems, etc.;
- ▶ Organizations that currently deliver good health services – especially those with wide networks – that could be mobilized to expand their range of services to include HIV/AIDS treatment; and
- ▶ Policy issues and cultural practices that either support or inhibit the capacity to deliver treatment services.

The Network Model

The strategy to achieve President Bush's Emergency Plan's ambitious goals focuses on improving health care system capacity to deliver effective and expanded HIV/AIDS prevention, treatment, and care services. The focus on health care systems provides a base from which to rapidly expand essential services. Health care systems in the target countries, and indeed in much of the world, are currently organized around the concept of a "network model" comprising central medical facilities,

district-level hospitals, and local health clinics, supplemented by private, often faith-based, facilities. This network concept of public and private health care institutions currently provides the backbone design of health care delivery systems, and many of the focus countries – Nigeria, Uganda, and Haiti, for example – have planned their HIV/AIDS strategies with networked health care systems as the foundation.

The current capacity of these existing health systems to deliver HIV/AIDS prevention, treatment, and care services is limited, however, particularly in rural areas. The Emergency Plan, in accordance with national health and HIV/AIDS strategies and with the intent to build long-term sustainability, will strengthen linkages between central facilities and international and private support to build the capacity of different network components and strengthen network-wide linkages in order to more effectively deliver quality HIV/AIDS services to those who need them most.

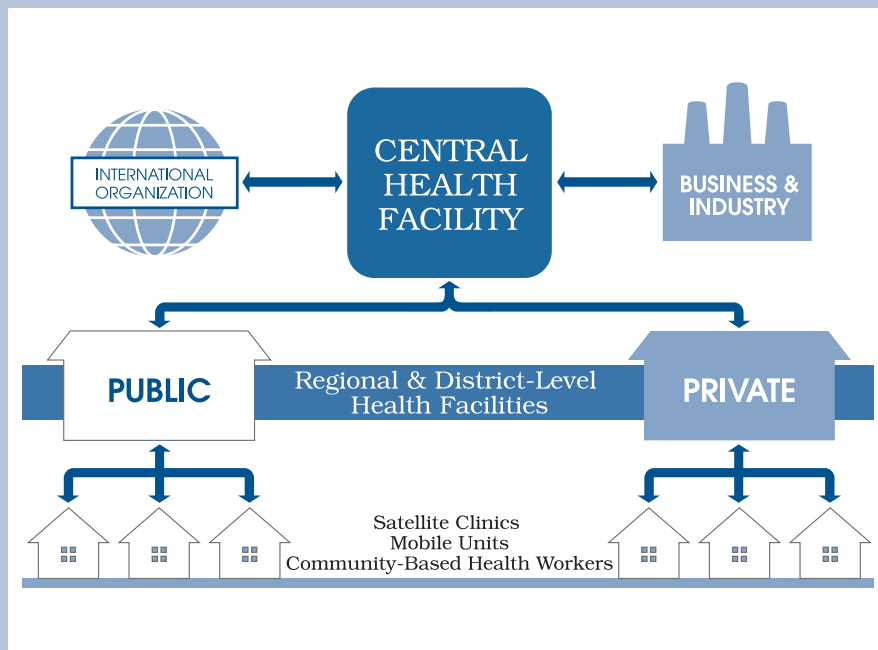
The Emergency Plan, in support of national HIV/AIDS strategies, aspires to the goal of well-functioning, well-managed health care networks in which central medical centers and referral hospitals

at the core of the network will have an adequate number of health care professionals highly trained in all aspects of HIV/AIDS clinical and program management. These facilities must also have adequate physical infrastructure and research capabilities. The central facilities will link through effective referral networks to a series of smaller regional hospitals and district facilities down to community-level satellite clinics, mobile units, and community-based services. To reach even the most rural areas, and to dramatically scale up access in the short term, community-based health care workers will deliver essential supplies, including medications, to patients in their communities, as currently practiced in Uganda. Nurses and community health care workers will be trained in

routine care, symptom management, and monitoring for treatment adherence, while highly trained doctors – currently in scarce supply – will use their expertise in specialized and difficult cases. Doctors, for example, would periodically visit a community to evaluate patients identified for advanced care by nurses and community health care workers.

The network ensures technical support and products flowing out from the center to facilities in the periphery that provide care. Facilities and health workers within the network, in turn, identify and refer patients for higher levels of care as needed. This might include HIV/AIDS patients exhibiting greater levels of complexity. Information systems link all levels of the network with regular feedback loops, enabling both providers and health policy-makers to make decisions based on solid data. Finally, the system will employ relatively uniform HIV/AIDS treatment and care protocols that are consistent with national strategies and guidelines.

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The results of this rapid assessment will be used to guide Emergency Plan interventions to strengthen the capacity of the HIV/AIDS network to deliver treatment within each of the focus countries. Plans for technical assistance, training, and program interventions will be closely coordinated with host-country counterparts and will be consistent with their national AIDS strategies.

Building on established clinical programs

Based on the results of the assessment, the Emergency Plan will mobilize immediately to scale up programs that already deliver ART or that have the necessary medical competence to do so quickly. Using existing programs (those already supported by the United States as well as those supported by others) as a platform for scale-up will allow for easier replication of best practices, more rapid mobilization of resources through institutions that already have functioning systems, and increased opportunities for twinning successful programs with those that show promise. President Bush's Emergency Plan will support communication efforts to prepare communities for the introduction of ARV drugs. Such efforts should describe ARV treatment programs, including the nature of taking ARVs for life, and include messages to combat the possible misperception that a cure has arrived.

The second phase of scale-up will focus on those facilities that do not provide ART but do provide good health or HIV/AIDS prevention and care services and have networks of sites and personnel that allow for rapid expansion and mobilization to provide ARV treatment. Through targeted technical assistance and training, many public health facilities, private FBOs and CBOs, and private commercial facilities in the focus countries will be able to add ART to their services in a relatively short period of time. FBOs will play an important role, as in some countries in Africa nearly half of all medical services are provided through mission hospitals and health centers.

Other programs that offer the possibility for rapid scale-up and development of program synergies include:

Tuberculosis control programs. Tuberculosis (TB) is frequently the first manifestation of HIV/AIDS disease and the reason many people first present themselves for medical care. Since both tuberculosis treatment and HIV/AIDS treatment require longitudinal care and follow-up, successful TB programs may provide excellent platforms upon which to build capacity for HIV/AIDS treatment. The Emergency Plan will support TB treatment for those who are HIV-infected and develop HIV treatment capacity in

TB programs. In addition, interventions that increase the number of persons diagnosed and treated for HIV/AIDS will increase the need for TB treatment and care services. Therefore, action is required to build or maintain necessary tuberculosis treatment capacity. Laboratories, clinical staff, community networks, and management structures used for TB control can be upgraded to accommodate HIV/AIDS treatment. Many of the techniques that have been found useful for TB control, such as directly observed therapy, may be applied to monitoring compliance with HIV/AIDS treatment. Because the prevalence of HIV infection is high among persons with tuberculosis, TB programs may be an important site for HIV testing in the focus countries.

Malaria control programs. Malaria infection during pregnancy increases the risk of mother-to-child HIV transmission. Therefore, the Emergency Plan will strengthen in-country program linkages between HIV/AIDS and malaria programs and provide technical assistance, training, and support to malaria prevention and control initiatives focusing particularly on HIV-positive pregnant women through PMTCT interventions. Bednets, an effective antimalarial intervention, will be incorporated into the Emergency Plan's coordination strategy with malaria control programs.

Rapidly training and mobilizing health care personnel to provide treatment services

Expanding the human resources necessary to implement this bold new treatment program will require both short- and long-term strategies. In the short term, the immediate need for greater numbers of trained health workers to manage ARV treatment will be met by rapidly expanding the training of existing health workers and supplementing their capacity with foreign volunteer health professionals. At this stage, technical assistance and in-service training will be the primary vehicles for building the skills of current health workers, including physicians, nurses, community health workers, pharmacists, and laboratory technicians. Training will focus on building health worker skills to improve ART case management for both adults and children, including administering drugs, monitoring patients for side effects and treatment failure, and promoting treatment adherence.

In order to facilitate rapid expansion, President Bush's Emergency Plan will support local and national efforts to broaden responsibility for patient treatment, care, and support to nurses, lay health workers and counselors, and health volunteers. Given the enormous human resource constraints, it will be critical to give greater responsibility, through training and supervi-

sion, to greater numbers of health workers in order to achieve treatment goals.

In addition to strengthening the skills of formally trained medical professionals, and as a way to extend services into the community, President Bush's Emergency Plan will explore options to involve traditional healers, birth attendants, family members, and other lay persons in a more substantial way. Building on previous U.S. Government-funded work in this area, programs will focus on building skills to recognize HIV complications, provide basic home-based care, support patients and caregivers, increase adherence to treatment regimens, and refer patients to appropriate health care services. The Emergency Plan will also support efforts to forge relationships with associations of people living with HIV/AIDS to train their members to provide patient education, adherence counseling, and patient follow-up in order to free clinical staff to perform higher-level tasks.

Recruiting and deploying volunteer doctors, nurses, pharmacists, laboratory technicians, and other health professionals from the United States and other nations is another important strategy to meet the human capacity needs for HIV/AIDS treatment. Short-term training and technical assistance by experienced professionals, possibly as part of a twinning program, will help fill human resource gaps in key technical areas and provide opportunities for on-the-job training and mentoring of host-country counterparts. The U.S. Global AIDS Coordinator is exploring various mechanisms and options for facilitating U.S. professionals in this effort under the President's Volunteers for Prosperity Initiative, including the Peace Corps' Crisis Corps program, Freedom Corps,

Volunteers for Prosperity

President Bush's Emergency Plan for AIDS Relief and many of its grantees will be participating in Volunteers for Prosperity, President Bush's call to international service to engage the people of the United States as part of U.S. Government assistance programs that meet global prosperity needs. The Volunteers for Prosperity initiative is part of President Bush's USA Freedom Corps volunteer service initiative that encourages highly skilled and trained individuals to volunteer with organizations promoting health and prosperity throughout the world. Volunteer service is a major component of the President's ongoing effort to involve all Americans in sharing compassion and skills with others in their own communities and around the world.

Monitoring Resistance to Antiretroviral Drugs

Careful monitoring of ARV treatment is essential to limit the development of resistant strains of the virus and ensure the long-term durability of treatment regimens. Currently, only a few countries have the sophisticated laboratory infrastructure, highly skilled laboratory staff, and rigorous health information systems necessary to support an ARV resistance monitoring program.

President Bush's Emergency Plan will help build the capacity of focus countries to monitor resistance to ARVs at the program level by providing technical assistance and training to upgrade laboratory capacity and strengthen monitoring and evaluation systems. The Emergency Plan will work with the U.S. Department of Health and Human Services and its constituent parts, the National Institutes of Health and the Centers for Disease Control and Prevention, and other research organizations to ensure that surveillance and research are supported to help detect viral resistance to ARVs and better understand the determinants of resistance in local settings. These studies will help inform decisions and policies related to clinical care, program management, and drug procurement. Clinical and operations research will identify and test appropriate alternative approaches to sophisticated laboratory monitoring of ARV therapy in resource-limited settings and increase understanding of ways to increase ARV regimen durability.

and other programs. Finally, telemedicine and distance education can be used to build the skills of health professionals in the focus countries and strengthen local, national, and international connections among medical institutions.

The twinning of U.S.-based institutions with African or Caribbean institutions (or African with Caribbean or African) offers an important means of establishing these types of relationships. The twinning mechanism that is part of President Bush's Emergency Plan will allow the creation and support of "centers of excellence" from which training, research, and talent can be diffused throughout the impacted regions. It is this ongoing sustained support for professional excellence that holds the key to increased capacity for care.

Enhancing the capacity of supply chain management systems to respond to rapid treatment scale-up

The development and implementation of logistics systems to manage the increased volume of products needed for an expanded treatment program will require both short- and long-term strategies. During rapid scale-up, the focus will be on procuring and delivering a continuous and secure supply of high-quality products to patients at all levels of the health system.

In most countries, the sharp increase in the volume of products provided through the Emergency Plan and other new sources such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria will likely challenge existing national supply systems. To facilitate rapid implementation of effective procurement and delivery systems, President Bush's Emergency Plan will explore options to enhance the immediate performance of national logistics systems through:

- ▶ Centralized or pooled procurement mechanisms at global or regional levels, including collaboration with other donor-funded programs – e.g., the Global Fund, the World Bank's Multi-Country HIV/AIDS Program for Africa (MAP), and WHO – and direct product donations;
- ▶ Outsourced transportation to secure courier services or purchase of dedicated vehicles for ARV drug delivery;
- ▶ Design of user-friendly, timely, and accurate methods of logistics data capture, collection, analysis, and feedback for resupply and forecasting;
- ▶ Product selection and packaging for better adherence;
- ▶ Provision of skilled people to perform logistics management functions;
- ▶ Strengthened collaboration between supply chain managers and program service managers to ensure coordination of patient enrollment and supply needs;
- ▶ Improvements in secure storage space and inventory management; and
- ▶ Facilitated development of national coordinating bodies to schedule donor financial and commodity commitments, develop medium-term procurement plans, and track actual funds and

products received in order to avoid duplication of investment.

For more information on supply chain management issues, see chapter X, *Supportive Interventions for U.S. Government Programs, Supply Chain Management*.

2. Build capacity for long-term sustainability of quality HIV/AIDS treatment programs

While mobilizing rapid scale-up for treatment availability, the Emergency Plan will also lay the foundation for sustainable high-quality treatment programs. This will be accomplished by:

- Strengthening national human resource capacity through health care worker recruitment and retention strategies, longer-term training, and technical assistance;
- Establishing, disseminating, and implementing treatment protocols;
- Developing the capacity of new partners; and
- Developing and strengthening health infrastructure.

Strengthening national human resource capacity through health care worker recruitment and retention strategies, longer-term training, and technical assistance

President Bush's Emergency Plan will focus on building long-term human resource capacity through training and technical assistance that directly supports national strategic plans for scale-up of HIV/AIDS programs. Short- and long-term training is the backbone of this strategy, including the incorporation of PMTCT and ART content into the basic training programs for doctors, pharmacists, laboratory technologists, nurses, and midwives, including rotational practice. Activities include:

- ▶ Curriculum development to incorporate management of HIV-related illness into the basic package of care offered through routine health services, including methodologies for promoting treatment adherence;
- ▶ Technical assistance and training to improve ART case management, including promoting adherence and monitoring patients for side effects, treatment failure, toxicity, and contraindications;

- ▶ Technical assistance and training in improved supervision and quality assurance;
- ▶ Technical assistance in long-term planning for infrastructure and manpower requirements;
- ▶ Development of innovative training programs, including faculty and student exchange programs and a practicum for health workers that allows trainees to gain experience in HIV/AIDS management by working under supervision in health clinics or hospitals providing high-quality treatment programs;
- ▶ Technical assistance to promote and improve treatment literacy for clients, through patient education, counseling, and community outreach to inform patients and their families about the drugs they are receiving, management of side effects, and the importance of adherence; and
- ▶ Promotion of policies to support the recruitment and retention of qualified health care professionals.

Establishing, disseminating, and implementing treatment protocols

It is important that every country have evidence-based national guidelines and protocols for managing ART and opportunistic infections. These guidelines and protocols must be constantly updated to reflect the nature of the epidemic and “state of the art” treatment, and they are an important tool for improving the quality of HIV/AIDS care. Thus, President Bush’s Emergency Plan will:

- ▶ Provide technical assistance and training to health ministries and professional organizations to strengthen the development, dissemination, and implementation of national guidelines and protocols for ART and treatment of opportunistic infections, based on evidence and experience gained in local settings and incorporating knowledge of the local health infrastructure and epidemiology of the epidemic in each country; and
- ▶ Provide technical assistance to develop clinical care guidelines and ARV regimens for children (which can significantly differ from those for adults), including methodologies for addressing treatment adherence and psychosocial support.

Developing and strengthening HIV/AIDS-related health infrastructure

A strong health infrastructure is the foundation that supports effective planning, delivery, and evaluation of HIV/AIDS treatment programs. Currently, health infrastructure within the focus countries is often not equipped to support the sustainable high-quality treatment services necessary to effectively address the epidemic. Thus, the President’s Emergency Plan will provide targeted technical assistance, training, and funding to improve and expand the infrastructure necessary to ensure optimal delivery of HIV/AIDS treatment services. By looking at the requirements at each level of care – and the linkages between them – support will be provided to:



Jimmy Kolker

- ▶ Equip health facilities and mobile units utilized for HIV/AIDS treatment services;
- ▶ Upgrade routine health information systems to improve treatment data management;
- ▶ Strengthen research and surveillance capacity;
- ▶ Develop twinning mechanisms for the broad engagement of institutions across a full range of infrastructure-strengthening activities;
- ▶ Support effective product procurement, storage, and distribution;
- ▶ Strengthen financial and management systems; and
- ▶ Improve laboratory capacity to diagnose infection and monitor ARV treatment.

Developing the capacity of new partners

In order to achieve its ambitious treatment goals, the Emergency Plan must help focus countries link communities with treatment services on an enormous scale. To facilitate this, the President's initiative seeks to leverage the comparative strengths of a wide range of different public and private sector partners to dramatically increase the number and reach of organizations providing treatment services. Activities to identify and engage new and innovative partners include outreach to and capacity building of:

Faith-based and community partners currently providing HIV/AIDS prevention and care services to add treatment support to their slate of services. Faith-based and other community partners have extensive reach and legitimacy in local communities and are among the most experienced organizations in providing HIV/AIDS prevention and care services. Expanding their services to treatment support will require training in both the technical aspects of treatment support services and building institutional capacity in program planning, financial and program management, and evaluation.

Corporate sector partners with resources and innovations to contribute. The corporate sector is a vibrant force for development worldwide. Partners from the corporate sector have enormous potential to bring significant new resources and innovative ideas to the fight against AIDS. The President's Emergency Plan will provide technical assistance to help the corporate sector identify ways to support and expand treatment programs through improved workplace policies, delivery of services, the leveraging of commercial resources, and the application of new technologies. Business "champions" who provide effective HIV/AIDS treatment and care support services will be identified. President Bush's Emergency Plan will also coordinate with private corporations to include treatment services for community members in their corporate health facilities.

Private sector networks such as unions and agricultural collectives to strengthen treatment programs through workplace-based HIV/AIDS programs, with support to employees and families where appropriate.

3. Advance policy initiatives that support treatment

President Bush's Emergency Plan will provide support to governments to implement their national HIV/AIDS strategic plans and develop a comprehensive set of policies to support their implementation through a collaborative process involving stakeholders

across multiple sectors. Most of the focus countries have committed to uphold the human rights of people living with HIV/AIDS and have begun to formulate policies in alignment with the 2001 United Nations General Assembly Special Session on HIV/AIDS (UNGASS) Declaration of Commitment on HIV/AIDS. Most have begun to consider how to address a wide range of HIV-related policies. President Bush's Emergency Plan will help create a strong enabling environment that will support the expansion of high-quality treatment programs by:

- Providing technical assistance in policy development, and
- Building political commitment.

Providing technical assistance in policy development

As accessibility to treatment is a relatively new phenomenon in the focus countries, the policies and structures needed to support effective planning, implementation, and evaluation of treatment programs are generally not yet in place. Policy reform to support HIV/AIDS treatment must begin immediately to ensure successful expansion of treatment services under the Emergency Plan. Treatment-related policy issues that may need to be addressed through technical assistance include:

- ▶ Product registration;
- ▶ Development of standard treatment guidelines and essential drug lists;
- ▶ Drug procurement and financing;
- ▶ Compliance with the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and other trade agreements;
- ▶ Regulations related to importation and taxation of drugs and medical supplies/equipment;
- ▶ Human resources policies, including broadened responsibilities for HIV treatment and opportunities for testing and diagnosis, so more nurses and community health workers can deliver care;
- ▶ Appropriate resource allocation and flow of national resources to HIV/AIDS programs;
- ▶ Barriers to treatment caused by stigma and discrimination;

-
- ▶ Insurance coverage of ART; and
 - ▶ Administrative policy relating to health sector reform.

Building political commitment

A primary strategy of President Bush's Emergency Plan is to build political commitment at the highest levels of government and ensure that a nation's policies and infrastructure support this commitment. Every opportunity will be used to make a persuasive case to formal and informal leaders of national governments, businesses, and faith-based and nonprofit organizations to follow President Bush's lead and take effective action and make compelling choices in support of treatment as a critical component of an effective HIV/AIDS program. The Emergency Plan will mobilize all the resources incumbent in the agencies it coordinates to convey the importance of HIV/AIDS treatment to national and international programs. It will support government, NGO, and private sector leaders to garner public support for effective policies and adequate resources for treatment programs. Public diplomacy and communication are essential in assembling the resources, political support, and citizen support needed to make a tangible, sustainable impact.

4. Collect strategic information to monitor and evaluate progress and ensure compliance with Emergency Plan and national policies and strategies

President Bush has insisted that his Emergency Plan place a high priority on maintaining program integrity, ensuring accountability, and assuring compliance with U.S. Government policies. A strategic information system to monitor treatment implementation and impact will be built upon:

- Surveillance information to track HIV incidence, prevalence, and mortality;
- Program monitoring information to measure provider capacity to treat clients, including individuals receiving ART and associated supply chain management and clinical care;
- Targeted evaluations to support evidence-based decisions regarding clinical programs; and
- Management information systems to increase data storage and flow.

An appropriate information technology framework has the potential to revolutionize the health information system supporting clinical care, program management, and international reporting. A strategic information system provides a vehicle for identifying those elements of a program that are most successful and highlighting those that could be more effective.

The Emergency Plan will help countries effectively collect and use appropriate data for decision-making and reporting on progress toward the achievement of results. A second critical activity is to harmonize indicators and reporting systems with international agencies such as UNAIDS and WHO and major international donors such as the Global Fund and the World Bank. Balance must be achieved between the need for immediate reports and results (e.g., timely demonstration of PMTCT core indicators) and the long-term objectives of building HIV country reporting capacity and institutionalizing locally useful and sustainable health information systems.

VI. CRITICAL INTERVENTIONS IN THE FOCUS COUNTRIES: Care

“Fighting AIDS on a global scale is a massive and complicated undertaking. Yet, this cause is rooted in the simplest of moral duties. When we see this kind of preventable suffering, when we see a plague leaving graves and orphans across a continent, we must act. When we see the wounded traveler on the road to Jericho, we will not, America will not pass to the other side of the road.”

President George W. Bush, April 29, 2003

The care activities of President Bush’s Emergency Plan will comprise palliative care for people with HIV/AIDS and care for children orphaned by AIDS and other vulnerable children. Palliative care spans a continuum of care from the time a person is diagnosed with HIV infection until death. The continuum of palliative care includes routine clinical care to evaluate the need for symptom relief (from diarrhea or headache, for example); treatment for HIV/AIDS-related diseases such as tuberculosis and opportunistic infections; preparing people for antiretroviral therapy where that is possible; and, when treatment is not available or has failed, compassionate end-of-life care.

HIV/AIDS and associated opportunistic infections cause severe pain, debilitating symptoms and death. Oral and esophageal infections can make eating and swallowing painful or impossible. Uncontrolled diarrhea can cause weakness to the point of total disability, and many of the conditions associated with HIV/AIDS cause severe pain. Pneumonia and other opportunistic infections can, if left untreated, kill. If basic HIV/AIDS care, supportive care, and compassionate end-of-life care for people living with AIDS are not provided, the burden of suffering, morbidity, and early death will continue on an immense scale.

Added to the millions who live in daily pain and suffering as a result of HIV/AIDS are the millions of orphans – over 13 million children under the age of 15 – left to grow up without the love and support of their parents. Without widespread access to basic needs such as food and shelter and essential services such as education and health care, this population of children is acutely vulnerable to a host of dangers, including HIV/AIDS, and can themselves become a high-risk population fueling the pandemic.

Basic medical care, including treatment of opportunistic infections, symptom management, and end-of-life care and support, is currently out of reach for many



millions of people infected and affected by HIV/AIDS, including orphans and other vulnerable children. Little end-of-life care is available to aggressively address symptoms, pain, and suffering. Basic care and social support needs are currently being addressed, in large part, by family members and neighbors, responding in whatever way they can to fellow community members in crisis. The enormous burdens of care are, however, stretching communities to the breaking point. The lack of services to meet basic care needs not only contributes to daily suffering for those infected and affected by HIV/AIDS. HIV/AIDS-related morbidity also reduces the productivity of both people with HIV/AIDS and their care providers. It diverts scarce family resources as income shifts to health care needs and affects social stability as people are unable to work, parent, teach, or carry out other social responsibilities.

Women bear the greatest burden of care – a load that negatively affects not only them but also their children and families. In most of the focus countries, families earn their subsistence through agriculture. Women are the major contributors to the agricultural workforce, feeding their families and earning a meager family income in the marketplace. When women’s

health deteriorates, or when they must provide care to other family and community members, basic needs such as food security come under threat. Thus, the lack of consistent care services contributes to many of the most severe consequences of HIV/AIDS and perpetuates the vicious cycle of poverty and HIV/AIDS.

The lack of strong care systems also fuels stigma and denial. As communities come under increasing strain, individuals who need care are increasingly left to fend for themselves. Rejection and discrimination feed fear and hopelessness and keep people from internalizing prevention messages or seeking testing and treatment.

HIV/AIDS care, then, has an enormous role to play in reducing AIDS-related morbidity, relieving stress on families and mitigating consequences of disease. Many faith- and community-based groups have been the first organized responders to the demands for care and have worked to strengthen and support family and community care strategies. President Bush's Emergency Plan will build on these and other opportunities, including national strategies to provide care for those infected and affected by HIV/AIDS, to expand, strengthen, and improve the quality and sustainability of programs to meet the needs of those now suffering, including orphans and vulnerable children.

Care Objective:

Provide care and support to 10 million people living with and affected by HIV/AIDS including orphans and vulnerable children in the focus countries

Care Strategies:

1. Rapidly scale up existing palliative care services (basic health care and support services, including symptom management, social and emotional support, and end-of-life care, for persons living with HIV/AIDS); rapidly scale up existing care services for orphans and vulnerable children
2. Build capacity for long-term sustainability of palliative care (basic health care and support services, including end-of-life care, for persons living with HIV/AIDS); build capacity for long-term sustainability of care services for orphans and vulnerable children
3. Advance policy initiatives that support basic health care and support, including palliative care, and care for orphans and vulnerable children
4. Collect strategic information to monitor and evaluate progress and ensure compliance with Emergency Plan policies and strategies

This care goal includes both care for orphans and vulnerable children as well as basic health care and support, including symptom management, social and emotional support and end-of-life care, for persons living with HIV/AIDS. Because of programmatic differences these will be discussed separately below. Additionally, many of the strategies and interventions that apply to care (such as supply chain management) are described in detail elsewhere in this document.

1. Palliative Care

1. Rapidly scale up existing palliative care services

Currently, palliative care needed by those living with HIV/AIDS is not widely available in the target countries. Most countries' ministries of health support district health centers, clinics, and hospitals but few of these are adequately staffed or equipped to meet the basic health care needs of large numbers of people living with HIV/AIDS. Hospitals and clinics supported by faith-based and other nongovernmental organizations also often lack supplies and trained personnel needed to address non-ARV treatment for the HIV-infected.

End-of-life care is now provided through some 40 hospice programs. These, by themselves, are inadequate to meet the need posed by this crisis. The number of people needing pain and symptom management as well as social, psychological, and practical support is simply too large. Home-based care programs have provided support to large numbers of individuals and families living with HIV/AIDS but rarely have the health care capacity or capability to provide minimum standards of palliative care. Principles of palliative care must be applied throughout the course of illness as well as at the end of life.

Operational strategies for rapid scale-up of basic health care, including palliative and end-of-life care include:

- Providing technical assistance and training to build and expand the capacity of existing care services;
- Providing technical assistance and training to build and expand the capacity of health care personnel;
- Integrating care services with current prevention and treatment programs; and
- Using U.S. volunteers.

Basic Health Care and Support, Including End-of-Life Care

Not all people living with HIV/AIDS need anti-retroviral treatment. All do need basic health care and support, however. When ART is not available, or it fails, many will require symptom management, social and emotional support and compassionate end-of-life care. Basic health care and support includes routine monitoring of disease progression, prophylaxis and treatment of opportunistic infections, cancers, and other complications of immune suppression.

Palliative care and support goes beyond the medical management of infectious, neurological, or oncological complications of HIV/AIDS, and addresses symptoms and suffering directly. Building upon definitions of palliative care developed by the U.S. Department of Health and Human Services' Health Resources and Services Administration (HRSA) and WHO, President Bush's Emergency Plan envisions expansion of an intradisciplinary approach to palliative care and support making use of interventions to relieve physical, emotional, practical, and spiritual suffering.

Palliative care that includes basic health care and support, symptom management, and end-of-life care will involve the following elements:

■ Routine clinical monitoring and management of HIV/AIDS complications

- ▶ Opportunistic infection prophylaxis and treatment
- ▶ Management of opportunistic cancers
- ▶ Management of neurological and other diseases associated with HIV/AIDS
- ▶ Symptom diagnosis and relief
- ▶ Social support, including organization of basic necessities such as nutrition, financial assistance, legal aid, housing, and permanency planning

■ End-of-life care

- ▶ Mental health care and support
- ▶ Social support including organization of basic necessities such as nutrition, financial assistance, legal aid, housing, and permanency planning
- ▶ Support for caregivers
- ▶ Bereavement support for family members

Providing technical assistance and training to build and expand the capacity of existing care services

Families and communities are already responding to the needs of those living with HIV/AIDS. Most often these informal caregivers are not adequately trained or supported. Building and expanding these networks by providing targeted technical assistance and education will help to increase their capacity and effectiveness. The Emergency Plan will work with existing health care delivery sites (public and private), hospices, home-based care providers, faith-based facilities, and other points of health care delivery to offer on-site training, technical assistance, and ongoing education for providers.

Providing technical assistance and training to build and expand the capacity of health care personnel

Specific medical and nursing training (focusing on prevention, recognition, and treatment of HIV complications and pain and symptom management) will be especially important to achieve rapid scale-up of basic health care services, including palliative and end-of-life care, for the HIV-infected in target countries. Following local policies, practices, and professional standards, nurses and other health care personnel may be given expanded training to extend the reach of basic health care systems into rural or remote areas. These health care personnel can also train community volunteers and family members in skills needed to provide home care.

Integrating care services with current prevention and treatment programs

Existing prevention and treatment programs offer another opportunity for expanding care, which in turn will strengthen prevention and treatment interventions. President Bush's Emergency Plan will seek to layer care services onto existing prevention and treatment programs by providing additional training for staff. This strategy establishes other important links between services – many who receive symptom management may be able to progress to ARV therapy. Also, palliative and end-of-life care interventions provide unique opportunities to promote prevention messages and should help inform messages used in behavior change programs. For example, involving at-risk youth as volunteers in care programs can help overcome stigma and denial and contribute to behavior change.

Using U.S. Volunteers

U.S. volunteers may provide an additional resource for rapid scale-up of care. A rapid local assessment of skills needed must be undertaken in order to ensure that there is an appropriate and helpful match of talent with need. In the early rapid scale-up phase of

implementation, it is likely specific technical skills in nursing, medicine, social work, palliative care, and pharmacy will be in greatest demand.

2. Build capacity for long-term sustainability of palliative care

As is the case for increasing long-term capacity for ART, increasing the availability of basic health care and support, including end-of-life care, will require a sustained partnership with ministries of health, non-governmental organizations, professional associations, and training institutions. The provision of basic health care and support services, including end-of-life care, must be based upon an adequate supply of professionals – doctors, nurses, social workers, pharmacists, and others. These individuals must be trained and provided with on-going continuing education, in topics relevant to the care of HIV-infected patients. A great deal of attention must be given, therefore, to establishing long-term professional and institutional relationships so that ongoing professional communications and referrals can be supported.

The twinning of U.S.-based institutions with African or Caribbean institutions (or African with Caribbean or African) offers an important means of establishing these types of relationships. The twinning mechanism that is part of the Emergency Plan will allow the creation and support of “centers of excellence” from which training, research, and talent can be diffused throughout the impacted regions. It is this ongoing sustained support for professional excellence that holds the key to increased capacity for care.

Increasing long-term capacity for end-of-life care poses some special problems. End-of-life care is a well-established field in only a few areas of the world. It is only now gaining stature in the United States, and in Africa there are only two academically associated training programs in end-of-life care and only about 40 hospices in all of the focus countries. A strategy that will advance palliative care will involve, therefore, capacity building in African and Caribbean academic training institutions, aggressive in-service training, and continuing education. Partnerships in this regard between the U.S. and other developed nations where end-of-life care is well established may be especially useful. Establishment and support of twinned hospices will also provide support and opportunities for training and technical assistance.

Operational strategies for building long-term sustainability for basic health care and support, including palliative care, include:

- Technical assistance for development of appropriate care protocols;
- Twinning;
- Curriculum change in health professional schools;
- Expansion and integration of hospice services;
- Identifying new public-private partnership opportunities; and
- Provision of essential supplies.

3. Advance policy initiatives that support basic health care and support, including palliative care

Policy reform must begin immediately to establish an environment that is conducive to the implementation of the basic health care and support and palliative care interventions and services described in this strategy. A key priority of the Emergency Plan will be to support implementation of good policies and effective legislation, in concert with national strategies and cognizant of local needs, particularly at the community level.

Strategic approaches will include the following areas:

- Human resources policy reform and development, including the broadening of responsibility for HIV/AIDS clinical care to lower levels of care providers, and policy reforms to recruit and encourage retention of care professionals; and
- Policy reforms to increase availability of pain medications.

Human resources policy reform and development

Focus countries face severe shortages of health care professionals. Devolving care skills and responsibilities to lower levels of care providers, such as nurses and clinic staff, will greatly increase the pool and reach of care providers.

In addition, recruiting doctors, nurses, and other health care professionals from countries with a surplus may be a short-term strategy for increasing the number of care providers in a given country. The Emergency Plan will work with policymakers to support the changes in immigration policy necessary to implement this strategy in the focus countries.

Difficulties in retaining trained health professionals are another common problem in these countries.

Policies to counteract the “brain drain” will be encouraged, as will programs to increase provider job satisfaction. Some of this policy work must be done on a regional basis to counteract cross-border migration of health professionals.

Policy reforms to increase availability of pain medications

People living with HIV/AIDS often need opioids and other analgesics to treat pain and mitigate other symptoms. The Emergency Plan will work with local regulatory authorities to remove barriers to the availability of these medications and to ensure they are used appropriately and not diverted for illicit use.

Specific areas of activity may include:

- ▶ Implementation of policies to expand the use of oral opioids (through, for example, working with community leaders to translate national policy changes into action);
- ▶ Liberalization of laws restricting medicinal use of opioids;
- ▶ Expanding the ability of nurses to dispense pain medication, including opioids, especially in the home setting; and
- ▶ Strengthening of laws to prevent diversion of opioids for illicit purposes.

4. Collect strategic information to monitor and evaluate progress and ensure compliance with Emergency Plan policies and strategies

A strong evidence base will support the Emergency Plan to provide services to relieve suffering. Palliative and related care supports both those who receive and those who do not receive ART. Strategic information to support care must measure both home- and clinic-based activities. Outcomes will be measured through surveillance activities, especially population-based surveys. Provider information on care capacity, training, and services will provide data to monitor the progress of care programs on an ongoing basis. Targeted evaluations will identify best care practices. A management information system will provide the backbone for reporting information.

The goals of providing care to 10 million individuals (palliative care and care for orphans and vulnerable children) over the five-year period will be measured using a variety of service-based statistics, surveys, and special studies. Indicators for measuring Emergency Plan progress toward achievement of care goals will include numbers of individuals served, numbers of

Meeting the Needs of Afflicted Families

Families are the cornerstone of a strong society. Families with children are especially impacted by HIV/AIDS - when parents and children are sick, the ability to cope with the impact of HIV/AIDS is dramatically diminished. President Bush's Emergency Plan will particularly focus on care, treatment, and prevention needs of families with children. Many of these families are, in fact, headed by children because parents are dead or sick. Best practices of community support for these households will be identified and promulgated. Mothers and fathers caring for sick children are likely to be HIV-infected themselves and will be encouraged to be tested and enter into life-sustaining treatment. Home-based care and support programs will be especially targeted to such families in order to do all that is possible to keep them in tact and organizations with particular expertise in family care will be targeted for funding.

persons trained to deliver care, and number of service delivery programs supported.

2. Care for Orphans and Vulnerable Children

Children affected by HIV/AIDS have the same basic needs – economic and food security, education, nutrition, health, and emotional well-being – as other children, but the pandemic's impact is eroding family and community capacity to meet these needs. AIDS is having a negative impact on the education, nutrition, health, economic and food security, and emotional well-being of children, including orphans and other children affected by AIDS. A variety of strategies must be used, depending on local context. Research has shown that resources – financial, human, public services – vary between and within countries. In many places, communities are mobilized and have systems in place to identify, protect, and provide basic necessities to the most vulnerable children. In other places – even in neighboring communities – the response from the community is minimal. Therefore, specific interventions must ultimately be based on identifying and strengthening already existing resources in a manner that does not undermine them. Areas of particular vulnerability in specific locations must be identified and interventions devel-

oped to strengthen existing community initiatives and fill the gaps. The exact mix of services provided and the number of beneficiaries will differ by location, existing resources, and types of vulnerability faced by the children in the intervention area.

Donors, governments, and NGOs should recognize that families, communities, and children themselves are the front-line of response to HIV/AIDS. Traditional community mechanisms for orphan care, in many cases, have been overwhelmed by the sheer numbers of orphans, yet that number is set to rise as high as 25 million by 2010. Thus, developing and strengthening local structures is of primary importance in laying the foundation for future efforts that will support the growing numbers of children affected by HIV/AIDS. Funding and activities must support communities in ways that do not undermine community ownership of interventions or the long-term capacity of communities to respond. Outside assistance should accordingly focus on engaging in long-term partnerships to support, strengthen, and sustain ongoing community initiatives through training and technical assistance, organizational development, and sustained financial and material support.

Two other overarching principles apply in President Bush's Emergency Plan's strategic approach to care for orphans and other vulnerable children. Because targeting specific categories of children can lead to increased stigmatization and discrimination, the Emergency Plan specifically identifies "orphans and other vulnerable children" as beneficiaries of care. Directing program efforts exclusively to children with a parent or parents who have HIV infection or have died of AIDS is both unrealistic and detrimental to those children. In addition, efforts should not focus solely on children whose parent or parents have already died. Long before they become orphans, children experience severe distress as a result of living with – and often caring for – a terminally ill parent. Throughout the world, communities have mobilized and developed systems to identify, prioritize, and care for those who are most vulnerable. These systems, where effective and sustainable, will be supported.

Finally, President Bush's Emergency Plan will seek where possible to support family and community mechanisms as opposed to institutional care. Alternatives to traditional orphanages, such as community-based resource centers, continue to evolve in response to the massive number of orphans left behind by the AIDS epidemic. These centers help families continue to support children within the community, providing support groups, counseling, temporary medical care for HIV-infected children, training in parent-

ing skills, skills training programs for older children, and daycare for parents or foster parents who need relief. They can also prevent children from entering the worst forms of child labor.

In some cases, however, institution-based activities are necessary. For abandoned children or children living on the street, an institution might be the only alternative to death from exposure and starvation. The challenge is to develop better alternatives, such as emergency and long-term foster care and local adoption. In addition, there has been an increase in facility-based palliative care for children living with



HIV/AIDS. Many of these institutions are also reaching out to provide care in local communities.

The Emergency Plan will help build, strengthen, and improve the quality and sustainability of programs to meet the needs of orphans and vulnerable children through rapid scale-up, capacity building, strengthening the enabling environment, and tracking progress and establishing best practices.

1. Rapidly scale up care services for orphans and vulnerable children

Rapid scale-up of services and support systems for orphans and other vulnerable children will rely on improving the quality and expanding the reach of existing responses. Rapid scale-up will be guided by the following operational strategies:

- Strengthening the capacity of families to cope with their problems;
- Mobilizing and strengthening community-based responses;

- Increasing the capacity of children to become proactive in meeting their own needs; and
- Integrating care services with existing prevention and care programs.

Strengthening the capacity of families to cope with their problems

Since the first and most important responses to HIV/AIDS are carried out by affected children, families, and communities, President Bush's Emergency Plan will support projects to increase the capacity of families and communities to provide care and support to children affected by the epidemic. Activities might include training caregivers, increasing access to education, promoting the use of time- and labor-saving technologies, supporting income-generating activities, and connecting children and families to essential health and social services where available.

Mobilizing and strengthening community-based responses

After family, the community is the next safety net for children affected by HIV/AIDS. The Emergency Plan will both provide direct support to community efforts and build the capacity of local NGOs and CBOs to support a greater number of community initiatives. Community support includes providing mentors for emotional support, resources such as food and school-related expenses, household help, child care, and farm labor. Other programs provide children and families with legal assistance to protect property rights and ensure protection from abuse.

Increasing the capacity of children and young people to become proactive in meeting their own needs

Children and adolescents affected by HIV/AIDS are active participants in mitigating the pandemic's impact, moving beyond the role of recipients of assistance. For example, young people are increasingly involved in making home visits to orphans and vulnerable children and helping HIV/AIDS-affected households. Additionally, the Emergency Plan will support initiatives that ensure that children and adolescents stay in school, are trained in vocational skills, and receive adequate nutrition and health services.

Integrating care services with existing prevention and care programs

Programs that focus on care for vulnerable children within the context of services for the greater population of people living with HIV/AIDS can enhance both prevention and care services. For example, adding care components such as access to medicine and food to prevention programs can draw in new populations for HIV/AIDS education. Programs that

support to HIV-positive women and their families, including their children, could be added to HIV/AIDS testing at sites offering PMTCT services. Special programs should also be developed for child victims of sexual exploitations and children working in prostitution.

2. Build capacity for long-term sustainability of care services for orphans and vulnerable children

Given the current disease burden in highly impacted countries, the number of orphans will continue to rise over the next decade. Thus, President Bush's Emergency Plan will pursue the following strategies in building capacity for sustainable quality care programs:

- Strengthening the organizational capacity of community- and faith-based organizations to address the needs of orphans and other vulnerable children;
- Strengthening early interventions with at-risk youth;
- Promoting collaboration and coordination among partners for a long-term response; and
- Identifying new public-private partnership opportunities.

Strengthening the organizational capacity of community- and faith-based organizations to address the needs of orphans and other vulnerable children

Building the organizational capacity of community- and faith-based groups is essential to ensuring long-term availability of care. The Emergency Plan will support activities to improve management skills, including planning, monitoring and evaluation, resource mobilization, and networking.

Strengthening early interventions with at-risk youth

Special efforts are needed to reach those young people, including orphans, who are most vulnerable to early sexual activity and other risky behaviors. These young people who are at highest risk are often hard to reach because they are not enrolled in school, do not attend religious institutions, and do not participate in mainstream youth organizations. Youth who lack parental support are especially vulnerable. President Bush's Emergency Plan will support CBOs, especially faith-based groups, for early outreach and intervention to prevent transactional and survival sex among these extremely vulnerable young people. These local groups will be supported to reach these young people early with HIV education, counseling, and social support to encourage abstinence and other safer behaviors.

Promoting collaboration and coordination among partners for a long-term response

The impact of HIV/AIDS around the world is so large and growing so rapidly that no single government, international organization, or donor can unilaterally make a sufficient difference. Collaborative action is key to mobilizing resources to better address the overwhelming needs that continue to escalate among children in AIDS-affected areas. Programs will be encouraged not only to coordinate their efforts with other stakeholders but to actively work to build collaborative responses to address the problems at scale and unify and expand the response to children and adolescents affected by HIV/AIDS.

Identifying new public-private partnership opportunities

The magnitude of the problems of orphans and vulnerable children will require the active involvement of a large number of new partners and significant leveraging of private sector resources. Industry and labor have long-standing social protection programs that will be mobilized to provide services to orphans and vulnerable children. The Emergency Plan will provide technical assistance to identify and support AIDS-affected youth and adults as candidates for jobs and, through partnerships with businesses, will link candidates to job opportunities with employers seeking to sustain and grow jobs in vulnerable communities. The President's initiative will also actively encourage corporations to provide direct services or seed-funding for community initiatives to help orphans and other vulnerable children. Public-private partnerships will support a number of strategies to mobilize and coordinate community care initiatives, including collaborative efforts of employers to address community problems collectively and industry/labor support for government efforts to provide care to this vulnerable population.

3. Advance policy initiatives that support care for orphans and vulnerable children

President Bush's Emergency Plan will work with government ministries and other organizations in focus countries to support initiatives to institute policy, program, and operational reforms, including reforms to ensure access to basic social services and to create special protection and care measures for children outside families and communities. Activities will promote supportive environments for vulnerable children and include advocacy for basic legal protections, transformation of public perceptions of HIV/AIDS, and strengthened school-based HIV prevention and care programs.

To support the Emergency Plan programs that will meet the needs of millions of orphans and vulnerable children, some critical policy areas must be addressed. These policy areas cover issues related to:

- Inheritances and succession,
- Bereavement among children,
- Child-headed households,
- Access to education and school-related expenses, and
- Protective services (e.g., against abuse, trafficking, child prostitution, and other worst forms of child labor, etc.).

4. Collect strategic information to monitor and evaluate progress and ensure compliance with Emergency Plan policies and strategies

There is a long history of measuring care and support for orphans and vulnerable children. This history will form the basis of measuring progress toward achieving

Emergency Plan goals in support of these children. Measurement will include:

- Population-based surveys of care and support for orphans and vulnerable children;
- Program monitoring of provider capacity and training;
- Targeted evaluations of best practices for outreach to and care for orphans and vulnerable children; and
- Management information systems to strengthen data transmission and storage.

The goal is to provide strategic information to programs, countries, donors, and the U.S. Government to strengthen the accountability and improvement of programs for orphans and vulnerable children. This strategic information strategy will support evaluation of programs on a timely basis, making it possible to discard models that are not working and to identify the best practices that contribute towards the care goals of President Bush's Emergency Plan.

VII. STRENGTHENING BILATERAL HIV/AIDS PROGRAMS

“By the legislation I will sign today, the United States of America will take the side of individuals and groups and governments fighting HIV/AIDS in Africa and other parts of the world. We’ll provide unprecedented resources to the effort. And we will keep our commitment until we have turned the tide against AIDS.”

President George W. Bush, May 27, 2003

In keeping with the United States’ position as the global leader in the fight against HIV/AIDS, President Bush’s Administration provides over 50 percent of bilateral international HIV/AIDS assistance. Through various agencies and departments, the United States has bilateral programs to combat AIDS in over 100 countries, including the focus countries, and is active through diplomatic and public diplomacy channels in dozens more.

Outside of the Emergency Plan’s focus countries, the profile of HIV/AIDS varies widely among nations. Some countries have a high disease burden; others have low incidence of HIV but are witnessing emerging epidemics through rapid increases in infections; and others have low HIV incidence rates but need to remain vigilant. Unfortunately, no country is unaffected by the problem.

These countries have diverse drivers of HIV/AIDS, including epidemics led and compounded by such factors as high-risk sexual behavior, injection drug use, unsafe medical practices, gender inequality, prostitution, and poverty. All have challenges in implementing integrated and effective prevention, treatment, and care strategies. Stigma and denial remain widespread challenges, as does the lack of correct and consistent information about HIV/AIDS. Testing is underutilized, and appropriate protocols and enabling policies are often lacking. The U.S. Government has collected many “lessons learned” over two decades of worldwide HIV/AIDS activity, and it is on the strength of best practices that we embark on an intensified effort in our bilateral HIV/AIDS programs to ensure coordination, effectiveness, and accountability.

The President’s Emergency Plan offers a fresh opportunity to develop and implement consistent HIV/AIDS policies and programs across our bilateral prevention, treatment, and care initiatives, drawing on the U.S. Government’s strong field presence and technical expertise. Our bilateral programs worldwide



will be an integral part of the President’s Emergency Plan for AIDS Relief and will be harmonized in policy and management to create the momentum that will truly turn the tide against HIV/AIDS.

Bilateral Program Objective:

Apply best practices in prevention, treatment, and care, and improve coordination, management, and accountability across all U.S. Government (USG) bilateral HIV/AIDS programs

Bilateral Program Strategies:

1. Strengthen quality and capacity of prevention, treatment, and care programs
2. Advance policy initiatives that support effective bilateral programs
3. Strengthen coordination, management, and accountability of programs, and ensure their consistency with the principles of the Emergency Plan

1. Strengthen quality and capacity of prevention, care, and treatment programs

Integrated prevention, care, and treatment programs are an established best practice. Integrated programs combat stigma, encourage behavior change and testing, and mitigate the consequences of HIV/AIDS. Countries are at different stages of HIV/AIDS response, but all HIV/AIDS programs of the U.S. Government should be working toward establishing a continuum of prevention, treatment, and care programs in proportions appropriate for the host country. Thus, USG efforts will be focused toward increasing the availability of high-quality, sustainable prevention, treatment, and care programs by:

Promoting evidence-based risk elimination and reduction programs

Successful strategies, such as the ABC approach and tailored interventions for high-risk groups like injection drug users, are helping to prevent new HIV infections. These strategies will be promoted across all USG bilateral HIV/AIDS programs.

Promoting strategies to increase testing

Worldwide, it has been estimated that some 95 percent of HIV-infected individuals do not know their status and thus do not have vital information to protect themselves and others. Testing is a crucial behavior change strategy, and new methods for increasing testing will be explored and promoted, including routine testing in health care settings.

Promoting strategies to combat stigma and denial

Stigma and denial remain primary barriers to addressing HIV/AIDS effectively. Programs will address stigma and denial by increasing the involvement of people living with HIV/AIDS, emphasizing the role of leadership, and providing consistent and correct HIV/AIDS information.

Offering technical assistance for the development of appropriate prevention, treatment, and care protocols.

Many countries lack appropriate prevention, treatment, and care protocols, contributing to ineffective and inconsistent program implementation. The U.S. Government will capitalize on its expertise and established best practices to promote and assist with the development of comprehensive national prevention, treatment, and care protocols to guide program development across all governmental and nongovernmental sectors.

Offering technical assistance and training of providers

Limited technical capacity is a barrier to increasing and strengthening prevention, treatment, and care interventions, and to ensuring compliance with established protocols. The focus of the U.S. Government's HIV/AIDS programs, and a necessary tool for ensuring sustainability, is building the capacity of local providers to implement effective programs. USG efforts will have as a priority capacity building of health care workers and CBOs to strengthen the quality and expand the reach of effective HIV/AIDS interventions.

Identifying and developing the capacity of new partners

Worldwide, efforts against HIV/AIDS are amplified through approaches that reach individuals where they live, learn, work, and pray. New partners can expand the reach of programs, fill gaps in service delivery, and contribute additional necessary resources to the fight against HIV/AIDS.

Coordinating with host governments and a wide range of organizations active in country

To be fully effective, USG programs should be coordinated with and complementary to existing programs and the host government's national AIDS strategy. The U.S. Government will work closely with the host government, the private sector, NGOs, FBOs, multilateral institutions, other bilateral donors, and others active in country.

2. Advance policy initiatives that support effective bilateral programs

The ability of programs and populations to address HIV/AIDS and mitigate its consequences are enormously impacted by policies related to the importation, regulation, and registration of essential medicines and supplies; the provision of basic social services such as health and education; and the allocation of resources. The President's Emergency Plan will promote policies reflecting best practices through:

Active diplomacy to advocate for the adoption of supportive policies

Through the U.S. Chief of Mission and U.S. Government representatives in sectors such as education, health, defense, and trade, the U.S. Government will engage with its leadership counterparts in host countries to advocate for the adoption of supportive HIV/AIDS prevention, treatment, and care policies.

Technical assistance for policy development

Drawing on its expertise and worldwide experience, the U.S. Government, through its representatives in the field, will provide technical assistance for the development and application of policies supportive of effective action against HIV/AIDS and its consequences.

3. Strengthen coordination, management, and accountability of programs, and ensure their consistency with the principles of the Emergency Plan

President Bush has placed a strong emphasis on increased accountability for program activities. The USG programs worldwide are currently implemented by a multitude of U.S. Government agencies and departments, each with different management and accountability processes. Programs can be uncoordinated, both with other U.S. Government agency programs and with host governments and other donors, leaving gaps in service delivery and needs unmet. The lack of uniform accountability methods, including program evaluation methodologies, poses difficulties in comparing program impact and ensuring effective and efficient allocation of resources.

President Bush's Emergency Plan will:

Coordinate leadership of U.S. Government bilateral HIV/AIDS programs through the leadership of U.S. Chiefs of Mission

The benefits of coordinated leadership, as demonstrated by the U.S. Global AIDS Coordinator and the U.S. Chief of Mission-led in-country USG teams in the focus countries, should be applied across USG bilateral programs. Government agencies will work as a united team under the leadership of the Chief of Mission, ensuring that programs are working toward shared goals.

Coordinate with host governments and other donors to eliminate duplication and ensure that needs are met

Coordination with host governments and donors will be strengthened. This will allow for more effective communication and evaluation of country-specific needs and circumstances, facilitate the effective and efficient use of funds, and determine and fill gaps in service provision.

Implement uniform standards for strategic information and evaluation

As a unified team implementing a coordinated country plan, all U.S. Government agency activities will be evaluated on their progress toward meeting established goals according to shared indicators that will facilitate the comparison of programs.

Hold U.S. Government programs accountable for results

U.S. Government programs will be funded according to their ability to indicate evidence-based success against specified goals. Improved accountability, in addition to uniform evaluation standards, will facilitate the identification of successful programs for scale-up and poorly performing programs for elimination.

Assist countries in developing their own strategic plans

Following from the coordination of leadership described above, U.S. Government departments and agencies will work with host-country governments to develop coordinated country plans that will identify opportunities to capitalize on the strengths of individual USG agencies and eliminate duplication in program services.

VIII. STRENGTHENING MULTILATERAL ACTIONS

“The United States is committed to working with other nations to reduce suffering and to spare lives. And working together is the key. Only through sustained and focused international cooperation can we address problems so grave and suffering so great.”

President George W. Bush, May 11, 2001

The crisis of global AIDS is too great for any one entity to solve. Turning the tide will require a sustained collaborative effort from a multitude of international, national, and local organizations leveraging their comparative strengths. Not only are there extraordinary resource needs, but the diverse drivers and consequences of the disease, and its many complicated interactions with a variety of other social, political, and economic circumstances, demand an equal number of diverse actors with varied expertise.

President Bush’s Emergency Plan makes an unprecedented commitment of resources and focuses funds on the U.S. Government’s strengths in providing technical assistance, training, research, and material resources to dramatically increase health care infrastructure and capacity to address HIV/AIDS effectively, including providing treatment. The Emergency Plan recognizes, however, that strengthened health care systems are but one powerful tool in combating HIV/AIDS. Many other essential requirements, including such basic needs as clean water and adequate nutrition, present barriers to a successful HIV/AIDS response. Conflict, famine, and gender inequality all make contributions to the spread of HIV and the devastation of AIDS, and must be addressed.

The President’s Emergency Plan commits a significant proportion of its resources to the Global Fund to Fight AIDS, Tuberculosis, and Malaria in recognition of the fact that the Fund is a promising global force in the fight against AIDS and offers important opportunities to address needs complementary to other elements of this strategy. Other multilateral institutions and international organizations, such as UNAIDS and its “Three Ones” principles, WHO and its “3 by 5” initiative, the World Bank, and the World Bank’s International Bank for Reconstruction and Development, have also provided essential global leadership, expertise, and resources, particularly in the areas of advocacy, government and civil society collaboration, HIV/AIDS and economic development,



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and health sector response (including HIV/AIDS surveillance, prevention, treatment, and care). Organizations such as the World Food Program (WFP), the United Nations Children’s Fund (UNICEF), the United Nations Development Program (UNDP), the International Labor Organization (ILO), United Nations Educational, Scientific and Cultural Organization (UNESCO), the United Nations High Commissioner for Refugees (UNHCR), and the International Committee of the Red Cross (ICRC) have HIV/AIDS programs focused on specific needs or populations, such as food security, mothers and children, workplace issues, refugees, migrant workers, and youth.

The contributions of these multilateral institutions and international organizations working with great dedication to combat HIV/AIDS provide a vital opportunity for a comprehensive response. The U.S. Government will strengthen its relationships with multilateral institutions and international organizations to amplify global action against HIV/AIDS by encouraging coordination to fill gaps in current activities and ensure efficient use of funds. Effective collaboration, however, requires addressing several of the

challenges currently facing the international community in its fight against HIV/AIDS.

Duplication of program efforts and an uncoordinated response, especially in the most afflicted nations where so many have initiated programs, must be avoided. Harmonized proposal, surveillance, reporting, and accountability requirements will avoid placing additional burdens on governments already weighed down by the disease burdens of HIV/AIDS, malaria, and tuberculosis. As an international community, donors should commit to promoting best practices and evidence-based interventions and adhere to high standards for resource allocation and management. At the same time, recognizing that HIV/AIDS is a global emergency, donors should ensure that funds are quickly dispersed to organizations effectively serving those in need, with an eye to building local capacity for a sustainable long-term response.

The U.S. Government will use the full range of diplomatic tools to engage international organizations as partners in the fight against HIV/AIDS. Under President Bush's Emergency Plan, efforts will be made to strengthen U.S. participation on governing boards and to consult closely and often with both the leadership and working levels of the multilateral and other international organizations working on HIV/AIDS. Across the world, the United States will coordinate programmatic and diplomatic efforts at the local level in order to enhance the effect of global contributions. Together with the strength of USG bilateral programs, effective multilateral engagement and action will win the war on AIDS.

Multilateral Objective:

Ensure a comprehensive and amplified response to global HIV/AIDS through leadership, engagement, and coordination with multilateral institutions and international organizations

Multilateral Strategies:

1. Coordinating programs to capitalize on the comparative advantage offered by each multilateral organization, including targeting multilateral strengths to unique challenges
2. Working to harmonize proposal, reporting, and strategic information systems across all multilateral and international organizations
3. Promoting evidence-based policies and sound management strategies
4. Encouraging expanded partnerships that build local capacity

1. Coordinating programs to capitalize on the comparative advantage offered by each multilateral organization, including targeting multilateral strengths to unique challenges

True progress against HIV/AIDS will require a comprehensive response that addresses the diverse drivers and consequences of disease. The United States will focus its interventions on health care and human services approaches to HIV/AIDS prevention, treatment, and care that capitalize on its expertise in technical assistance, training, and research. Many multilateral organizations have vital expertise in specific areas. For instance, WHO addresses the health sector to HIV/AIDS and works closely with health ministries. The ILO focuses on HIV/AIDS in the workplace and the rights of workers living with HIV/AIDS, while the WFP focuses on food security and nutritional needs. ICRC and UNHCR are able to reach refugees and displaced persons, while many other organizations focus on improving the status of women. Each of these interventions, and those from other agencies both in and out of the U.N. system, is important to a comprehensive and effective response to global HIV/AIDS, and contributions are amplified when they are coordinated.

The U.S. Government will strongly encourage coordination to fill gaps by:

- Engaging, through the U.S. Global AIDS Coordinator, the leadership of multilateral and international organizations to identify and then complement comparative strengths;
- Encouraging the development of one in-country structure that can facilitate coordination between donors, host governments, people living with HIV/AIDS, and NGOs; and
- Ensuring that U.S. missions, through their networks of public affairs, refugee, economic, health, and development assistance officers and other specialists, are working with their in-country counterparts in the field.

2. Working to harmonize proposal, reporting, and strategic information systems across all multilateral and international organizations

Harmonization of proposal, reporting, surveillance, management, and evaluation procedures across all multilateral and international organizations is a key to the success of global HIV/AIDS efforts. Harmonized procedures both ensure comparability of different programs across countries and decrease the burden on host organizations and governments. The U.S.

SPECIAL FOCUS: The Global Fund

On May 11, 2001, President George W. Bush, flanked by U.N. Secretary-General Kofi Annan and Nigerian President Olusegun Obasanjo, made the first pledge to what would become the Global Fund to Fight AIDS, Tuberculosis, and Malaria. The U.S. Government was a leader in the creation of the Global Fund as the embodiment of a new way of doing business, bringing together diverse partners, including the public and private sectors, donors and recipients, and NGOs and affected communities, to quickly and effectively mobilize resources for combating HIV/AIDS and the other two diseases. The Fund's existence is based on strong public-private partnerships, results-based management, and a focus on local capacity building.

The Global Fund is a private nonprofit foundation based in Switzerland, with a "limited financial partnership" board model that includes a balance between donor and recipient nations. In an arrangement unique among international organizations, the private sector has its own seat and vote, as do private foundations and "northern" and "southern" NGOs. The Fund has the potential to revolutionize the provision of assistance, and the United States is committed to the fulfillment of this vision and the Fund's full potential.

The United States leads the world in donations to the Fund, with \$623 million in contributions to date and has pledged a total of \$1.97 billion from the inception of the Fund through 2008 (with cumulative contributions not to exceed one-third of the total contributions to the Fund from fiscal years 2004 to 2008). The United States accounts for 37 percent of total pledges and 29 percent of contributions to the Fund. Secretary of Health and Human Services Tommy Thompson was elected Chairman of the Fund's Board in January 2003, giving the U.S. Government a special leadership responsibility through January 2005. Secretary Thompson has traveled throughout the world on behalf of the Fund, enlisting and engaging government, private sector, and NGO actors to support the Fund's efforts to combat global AIDS.

Over the next five years, the United States will remain deeply engaged in working to ensure the realization of the Fund's unique potential as an effective actor to combat HIV/AIDS, tuberculosis, and malaria. The United States will:

- Work to ensure the Fund maintains its unique public-private character, with a strong and active board and a secretariat accountable to that board;
- Support projects built on proven best practices that incorporate the principles of results-based management and strong mechanisms of accountability for both in-country and Fund project managers;
- Work to ensure harmonization of reporting, monitoring, and evaluation of projects;
- Work to strengthen mechanisms that increase coordination of the Fund's country activities with those of other donors;
- Continue to strongly support the Fund's mandate of local capacity building of governments, NGOs, and the private sector, with embassy and in-country program support for the Fund to establish such capacity where it does not exist;
- Continue its strong support for the concept of "additionality" for Fund projects, so that the Fund acts in addition to (rather than replaces) local and bilateral HIV/AIDS efforts; and
- Strengthen efforts to coordinate with the Global Fund so that in-country resources are leveraged to ensure that gaps in service are met and overlaps are minimized or eliminated.

Government will actively participate in harmonization efforts with WHO, UNAIDS, the Global Fund, and other multilateral organizations, through the participation of U.S. Government representatives to each of these bodies. Harmonizing multilateral efforts includes engaging all the partners within a given organization to follow through on agreed commitments. The United States will use its bilateral relationships to further and strengthen the U.S.-supported goals of multilateral organizations. Activities include:

- Actively working to ensure that all resolutions and commitments agreed to in the multilateral area are compatible with our bilateral policies;
- Using our bilateral relationships to come up with creative ways to work together to further those goals agreed upon within our common organizations; and
- Working to adopt the same monitoring and evaluation, procurement, and reporting standards to ease the work of recipients.

3. Promoting evidence-based policies and sound management strategies

President Bush's Emergency Plan recognizes that the nature of the HIV/AIDS crisis urges immediate action, yet interventions must reflect sound science and management. The large influx of resources for combating global HIV/AIDS from both bilateral and multilateral donors makes best practices and accountability for use of those funds even more important, particularly to sustain public support for the AIDS effort. The U.S. Government will strive to ensure accountability for its contributions, both through multilateral and bilateral efforts, and will encourage partners to do the same.

To achieve maximum impact against the disease, funds must be targeted to effective interventions. Two decades of HIV/AIDS work have revealed an evidence base on which to begin building effective programs. The United States will work closely with technical organizations such as WHO to determine the best range of options for treatment, prevention, and care, and will promote the adoption of such established best practices across all areas of multilateral action. Specifically, the U.S. Global AIDS Coordinator will:

- Actively work with the Global Fund Secretariat, through the U.S. Executive Director's Office at the World Bank and elsewhere, to ensure a focus on results-based management of HIV/AIDS projects;

- Use the "parallel project review" process mandated by Congress to lead an internal USG review to ensure that all proposals recommended to the Global Fund Board for approval are technically and developmentally sound, demonstrate that added resources will bring results, and meet high programmatic and financial accountability standards;
- Use the programmatic expertise of the Department of Health and Human Services and policy experts at the Department of State, both in the United States and in countries in which the U.S. Government has HIV/AIDS program presence and expertise, to evaluate proposals and their impact potential on the ground;
- Provide guidance to U.S. Government representatives to multilateral organizations on the technical efficacy, need, and management strategies of proposed programming; and
- Collaborate with other donors, including the Global Fund Secretariat, to encourage other nations to undertake a similarly detailed review in countries where they have expertise to ensure the best possible outcome for recommended projects.

4. Encouraging expanded partnerships that build local capacity

The U.S. Government will encourage multilateral organizations to work through local partners and existing mechanisms within the host country's national strategy wherever possible, and, where this is not possible, to make building local capacity a strong priority. Multilateral organizations that serve as in-country implementing partners will also be encouraged to have phase-out goals for a country's "graduation" from the need to rely on outside sources for management or implementation of programs.

Governments, NGOs, and the private sector all have a role to play in this effort. The U.S. Government will work both within multilateral organizations and through embassies to identify and support NGO and private sector providers to participate in partnerships and build their capacity to manage programs at the local level. The U.S. Government will:

- Set an example in capacity building by including "graduation" language in our contracts for bilateral grants with all non-local organizations;

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- Continue to support the Global Fund’s commitment to including similar “exit strategies” in their grant agreements with UNDP and other major multilaterals serving as temporary principal recipients and will work to ensure this goal is achieved; and
 - Facilitate the creation of co-investment strategies with private sector partners and/or local government partners to deliver services that will serve as models for the rest of the world.

IX. IMPLEMENTATION AND MANAGEMENT

“As Global AIDS Coordinator . . . he will coordinate all of our international HIV/AIDS activities for all of our government departments and agencies. He will oversee all resources of this program. And he will work with the faith-based and community groups to get the job done. He will report regularly to Congress on the progress and effectiveness of our efforts.”

President George W. Bush, July 2, 2003

Meeting the challenge of the global AIDS crisis is a monumental task that will require – along with strong leadership and vision – robust and flexible administrative structures. This section describes the Office of the U.S. Global AIDS Coordinator’s organization and implementation strategy for President Bush’s Emergency Plan for AIDS Relief.

The implementation strategy of President Bush’s Emergency Plan is designed to meet the goals he set in his historic State of the Union message of 2003. The U.S. Global AIDS Coordinator’s response must be rapid, effective, and evidence-based, and make efficient and focused use of all relevant government capabilities through coordination, collaboration, and cooperation across U.S. Government agencies. It must also reflect administration policy and statute; respond to the diverse needs of the various communities around the world in which the U.S. Government works; and account for progress toward achieving the President’s goals.

Additionally, as implementation moves forward, a growing number of public and private entities will become active partners in the United States’ fight against global AIDS. This is, in fact, a focus of this initiative – to bring the breadth and depth of American public and private talent to the fore to meet the challenge of global AIDS. Coordination of these activities will pose an ever-increasing challenge and will be taken into account as the Emergency Plan is implemented.

The Office of the U.S. Global AIDS Coordinator will lead an integrated U.S. Government global HIV/AIDS effort; provide a rallying point for private sector, FBO, and NGO efforts; and make necessary decisions and take actions to ensure that policies are harmonious, programs synergistic, and operations efficient and effective. An overarching objective is to create a single coordinated U.S. Government global AIDS response. The U.S. Global AIDS Coordinator



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will lead a unified global projection of U.S. resources and talent to turn the tide against HIV/AIDS.

It is important that a consistent philosophy permeate all activities overseen by the U.S. Global AIDS Coordinator. The strategic guidance outlined at the beginning of this document applies to all U.S. bilateral activities. Across all programs, implementation efforts will follow the President’s vision for the Emergency Plan. They will focus on the urgency of response and the desire to seek new approaches and foster bold leadership. Reliance on evidence-based approaches and accountability, and the recognition that planning and implementation must be based on local conditions and follow the lead of local government, will inform program implementation. Bilateral programs outside of the focus countries will also experience dynamic improvements in their programs and activities as they will specifically benefit from strengthened management, coordination, and best practices identified through focus country activities.

The following sections describe broad categories of implementation and management activities that will drive President Bush’s Emergency Plan.

Coordination

The position of the U.S. Global AIDS Coordinator was specifically mandated to provide coordination and oversight across all U.S. international HIV/AIDS activities, including those run by specific U.S. agencies or through multilateral organizations. Coordination with other stakeholders, including national governments and nongovernmental service providers, is key to the amplified response expected under President Bush's Emergency Plan. The U.S. Global AIDS Coordinator is thus responsible for both internal and external coordination of HIV/AIDS activities.

The U.S. Global AIDS Coordinator: A New Leadership Model

The U.S. Global AIDS Coordinator, Ambassador Randall L. Tobias, was appointed by President Bush and confirmed by the Senate to coordinate and oversee the U.S. global response to HIV/AIDS. Reporting directly to Secretary of State Colin Powell, the U.S. Global AIDS Coordinator will:

- ▶ Lead the U.S. Government's international HIV/AIDS efforts;
- ▶ Ensure program and policy coordination among the relevant USG agencies and departments and nongovernmental organizations, avoiding duplication of effort;
- ▶ Pursue coordination with other countries and international organizations;
- ▶ Resolve policy, program, and funding disputes among the relevant USG agencies and departments;
- ▶ Directly approve all activities of the United States relating to combating HIV/AIDS in 15 focus countries; and
- ▶ Promote program accountability and monitor progress toward meeting the Emergency Plan's goals.

The U.S. Global AIDS Coordinator is particularly aware of the need for the Emergency Plan's programs to be accountable to both the President of the United States and the Congress. Accordingly, the Global AIDS Coordinator is committed to regular communication and consultation about the Emergency Plan's progress and achievements.

Internal Coordination. The Office of the U.S. Global AIDS Coordinator will undertake an ongoing planning, policy development, and program implementation process that involves all relevant U.S. Government departments and agencies and draws on the technical strengths of central and in-country staff. The U.S. Global AIDS Coordinator's office will conduct regular intergovernmental program and policy meetings and will support collaborative planning, implementation, and objective review processes that will involve bringing in-country staff to headquarters for short-term technical exchanges.

Country-specific response teams composed of agency and U.S. Global AIDS Coordinator staff have been organized for the focus countries. These teams provide each U.S. Mission with a consistent, competent, and informed point of contact in the central office and ensure that central office staff are aware of specific issues, situations, and factors that influence implementation in the field.

At the same time, staff will coordinate with U.S. Government agencies or offices that are not specifically involved in HIV/AIDS efforts but promote initiatives supportive of the fight against HIV/AIDS in important additional areas, such as food and other development assistance programs, research activities, and faith-based initiatives.

External Coordination. Coordination with local policies, programs, and strategic plans is crucial to the sustainability of programs and efficient use of resources. Coordination with other donors and contributors is also crucial to combating HIV/AIDS. In order to work smoothly in the target countries, the U.S. Global AIDS Coordinator will task field offices to ensure that donors with significant equities are included in the local planning process. On the multilateral level, the U.S. Global AIDS Coordinator will liaise with representatives in multilateral institutions to avoid conflicts and duplication of efforts. Again, coordination with multilateral institutions and international organizations is intended to mobilize a comprehensive response to global HIV/AIDS that capitalizes on the expertise of various groups.

It is also important that the Coordinator learn from the experiences of others working in this arena. Close proactive liaison with private sector organizations, businesses, and faith-based and other organizations involved in global HIV/AIDS will help to support an environment that strengthens and fosters innovation.

Country Planning

At the core of the implementation strategy is a robust ongoing in-country planning effort. This will begin in the focus countries where the U.S. Global AIDS Coordinator will ask each Chief of Mission to undertake a strategic planning process to develop a five-year plan for strengthening the quality, availability, and sustainability of treatment, prevention, and care services. The planning process will include all relevant USG entities as well as the host-country government, the NGO sector, people living with AIDS, other bilateral and multilateral donors, and additional stakeholders. The plan will identify relevant U.S. Government agencies, existing resources, needs, gaps, partners, programs, objectives, performance measures, staffing, and technical assistance requirements. Coordination will thus be improved and resources best matched to local needs and conditions.

The in-country strategic planning process is critical to the success of the Emergency Plan and will be strongly supported by technical assistance from the Office of the U.S. Global AIDS Coordinator and other federal agencies. Plans will be submitted to the

Limitation on the Use of Funds

PL. 108-25 includes certain restrictions on the use of international HIV/AIDS funds and requires recipients of those funds to have certain policies in place. The Office of the Global AIDS Coordinator is committed to ensuring that the following provisions are incorporated into program implementation efforts:

SEC. 301, Assistance to Combat HIV/AIDS

(e) Limitation.—No funds made available to carry out this Act, or any amendment made by this Act, may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

(f) Limitation.—No funds made available to carry out this Act, or any amendment made by this Act, may be used to provide assistance to any group or organization that does not have a policy explicitly opposing prostitution and sex trafficking.

Coordinator for review, in consultation with field offices, technical experts, and agency officials. Final approval by the Coordinator will ensure consistency with congressional intent, administration policy, and program objectives.

Planning for services is critical in every U.S. mission and for every country, be it a focus country or not. Increasing attention will be directed to non-focus countries in the months and years ahead. Staff in non-focus countries will work with local governments to develop national strategic plans for prevention, treatment, and care. Best practices in the focus countries will be emphasized and technical assistance from USG staff and relevant experts in focus countries will be facilitated by the U.S. Global AIDS Coordinator.

Allocation of Funding

The President's Emergency Plan relies on a variety of funding allocation mechanisms in order to maximize flexibility and encourage innovation while responding to specific country needs.

Allocations by Country. Funding levels for focus countries will be allocated on the basis of five-year strategic plans, and funds will be released upon approval of annual country operational plans by the U.S. Global AIDS Coordinator. The Coordinator will not predetermine annual funding levels agency by agency but will instead consult with the agencies and Chiefs of Mission to determine the optimal mix of U.S. Government agency support appropriate for local conditions, capabilities, and needs. This process will leverage the comparative advantages of various USG organizations, ensure coordination, and stimulate innovation. An annual review will be conducted for other ongoing HIV/AIDS bilateral programs.

Central Funding Mechanisms. Some resources will be disbursed through central office initiatives. Some NGOs have existing capacity to respond quickly and effectively in more than one country, making it more efficient to fund multiple country projects. In other cases, the U.S. Government will seek out organizations that can provide technical assistance and support for activities such as professional training or twinning programs on a regional basis. In both cases, these organizations will be included in local strategic plans and subject to approval by the Chiefs of Mission in the targeted countries so that, if performance is acceptable, they will receive ongoing support through field mechanisms. This process will ensure efficiency as well as policy consistency and coherency.

In the case of central funding mechanisms, the U.S. Global AIDS Coordinator will assign implementation

responsibility to the central office of a U.S. Government agency. In consultation with the Office of the U.S. Global AIDS Coordinator, the agency will solicit proposals, conduct reviews, and award grants, contracts, or cooperative agreements through a transparent competitive process.

Evidence-Based Allocations. The U.S. Global AIDS Coordinator's funding decisions will be evidence-based. A strong monitoring and evaluation function will be established (see chapter X) with the goal of gathering strategic information necessary to allocate resources for maximum impact and ensure accountability to American taxpayers and their congressional representatives. Allocations of funds among and within the focus countries will be based upon performance in reaching treatment, prevention, and care targets. These targets will be derived from the "2-7-10" goals set by President Bush in his 2003 State of the Union address – 2 million people in treatment, 7 million infections prevented, and 10 million people provided with care.

Fiscal Controls

Congress has entrusted the U.S. Global AIDS Coordinator with unprecedented resources to fight global HIV/AIDS. Utilizing existing capabilities and processes within U.S. Government agencies, the U.S. Global AIDS Coordinator has established mechanisms to track funds accurately and control disbursements so that resources will be correctly directed to their intended use and will be deployed rapidly. Careful attention will be paid to distinguish obligations from expenditures in order to make realistic budget projections to fund services for those in need as aggressively as possible.

Communications/Liaison

Transparency in implementation is critical. Over half of all international assistance donated to fight global HIV/AIDS comes from U.S. taxpayers, and they, as well as the people and communities being served, should be able to readily understand how funds are allocated, distributed, and used; what impact they are having; and who is benefiting from them.

Allocation of Funds

In PL. 108-25, the "United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003," Congress provided recommendations for an effective distribution of funds appropriated under the Act and specified out-year allocations.

SEC. 402 SENSE OF CONGRESS

(b)Effective Distribution of HIV/AIDS Funds.—It is the sense of Congress that, of the amounts appropriated pursuant to the authorization of appropriations under section 401 for HIV/AIDS assistance, an effective distribution of such amounts would be—

- (1)55 percent of such amounts for treatment of individuals with HIV/AIDS;
- (2)15 percent of such amounts for palliative care of individuals with HIV/AIDS;
- (3)20 percent of such amounts for HIV/AIDS prevention consistent with section 104A(d) of the Foreign Assistance Act of 1961 (as added by section 301 of this Act), of which such amount at least 33 percent should be expended for abstinence-until-marriage programs; and
- (4)10 percent of such amounts for orphans and vulnerable children.

SEC. 403. ALLOCATION OF FUNDS.

- (a)Therapeutic Medical Care.—For fiscal years 2006 through 2008, not less than 55 percent of the amounts appropriated pursuant to the authorization of appropriations under section 401 for HIV/AIDS assistance for each such fiscal year shall be expended for therapeutic medical care of individuals infected with HIV, of which such amount at least 75 percent should be expended for the purchase and distribution of antiretroviral pharmaceuticals and at least 25 percent should be expended for related care. For fiscal years 2006 through 2008, not less than 33 percent of the amounts appropriated pursuant to the authorization of appropriations under section 401 for HIV/AIDS prevention consistent with section 104A(d) of the Foreign Assistance Act of 1961 (as added by section 301 of this Act) for each such fiscal year shall be expended for abstinence-until-marriage programs.
- (b)Orphans and Vulnerable Children.—For fiscal years 2006 through 2008, not less than 10 percent of the amounts appropriated pursuant to the authorization of appropriations under section 401 for HIV/AIDS assistance for each such fiscal year shall be expended for assistance for orphans and vulnerable children affected by HIV/AIDS, of which such amount at least 50 percent shall be provided through non-profit, non-governmental organizations, including faith-based organizations, that implement programs on the community level.

Communication is therefore another key element of implementation. The U.S. Global AIDS Coordinator will ensure that the public is given timely, accurate, and complete information regarding the President's Emergency Plan for AIDS Relief. A variety of mechanisms, including Web technology, reports to Congress, and media outreach will serve this purpose.

Office of the U.S. Global AIDS Coordinator

With the authority to act internationally, to transfer and allocate funding to executive branch agencies, and to contract with NGOs, including faith- and community-based programs, the U.S. Global AIDS Coordinator has been given the necessary tools to lead a unified, coordinated U.S. Government global AIDS response. As champion of the vision and strategic direction of the President's Emergency Plan, the U.S. Global AIDS Coordinator will also determine resource allocation and program effectiveness.

In broad terms, the Office of the U.S. Global AIDS Coordinator will be organized to provide strategic and policy direction as well as technical and program management to oversee global HIV/AIDS program activities. In addition, the Office of the Coordinator will provide communications, administrative, and diplomatic resources for managing bilateral and multi-lateral activities. Recognizing that the implementation of the Emergency Plan will be carried out largely by other departments and agencies (centrally and in the field), the Office will be a small organization focused on leadership, coordination, learning, and oversight, and will strive to remain flexible and innovative in its approaches.

Functions of the Office of the U.S. Global AIDS Coordinator

The Office of the Global AIDS Coordinator is organized and will be staffed to lead the implementation of President Bush's Emergency Plan for AIDS Relief. The Office is organized into units of specialized function as follows:

- ▶ The *Leadership* of the Office is responsible for overseeing all activities and ensuring that the programs and activities of the Emergency Plan are accountable to the President and the Congress.
- ▶ The *Program Services* unit is responsible for development and compliance monitoring of implementation plans for each of the Emergency Plan's focus countries. This unit will also serve as a technical and clinical support resource for the focus countries and all other activities conducted by the U.S. Global AIDS Coordinator. It

will also serve as a technical resource for human capacity development activities and will develop, implement, and monitor programs that respond to training needs.

- ▶ The *Strategic Information and Evaluation* unit will be responsible for gathering the information necessary to ensure that Emergency Plan goals are reached and that those goals have the expected impact. This unit will work with the international community to harmonize strategic information collection and will also serve as a liaison to the research community as well as the research and information components of implementing agencies.
- ▶ The *Management Services* unit will provide operational support to the Office and will track the disbursement of program funds.
- ▶ The *Diplomatic Liaison* unit is responsible for strategic planning and activities to foster leadership and develop a coordinated international response on HIV/AIDS by working with international institutions, foreign governments, NGOs, and others.
- ▶ The *Government and Public Liaison* unit will have the responsibilities of responding to congressional requests for data and information and communicating policy to Congress. It will prepare congressional reports and compliance documents. It serves as the technical resource for the U. S. Global AIDS Coordinator on budget and appropriations issues. The unit is also responsible for developing the annual budget and will serve as the liaison to the White House and to administration departments and agencies and their budget offices.
- ▶ The *Public Affairs and Communications* unit will plan and implement domestic and foreign communications in support of Emergency Plan activities and will conduct outreach activities to promote involvement of various public and private organizations that could be beneficial in the fight against HIV/AIDS.

X. SUPPORTIVE INTERVENTIONS FOR U.S. GOVERNMENT PROGRAMS

“It’s more than money we bring, we bring expertise and compassion and love and the desire to develop a comprehensive system . . .”

President George W. Bush, April 29, 2003

Interventions that support implementation of the President Bush’s Emergency Plan will include an effective and accountable supply chain; a strong research program to provide the evidence base necessary to guide policies and programs, including a coordinated strategic information system; and enhanced public-private partnerships.

Supply chain management is critical to ensure the delivery of essential drugs, supplies, and equipment that make HIV/AIDS programs possible. Under the Emergency Plan, attention will be focused on supporting a secure and sustainable supply chain management system that is reliable and coordinated with complementary programs, such as donated ARV drug programs. Efforts will also be targeted toward reducing and eliminating diversion, counterfeiting, and the sale of HIV/AIDS products and supplies on the black market.

A robust evidence base is needed to direct the Emergency Plan’s treatment, prevention, and care programs. A strong research program will both provide new knowledge (e.g., more effective ARV therapy or discovery of effective prevention methodologies) as well as give direction to policy and program decisions (operational studies). Moreover, by strengthening linkages between the research community and the Emergency Plan, implementation successes and failures can inform future research agendas. A second set of evidence will be collected through a strategic information system that will track programs to ensure that they are meeting targets (monitoring) and that activities have measurable impact (evaluation). Best practices for HIV/AIDS treatment, prevention, and care will be identified through both of these processes.

Public-private partnerships will mobilize private sector resources to build sustainable systems of HIV/AIDS treatment, prevention, and care. The comparative advantages of these partnerships will be maximized to



White House Photo Office

complement the services provided by the public and NGO/FBO sectors.

1. Supply Chain Management

Comprehensive HIV/AIDS programs require a large number of products. Effective supply management is critical to the delivery of these products. To ensure sustainability of HIV/AIDS programs, essential supply chain management personnel will be trained and health logistics systems strengthened. Efforts will need to be taken to minimize drug diversion, counterfeiting, and waste, with a special focus on ARVs, given the high cost of these drugs and the risk of drug resistance if they are administered inappropriately. Opioids also need similar strong management to avoid diversion and misuse. President Bush’s Emergency Plan will coordinate with other donors so that supply chain synergies are maximized and gaps in distribution systems minimized.

Currently, the U.S. pharmaceutical industry estimates the cost of distribution from manufacturer to retailer to be about 20 to 25 percent of the drug’s retail cost. The Office of the U.S. Global AIDS Coordinator

anticipates investing a comparable percentage of product costs for supply chain management.

Supply Chain Management Objective:

Create, enhance, and promote an uninterrupted supply of high-quality, low-cost products that flow through an accountable system

Supply Chain Management Strategies:

1. Rapidly scale up supply chain management to support HIV/AIDS treatment, prevention, and care
2. Build capacity for long-term sustainable procurement and distribution
3. Ensure quality control of drugs, test kits, and other supplies
4. Focus on intellectual property law at international and national levels

1. Rapidly scale up supply chain management to support HIV/AIDS treatment, prevention, and care

The development and implementation of logistics systems to manage the increased volume of products and supplies for the full continuum of care will require both short- and long-term strategies. The focus of all strategies will be on procuring and delivering a continuous and secure supply of high-quality products to patients who need them at all levels of the health system. In the short term, the approach will require a combination of outsourcing some logistics functions to the private sector, rapidly building a vertical distribution and information management system with external technical assistance, and improving the storage conditions, distribution networks, and human capacity skills at sites providing HIV care and treatment.

In most countries, the sharp increase in the volume of products provided through President Bush's Emergency Plan, and other new sources such as the Global Fund, will probably challenge existing national supply systems. To ensure product supply and quality, the Emergency Plan will explore options to enhance the immediate performance of national logistics systems, including:

- Centralizing or pooling procurement mechanisms at global or regional levels;
- Outsourcing transportation to secure courier services or purchases of dedicated vehicles for the delivery of ARVs, other drugs, and other essential products (e.g., palliative care supplies);

- Designing user-friendly, timely, and accurate methods of logistics data capture, collection, analysis, and feedback for resupply and forecasting;
- Selecting products and improving packaging to support patient adherence;
- Providing skilled individuals to perform logistics management functions; and
- Improving secure storage space and inventory management systems.

Key to success will be the seamless collaboration between the supply chain managers and program service managers. Overall program impact will be ensured through coordination of patient enrollment, product availability, and service capacity. Collaboration with other donors and stakeholders is also imperative. For example, a logistics system that manages products procured under the Emergency Plan may be able to take on management of similar products funded through other sources, such as the Global Fund or the World Bank's Multi-Country HIV/AIDS Program for Africa (MAP), in addition to existing donor basket funds and direct product donations. President Bush's Emergency Plan will work to facilitate the development of national coordinating bodies to manage donor financial and product/supply commitments, develop medium-term procurement plans, and track actual funds and products received. The coordinating body will promote a synergistic approach to donor inputs to avoid duplication of investment and waste of resources.

2. Build capacity for long-term sustainable procurement and distribution

President Bush's Emergency Plan will build on lessons learned through other public health programs, such as those that manage essential drug, immunization, family planning, and child survival initiatives. To improve program effectiveness, procurement and supply management considerations will be built into program design and implementation. The Emergency Plan will provide technical assistance and training to strengthen procurement and distribution systems in the areas of:

- Product selection, and
- Distribution.

Product selection

Products identified for procurement must be compatible with national essential drug lists, testing policies, treatment protocols, and product registration proce-

dures. The development of safe and effective fixed-dose combination (FDC) antiretroviral medications is a goal the Administration supports, and to that end the U.S. Government is cosponsoring, with WHO, UNAIDS, and the Southern Africa Development Community, an international scientific conference in the spring of 2004 to produce an international consensus document that will set out principles that need to be taken into account when considering FDC drug products. The document will contain definitions of terms and set out principles that relate to the safety, quality, effectiveness, and ongoing quality assurance for these products. It will deal with such issues as bioequivalence, bioavailability, and stability, as well as how drug regulatory authorities should approach reviews of these products. The document will not issue guidelines or regulatory guidance, nor will it deal with procurement, clinical issues, blister packs, or compliance – only technical and scientific issues.

Distribution

President Bush's Emergency Plan will address in-country distribution by focusing on building local capacity to negotiate, purchase, manage, and supply goods. This will be accomplished by improving coordination among donors, developing and applying logistics management information systems, building the local capacity of human resources, strengthening customs processes, improving storage facilities and practices, enhancing transportation systems, and preventing diversion of products into commercial or black markets.

3. Ensure quality control of drugs, test kits, and other supplies

Under the Emergency Plan, products of the highest quality will be purchased at the lowest price. Ensuring high quality is absolutely essential for HIV/AIDS drugs, test kits, and other supplies. Therefore, products will be procured from reliable manufacturers to ensure product safety and efficacy. The Emergency Plan will enhance in-country capacity to perform quality-testing procedures and, where appropriate, will support the development of regional testing facilities to ensure product quality.

4. Focus on intellectual property law at international and national levels

Through President Bush's Emergency Plan, the Office of the U.S. Global AIDS Coordinator is eager to work with all parties who are interested in contributing to this important effort to combat the global HIV/AIDS epidemic by ensuring that high-quality affordable drugs are available to those in need of them.

Within this context, Emergency Plan funds used to purchase products will be directed to obtaining high-quality goods at the lowest possible price. This could mean bioequivalent versions of branded ARV and other medications. Voluntary differential pricing already exists, and there is no evidence that the market is not working or that companies are preparing to rescind their preferential pricing offers for poor countries. Major research-based companies are responding to the evolution of a market in the developing world to bid competitively, even beating per-patient generic prices in some markets in the developing world, and these companies are encouraged to compete for tenders that will use Emergency Plan funds. Brand-name companies have also done an exemplary job of donating their products to roll out treatment and care for patients with HIV/AIDS. Public-private partnerships (like the Merck/Gates Foundation/Harvard collaboration in Botswana or the Global Alliance for Vaccines and Immunization) are providing drugs and vaccines at no or very low cost in many places in the developing world. Voluntary out-licensing proposals to encourage market competition in the production of pharmaceuticals, such as Pharmacia's arrangement with the International Dispensary Association in the Netherlands for manufacturing one of its AIDS drugs in the developing world, are potential models as well.

Grantees will be expected to follow national laws in the countries in which they will be operating and to respect applicable international obligations regarding intellectual property. All procurement under the Emergency Plan will have to fit within the parameters of existing federal and international law for the protection of intellectual property rights.

There is a need for balance between the needs of poor countries without the resources to produce or pay for cutting-edge pharmaceuticals and the need to ensure that the patent rights system, which provides the incentives for continued development and creation of new lifesaving and life-extending drugs, is promoted. Because a high percentage of all new medicines are invented in the United States, the new medicines that will solve the health problems both of today and tomorrow will likely come from U.S. companies. In this regard, intellectual property rights are not the problem but a part of the solution – they provide the incentive for innovation in creating new medicines, including vaccines, and private enterprises are the principal entities that bring new health technologies to market.

The United States supports the decision of the General Council of the World Trade Organization (WTO) on August 30, 2003, regarding the implemen-

tation of Paragraph 6 of the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) and Public Health. This decision represents an expeditious solution to the difficulties that developing-country WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of the flexibilities contained in the TRIPS Agreement.

The United States expects that all countries will cooperate to ensure that the drugs and active ingredients produced under the terms of the Paragraph 6 solution – as well as other drugs sold or donated in developing countries – are not diverted from countries in need to wealthier markets. There is also insufficient government action in many developing countries to prevent the marketing, sale, and use of substandard and counterfeit drugs, some of which find their way back to developed markets. In the last year, police and drug regulators have discovered crime rings that were diverting donated or reduced-price AIDS drugs from developing nations and selling them in Europe. European nations also are experiencing growing problems with counterfeit or substandard medicines imported from Africa and Asia, and counterfeit AIDS medications have begun to circulate in Africa as well.

Tariffs and duties on pharmaceuticals pose another problem. These are barriers that can be important elements in increasing the cost of drugs in developing countries and work at cross-purposes with initiatives that NGOs, governments, and industry are undertaking to improve access to medicines.

2. Evidence-Based Programs

Policy and program decisions for the President's Emergency Plan will be evidence-based. The evidence needed includes:

- **Research:** The U.S. Global AIDS Coordinator's Office will bring together publicly and privately supported projects to inform the evidence base of President Bush's Emergency Plan; will work to ensure the highest scientific and ethical standards in research; and will communicate scientific findings in transparent and useful ways.
- **Strategic information:** Strategic information systems will address questions such as: "Are federal agencies and partners meeting targets?" and "What is the impact of actions taken?"

Research

Research important to the Emergency Plan can be broadly divided into two parts: (1) research to pro-

duce new knowledge, and (2) targeted research to support the programs and policies of the initiative.

Basic, clinical, social science, translational, and operational clinical research will be supported through the Department of Health and Human Services' National Institutes of Health (HHS/NIH) and will follow the HHS/NIH Office of AIDS Research (OAR) annual strategic plan for HIV/AIDS research as described in appendix H. The HHS/NIH annual AIDS research strategic plan addresses the following research areas: natural history and epidemiology, etiology and pathogenesis, therapeutics, vaccines, behavioral modification research, microbicides, HIV prevention, women and girls, training and infrastructure, and information dissemination, as well as a component devoted to international AIDS research. Similarly, the U.S. Agency for International Development (USAID) will continue to support applied and operational research as well as focused activities on vaccines and microbicides, as described in appendix I. Although HHS and USAID research activities will generally not be funded through the Emergency Plan, the U.S. Global AIDS Coordinator will work closely with both HHS and USAID leadership to make sure that goals and needs of the Emergency Plan are supported by these research priorities. These collaborative efforts will also work to rapidly translate research into practice in the initiative's activities.

The many programs and activities undertaken to reach the goals of the President's Emergency Plan will require a certain amount of targeted evaluation and research that addresses special circumstances in the diverse settings of the focus countries. New approaches to prevention, treatment, and care must be rigorously analyzed as to their relative merit and effectiveness. Clinical decision-making will require studies to determine optimal treatment in diverse settings and conditions. While some of these studies will fall under the mandate of HHS or other departments, others may not. In these cases, the Office of the U.S. Global AIDS Coordinator, in consultation with HHS, the U.S. Agency for International Development, the Department of Defense, and other partners and interested parties, may need to fund a program of special studies. The agenda for these special studies includes developing clinical guidelines, addressing optimal program and policy formulation, seeking solutions to barriers to care, and conducting other studies to assist programs in meeting the goals of the President's Emergency Plan.

Finally, global research capacity is a key component of sophisticated health systems development. The NIH research agenda, by developing research capacity in

the focus countries and around the world, will enhance clinical care in those countries. At the pinnacle of health systems networks are research institutions that will be able to work with NIH and other international research organizations. This research capacity will, in turn, help support achievement of national HIV/AIDS strategies as well as programmatic efforts to meet the goals of President Bush's Emergency Plan.

Strategic Information

Strategic information for the President's Emergency Plan for AIDS Relief is the systematic collection, analysis, and dissemination of information about reaching the Emergency Plan's objectives, as well as the related programmatic activities funded to reach these goals. It includes surveillance, monitoring, and evaluation of HIV programs supported by the U.S. Government and is essential to meet legislated goals and program objectives and to inform the public and their representatives in Congress.

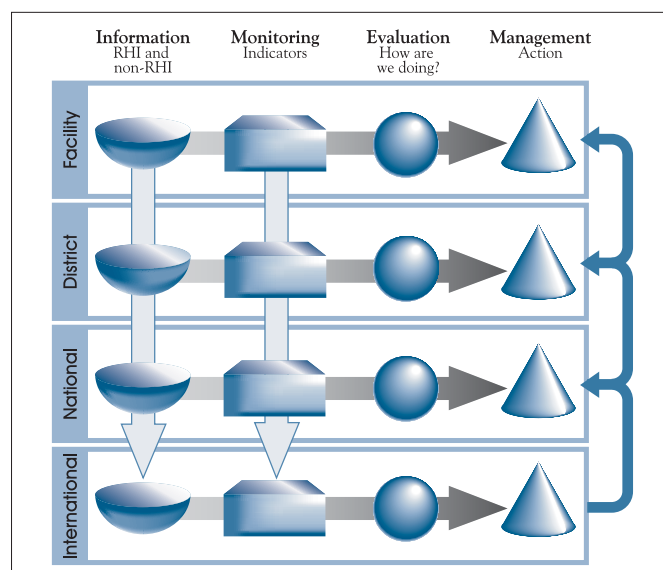
We plan, through strategic information, to:

- Provide assistance to countries in the collection of core indicators (some of which rely on facility-based information) for the timely production of monitoring and evaluation reports based on these data. Core indicators will include outcome indicators addressing the Emergency Plan's "2-7-10" goals of 2 million people treated, 7 million infections prevented, and 10 million persons provided with care. Program progress indicators include numbers of facilities supported, numbers of practicing professionals and community workers trained, and numbers of clients reached through prevention, treatment, and care interventions.
- Develop and improve capacity to collect client-level and clinical service and surveillance information that will assist in daily management of individual patient care, and to evaluate and routinely report on the quality and outcomes of that care.
- Develop and improve capacity to collect facility- and district-level information that will assist clinic and program management, such as targeted prevention activities and HIV testing and counseling.
- Supplement the periodic collection of information with targeted evaluation studies that address program effectiveness, the feasibility of different intervention technologies, and improved surveillance methods.

- Design country-appropriate HIV management information systems (MIS) that integrate separate HIV information systems, including patient care management, facility and program management, laboratory reporting, logistics management, and routine reporting of indicators to the national level and to the U.S. Government.
- Integrate HIV/AIDS facility-based MIS into broader regional or national health information systems to support the provision of holistic and continuous care and to reduce the duplication and burden of data collection and reporting within the facilities.

In order to build sustainable management systems over the long term, the strategic information system must take into account the broader health care delivery system in which it will be implemented. A facility-based MIS structure should permit generation of the necessary strategic information for rational decision-making at each level of the health system, from the facility to national and donor levels. As seen below, each user requires reliable and timely information to support its own set of management functions. These functions include individual patient care management, facility management, and health program management at district, national, and international levels.

The first step in the long-term development of strategic information for HIV/AIDS facility-based interventions will be to define management functions at each level, starting with the patient/client level. This process will ultimately make it easier to identify the information required at each management level for decision support. Basic data elements (e.g., the number of new clients served) should not be lost as they are reported "up." However, indicators and analysis of the information may differ at each level. Core indica-



tors focus mainly on program management functions at district, national, and international levels. Health facilities require a different set of indicators for patient and facility management.

At the level of the U.S. Global AIDS Coordinator's Office, USG country offices will report critical indicators into one U.S. Government reporting system that is transparent, communicates with other international donors, and provides access for the public to program information. Initial reporting will be on a semiannual basis.

This system will need to be built from the ground up. Existing facility-based health information systems in most countries are unable to provide the information support needed to manage a broad range of health system interventions. Some of the main reasons for this are inadequate financial and human resources; irrelevance and consequentially poor data quality collected at the facility level; centralization and/or fragmentation of information system management; and poor health information system infrastructure. Experience in several countries in the last two decades has shown that decentralization of information management is an effective strategy to improve facility-based management information systems. To support this approach we will need to adapt information needs to the specific management functions at each level, produce high-quality information in a timely fashion, and ensure sufficient health information resources and careful management of the system.

To measure the "2-7-10" goals of President Bush's Emergency Plan, surveillance and program reporting systems will need to indicate (1) the total number of clients reached with ART (including through PMTCT initiatives); (2) the total number of clients receiving care and support services, including TB/HIV clinical care and palliative care through home- or community-based programs; and (3) the total number of orphans and vulnerable children reached with care and support. The number of infections prevented will be determined through modeling techniques using both antenatal surveillance clinical information and behavioral surveillance data. Appendix G presents the Emergency Plan's program-level monitoring framework.

The strategic information underlying the President's Emergency Plan will not be accomplished by U.S. Government efforts alone. It will build upon international strategic information efforts to harmonize informational measures, provide monitoring and evaluation training in affected countries, and share gathered data. Both WHO and UNAIDS have

formed donor coordinating groups for strategic information that address surveillance, monitoring and evaluation, and MIS. The United States will actively participate in these groups beginning with adoption of the WHO and UNAIDS guidelines on the construction of core HIV indicators. In consultation with the World Bank and the Global Fund, the Emergency Plan will ensure that informational data collection by donors is aligned in targeted countries to minimize the burden of information collection and to maximize the focus on HIV prevention, treatment, and care.

The task of health information system reform is both formidable and complex, particularly in the context of developing countries. The Office of the U.S. Global AIDS Coordinator will provide the leadership, consensus building, and commitment at the U.S. Government level to implement the health information restructuring that is needed to measure progress under the President's Emergency Plan.

3. Public-Private Partnerships

President Bush believes that public-private partnerships offer a unique and sustainable opportunity for the provision of quality HIV/AIDS services with wide reach, as they combine the strengths of government, business, and civil society. Private sector innovations, resources, and expertise are essential to the battle against HIV/AIDS, which has strained government and civil society responses.

As one example of the power and reach of public-private partnerships, innovations in the workplace can have broad impacts on families, communities, and the entire socioeconomic fabric of a country. An estimated 26 million people – more than 60 percent – of the 40 million living with HIV/AIDS are workers between the ages of 15 and 49, the most economically active segment of society and the mainstay of families, communities, enterprises, and national economies. UNAIDS projects that high-prevalence countries will see their workforces decrease by 10 to 34 percent as a result of AIDS by 2015 and that gross domestic product in the hardest-hit countries may decline by as much as 8 percent by 2010.

The primary vehicle for protecting the workforce is the workplace. Workplaces, ranging from small businesses to multinational corporations, provide regular access to workers, and by extension, their families and communities. Experience in Africa and the Caribbean has shown that workplace-related programs are often the only source of prevention, treatment, and care services for workers, their families, and their communities, and that combating stigma and discrimination

in the workplace is essential to increasing the utilization of HIV/AIDS services. In some cases, multinational companies operating in Africa and the Caribbean have been the first to introduce HIV/AIDS programs and policies and have set standards for the community at large, serving as models for the development of national strategies. President Bush's Emergency Plan will coordinate with private corporations to provide HIV/AIDS services to community members through corporate health facilities.

The capacity of the private sector to reach broad sections of the population through workplaces and information campaigns can promote a supportive culture throughout the community for defeating HIV/AIDS. In addition, public-private partnerships such as twinning of private sector technical expertise with groups developing HIV/AIDS programs can play a crucial role in rapidly scaling up quality HIV/AIDS services.

Public-private partners share risks and accomplishments, as well as resources, including finances, infrastructure, information, and people to achieve a common goal. Private sector initiatives contribute resources outside of the traditional health infrastructure and are critical for creating the social, cultural, and political environment that will enable the achievement of Emergency Plan goals.

Public-Private Partnerships Objective:

Foster public-private partnerships and provide support for the development of HIV/AIDS initiatives that complement the treatment, prevention, and care goals of the Emergency Plan for AIDS Relief

Public-Private Partnerships Strategies:

- Encouragement for the establishment and strengthening of public-private partnerships at the international, national, and enterprise levels to strengthen HIV/AIDS initiatives

- Mobilization of private sector resources for HIV/AIDS programs, including pooling of resources to gain economies of scale
- Creation of an enabling environment for the private sector to contribute their respective core competencies to the development of national AIDS strategies
- Inclusion of private sector representatives (including experts on child labor) on country assessment and planning teams
- Identification of workplace facilities/resources for inclusion in clinical capacity building through the health network model
- Provision of technical assistance to move existing workplace programs into the community at large, strengthening the sustainability of public programs and coverage of women
- Creation of synergies to meld private sector initiatives with broader national, regional, sectoral, and civil society efforts already underway

XI. APPENDICES

Appendix A: Human Resources Capacity

In sub-Saharan Africa, the Caribbean, and many other parts of the world inadequate human resource and training policies and weak institutions contribute to the insufficient supply of health care workers. In Kenya, for example, the Medical Association has more than 5,000 registered doctors but only 600 work in public hospitals, and the government in 2001 received only eight applications for 100 advertised vacancies. The weak labor supply throughout the region is further adversely affected by the emigration of trained and skilled health care personnel (see “Brain Drain” section below). There is thus an urgent need to increase health sector human resources, especially skilled health workers such as physicians, nurses, pharmacists, and managers to address HIV/AIDS. Although not specifically addressed here, efforts must also be undertaken to remedy the lack of personnel with clerical, data entry, and administrative skills necessary to run effective programs.

Increasing and developing human resources has both short-term and long-term strategies. Professional training, especially of physicians, takes years. Investments in schools made today may, therefore, not have a measurable impact for some time. In the shorter term, providing HIV/AIDS specific training to already practicing professionals can be of great benefit.

There is also an immediate for workers to provide counseling and testing, antiretroviral therapy (ART), and other treatment and care services. These will be developed by recruiting and training community health workers, foreign volunteer health professionals, and short-term in-country training of medical staffs.

Volunteer doctors, nurses, pharmacists, and other health care workers from the United States will be recruited and deployed as a key component of our short-term strategy to meet the human capacity needs for HIV/AIDS treatment. There are a large number of mechanisms, both public (Peace Corps, Freedom Corps, Crisis Corps, and various DHHS mechanisms) and private, by which such volunteers can be identified and supported. The Office of the U.S. Global AIDS Coordinator will undertake a systematic review of these options and, in consultation with host countries, ministries of health, nongovernmental organizations, Congress, and others develop an approach to deployment of volunteers that is effective, efficient,

and driven by the needs and priorities identified in the field.

The twinning of U.S. with foreign institutions will allow for multifaceted exchanges of personnel and volunteers. Curricula can be exchanged and technical assistance and expertise provided. These activities can be expected to be of great benefit to the U.S. institutions as well as foreign. Many innovative approaches to HIV/AIDS care, treatment, and prevention developed in Africa, the Caribbean, and elsewhere in the world can and should be adapted for use in the United States.

President Bush’s Emergency Plan will also support local and national efforts to broaden responsibility for treatment, care, and support, possibly including nurses, paramedics, lay counselors, and health volunteers. Community workers have been used to extend the medical system for successful provision of ART in some resource-poor settings. Community workers, volunteers, and family members have been trained to dispense drugs, note occurrence of signs and symptoms of disease, note drug reactions, and refer to higher levels of care. This strategy is essential in countries where the number of trained health care workers is limited. Efforts will focus on determining the tasks that must be completed in order to deliver quality ART (e.g., diagnosis, prescribing, counseling, monitoring adherence, follow-up) and identifying and training the appropriate people to undertake these functions, with a focus on expanding ART services to the greatest number possible while maintaining quality standards. To further extend treatment services into the community, President Bush’s Emergency Plan will also explore options to involve traditional healers and birth attendants, by training them to recognize HIV complications, provide basic home-based care, communicate key messages, and refer patients to appropriate health care.

1. Training

Short-term training of existing health care professionals will build capacity. This can be accomplished through training exchanges as part of twinning programs. Training can also be provided by clinical experts who visit facilities in the focus countries for days, weeks, or months to provide lectures and clinical oversight. Finally, telemedicine can provide case management support to clinicians, and distance education can address short-term training needs. Training must include both didactic as well as clinical experiences. Care must be taken to establish procedures for supervision of staff and regular monitoring of service quality. These short-term training exercises will be

focused on skills-building, not diploma- or credential-building.

Long-term human resource needs must be included in national strategic planning of each country. Increasing the quality and number of graduates from health care professional schools will be necessary. Capacity building in health care training will include curriculum development, creation of faculty and student exchange programs, and development of a comprehensive plan for long-term human resource needs. Training curricula at all medical, nursing, dental, pharmacy, and public health schools need to be reviewed and revised to incorporate the latest information on HIV/AIDS prevention, care (including palliative care), and treatment. Developing and adopting relevant, applicable training programs can help minimize the difficulties and frustrations experienced by health care professionals working in resource-poor environments. In-service training and lifelong learning opportunities with emphasis on linkages between the learner's practical work experience and primary health care can help attract and retain workers.

Programs are also increasingly forging relationships with associations and groups of people living with HIV/AIDS to train their members to provide patient education, adherence counseling, and patient follow-up in order to free clinical staff to perform higher-level tasks. Given the enormous human resource constraints, it will be critical to give greater responsibility, through training and supervision, to greater numbers of health and human services workers in order to achieve treatment, prevention, and care goals.

2. Recruitment and retention

In general, the ratios of health personnel to population in Africa are very low compared to those of other developing countries. Few African countries meet the WHO "Health for All" standard of one doctor per 5,000 population. In the late 1990s, the Emergency Plan focus countries of Côte d'Ivoire, Ethiopia, Mozambique, Rwanda, Tanzania, Uganda, and Zambia all had a ratio of one doctor per 10,000 people or more. The current ratio in Uganda is only one doctor per 24,700 people. Comparable countries like Bolivia, Honduras, and India, have one doctor for every 2,000 to 3,000 people. The ratio of nurses to population is also very low in sub-Saharan Africa - in Uganda, for example, it is one nurse per 5,000 people.

Labor supply in health sectors is thus a major concern to program policymakers and planners. The "brain drain" of medical and health professionals to developed countries is overwhelming and a major contributing factor to the low health

worker-to-population ratios. Practical strategies are needed to recruit and retain health professionals, ensure well-trained workforces, and prevent the brain drain emigration of health workers.

Domestic conditions can be improved by providing incentives and creating policies that reduce workforce attrition and attract medical professionals to return from affluent countries. More effective human resource management may involve going beyond the narrow issues of salary and training to consider broader incentives and systems for encouraging and managing good performance. For example, Thailand and Ireland have reversed their brain drain through programs that offer generous research funding and monetary incentives as well as improved benefits and assistance. Sub-Saharan African countries similarly need to address structural, political, and economic problems that lead to brain drain. Host-government actions might include increasing salaries for health professionals, permitting health professionals in the public sector to do some private practice, providing educational benefits for their children, and providing house mortgages and car loans at low interest rates.

Practice conditions will improve as infrastructure and institutional capacity are developed, creating a stimulating environment for professional growth. Agreements should be sought with developed countries to ensure that donor-funded programs do not offer exceptionally high salaries. Bilateral and international agreements about recruiting processes that minimize adverse effects on health care in exporting countries are also needed. The Pan American Health Organization, for example, is developing a program of managed migration of nurses in the Caribbean, traditionally a major source of employees for foreign recruiters.

While the focus countries all have health care human resource shortages, some countries (Uruguay, for example) have a surplus. Recruitment of health care professionals from countries with a surplus of human resources may be a useful strategy for some countries. This recruitment will require changes in immigration and licensure policies in some of the countries. President Bush's Emergency Plan will address these issues of policy reform and locating and recruiting doctors, nurses, pharmacists, and other trained health care professionals.

3. The "brain drain" of health care human resources from sub-Saharan Africa and the Caribbean

The already inadequate supply of health care workers in sub-Saharan Africa and the Caribbean is further

affected by the “brain drain” of trained medical and public health personnel to industrialized countries. Although “brain drain” emigration is not a new phenomenon, the growing number of health workers leaving sub-Saharan African countries exacerbates the shortage of health care personnel to fight the HIV/AIDS pandemic.

The effects of brain drain are abundantly clear. In Zimbabwe, only 360 of 1,200 doctors trained in the 1990s are practicing domestically. Information from South African medical schools suggests that one-third to one-half of their graduates emigrate to developed countries, mainly Canada, the United Kingdom, and New Zealand. WHO estimates that Zambia’s health system needs 1,500 doctors but there are only about 800 doctors registered in the country (only 50 of whom work in the public sector), while many have migrated to work in affluent countries. The loss of nurses to developing countries is also extreme. For instance, 18,000 of Zimbabwe’s nurses work abroad, mainly in the United Kingdom. Ghana loses more nurses annually to foreign employment than its nursing schools can graduate.

African health workers who emigrate represent a serious economic setback to their countries. Many African governments heavily finance these workers’ training. The U.N. Commission for Trade and Development has estimated that each migrating African professional represents a loss of \$184,000 to Africa, while Africa spends \$4 billion a year on the salaries of 100,000 foreign experts.

Factors fueling the brain drain. “Push” factors in developing countries that motivate health care personnel to migrate include professional dissatisfaction as a result of low remuneration, poor working conditions, and institutional inadequacies such as lack of technology and equipment, inadequate structures, weak internal systems and practices, lack of autonomy and incentives, and lack of funding for research. In many countries in Africa, larger social or political problems such as civil or ethnic strife, poor security, oppressive political climate, and persecution of or discrimination against intellectuals are factors. On the personal level, limited career prospects at home, poor intellectual stimulation, and the desire to seek a good education for children are motive for migrating.

Major “pull” factors (deliberate or unintended actions of the destination countries that attract health care professionals to recipient countries) include the high demand for health professionals in developed countries with aging populations who require increasing amounts of care. For example, the United States had

126,000 unfilled nursing posts in 2002; by 2015, this shortage will increase to 500,000. Canada currently needs 16,000 nurses and will need up to 113,000 nurses by 2011. In the United Kingdom, it was estimated that 15,000 foreign nurses were recruited for positions in 2001, with 35,000 more needed by 2008. In 2006, Australia expects 31,000 nursing vacancies. To meet these needs, active recruitment of health care personnel is ongoing in sub-Saharan African countries such as Kenya, Ghana, South Africa, Uganda, and Zambia. According to the U.S. Immigration and Naturalization Service, immigrants during fiscal year 2002 with medicine- and health-related occupations included 64 from Kenya, 181 from Nigeria, 212 from South Africa, 15 from Uganda, 11 from Zambia, and 31 from Zimbabwe.

Impacts of the brain drain. The loss of health workers to affluent countries is particularly harmful to sub-Saharan African and Caribbean countries in the era of HIV/AIDS. Effects of the brain drain include:

- Decline in quality of care;
- Increased workloads for health workers left behind;
- Adverse effects on leadership and morale;
- Public sector costs for educating and training the emigrating workers; and
- Less effective and efficient use of other health infrastructure resources

Clearly, Africa’s human resources crisis in health care has a global dimension and an international inquiry and response is needed. The emigration of its health professionals needs to be urgently addressed to help stabilize its health care systems and institutions.

Appendix B: Human Papilloma Virus in Sub-Saharan Africa and the Impact of Condom Use on Its Spread

Human papilloma virus (HPV) is used to describe more than 100 different types of related viruses. HPV can be transmitted through contact with skin surfaces or genital fluids infected with the virus.¹ Genital HPV infection is usually, though not always, sexually transmitted. While many other sexually transmitted infections (STIs) have been associated with increased risk of acquiring or transmitting HIV, this association has not been observed for HPV. However, persons with HIV/AIDS seem to be at increased risk for HPV

infection and associated sequelae of HPV infections such as genital warts and dysplasia.²

Cervical and anal/genital cancers, precancerous cervical tissue abnormalities, genital warts and wart-like lesions, and cervical cell dysplasia have been associated with infection with specific HPV types. Cervical cancer is the leading cancer among women in Africa.³ The report of a workshop sponsored by the National Institutes of Health National Institute of Allergy and Infectious Diseases (NIH/NIAID) within the Department of Health and Human Services (HHS) on the evidence of the effectiveness of condoms to prevent sexually transmitted diseases (STDs) concludes that co-infection with HPV and HIV may lead to increased risk of cervical neoplasia and anal cancers among persons infected with HIV, as HIV suppresses the body's immune system.⁴

There is little known about the prevalence of HPV in sub-Saharan Africa.^{5,6,7} Few studies on the prevalence of any STI, let alone HPV, have been conducted in the region. Of the available recent published reports, HPV research often covers specific populations in geographically specific areas of a country. For example, a 2001 study of HPV genotypes among 262 women in a rural area of Mozambique found that 40 percent of women in the study tested positive for at least one type of HPV.⁸ A 2003 study of 429 female family planning clinic attendees in urban Nairobi, Kenya, found an HPV prevalence of 44 percent. In addition, research sample sizes have been small and non-representative, making it difficult to generalize to entire populations, and advanced definitive diagnostic methods for HPV have only recently been made available. There have been no national or sentinel surveillance programs to assess HPV infection in sub-Saharan Africa. Therefore, it is difficult to accurately HPV prevalence in the region.

Additional HPV epidemiological research in developing countries is needed to develop more effective HPV and cervical cancer prevention strategies. The focus of this research should include the prevalence of specific HPV strains associated with cervical cancer, the prevalence of cofactors affecting the progression to cervical cancer, region-specific risk factors for HPV infection and cervical cancer, and the association between HIV infection and HPV epidemiology. Screening and treatment programs for cervical cancer are also recommended to prevent cervical cancer deaths in sub-Saharan Africa.

Condoms have been shown to be effective in preventing the transmission of many STIs, including HIV/AIDS. Because HPV is transmitted via skin-to-skin contact and genital fluids, HPV is not entirely preventable through condom use. Laboratory and field-based research to evaluate the effectiveness of condoms in preventing HPV transmission has been limited, but correct and consistent use of condoms can be expected to decrease (though not eliminate) the risk of transmitting HPV.⁹ The U.S. Centers for Disease Control and Prevention reports that a number of studies show an association between condom use and a reduced risk of HPV-associated diseases, including genital warts, cervical dysplasia and cervical cancer.¹⁰ The previously mentioned 2001 NIAID workshop report recommended that "robust research be pursued to ascertain the true benefits and limitations of an available risk reduction technology – latex male condoms – for preventing the transmission of STDs. At the same time, research on additional prevention technologies and behavioral interventions must also be pursued in order to advance the health of the public in the U.S. and abroad."¹¹

¹National Institute of Allergy and Infectious Diseases. 2001. "Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention." June 12-13, 2000. Hyatt Dulles Airport. Herndon, Virginia.

²Ibid.

³De Vuyst, H. et al. 2003. "Distribution of Human Papillomavirus in a Family Planning Population in Nairobi, Kenya." *Sexually Transmitted Diseases* 30(2): 137-42.

⁴National Institute of Allergy and Infectious Diseases. 2001. "Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention." June 12-13, 2000. Hyatt Dulles Airport. Herndon, Virginia.

⁵Castellsague, S. et al. 2001. "Human Papillomavirus genotypes in Rural Mozambique." *Lancet* 358: 1429-30.

⁶De Vuyst, H. et al. 2003. "Distribution of Human Papillomavirus in a Family Planning Population in Nairobi, Kenya." *Sexually Transmitted Diseases* 30(2): 137-42.

⁷Okobia, M.N. 2003. "Cancer Care in Sub-Saharan Africa – Urgent Need for Population-based Cancer Registries." *Ethiopian Journal of Health and Development* 17(2): 89-98.

⁸Castellsague, S. et al. 2001. "Human Papillomavirus genotypes in Rural Mozambique." *Lancet* 358: 1429-30.

⁹National Institute of Allergy and Infectious Diseases. 2001. "Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention." June 12-13, 2000. Hyatt Dulles Airport. Herndon, Virginia.

¹⁰CDC. No date. "Male Latex Condoms and Sexually Transmitted Diseases." Fact Sheet for Public Health Personnel.

¹¹National Institute of Allergy and Infectious Diseases. 2001. "Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention." June 12-13, 2000. Hyatt Dulles Airport. Herndon, Virginia.

Appendix C: Core Expertise of U.S. Government Agencies With Existing International HIV/AIDS Programs

The following list provides a brief description of the U.S. Government agencies and departments that are currently responding to the international HIV/AIDS pandemic.

Department of Commerce

The HIV/AIDS initiative of the Department of Commerce (DOC) serves as a conduit to the private sector, particularly to U.S. companies already engaged in HIV/AIDS activities or those not yet actively involved but interested in partnering to combat HIV/AIDS. DOC's initiative promotes cross-sector collaboration; provides information on opportunities to foster partnerships, leverage resources, and transfer technologies to African countries; and creates a dialogue with African countries to reduce trade barriers to health care products and delivery systems.

Department of Defense

The Department of Defense (DOD) currently supports military-to-military HIV/AIDS awareness and prevention education in Africa and has supported the development of policies for dealing with HIV/AIDS in a military setting and the construction of facilities used for HIV/AIDS activities funded by other U.S. Government agencies. The Department's HIV vaccine research program has been transferred to HHS.

Department of Health and Human Services (HHS)

HHS, through its Centers for Disease Control and Prevention (CDC), its National Institutes of Health (NIH), and its Health Resources and Services Administration (HRSA), supports prevention, care, and treatment programs in developing countries and conducts HIV/AIDS research.

- CDC's Global AIDS Program provides technical assistance to countries in the areas of primary prevention, surveillance and infrastructure development, and care, support, and treatment.
- NIH supports a comprehensive program of basic, clinical, and behavioral research on HIV infection and its associated opportunistic infections and malignancies that will lead to a better understanding of the basic biology of HIV, the development of effective therapies to treat it, and the design of better interventions to prevent new infections, including vaccines and microbicides. NIH supports an international research portfolio encompassing more

than 50 countries and is the lead agency for biomedical research on AIDS.

- HRSA provides training and technical assistance, including twinning, nurse training, and palliative care programs in collaboration with CDC in the HHS Global AIDS Program countries.
- In addition, the Food and Drug Administration serves as an important advisory resource on drug quality, safety, and efficacy, and conducts related HIV/AIDS activities.

Department of Labor

The Department of Labor (DOL) supports projects that target the workplace for prevention education and strengthen the response to HIV/AIDS by providing technical assistance to governments, employees, and labor leaders. DOL also funds an international assistance program to reduce workplace stigma and discrimination against people living with HIV/AIDS. It also has an extensive international technical assistance program focused on child labor that works with the International Labor Organization, UNICEF, NGOs, and FBOs to implement programs targeting HIV-affected children forced to work and children involved in prostitution.

Department of State

The Office of the U.S. Global AIDS Coordinator is located within the Department of State. The Coordinator has primary responsibility for the oversight and coordination of all resources and international activities of the U.S. Government to combat the HIV/AIDS pandemic, including the President's Emergency Plan for AIDS Relief. In addition the Department of State supports a wide range of HIV/AIDS activities and small-scale programs through its embassies in 162 countries. Most of these activities and small programs focus on prevention. Chiefs of Mission and other American officials engage in policy discussions with leaders to generate additional attention and resources for the epidemic. Small projects usually are closely targeted at the specific needs of the host country, developed in coordination with local nongovernmental organizations and municipalities, and spearheaded by the U.S. Ambassador. Embassies also use the tools of public diplomacy to reach out through print and electronic media, to facilitate exchange programs, etc. In many countries, the Ambassador's Self-Help Program provides small-scale assistance to projects that entail extensive community involvement.

Peace Corps

The Peace Corps has more than 3,000 volunteers working on HIV/AIDS projects, including 1,000 volunteers committed as a result of the Emergency Plan. The goal of the Peace Corps HIV/AIDS program is to build community-level capacity to address the pandemic's social, economic, and health impacts, particularly in rural areas. All volunteers serving in Africa, regardless of sector, are trained to serve as advocates and educators for HIV/AIDS prevention. In addition, the Peace Corps offers a short-term program called the Crisis Corps that mobilizes former Peace Corp Volunteers to help countries address critical needs, including HIV/AIDS.

U.S. Agency for International Development (USAID)

USAID has been the lead U.S. Government agency fighting the global AIDS pandemic since 1986. Currently, USAID has bilateral programs in 50 countries and reaches an additional 48 countries through regional programs. USAID provides assistance through an "expanded response" operational plan, which focuses on countries where the magnitude and severity of the disease is high with strategies designed to respond to a particular country's epidemic. In addition to its prevention, treatment, and care programs, USAID also has expertise in the management of pharmaceutical logistics; supports operational and biomedical research; and strengthens health systems so countries are better able to respond to HIV/AIDS. USAID's HIV/AIDS programs are coordinated with other development programs, including food aid, housing, education, rule of law, as well as with health care activities in tuberculosis, malaria, and maternal health.

Appendix D

THE EMERGENCY PLAN FOR AIDS RELIEF USG CONTRIBUTIONS TO GLOBAL HIV/AIDS, TB, & MALARIA FY 2003-2005 (dollars in millions)

	2003	2004	2004	2005
EXISTING BILATERAL PROGRAMS	Enacted	Budget	Enacted	Budget
USAID Bilateral Programs:	655	645	750	645
Child Survival HIV/AIDS	488	500	513	500
Other Accounts HIV/AIDS	38	40	53	40
Child Survival TB and Malaria	129	105	184	105
HHS Bilateral Programs:	421	445	493	524
CDC HIV/AIDS	154	155	154	154
NIH HIV/AIDS Research	252	275	324	355
CDC TB and Malaria	15	15	15	15
State/Foreign Military Finance	2	2	1	2
DOL Bilateral Programs	10	0	10	0
DOD Bilateral Programs	7	0	4	0
Sub-total Existing Bilateral Programs:	1,095	1,092	1,258	1,171
ADDITIONAL RESOURCES FOR FOCUS COUNTRIES				
U.S. Global AIDS Coordinator's Office	0	450	488	1,450
Mother and Child HIV/AIDS Prevention Initiative:¹	139	300	149	0
USAID Child Survival	99	150	0	0
HHS/CDC	40	150	149	0
Sub-total Additional Resources for Focus Countries:	139	750	637	1,450
Global Fund to Fight HIV/AIDS, TB and Malaria:	347	200	547	200
USAID Child Survival	248	100	398	100
HHS/NIH	99	100	149	100
TOTAL, GLOBAL HIV/AIDS, TB & MALARIA	1,581	2,042	2,442	2,821
TOTAL, GLOBAL HIV/AIDS	1,437	1,922	2,243	2,701
TOTALS BY AGENCY				
State	2	452	489	1,452
USAID	1,002	895	1,148	745
HHS	560	695	791	624
DOL	10	0	10	0
DOD	7	0	4	0
TOTAL, GLOBAL HIV/AIDS, MALARIA & TB	1,581	2,042	2,442	2,821
State	2	452	489	1,452
USAID	873	790	964	640
HHS	545	680	776	609
DOL	10	0	10	0
DOD	7	0	4	0
TOTAL, GLOBAL HIV/AIDS	1,437	1,922	2,243	2,701

¹ Beginning in FY 2005, these activities will be supported through President Bush's Emergency Plan for AIDS Relief at the Department of State.

Appendix E: Focus Country HIV/AIDS Profile Information

2001 HIV/AIDS Data for Focus Countries of the President's Emergency Plan for AIDS Relief

Country	Adults (15-49) With HIV/AIDS	Adult (15-49) Infection Rate (%)	Children (0-14) With HIV/AIDS	Orphans (0-14) Currently Living	AIDS Deaths Adults and Children
Botswana	300,000	38.8	28,000	69,000	26,000
Côte d'Ivoire	690,000	9.7	84,000	420,000	75,000
Ethiopia	1,900,000	6.4	230,000	990,000	160,000
Guyana	17,000	2.7	800	4,200	1,300
Haiti	240,000	6.1	12,000	200,000	30,000
Kenya	2,300,000	15.0	220,000	890,000	190,000
Mozambique	1,000,000	13.0	80,000	420,000	60,000
Namibia	200,000	22.5	30,000	47,000	13,000
Nigeria	3,200,000	5.8	270,000	1,000,000	170,000
Rwanda	430,000	8.9	65,000	260,000	49,000
South Africa	4,700,000	20.1	250,000	660,000	360,000
Tanzania	1,300,000	7.8	170,000	810,000	140,000
Uganda	510,000	5.0	110,000	880,000	84,000
Zambia	1,000,000	21.5	150,000	570,000	120,000

Source: UNAIDS, 2001

Note: Per the requirement in P.L. 108-199 (FY 2004 Consolidated Appropriations bill), a 15th country will be named shortly as a focus country not located in Africa or the Caribbean region.

Appendix F: U.S. Government HIV/AIDS Bilateral Programs of the President's Emergency Plan for AIDS Relief (Focus countries in bold)

The U.S. Government, through USAID and HHS, has substantial programs in 101 countries, including the Emergency Plan focus countries. In addition, through DOD, DOL, and Peace Corps, the U.S. Government has a number of smaller bilateral programs in additional countries.

Region/Country	USAID	HHS	DOD	DOL	Peace Corps
Sub-Saharan Africa					
1 Angola	B	B	B		
2 Benin	B		B	B	V
3 Botswana	R	B	B	B	V
4 Burkina Faso	R		B		V
5 Burundi	R		B		
6 Cameroon	R		B		V
7 Cape Verde	R				
8 Chad	R		B		V
9 Congo, D.R. of	B	B	B		
10 Côte d'Ivoire	R	B			
11 Djibouti	R				
12 Eritrea	B		B		
13 Ethiopia	B	B	B	B	
14 Gabon			B		V
15 Gambia, The	R				
16 Ghana	B		B	B	V
17 Guinea Bissau	R				
18 Kenya	B	B	B	B	V
19 Lesotho	R		B	B	V
20 Liberia	R				
21 Madagascar	B		B		V
22 Malawi	B	B	B	B	V
23 Mali	B		B		V
24 Mauritania	B				
25 Mozambique	B	B	B	B	V
26 Namibia	B	B	B	B	V
27 Niger	R				V
28 Nigeria	B	B	B	B	
29 Rwanda	B	B			
30 Senegal	B	B	B		V
31 Sierra Leone	R		B		
32 Somalia	R				
33 South Africa	B	B	B	B	V
34 Sudan	R				
35 Swaziland	R		B	B	V
36 Tanzania	B	B	B	B	V
37 Togo	R		B	B	V
38 Uganda	B	B	B	B	V
39 Zambia	B	B	B	B	V
40 Zimbabwe	B	B	B	B	

B = bilateral program; R = regional program; V = volunteers, prevention education. In addition, the State Department has public diplomacy and some smaller-scale HIV/AIDS prevention programs at many of its posts abroad.

Appendix F, continued

Region/Country	USAID	HHS	DOD	DOL	Peace Corps
Asia and Near East:					
41 Bangladesh	B				
42 Burma	R				
43 Cambodia	B	B	B	B	
44 China	R	B			
45 East Timor	R				
46 Egypt	B		B		
47 India	B	B	B	B	
48 Indonesia	B		B	B	
49 Jordan	B				
50 Laos	R			B	
51 Nepal	B			B	V
52 Papua New Guinea	R				
53 Philippines	B				
54 Thailand	R	B	B		
55 Vietnam	R	B	B	B	
56 West Bank/Gaza	B				
Europe and Eurasia:					
57 Albania	B				V
58 Armenia	B				
59 Azerbaijan	B				
60 Belarus	B				
61 Bosnia	R				
62 Bulgaria	R				
63 Croatia	R				
64 Estonia	R				
65 Georgia	B		B		
66 Kazakhstan	B		B		V
67 Kosovo	B				
68 Kyrgyzstan	R		B		
69 Latvia	R				
70 Lithuania	R				
71 Macedonia	R				
72 Moldova	B				
73 Romania	B	B		B	V
74 Russia	B		B		
75 Serbia	R				
76 Tajikistan	R		B		
77 Turkmenistan	R				V
78 Ukraine	B		B	B	V
79 Uzbekistan	R		B		V

B = bilateral program; **R** = regional program; **V** = volunteers, prevention education. In addition, the State Department has public diplomacy and some smaller-scale HIV/AIDS prevention programs at many of its posts abroad.

Appendix F, continued

Region/Country	USAID	HHS	DOD	DOL	Peace Corps
Latin America and the Caribbean					
80 Antigua & Barbuda	R				V
81 Argentina			B		
82 Bahamas		B			
83 Barbados	R				
84 Belize	R		B	B	V
85 Bolivia	B		B		V
86 Brazil	B	B	B		
87 Chile			B		
88 Colombia			B		
89 Costa Rica		B	B		
90 Dominica	R				V
91 Dominican Republic	B	B		B	V
92 Ecuador			B		V
93 El Salvador	B				V
94 Grenada					V
95 Guatemala	B				V
96 Guyana	B	B		B	V
97 Haiti	B	B		B	V
98 Honduras	B	B	B		V
99 Jamaica	B	B			V
100 Mexico	B				
101 Nicaragua	B				V
102 Panama	R		B		V
103 Paraguay			B		V
104 Peru	B	B	B		V
105 St. Lucia	R				V
106 St. Kitts and Nevis	R				V
107 St. Vincent & Grenadines	R				V
108 Suriname	R				V
109 Trinidad and Tobago	R	B			
110 Uruguay			B		
111 Venezuela			B		

B = bilateral program; **R** = regional program; **V** = volunteers, prevention education. In addition, the State Department has public diplomacy and some smaller-scale HIV/AIDS prevention programs at many of its posts abroad.

Appendix G: The Emergency Plan's Program-Level Monitoring Framework

	Number of facilities and/or programs	Number of faith-based facilities and/or programs	Number of abstinence/faithfulness-focused programs	Number of clients served	Number of new clients served	Number of current clients in continuous services for more than 12 months	Number of people trained
Prevention	x	x					
PMTCT	x			x			x
Risk Avoidance/Reduction							
Mass Media	x		x	x			x
Community Outreach	x		x	*			x
Medical Transmission							
Blood Safety	x						x
Injection Safety	x						x
STI Diagnosis and Treatment	x			*			x
Counseling and Testing	x	x		*			x
Care, Treatment, and/or Support	x	x		x			x
Treatment							
ART	x			*†	*†	*†	x
PMTCT	x			*†	*†	*†	x
Clinical Care (non-ART care)	x			*			x
TB/HIV	x			*			
Palliative Care	x			*			x
OVC	x	x		*			x
Labs	x						x
Strategic Information							x
Other							
Policy							
Capacity Building							

* Number of clients to be collected disaggregated by sex

† Number of clients to be collected disaggregated by pregnancy status

Appendix H: Summary of HHS Research Strategy

The National Institutes of Health Revitalization Act of 1993 (Public Law 103-43) provided that the Director of the Office of AIDS Research (OAR) “shall plan, coordinate and evaluate research and other activities conducted or supported” by the NIH. The Director of OAR “shall act as the primary Federal official with responsibility for overseeing all AIDS research conducted or supported by the National Institutes of Health” and “shall establish a comprehensive plan for the conduct and support of all AIDS activities of the agencies of the National Institutes of Health...; ensure that the Plan establishes priorities among the AIDS activities that such agencies are authorized to carry out; ensure that the Plan establishes objectives regarding such activities...; and ensure that the Plan serves as a broad, binding statement of policies regarding AIDS activities of the agencies, but does not remove the responsibility of the heads of the agencies for the approval of specific programs or projects, or for other details of the daily administration of such activities, in accordance with the Plan.” The law further provides that “the Director of the OAR shall ensure that the Plan provides for basic research; provides for applied research; provides for research that is supported and conducted by the agencies; provides for proposals developed pursuant to solicitations by the agencies and for proposals developed independently of such solicitations; and provides for behavioral research and social science research.”

Highlights from the plan are provided below. More detailed information can be obtained at <http://www.nih.gov/od/oar/public/public.htm#PLAN>.

Vaccine development

A safe and effective HIV vaccine would provide a valuable tool to prevent HIV infection. Despite years of extensive research, however, a vaccine to prevent HIV infection remains elusive. Private- and government-sponsored research continues, focusing on defining necessary vaccine components and the best means of vaccine delivery to ensure the optimal protective response.

The process of vaccine development will benefit from a strategic alliance that ensures coordination among the agencies working to identify a safe and effective HIV/AIDS vaccine, particularly as activities to evaluate promising candidate vaccines in developing countries progress. The Emergency Plan offers an unprecedented opportunity to develop interagency alliances. The Department of Health and Human Services (HHS) has created a new strategic alliance –

Partners in AIDS Vaccine Evaluation (PAVE) – in which the National Institute of Allergy and Infectious Diseases (NIAID/HHS) will be joined by the NIH Office of AIDS Research, the Centers for Disease Control and Prevention (CDC), the Department of Defense (DOD), and the HIV Vaccine Trials Network. PAVE will invite participation from non-governmental organizations that are collaborating directly with government agencies on HIV vaccine development. PAVE will serve as a forum to achieve increased efficiencies and cost-effectiveness for all vaccine evaluations under its auspices. A steering group comprising the principals from the three governmental agencies and the chair of NIH’s AIDS Vaccine Research Working Group will serve as PAVE’s principal advisory group.

PAVE will focus initially on preparing for phase III trials, which will involve:

- Developing common immunological, virological, safety, and other laboratory capabilities worldwide;
- Strengthening clinical trial site capacity in developing countries, including the development and use of common training modules and site development priorities and standards; and
- Developing shared, compatible protocols.

Strategies include:

1. **Central medical centers:** Institutions suitable for hosting central medical centers to serve as hubs or referral centers for institutions conducting HIV vaccine trials will be identified. Logistical, managerial, operational, ethical, and regulatory support will be provided to ensure adequate capacity for conducting large-scale trials and to help link existing networks to future central medical centers.
2. **Efficacy trials:** Support will be provided to identify and advance promising candidate vaccines to efficacy trials, including trials in five to seven targeted countries. These trials will evaluate vaccine safety and efficacy against locally circulating strains of HIV.
3. **Phase I/II studies:** Phase I/II studies in two to three targeted countries will be conducted to evaluate the safety and immunogenicity of promising candidate vaccines; to train research staff in the conduct of HIV vaccine trials; to establish standard operating procedures for high-quality, ethically sound trials; and to ensure that appropriate reporting and oversight procedures are in place. Knowledge from clinical trials will be used to

improve vaccine design and make vaccines more effective.

4. **Capacity building:** Health care delivery networks need to be strengthened so they have the components and capacities necessary to conduct trials of the highest caliber and integrate these activities into care and prevention programs. These components and capacities include:
- ▶ Sufficient numbers of motivated and trained medical, laboratory, and support personnel;
 - ▶ Equipment to plan, conduct, and oversee quality vaccine trials;
 - ▶ The capacity to follow patients for prolonged periods;
 - ▶ The ability to maintain medical records according to international standards; and
 - ▶ Appropriate reporting and oversight procedures to ensure the protection of human subjects, data quality, and study integrity.

The linkages among federally supported vaccine development programs need to be strengthened with emphasis on preparing sites for HIV vaccine efficacy trials.

5. **Public-private partnerships:** Expansion of public-private partnerships in HIV vaccine development will help engage the expertise necessary to advance candidate vaccines through the clinical pipeline. Partnerships should provide support to companies for developing manufacturing and testing processes and producing sufficient doses of the most promising candidate vaccines for efficacy trials.

Microbicide development

In the absence of a safe and effective vaccine, the options for sexually active women – particularly those who are coerced or forced to have sex – to protect themselves from HIV and other sexually transmitted infections remain minimal. A safe and effective topical microbicide (i.e., an antimicrobial product applied topically that inhibits or inactivates HIV) would offer another means of protection for women beyond condoms.

Under the Emergency Plan, HHS will continue to support a comprehensive program for discovering, developing, testing, and evaluating microbicides for HIV prevention.

NIH is the major federal sponsor of microbicide research and development, supporting microbicide design research and microbicide development and production. Under the Emergency Plan, NIH will expand the HIV Prevention Trials Network, a worldwide network for collaborative multidisciplinary, multisite clinical trials established by NIH to evaluate the safety and efficacy of non-vaccine HIV prevention interventions.

NIH has also spearheaded an effort to develop a U.S. Government strategic plan for microbicides, which incorporates the microbicide activities of agencies within HHS such as NIH, CDC, and the Food and Drug Administration, as well as USAID. This strategic plan provides a blueprint for a coordinated effort structured to address each step involved in developing and testing potential microbicides and their subsequent implementation in prevention activities.

Strategies include:

1. **Basic biological and physiological research related to microbicides:** This research will elucidate the basic mechanisms of HIV transmission (both virus and host factors) and other sexually transmitted infections at mucosal surfaces. Such research is important for developing and applying microbicides in diverse populations.
2. **Microbicide development and preclinical studies:** The Emergency Plan will support the discovery, development, and preclinical evaluation of topical microbicides alone and in combination.
3. **Microbicide formulations and modes of delivery:** Programs will develop and assess acceptable formulations and modes of delivery for microbicides, bridging knowledge and applications from the chemical, pharmaceutical, physical, bioengineering, and social sciences.
4. **Clinical trials of microbicide products:** Clinical studies of candidate microbicides will be conducted to assess their safety, acceptability, and effectiveness in reducing the transmission of HIV and other sexually transmitted infections in diverse populations in domestic and international settings.
5. **Behavioral and social science research related to microbicides:** Basic and applied behavioral and social science research will be conducted to enhance microbicide development, testing, acceptability, and use domestically and internationally.

6. **Training and infrastructure:** Infrastructure and training needs will be met to permit international and domestic microbicide research to proceed and to accelerate access to microbicidal products in diverse populations.

Therapeutics research

Considerable progress has been made in understanding how HIV attacks the immune system and how to treat it. Researchers have developed new methods to detect and measure HIV in blood and tissue and to test for antiretroviral (ARV) drug resistance. Therapeutic regimens using combinations of drugs have extended and improved the quality of life for many HIV-infected people in developed nations and have led to declines in AIDS-related mortality.

There is an urgent need today to extend these benefits to developing countries hardest hit by the disease. Research is needed to determine how best to deliver and monitor antiretroviral therapy (ART) and to manage the clinical treatment of adults and children in resource-limited settings. Additionally, research is needed to determine the spectrum of opportunistic infections and co-infections in threatened populations and their impact on HIV infection and disease progression.

Under the President's Emergency Plan, the United States will support the expansion of preclinical drug development resources; feasibility studies and efficacy trials for ARV and antimicrobial drugs; and the provision of laboratory support for diagnostics, clinical trials, and expanded treatment delivery. As part of this effort, NIH is working with France's Agence Nationale de Recherche sur le SIDA and the Antiretroviral Therapy Cohort Collaboration to develop a database that will collect treatment-related data from a large number of research sites in developing countries. Systematic analyses of the database may permit comparisons of the short- and long-term effectiveness of ART in these sites and developed countries. The database also will facilitate studies on other aspects of treatment-related operational research. Findings from this project may provide important models for multisite, multicountry operational research that will complement traditional clinical research models in establishing the effectiveness of antiretroviral strategies in developing countries.

Tuberculosis research

Worldwide, tuberculosis is the leading cause of death in HIV-infected persons. Research is needed to determine the incidence of TB infection and co-infection, improve diagnostic capability, and develop and deliver affordable and effective therapies to adults and chil-

dren in developing countries. Important research questions include the effectiveness and tolerance of different dosing regimens and comparisons of providing concurrent TB/ARV treatment and providing TB treatment before ART.

Research is needed to:

- Determine incidence of TB infection and co-infection;
- Improve diagnostic capability, especially given the significant lower sensitivity of current methods in person infected with HIV;
- Develop and deliver affordable and effective therapies to adults and children in developing countries;
- Determine the effectiveness and tolerance of different dosing regimens and comparisons of providing concurrent TB/ARV treatment;
- Optimize timing of providing TB treatment before ART;
- Develop new drugs to combat the problem of emerging drug resistance;
- Develop and test molecular targets for tuberculosis vaccines tailored for HIV-infected persons, including those in largely BCG-vaccinated populations;
- Develop models for building community-research partnerships with local health units in ethnically diverse communities;
- Focus on the special problems of children co-infected with tuberculosis and HIV; and
- Refine cooperative strategies between tuberculosis and HIV prevention and control activities.

Malaria research

Malaria is a major cause of death and disability in Africa. The research agenda will include:

- The genome sequencing of the malaria parasite *Plasmodium falciparum* and of its mosquito vector *Anopheles gambiae*;
- Development of molecular tools to genetically manipulate the parasite and vector in studies relevant to drug and vaccine discovery;
- Pathogenesis and vector control;

- Identification of the genes mediating chloroquine and insecticide resistance and molecular techniques to characterize drug-resistant parasites from clinical isolates;
- An accelerated malaria vaccine research and development program;
- Quantification of the economic impacts of malaria in endemic countries;
- Discovery and development of new antimalarial drugs from plants, animals, and microorganisms; and
- Development of predictive models of the transmission risk for many infectious diseases, including malaria, in relation to major environmental disturbance events.

Appendix I: USAID's HIV/AIDS Research Strategy

The U.S. Agency for International Development has been a leader in fighting HIV/AIDS since 1986. One of the key components of USAID's HIV/AIDS program has been to conduct biomedical and operational research to develop and evaluate new tools for providing antiretroviral therapy, preventing HIV transmission, and caring for people living with AIDS.

The major focus of USAID's research is to address needs for program implementation in resource-limited settings. USAID-funded research is comprehensive, from identifying a program problem to research and efficacy verification, to field testing and then finally full implementation in developing countries.

Treatment

Antiretroviral Therapy

There are many complex issues related to the introduction and impact of antiretroviral therapy in resource-constrained settings. Current research examines methods to improve ease of administration and adherence to therapy and methods to decrease drug tolerance and side effects. Antiretroviral therapy implementation sites also serve as learning sites. Three USAID introductory sites are models for antiretroviral treatment.

Preventing Mother-to-Child Transmission

Operations research currently underway includes:

- Studies to determine the effectiveness of introducing a package of prevention of mother-to-child transmission services into existing antenatal, maternal, and child health services; and
- Development and implementation of packaging options that could create a sustainable supply of nevirapine in single or small-dose packaging.

Prevention

ABC: Abstinence, Be Faithful, Use Condoms

USAID has carried out pioneering studies in the area of behavior change for successful HIV prevention, including a recently funded six-country study on ABC and has published an important paper analyzing the success of the ABC approach in Uganda. New studies are being planned to optimize the implementation of ABC interventions for youth and at-risk groups.

Male Circumcision

Clinical trials are currently underway to review whether male circumcision has a strongly protective effect on HIV transmission. USAID is supporting research in Haiti, Zambia, Kenya, and South Africa to learn more about issues of safety and complications, acceptability and feasibility, and the logistical issues involved in developing pilot demonstration services for safe/affordable male circumcision and male reproductive health.

Injection Safety

In addition to the transfusion of HIV-infected blood, transmission of HIV in the health care setting can occur through unsafe injections and other unsafe medical practices, including occupational exposure to blood. USAID is supporting research in this area, including:

- Evaluation of health care worker acceptance of single-use devices;
- Field safety comparisons of new devices; and
- Pioneering and evaluating the use of bundling an injectable contraceptive commodity with auto-disable syringes and safety boxes.

Care

Nutrition

HIV infection affects nutrition through reduction in dietary intake, nutrient malabsorption, and complex metabolic alterations that culminate in weight loss and wasting. USAID is implementing research on:

- The impact/effectiveness of providing nutrition supplements on adherence to antiretroviral treatment and return for HIV care;
- Cost and feasibility of incorporating nutrition supplements into antiretroviral treatment programs; and
- Nutrient and caloric formulation of nutrition supplements in children and adults living with HIV/AIDS.

Orphans and Vulnerable Children

USAID-supported projects for orphans and vulnerable children aim to increase a family's ability to provide care and support to children affected by AIDS. USAID supports research to identify successful approaches, including studying:

- Effectiveness of interventions to help parents and families affected by HIV plan for their children's future care;
- Psychosocial issues affecting adolescent orphans and vulnerable children; and
- Different models to enhance food security and nutrition in programs assisting orphans and vulnerable children.

Biomedical Research

Microbicides

Because standard prevention strategies are often out of the control of women, USAID is actively developing microbicides – a female-controlled chemical barrier to the AIDS virus. USAID's research priorities are the identification of the best active agents for use in new microbicial products, early-stage clinical studies to establish the safety and acceptability of potential new microbicides, advanced clinical studies to test the effectiveness of the most promising microbicide candidates in large-scale trials, and planning the introduction of the most appropriate microbicides in the context of developing countries.

Vaccines

Prevention of HIV infection remains a primary strategy in the fight against the worldwide HIV pandemic, and a safe and effective HIV vaccine would provide an extremely important tool for this purpose. USAID funds the International AIDS Vaccine Initiative to accelerate the development and introduction of new vaccine candidates and technologies and link vaccine designers with manufacturers and with developing

country sites suitable for testing promising HIV vaccine candidates.

USAID's Tuberculosis and Malaria Research Strategies

Tuberculosis

USAID's investment in global tuberculosis control includes support for focused research in a number of critical areas. Of the 40 million HIV-infected people worldwide, almost one-third are also infected with TB. USAID's research in this area includes:

- Development of new and improved diagnostics appropriate for use in developing and transitional countries and functional in a variety of settings (including areas of high HIV-prevalence);
- Development of new drug treatment regimens and new drugs which are easier to use, safer, lower in cost, and less labor-intensive to administer;
- Strengthening of clinical trial capacity for the evaluation of new diagnostics, drugs, and drug treatment regimens, and strengthening of operations research capacity at the country level;
- Improving the management and delivery of care for multidrug-resistant TB;
- Research on the impact of antiretroviral therapy on TB infection;
- Testing model approaches to improve care and support within general health services to persons with HIV and TB; and
- Generating evidence on the best mix of TB/HIV activities according to different levels of HIV prevalence.

Malaria

As many as 900 million cases of malaria occur every year, directly and indirectly causing up to 2.7 million deaths. Priority research areas include:

- Malaria vaccine research;
- Issues on delivery and rapid deployment of the most promising malaria treatment currently available;
- New drug development in collaboration with the Medicines for Malaria venture

- Community approaches to vector management; and
- Issues related to co-infection of malaria and HIV.

Appendix J: Summary of Testimony and Recommendations Received 12/18/03 at the PACHA Townhall Meeting

The commentary and papers received by the PACHA International Committee on behalf of Ambassador Tobias and the President's Emergency Plan for AIDS Relief were broadly focused and rich in experience and passion. Together they provided a number of consistent messages and subsequent recommendations that will hopefully enhance the efforts underway and still being developed to ensure the success of the Emergency Plan. Below is a brief summary of the principal issues and themes that arose in the verbal and written comments received during the Townhall Meeting based on the three questions disseminated before the meeting.

1. **What lessons can you provide/share regarding planning, implementation, and outcome measurements strategies that have worked best and what did not work and why?**
2. **What are the vital aspects of effective partnerships and with whom?**
3. **How have you been able to effectively involve people living with HIV/AIDS in your work?**

HIV treatment/access to antiretroviral drugs:

Nothing should get in the way of the overarching goal of providing universal access to treatment. Parallel issues, such as trade agreements on intellectual property rights and generic medicines, should be congruent with this goal, as well as decreasing the costs of medicines.

Access to ARVs is an absolute priority that reduces stigma, improves health of the individual, the community, the economic viability and social structures of a nation. ARVs are being done, can be done effectively and safely and can be scaled up quickly in most of the Emergency Plan's focus countries. Such implementation requires a different approach to the "the western medical model." Barriers must be reduced to allow the use of combination pills (generics), new algorithms of treatment success, and understanding that a perfect model of implementation does not exist. Many models must be urgently instituted with failures in some

expected, but with the understanding that the good outweighs the bad in this approach in lives saved and children raised by their own parents.

Access to holistic care includes non-ARV health interventions that have also been proven effective in reducing morbidity and mortality. Care needs to be comprehensive and not just focused on medication distribution. Many were concerned too much emphasis is currently on ARVs, that other important aspects may be getting inadequate attention, such as:

- Adequate nutritional supplementation and food security
- Clean water
- Palliative care (treatment of suffering, and symptom management)

There was an emphasis on paying attention to the social/family dynamics of the disease:

- The need to attend to the care of orphans
- Make care family-centered
- Utilize friends and family members (natural support systems) as part of the care model
- There is a continued need to address the issues of stigma reduction

There is a need to accelerate AIDS vaccine research. It was suggested that this, and the development of effective microbicides, should have comparable federal incentives as the research of TB-related vaccines.

Communication strategies require the development of sound evidence-based messages that utilize multiple communications media and technologies that cater to the learning needs, languages, culture, and access requirements of specific groups, especially in remote areas for women, men, youth, and children.

Treatment and care must be simple, adapted to local conditions and decentralized.

Design of service delivery strategies should include: Multisectoral in response – including a health response (technical), social, economic, financial, and political responses. Multifaceted problems require multifaceted solutions.

Community in all aspects from care delivery to leadership and decision-making.

In-country collaboration broadly defined to include local leadership, public-private partnerships, ministries of health, faith-based organizations, and health worker collaborations among the various disciplines. Also necessary is collaboration among the donor agencies working with specific organizations. The lack of streamlined and compatible technology was identified as a potential barrier to effective programming and collaboration, as many different organizations, each with different information processing systems, are involved in combating HIV/AIDS. Logistics, specifically the ability to have consistent access to quality supplies, was also identified as a barrier to the success of programs.

Culturally appropriate and relevant solutions, delivery strategies, and training methodologies that include respect for the oral traditions of learning and retention of information, the learning style and the proven strategy of the message being delivered by trusted members within the group, peer-to-peer learning, and interventions be instituted at all levels of strategies.

Focus on women and families with key support for prevention efforts and treatment shifts to reduce the burden of new infections as well as reduce the number of children becoming orphans.

Local capacity building and use of volunteers is an important part of any strategy that brings a different motivation to the rebuilding of communities and health delivery strategies. While extremely important, this has to be done with caution as communities are already overwhelmed with too much emphasis and reliance on their function.

Non-physician health workers such as nurses, community health workers, midwives, and traditional healers who are the main providers of the African health delivery system. The focus on physician-driven efforts and training, while valuable in the long term, are neither immediate and are limited in their effect in the field. The immediate relevant inclusion of non-physician health workers into decision-making, leadership, resources, and scale up to sustain work and practice is critical to the success of the Emergency Plan. The training provided to this group must be developed and delivered by peers. These training initiatives and linkages to the ministries of health are new models (in fact the U.S. health delivery leaders have little experience with these type of educational and training models) that have hidden power barriers that can limit the ability of these workers to be enhanced and will

require significant leadership on how to work collaboratively and truly empower this group to be effective. Nurses were significantly pointed out in over 10 of the commentaries.

Use of existing infrastructures such as faith-based care centers that already mandate holistic care, respect for the community, and demonstrate willingness can ensure effective use of Emergency Plan funds and sustainability over time. A modest investment can go a long way.

Promoting behavioral change:

Prevention as the primary weapon to combat HIV. Turning the tide requires dramatically reducing the number of new infections. A few organizations emphasized abstinence and fidelity as appropriate, effective, and necessary preventions strategies. Participants testified that treatment has a huge role to play in mitigating the consequences of HIV/AIDS, but prevention has to remain a primary aim.

Behavior change for sexual transmission is proving effective on a number of fronts that include each component of the ABC model. Caution to the use of a one-size-fits-all approach was repetitious in the commentary. The emphasis on A and B was welcome especially by the faith-based groups and churches that are providing the bulk of health care delivery and social modeling. Culturally relevant and community-driven prevention efforts should be the long-term focus and goal.

Behavior change in health delivery requires immediate attention and the systems that support the spread of non-sexual transmission of HIV such as safety for health workers, equipment in treatment facilities and policies that support the reduction of this underreported transmission route. This also impacts the sustainability of a health workforce. We heard that 2-3 nurses are dying monthly in Kenya from possible occupational exposure. The immediate treatment of the health workforce must be part of the Emergency Plan. With examples such as Daimler-Chrysler and the Global Business Council using comprehensive workforce policy and programs, the President's Initiative should ensure that this style of health workforce program be enacted in both the public (Ministries of Health) and the private (Mission) sectors. The Mission health systems are providing about 40-70% of all health delivery in many of the Emergency Plan focus countries and will require resources to move forward on this end.

The development of alternatives to condoms must be enhanced, such as microbicides and gender rights

issues. As women are increasingly infected, the previously heavy reliance on condoms or other male-driven responsibility measures must be attended to. The development of female-centered technologies should be prioritized so that other methods of prevention besides condom use can be promoted specifically with women. Strategies must be put in place to address vulnerabilities of women, including social rules that inhibit their ability to negotiate sex and the use of condoms. Participants emphasized that a gender strategy intended to empower women must target men and boys to change attitudes.

People living with HIV/AIDS are vital contributors to prevention efforts, fighting stigma, and planning effective interventions. Their involvement is crucial.

Youth make the greatest proportion of new infections, participants emphasized strategies that target youth.

Program interventions to assist orphans and vulnerable children must be community-based, building on community coping mechanisms with an eye to sustainability.

Issues of program effectiveness in HIV/AIDS:

Programs must strike a balance between the urgency of the pandemic and the long-term investments and strategies required to develop sustainable services.

Well-conceived and thought-out community planning processes built on bottom-up approaches have had greater success in mobilizing community involvement and ownership. This has led to lower costs in service delivery and greater access to resources for families.

Programs need to take better advantage of skills and resources of health professionals at the local level.

We need to develop new kinds of community involvement to prevent social fatigue, such as patient-centered adherence and programs to de-stigmatize HIV/AIDS.

Operations research has not been part of funding strategies in development work and must be considered as the Emergency Plan is initiated to measure progress, identify lessons learned and improve program effectiveness on a continuing and permanent basis. Developing national capacities for data collection and implementation monitoring will be important for creating successful programs.

Sustainability:

Another consistent thread was for HIV/AIDS health services to be addressed in a broader scope of devel-

opment and poverty reduction that are fueling the HIV pandemic. Incorporating collaborations that address nutrition, food security, clean water, reproductive health care, sanitation, economic/job solutions to family members ill that cannot support the health of the family is crucial.

Scaling up successful pilot projects has had dismal results to date. While outcomes research as the test of the success of a program is important, they must now include operations research to ensure that scale up can be effective.

Successful HIV programs are one part ARV and nine parts development. Programs should be comprehensive and address the multifaceted nature of human health and welfare as it relates to HIV/AIDS.

Administrative policy in the Emergency Plan for AIDS Relief:

The structure of the procurement process for grants from the Emergency Plan should facilitate and encourage partnership arrangements to the greatest extent possible.

The Emergency Plan should revisit, on a permanent basis, the procurement rules to ensure that they are not too rigid and burdensome.

Local institutions:

Links with local institutions are critical to successful interventions. However, it is important not only to view local institutions as a means to achieving program goals, but to recognize them as institutions in their own right, with their own identity that form a part of a social fabric for development.

Working with local churches who are providing HIV care and treatment as well as education should be strengthened and expanded. Patient fellowships between PLWA through local churches are one way to develop new social networks for prevention, treatment, and care.

National and global coordination:

Initiatives promoted by the President's Initiative should be articulated and integrated into the national AIDS plans of the countries in which they are implemented, focusing on strengthening national capacities to facilitate local initiatives.

The Emergency Plan should develop effective coordination and collaboration mechanisms with the Global Fund and the World Health Organization three by five program.

In addition to the above summary from the public comments, the PACHA International Subcommittee would like to make the following suggestions:

The Emergency Plan should institute a vigorous evaluation component to ensure desired outcomes and the mandate from Congress is achieved.

The Initiative's program strategies should encourage HIV/AIDS care burden-sharing with recipient's countries. The countries should be mandated to do their fair share of providing adequate health care to citizens. The success of any program in Africa requires firm commitment and active participation of local governments of the African countries. The political will and determination of the African governments

are necessary to ensure the success of combating HIV/AIDS in their countries.

Emergency Plan funding should be used to complement and not serve as a substitute or replacement for HIV activity work that is currently in place through various international and local agencies.

In-country community mobilization and capacity building is a crucial aspect of all programs.

The Request for Proposals (RFPs) process should be made less cumbersome. It was clear that there was considerable confusion about the "process" of the RFPs that had recently been solicited. The time frame and the nature of it needs to be explained going forward especially in light of the fact that there will be "different" RFPs coming down the pike.

Appendix K: ACRONYMS

AIDS	Acquired immune deficiency syndrome
ART	Antiretroviral therapy
ARV	Antiretroviral (drugs, treatment, etc.)
CBO	Community-based organization
CDC	Centers for Disease Control and Prevention (HHS)
DOC	Department of Commerce, U.S.
DOD	Department of Defense, U.S.
DOL	Department of Labor, U.S.
FBO	Faith-based organization
FDC	Fixed-dose combination
FY	Fiscal year
HHS	Health and Human Services (U.S. Department of)
HIV	Human immunodeficiency virus
HPV	Human papilloma virus
HRSA	Health Resources and Services Administration (HHS)
ICRC	International Committee of the Red Cross
ILO	International Labor Organization
MAP	Multi-Country HIV/AIDS Program for Africa (World Bank)
MIS	Management information system
MTCT	Mother-to-child transmission
NGO	Nongovernmental organization
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health (HHS)
OAR	Office of AIDS Research (HHS/NIH)
PACHA	Presidential Advisory Council on HIV and AIDS
PAVE	Partners in AIDS Vaccine Evaluation
PMTCT	Prevention of mother-to-child transmission
RFP	Request for proposal
STD	Sexually transmitted disease
STI	Sexually transmitted infection
TB	Tuberculosis
TRIPS	Trade-Related Aspects of Intellectual Property Rights (Agreement)
UNAIDS	Joint United Nations Program on HIV/AIDS

UNDP	United Nations Development Program
UNGASS	United Nations General Assembly Special Session
UNHCR	United Nations High Commissioner for Refugees
UNICEF	United Nations Children’s Fund
USAID	United States Agency for International Development
USG	United States Government
WFP	World Food Program
WHO	World Health Organization
WTO	World Trade Organization

