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Collection/Record Group: Clinton Presidential Records

Subgroup/Office of Origin: National AIDS Policy Office

Series/Staff Member:

Subseries:

OA/ID Number: 19405

FolderID:

Folder Title:

US Department of State International Response Strategy [1]

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U.S. Department of State

Agency Mandate Relevant to HIV/AIDS

U.S. Dept of State
International
Response
Strategy

POS

The Department of State is the lead U.S. foreign affairs agency. It advances U.S. objectives and interests through formulating, representing, and implementing the President's foreign policies. The United States maintains diplomatic relations with some 180 countries and also maintains relations with many international organizations. The Department of State has more than 250 diplomatic and consular posts around the world: country mission components--including embassies and consulates; and delegations and missions to international organizations.

The Department of State implements its mission through overseas posts; in its Washington, D.C. headquarters; and through other offices in the United States. In addition to representing U.S. policy and interests at these posts, the Department of State is the primary provider of foreign affairs information used to formulate policy. Information received from U.S. posts--including in-depth analyses of the politics, economic trends, and social forces at work in foreign countries--is provided to some 60 Federal agencies.

In the area of international health, the role of the Department of State is to develop and coordinate support from other nations and international bodies to raise the level of priority accorded HIV/AIDS and infectious diseases. Through the coordinating efforts of the Bureau of Oceans and International Environmental and Scientific Affairs/Emerging Infectious Diseases and HIV/AIDS Program (OES/E/EID), the Department works with USAID and other Federal agencies to develop the bilateral and multilateral partnerships for international collaborations to address the unique implications of HIV/AIDS and other infectious diseases. Through the diplomatic infrastructure, OES/E/EID negotiates cooperative agreements with other nations to establish a global surveillance and response network. It works with other agencies to enhance awareness and national capacities around the world to prevent, diagnose, report, and respond to the threat of disease.

The Bureau of Population, Refugees and Migration (PRM) coordinates efforts among the Department of State, other U.S. Government agencies, private voluntary organizations, and international agencies to implement a more comprehensive international population policy. PRM's oversight includes broadening population assistance programs to cover a wider range of reproductive health services, including family planning. It also provides assistance to refugees in first-asylum countries.

The Bureau of Democracy, Human Rights, and Labor (DRL) oversees initiatives and policies to promote and strengthen civil society and respect for human and worker rights. DRL ensures that human rights in foreign countries are taken into account in the U.S. policymaking process and submits an annual report to Congress extensively reviewing human rights practices in each country.

The President's Interagency Council on Women, which is chaired by the Secretary of State, is charged with coordinating the implementation of the Platform for Action adopted at the UN Fourth Conference on Women. The Platform recommends actions to increase women's access to appropriate, affordable, and quality healthcare, information, and related services; encourage both women and men to take responsibility for their sexual and reproductive behavior; and undertake gender-sensitive initiatives that address sexually transmitted

diseases, HIV/AIDS, and sexual and reproductive health issues.

Agency Strategy for Specific Issues

Promoting Active Involvement by National Governments

The Department of State hopes to bring the message to leaders around the world that HIV/AIDS and infectious diseases are the silent enemies of economic and social development, political stability, and economic productivity. No member of the global community can afford, either in terms of human suffering or economic costs, to fail to recognize or to forestall the impending devastation that has already begun to ravage national economies, security and social infrastructure. Political commitment at the highest level of national government makes the critical difference in stemming the spread of HIV/AIDS. Where such commitment is present, such as in Uganda and Thailand, the transmission rates are being effectively reduced.

Working in cooperation with U.S. Government technical agencies, through regional bureaus, embassies and missions abroad, the Department's goal is two-fold: to enhance U.S. diplomatic efforts to raise the level of priority by all governments to more effectively meet the challenges of HIV/AIDS and infectious diseases of all kinds, and to enhance international collaboration on international health.

HIV/AIDS will be introduced to a greater extent in the U.S. diplomatic and policy dialogue to underscore the recognition of HIV/AIDS as an international problem with political, social, and economic impacts that go well beyond the boundaries of the traditional health sector. Nations should address HIV/AIDS as a pandemic fueled by socioeconomic inequities, human rights issues, and questions of gender status.

The Department of State and senior officials must play a central role in raising the subject of HIV/AIDS in international fora and is redoubling efforts to put the full weight of the U.S. diplomatic infrastructure behind enhanced political commitment for overseas national action.

Recognizing the problem and promoting AIDS education and prevention programs by high-level government officials is vital to the success of AIDS prevention. Posts, through our mission-planning process, will be charged and held accountable for their active interventions to raise awareness with host-government officials. Ambassadors and other foreign policy officials at posts are directed to:

- Urge foreign leaders to openly address the HIV/AIDS pandemic in their own countries;
- Urge governments to consider the adverse economic, political and social impact of HIV/AIDS in their countries;
- Urge governments to increase spending or to reallocate funds to prevent the spread of HIV/AIDS and facilitate AIDS research efforts;
- Emphasize the importance of National AIDS Action Plans, which involve all relevant governmental agencies, ministries, NGOs, and the private sector;
- Encourage foreign leaders to support the Joint U.N. Programme on AIDS (UNAIDS); and

- Incorporate AIDS issues into foreign policy interactions with all government and international organizations.

The Department of State, through formalized briefings as part of our National Foreign Affairs Training Center curricula and by country-specific regional briefing to senior officials, is working to heighten the awareness of the foreign policy implications of HIV/AIDS to the foreign policy community through all available mechanisms.

The Department will convene regular interagency meetings to discuss the international calendar and to develop common approaches on HIV/AIDS and other infectious disease issues.

The Department of State seeks to enhance diplomatic support for HIV/AIDS programs in developing countries and HIV/AIDS vaccine research and policy collaborations with international partners.

Using the HIV/AIDS component of the Common Agenda with Japan as a model, the Department of State and USAID will pursue agreements with other donors to work more closely on HIV/AIDS in priority countries.

Promoting Human Rights

The United States regularly supports UN resolutions before the Commission on Human Rights for the protection of human rights in the context of HIV/AIDS. The resolutions set out guidelines nations may follow in dealing with the health crisis and human toll of AIDS and HIV. The resolutions also ask the UN Secretary General to solicit input from countries, specialized agencies, and related governmental and non-governmental organizations in order to provide progress reports to the Commission on follow-up. The next session of the Commission at which an HIV/AIDS resolution is expected for consideration will take place in March 1999.

The Department of State will continue to include HIV/AIDS-related discrimination and human rights abuses in regular embassy reporting and in its annual "Country Reports on Human Rights Practices" and represent these interests before the Human Rights Commission.

The United States helped to negotiate a partnership arrangement between the Office of the High Commissioner for Human Rights (OHCHR) in Geneva and UNAIDS. It strongly supports OHCHR's efforts to mainstream human rights into the activities of other UN departments and agencies and especially the cooperation this partnership represents in combating the devastating worldwide crisis of HIV/AIDS.

U.S. Agency for International Development

Agency Mandate Relevant to HIV/AIDS

The U.S. Agency for International Development (USAID) is the global leader in developing and implementing international HIV/AIDS/sexually transmitted infections (STI) prevention and control programs. USAID's HIV/AIDS/STI mandate is to achieve a sustainable reduction in HIV/STI transmission among key populations in developing countries and to reduce the impact of the epidemic on individuals, communities, and societies in general. This mandate fits within the broader Agency goal of stabilizing world

population and protecting human health in a sustainable fashion.

USAID's regional and bilateral programs are the core of the Agency's HIV/AIDS/STI prevention activities, while the central programs provide complementary technical and programmatic support. The Global Bureau, Center for Population, Health and Nutrition, Office of Health and Nutrition, HIV/AIDS Division (G/PHN/HN/HIV-AIDS) is the Agency unit charged with the primary responsibility for developing program interventions. In collaboration with USAID field missions and other partners and stakeholders, the HIV/AIDS Division has developed a detailed strategic framework that is consistent with the overall Agency mandate and lays out a future-oriented HIV/AIDS/STI program for the next 7-10 years.

USAID's strategy continues to focus on three key approaches to HIV/AIDS prevention, each of which, over time, has had demonstrable impact in multiple country settings:

- Reducing high-risk sexual behavior through behavioral change interventions (BCI). These include not only mass and interpersonal communication strategies but also policy and legislative reforms that enhance communication strategies and campaigns and build awareness and support for health infrastructure change;
- Increasing demand for and access to condoms, mainly through condom social marketing (CSM) programs;
- Treating and controlling sexually transmitted infections (STI) and sexually transmitted diseases (STD).

The first decade of HIV/AIDS programming has revealed that effective, individually focused approaches must be complemented or supplemented by services more attuned to the environment in which individuals live and make sexual and health decisions. This implies greater emphasis on interventions that address couples, parents, and children, social networks, religion, worksites; the interaction of sexual and health beliefs; and the norms, values, and policies that determine the social and sexual context in which people live.

In addition to continuing the three major interventions stated above, the expanded strategy now includes selected basic care and psychosocial support for HIV-infected individuals and their survivors. This will enhance the prevention agenda, and slow the deterioration of economic and social development. The expanded strategy includes increased emphasis on supporting HIV/STI surveillance systems that will assist in our understanding of the growth of the epidemic, as well as allow the assessment of the impact of interventions. There are now innovative initiatives to perform operations research to identify best practice, to expand policy dialogue to include issues such as discrimination and resource allocation, to increase private voluntary organization (PVO) and non-governmental organization (NGO) capacity-building, and to conduct targeted biomedical research.

The expanded strategy responds to concerns raised by many observers (field mission staff, stakeholders, other donors, PVO/NGO representatives, and program evaluators and auditors) that USAID's HIV/AIDS/STI program interventions should concentrate on achieving well-defined program targets and results at country, regional, and G/PHN levels. Interventions should be closely coordinated with, and provide technical support to, regional bureau and field mission programs. Likewise, to expand global knowledge of the status of the regional and global HIV/AIDS epidemics, AIDS Control and Prevention Project (AIDSCAP) formed the Monitoring the AIDS Pandemic (MAP) Network of more than 120 HIV/AIDS specialists in 50 countries with its founding partners, UNAIDS and the Harvard School of Public Health.

To operationalize the strategic framework presented above, the HIV/AIDS Division developed a results-oriented program of grants, cooperative agreements, interagency

agreements, and contracts that will continue the Agency's focus on preventing sexual transmission of HIV. This program is accomplished through the following 10 activities:

- **Horizons:** This cooperative agreement with the Population Council (and collaborating partners: International Council for Research on Women; Program for Appropriate Technology in Health; International HIV/AIDS Alliance; University of Alabama; and the Futures Group) will develop and disseminate the most effective ways of combating HIV/AIDS, through operations research, field testing of program interventions, and the review of scientific studies and publications.
- **IMPACT:** This cooperative agreement with Family Health International (and collaborating partners: Program for Appropriate Technology in Health; Population Services International Management Sciences for Health, University of North Carolina; and Institute of Tropical Medicine in Brussels) offers opportunities for field support (technical assistance, training, materials production, support for HIV/AIDS/STI programs, including the development of behavior change communication campaigns and delivery of STD clinical services and HIV/STI care programs, as well as surveillance, monitoring, evaluation, and voluntary testing and counseling) to missions and countries to implement prevention and mitigation programs.
- **AIDSMark:** This cooperative agreement with Population Services International (and collaborating partners: Program for Appropriate Technology in Health; Management Sciences for Health; International Planned Parenthood Federation; International Council for Research on Women; DKT International; and Family Health International) provides support for developing regional and country HIV/AIDS social marketing program interventions. AIDSMark will focus on the social marketing of critical public-health products that are appropriate and timely for the setting (male and female condoms, STI treatment drugs, STD diagnostics, etc.)
- **DMELLD:** This contract will be awarded in early 1999 and will offer field missions access to technical assistance for program design, monitoring, and evaluation. It will also collect technical lessons learned from all components of the portfolio and disseminate these to field missions, cooperating agencies, governments, and international donors.
- **UNAIDS WHO, UNICEF, UNDP, UNICEF, UNFPA, World Bank):** USAID is the lead donor to the Joint Coordinated UN Programme on HIV/AIDS (UNAIDS). UNAIDS coordinates UN activities at country level; supports national strategic planning; generates best-practice recommendations; and advocates for increased resources to combat the pandemic.
- **PVO/NGO Capacity-Building:** USAID supports this activity through four separate agreements with the National Council for International Health, International HIV/AIDS Alliance, CDC, and Peace Corps. These organizations focus on building indigenous PVO/NGO capacity through technical assistance, training, technology exchange, and institutional partnering.
- **Operations Research for Implementing the Prevention to Care Continuum:** This activity supports focused operations and applied research and provides selected technical assistance to missions and selected service delivery projects in order to address key questions regarding the prevention to care continuum.
- **Biomedical Research:** USAID provides support for biomedical research for developing selected technologies, including an effective topical microbicide to reduce sexual transmission of HIV/STIs; rapid, simple, inexpensive STI diagnostic tests; and realistic interventions to reduce mother-to-child HIV transmission.

- **Policy Reform:** USAID supports policy initiatives that focus on increasing commitment to prevention/care interventions, assisting with resource allocation decisionmaking, discrimination, and other key policy areas that enhance and facilitate prevention and mitigation activities.
- **Strengthening Surveillance Systems:** Through agreements with CDC, the U.S. Bureau of Census, and UNAIDS, consensus guidelines will be finalized on minimum surveillance packages for developing countries based on the phase of the epidemic. Technical assistance to missions and host governments will be available to establish and maintain credible surveillance systems, and operations research will develop and refine methodologies to estimate HIV incidence.

In addition to the strategic framework of the Global Bureau, outlined above, USAID's regional bureaus have also developed HIV/AIDS programs that are tailored to meet the needs of each region and are consistent with the Agency's overall HIV/AIDS strategic objective. Each of USAID's geographic bureaus has its own approach.

Africa Bureau--USAID's Africa Bureau provides leadership in the area of integration of HIV/AIDS activities into ongoing maternal-child health programs. It has been in the forefront for its strong support for developing a solid research and analytical agenda for HIV/AIDS. Topics include information, education, and communication strategies for behavioral change; evaluation of integration strategies; analysis of HIV/AIDS inputs from other development sectors; STD service delivery system strengthening; and monitoring/evaluation. The Africa Bureau also is a strong proponent of sensitizing policymakers to the adverse impact of HIV/AIDS on other development sectors, such as education and agriculture.

Latin America/Caribbean Bureau (LAC)--The LAC Bureau's HIV/AIDS strategy focuses on countries where the majority of HIV/AIDS infections occur, e.g., Brazil, Haiti, Mexico. The LAC HIV/AIDS program approaches vary by country depending upon the country's experience level with the epidemic. In some countries, such as those in Central America, USAID's HIV/AIDS efforts stress improving the policy environment, NGO strengthening, and condom promotion. In other countries such as Brazil and Haiti, HIV/AIDS activities focus on targeting high-risk groups such as women, youth, commercial sex workers and men who have sex with men.

Eastern Europe/Newly Independent States (ENI)--HIV/AIDS programs in this region are just beginning as policymakers become increasingly aware of the significance of the skyrocketing problem in this region. HIV/AIDS specific interventions currently are being developed in Russia and Ukraine. HIV/AIDS assessment activities have been completed and initial program plans have been developed. The focus of these early program efforts will be on policy formulation, public education regarding HIV/AIDS prevention, STD/diagnosis and treatment, NGO capacity-building, condom promotion, and targeting high-risk groups, such as youth and injecting drug users. USAID-financed HIV/AIDS interventions in other countries of the region remain to be developed. Some beginning HIV/AIDS education and counseling activities exist in countries such as Romania, where HIV/AIDS information is integrated within an overall women's health strategy.

Asia Near East (ANE)--This region has been identified as the site of the next wave of the HIV/AIDS epidemic. The ANE Bureau has developed a regional strategy that includes the funding of an Asia Regional Office in Bangkok, which provides critical technical support to many USAID-mission bilateral programs. The ANE regional strategy depends heavily on the services provided by cooperating agencies through agreements managed by the HIV/AIDS Division of the Global Bureau PHN Center. Many countries, such as Bangladesh, Cambodia, India, Indonesia, Nepal, and the Philippines, have developed full-scale, USAID-financed bilateral HIV/AIDS prevention programs. Other countries will

rely on USAID assistance provided through the ANE regional bureau in close cooperation with the G/PHN/HIV-AIDS Division. The focus of these regional efforts will be on limiting cross-border and seafarer's HIV/AIDS transmission routes; developing prevention programs in low-prevalence countries; upgrading surveillance systems to improve analysis of HIV/AIDS regional trends; targeting high-risk groups, such as commercial sex workers; and working on specialized issues, including the trafficking of women, condom social marketing, HIV/AIDS/STI case management, behavioral change communications, and policy advocacy. Other regionally supported activities include building and strengthening local NGO programs and identifying local sources of HIV/AIDS technical assistance.

Funding

Since 1986 USAID has committed nearly \$1 billion for HIV/AIDS/STI prevention and mitigation programs in developing countries, where more than 90 percent of the current and new infections occur. The Agency has maintained an HIV/AIDS annual funding level of approximately \$121 million since 1993. For FY-1999 a modest increase to \$125 million was authorized. Also, an additional \$10 million was authorized for FY-1999 only to be used for children affected by HIV/AIDS. These resources are distributed within geographic regions in a pattern that reflects the severity of the pandemic. Approximately 45 percent of the total HIV/AIDS/STI funding goes to Sub-Saharan Africa; 17 percent to Asia/Near East; 12 percent to Latin America/Caribbean; and the remaining 26 percent is provided for worldwide programs, including UNAIDS. If, as experts predict, the severity of the pandemic shifts toward Asia, USAID will need to reconsider resource allocations to reflect the new situation. USAID provides approximately 25 percent of the UNAIDS' budget (\$15 million of a total \$60 million annual budget).

In spite of the fact that USAID is a major international funder for HIV/AIDS/STI prevention programs in the developing world, the financial resources available to combat the pandemic clearly are inadequate to mount an effective, truly global response in view of the steadily increasing HIV/AIDS/STI infection rates. Approximately \$550 million is currently expended per year for HIV prevention and care in the developing world. This includes funding from the international donor community, loans through the World Bank and expenditure by host country governments. By comparison, the annual U.S. expenditure for HIV/AIDS/STI prevention activities domestically is approximately \$700 million. In order to deal with the implications of this funding inadequacy, USAID has strategically focused its efforts on key countries and targets its programs to those most likely to transmit or acquire HIV infection. (The emphasis countries for USAID prevention and mitigation programs are listed on page 31.)

Agency Strategy for Specific Issues

Prevention

While HIV infection is deadly, it is also preventable. In the developing world, where costly, complex antiretroviral therapies are only accessible to a few, primary prevention remains the best, most cost-effective response to the pandemic. Some 80 percent of infections worldwide are attributed to sexual transmission. Over the past 10 years, in over 70 countries worldwide, USAID's prevention strategy has focused first on promoting and facilitating sustained reduction in sexual risk behavior and, more recently, on modifying environmental conditions, such as poverty and the subordination of women, that provoke or facilitate risk behavior.

The behavioral outcomes that increase protection against sexual transmission of HIV and STI are clear: abstinence, long-term mutual monogamy among seroconcordant partners (i.e., HIV status for both partners is the same), reduced rates of partner change (reduced

number of partners), and correct, consistent condom use. Unfortunately, only approximately 10 percent of persons in the developing world currently have access to accurate and confidential HIV testing. However, no two countries and target audiences are alike, and USAID has learned that there is no single blueprint for prevention programs to achieve these outcomes. Rather, the agency has established a process for developing and implementing HIV prevention programs in partnership with host-country governments, non-governmental organizations, technical experts, and intended beneficiaries. This enables USAID-funded services to reach the people at the grassroots level and are shaped to meet the needs of specific target audiences and their cultural, economic, and political environments.

The three pillars of USAID's HIV/AIDS prevention strategy respond to the principal determinants of sexual risk behavior. The first, behavior change communication, is used to transmit information and to engage people in dialogue about HIV/AIDS, STI, reproductive health, gender power, and sexual norms--because people must understand the risks and means of protection, and must be motivated to act to protect themselves and others. The second is condom social marketing, which uses private-sector advertising and commercial distribution approaches to make condoms more widely and sustainably accessible to people who know and are motivated to use them. The third is improved STI services, including improved and more accessible curative care, partner referral, and prevention counseling, because STIs are health threats in their own right, and because they significantly increase the risk of HIV transmission.

Our three core prevention strategies are supported by policy dialogue, behavioral research, and monitoring and evaluation. Improving policy dialogue, for example, through assisting community-based organizations and government officials to consult and work together, helps to shape policy and normative environments so that they facilitate rather than impede risk reduction. Behavioral research is essential for identifying and understanding risky behaviors and the populations who practice them, the characteristics and preferences of key audiences, the language and content of messages that will appeal and "speak" to particular audiences, and other site-specific details. Transferring skills in monitoring and evaluation enables USAID and our partners to track our programs, test assumptions, make mid-course corrections, and document the successes and shortcomings of our activities to inform future programming.

In nascent and concentrated epidemics, our programs prioritize work with so-called "high-frequency transmitters," such as sex workers and their clients, other men whose work takes them away from home for long periods (e.g., military, long-distance truckers), or women and men with large, open sexual networks.

USAID programs have developed an array of methods and innovative models for reaching and serving even hard-to-reach populations at risk of HIV, who often include poor, marginalized groups, such as street children or people living with HIV/AIDS. Key to the success of the programs are procedures for defining specific audiences and tailoring interventions to fit the need, which have been shared among AIDS and reproductive health researchers worldwide. The AIDSCAP program alone supported over 800 projects in over 45 countries, reaching urban university students to rural traders, secondary school students to factory employees, legions of women attending antenatal care clinics to fledgling networks of people living with HIV, and private medical practitioners and pharmacists to traditional healers.

Whether focused services for localized groups or national programs reaching the general population, behavior change interventions strive for both consistency and dynamism. The most effective programs deliver not one but an array of consistent messages through multiple, mutually reinforcing channels (e.g., newspaper, radio, billboards, community theater). And while coherent, these messages need to move with the public ethos, the stage

or readiness of the audience to change, and evolution of the epidemic itself. Thus, new to our programs in the second decade is a more balanced set of messages about HIV/STI prevention, HIV/AIDS care, and clarifying and defending the human rights of people already HIV positive. USAID and its partners across the globe have found that people living with HIV or AIDS are the most convincing educators and advocates in prevention programs, and in high-prevalence settings, communities need help in devising ways to care for families and orphans devastated by HIV/AIDS.

Creating environments where Persons Living with HIV and AIDS (PLWHA) can come forward safely to serve as HIV/AIDS educators and community mobilizers requires confronting and overcoming HIV/AIDS stigma, and combating discrimination and oppression of people with or associated with HIV. This has become an important new focus in USAID's strategy for prevention. In addition, the sustainability of programs hinges upon local participation and ownership, and upon resources that require local private-sector and political support. Overcoming HIV/AIDS stigma both facilitates and follows community and policymaker support for HIV/AIDS prevention and care. In short, while carrying forward the successes of the three "pillars" (BCI, CSM, and STI interventions), plus policy dialogue, behavioral research, and monitoring and evaluation activities, USAID's HIV/AIDS prevention strategy has been expanded, based on a decade of field experience that shows the importance of preparing communities and service providers to respond to a range of individual, family, and community needs along the prevention-care continuum.

Care and Support

USAID supports care activities because they improve our efforts to achieve sustainable development, enhance overall public health, and support our efforts to prevent further spread of HIV. Rather than take a narrow biomedical view of care, USAID advocates care and support activities that are broad in nature and are critical to the continued efforts of communities, governments, and donors to promote sustainable development in the face of the HIV/AIDS epidemic. Care and support activities include:

- Protection of basic human rights;
- Psychosocial care of persons infected with and affected by HIV/AIDS;
- Palliative care for persons with HIV-related symptoms, such as pain, fever, or diarrhea;
- Prevention and treatment of common opportunistic infections;
- Programs that provide economic support to those communities hard hit by HIV/AIDS; and
- Support for foster and extended families for the millions of children who have been orphaned by AIDS.

HIV/AIDS care and support activities enhance sustainable development by shoring up fragile infrastructures. For example, community-based care and retraining of key personnel are essential to preserve the health and education sectors, where in some east African countries up to 40 percent of these workers are already infected with HIV.

HIV/AIDS care and support activities contribute to decreasing secondary epidemics, most notably tuberculosis (TB). The global HIV pandemic is driving a secondary explosion of TB, which is responsible for 35 percent of the deaths of HIV-infected persons in the developing world.

HIV/AIDS care and support enhance all of our primary prevention efforts. Presenting

information and education messages to include everyone in the community increases the acceptance, credibility, ownership, and ultimately the response to behavior-change messages. In addition, programs to protect the basic human rights of HIV-infected individuals and those most at risk for infection open the door for implementing far more effective behavior change campaigns. Prevention efforts, to be effective, must mobilize those living with HIV/AIDS as spokespersons for change. Ultimately, the person who is carrying the virus, particularly one with multiple sexual contacts, is the single most important recruit for prevention programs promoting reduced risk behavior. If programs appear to abandon people living with HIV/AIDS and their families, or to ignore their needs and concerns, we cannot expect them to be of any help.

USAID is also supporting operational research to determine the most cost-effective ways to provide care and support to persons infected. USAID does not at this time support the large-scale procurement of antiretroviral drugs for developing countries. Using antiviral drugs in treatment regimens similar to those used in the United States would cost approximately \$35 billion per year to treat those infected in the developing world. In addition to the enormous cost, these treatments require sophisticated health provider and laboratory infrastructures that do not exist in most of the developing world, where the average health expenditure per person per year is about \$10.

AIDS-Orphaned Children

The number of children affected by AIDS, including those who are orphans or caring for sick parents, continues to escalate. There has been growing recognition and concern for these children. In a study funded by USAID, "Children on the Brink, Strategies to Support Children Isolated by HIV/AIDS," the U.S. Census Bureau estimated that 15.6 million children will have lost their mothers or both of their parents by 2000 in 23 countries heavily affected by HIV/AIDS. That number will increase to 22.9 million by 2010, largely as a result of the HIV/AIDS pandemic. During the Twelfth World AIDS Conference in Geneva, the problems posed by this issue were referred to as a "massive social time bomb." In 1996, USAID expanded its HIV/AIDS strategic objective to include issues related to care and support of those affected by the disease.

More recently, USAID completed a series of discussion papers focusing on issues related to care and support of persons affected by HIV/AIDS. Included among these papers is a document entitled "Responding to the Needs of Children Orphaned by HIV/AIDS," specifically focusing on the effect of the disease on youth. These papers provide background information that will be used to develop the HIV/AIDS strategy on care and support. The strategy will influence future related projects conducted by USAID cooperating agencies and missions.

In addition, "HORIZONS," the HIV/AIDS operations research project, is currently exploring avenues for conducting research to develop "best practices" for setting up community-based methods of providing care and support to people affected by HIV/AIDS, including children. AIDSCAP supported care projects in Haiti, Tanzania, Nigeria, and India, and IMPACT has expanded the capacity of field projects to support community-based care services. Representatives of the HIV/AIDS Division have been actively involved in meeting with other donors and organizations that are working with children and families affected by HIV/AIDS. They have also established an electronic network to exchange technical information among a wide variety of donors and other organizations. These activities contribute toward identifying the scope of the problem, sharing information about how to address it, and coordinating activities to do so.

Women and Health

USAID recognizes that women and girls are at the epicenter of the HIV/AIDS epidemic in every community, both as positive agents of change and as individuals in need of services

and support. Though not recognized as a key audience for HIV interventions until the early 1990s, in most regions women and girls represent the fastest-growing segment of the HIV-infected population.

The impact of HIV/AIDS on women is not solely a function of their greater biological and social vulnerability to infection. It is also because, when family members become ill with HIV disease, the burden of care falls disproportionately on women and girls. Data from a wide range of studies on health and nutrition have confirmed the critical role women can play in improving the health of their families when they have access to information, skills, and some control over resources. USAID's HIV/AIDS programs aim to alert and mobilize communities to respond to the care needs of people living with HIV/AIDS (PLWHA) without sacrificing the progress achieved in women's education and economic participation, because that progress is beneficial for all.

Finally, as noted previously, the ability of an antiretroviral treatment regimen to decrease the risk of mother-to-child transmission (MTCT) has focused attention on another situation where there is a potential risk that a woman's own health and welfare may be given lower priority than the health of her children and family. By aiming to have all USAID programs examined through a gender lens, and by listening to and involving women at all stages of project identification, design, implementation, and evaluation, the USAID strategy acknowledges the complexity of women's lives and roles, and gives priority to programs and approaches that respond to their expressed concerns.

Vaccine Research

Although USAID lacks the resources to independently fund vaccine research, it has a strong interest in the vaccine development process, and it is uniquely positioned to facilitate the implementation of vaccine trials in developing countries. Because of the tremendous genetic diversity of HIV, one of the greatest challenges facing vaccine developers is to produce a vaccine that can protect against infection with diverse viral isolates. This avoids the need for many isolate-specific vaccines. However, because this type of vaccine may not be developed in the near future, there is concern that initial vaccines will be effective only against those strains of virus found predominantly in North America and Western Europe.

It is the U.S. Government view that vaccine candidates should have broad activity against the most common genetic subtypes of virus for two reasons. First is the issue of impact on the epidemic. Approximately 90 percent of all new HIV infections occur in sub-Saharan Africa and Asia, whereas about 1 percent occur in North America and Europe. In order to have an impact on the growth of the epidemic, candidate vaccines should be targeted to those strains responsible for the most new infections.

The second reason to advocate for vaccines with the broadest possible coverage is to prevent selective pressure for new epidemics. A vaccine that provides protection for only the viral subtypes currently prevalent in a community will reduce transmission of those types of virus while leaving the community vulnerable for a new epidemic caused by subtypes not covered by the vaccine.

USAID can assist the vaccine development processes in the following ways:

- Take the lead in educating stakeholders in developing countries. This task entails explaining the importance of clinical trials; making accurate information widely available; responding to questions; ensuring ethical designs; countering misinformation; and lining up high-level support from both host country and U.S. officials.
- Assist in developing the methodology of community-level interventions; fostering long-term, sustained relations with local communities; measuring indirect effects; and

doing impact modeling. By working closely with local communities, USAID could ensure that they are ready to participate in clinical trials.

- Advocate for research on broad-activity vaccines.

Behavioral Research/Behavioral Change Interventions

HIV/AIDS prevention and care hinges upon changes in patterns of risky behavior--be they relating to sex, illicit drugs, or exposure to infected blood through medical waste or unsterile needles, razor blades, and other instruments. Even improvements in STI services will not fulfill their potential impact unless people with STI symptoms and signs change their help seeking behavior, and unless allopathic and traditional practitioners improve their diagnostic and therapeutic practices to recruit people at risk of STI and to satisfy them with their services. Thus, USAID supports behavioral research in our partner countries both to develop new intervention models and to adapt and apply existing models for new settings.

USAID's cooperating agencies conduct behavioral research in:

- Diagnostic studies to define the specific behaviors that put people at risk in a given setting;
- Defining of the distribution of risky behaviors in a population, so as to identify subgroups or target audiences for intervention development;
- Formative research to build understanding of the causes and meanings of risky practices and to pretest intervention ideas and messages with the intended audience; and
- Testing and documentation of the effectiveness of interventions, where changes in behavior are key outcomes of intervention trials.

Under the AIDS Technical Support Project, completed in 1997, USAID's investment in behavioral research comprised a major increase in the resources available for studying the interactions of culture, health, gender, and sexuality in the developing world. The AIDS Behavioral Research Grants Program, funded jointly with NIH, supported partnerships between U.S. and developing-country NGOs (including universities) to revise and adapt theoretical models of health behavior to strengthen HIV/AIDS behavioral interventions in non-Western settings. The nine studies have provided baseline data for local policy and intervention development. They are also helping to build a more representative, international base for evaluating the roles of culture, society, and behavioral biology in human sexuality and health behavior and for guiding the design of behavior-change interventions appropriate for particular audiences and settings.

USAID-funded projects have established formative behavioral research as a prerequisite of technically sound intervention development. Most of our future interventions will contain data collection components that enrich the knowledge base for understanding HIV risk behavior and opportunities for prevention and care. In addition, the HORIZONS project will extend these achievements through a program of developing research to answer selected research questions in nine thematic areas: 1) STI prevention and management; 2) HIV care and support services; 3) stigma and discrimination; 4) risk assessment and behavior change; 5) policy analysis and change; 6) social marketing and private-sector involvement; 7) NGOs and community mobilization; 8) integration of HIV/STI, family planning, and maternal and child health services; and 9) community mobilization.

In addition to pursuing some relatively new topics in developing countries (e.g., HIV/AIDS stigma), USAID has mandated all projects under the Global Bureau's HIV/AIDS strategic

objectives to document and develop knowledge about the following cross-cutting issues: gender inequalities and their effects on risk reduction and program success; the vulnerability of youth; involvement of PLWHA in HIV/STI intervention programs; building local NGO and community-based organization (CBO) capacity; links between prevention and care services; sustainability of services; costs and cost-effectiveness of service modalities and models; and methods and costs of taking successful pilot projects to scale.

Microbicide Development

USAID has been a major contributor to the search for a topical microbicide. Topical microbicides are products that ideally can be used, without the cooperation or consent of a sexual partner, to protect from the possibility of acquiring HIV and other sexually transmitted diseases (STD). The agency has supported laboratory work to identify and test promising compounds, as well as the Women's Health Advocates for Microbicides (WHAM), an innovative group that advocates for the product and promotes international collaboration and involvement of women at all stages of product development.

Most products that have been developed and tested in the past several years have been based on a product known as Nonoxynol-9 (N-9), which, unfortunately, has not proved effective as of this date. In collaboration with the Research Division in the Office of Population, the HIV/AIDS Division is currently supporting a trial of a new microbicide, developed with support from USAID, which has a unique mechanism of action and has been shown to be safe in preliminary studies. The study is expected to continue for approximately 2 years and provide information on safety and effectiveness of the product.

Donor Coordination

Donor coordination is key to the success of the U.S. response to the HIV/AIDS global pandemic. USAID's G/PHN Strategic Objective 4 "to increase the use of improved, effective, and sustainable responses to reduce HIV transmission and to mitigate the impact of the HIV/AIDS pandemic," includes donor coordination and partnership at global, regional, and country levels. USAID has been an active partner with the United Nations in providing financial support for international HIV/AIDS program efforts. Since 1986, USAID has been a major contributor to the WHO Global Program on AIDS. As that program terminated in 1995, USAID support shifted to a new United Nations HIV/AIDS endeavor that officially began in January 1996.

Also, in countries where USAID missions include HIV/AIDS as part of their country strategy, PHN offices coordinate closely with the Joint United Nations Programme and other donors that may be in-country. In addition, there are a series of specific donor coordination activities, including the U.S.-Japan Common Agenda, collaboration with the United Kingdom's Department for International Development (DFID), the European Union (EU), and a number of other selected partners. There are also excellent examples of strong coordination, through funded activities with national governments, PVOs/NGOs, and local organizations.

Capacity-Building

Effective HIV/AIDS programs work to sustain changes in behaviors that contribute to the risk of HIV infection and to establish, improve, and maintain systems and practices to appropriately manage the effects of HIV and AIDS. As HIV/AIDS becomes endemic in many countries, the need for programs to achieve and sustain these results over the long term is heightened. The time period to achieve sustained changes in risk behaviors and manage the effects of HIV will exceed the timeframe of many external technical inputs and donor contributions. Therefore, a programming strategy that prioritizes building local capacity within the public and private sector is essential.

The USAID HIV/AIDS program works to build the local public- and private-sector response to HIV/AIDS by increasing political awareness and commitment in local government, and by increasing the technical and managerial capacity of local public, commercial, and nonprofit entities to provide services and commodities required for sustainable HIV/AIDS programs. Within the public sector, USAID and its partners work with government ministries of health and other sectors to increase:

- Political awareness of the effects of HIV and the importance of preventing HIV infection and appropriately caring for those who are infected;
- Technical quality and use of surveillance information in monitoring the epidemic and in program management and evaluation;
- Quality and reach of public-sector services needed in HIV programming, such as STI diagnosis and treatment, logistical systems for commodities (i.e., essential drugs and condoms), and training in counseling and home-based care;
- Collaborations between the public and private sector.

USAID and its partners strengthen the technical and managerial capacity of indigenous NGOs so that they have greater competence in, impact on, and influence over the design, implementation, and evaluation of sustainable HIV/AIDS prevention and care programs. USAID also works to build and improve regional and local networks and coalitions. The networks provide technical support and improve advocacy efforts by building relationships across public- and private-sector institutions.

USAID works to strengthen commercial-sector involvement by increasing the awareness of the potential impact of HIV and by building HIV-prevention programs for the business environment. In addition, some USAID programs work to leverage local commercial markets for condoms and other commodities, such as essential drugs for STI treatment. Sustained local responses to HIV will depend upon public- and private-sector involvements that supplement and complement each other. As we enter the second decade of the HIV/AIDS pandemic, it is clear that the populations requiring HIV prevention and care and support services are changing and increasing. Building the capacity of local institutions to recognize these changes and respond to these increasing demands is critical in order to stem the impact of this pandemic.

Reducing Mother-to-Child HIV Transmission

Mother-to-child transmission (MTCT) is the second leading route of transmission of HIV in the world. Annually, over 590,000 infants are infected by their mothers. This transmission takes place during one of three times: before birth, during labor and delivery, or during breastfeeding.

Following the ground breaking ACTG 076 study, in February 1998, researchers from the U.S. Centers for Disease Control and Prevention announced the results of a randomized placebo-controlled study in Thailand. This study demonstrated that a short course of AZT given to HIV-infected women in the last trimester of their pregnancy, plus high doses of AZT during labor, could achieve a 50 percent reduction of transmission of HIV to their infants. Because this compared favorably to a much more costly and complex regimen used in developed countries, the results of the Thai study have raised global hopes that a significant reduction in the number HIV-infected infants can be achieved.

Despite the very exciting results of the Thailand study, a number of questions remain to be answered before the promise of this research can be realized. These are:

- **Breastfeeding:** The Thai study worked with a non-breastfeeding population. Can similar results be achieved in populations that breast-feed? To do so will require that mothers use infant formula in settings where this is not a common practice. What effect will the use of formula have on infectious disease deaths associated with bottle feeding. Will HIV-negative women stop breastfeeding?
- **Voluntary HIV counseling and testing (VCT):** More than 90 percent of HIV infected women in developing countries do not know they are infected and have little or no access to voluntary, confidential HIV counseling and testing. How can this service be made available at a scale large enough to have a broad impact without sacrificing the quality and confidentiality of the services?
- **Infrastructure and capacity:** Many antenatal care settings in developing countries are struggling to provide basic care for pregnant women. If MTCT programs are added to existing activities, can they be carried out properly? Will they achieve in practice what was seen in a clinical trial? Conversely, will the additional burden of MTCT programs compromise the quality of basic antenatal care?
- **Stigma and discrimination:** Stepped up VCT, special antenatal programs, and the use of infant formula all have the potential to reveal a woman's HIV status to the community. Women who reveal their HIV status are at a very high risk of domestic violence, stigmatization and ostracization by family, friends, and community. How can MTCT programs prevent or minimize these negative consequences?

USAID believes that before MTCT initiatives are taken to a large scale, these and other questions need to be answered. We are thus collaborating with UNICEF, UNAIDS, and host-country researchers to conduct a series of operational research studies in two or three developing countries. In 18 to 24 months these studies will give us many of the tools we need to appropriately and effectively use the recent scientific findings.

Impact of USAID Programs-- Monitoring and Evaluation

At the country level, we can now point to two major categories of success. In one set of countries (e.g., Senegal, Philippines, Indonesia), early, comprehensive HIV intervention programs, supported by USAID and other donors, have helped curtail and prevent a major epidemic. For example, USAID-supported prevention campaigns that included policy dialogue, behavior change efforts, better treatment of STDs, and improved access to simple technologies like condoms to reduce HIV transmission.

Even more dramatic, we now see another set of countries (e.g., Uganda, Dominican Republic, Thailand) where intensive HIV/AIDS programs were launched after major epidemics had erupted, yet the numbers of new infections are now actually decreasing. For example, sentinel surveillance in Ugandan antenatal clinics shows that the rate of HIV has fallen by 35 percent among young women aged 15-24. In Thailand, USAID supported an intervention study that developed an educational and sexually transmitted infections screening program that was expanded for the entire military. The rate of new infections among military recruits fell from 3 percent to under 1 percent as a result. These are amazing achievements, every bit as significant as the breathtaking progress in HIV treatment in the United States.

Our ability as a global community to achieve these reductions in new infections is predicated on a basic lesson learned from the past 10 years of program implementation: We can reduce unsafe sexual behavior in a sustainable way. We now have ample evidence that public health programs can affect change in the most private and basic of human behaviors, sex. While it is impossible to attribute declining national HIV rates to any single program,

USAID-funded research has shown that people are responding to widespread, consistent education messages about HIV/AIDS prevention and care and to dramatic increases in the availability of key tools and services.

USAID's evaluation research in poor urban neighborhoods in the Dominican Republic where our program operates, found that rates of sexually active youth declined from 73 percent in 1993 to 30 percent in 1996, and rates of participation in "transactional sex" (exchanging food, money, school fees, etc., for sex)--declined from 27 percent to 7 percent among males. The proportion of Ugandan girls who have ever had sex declined by almost half between 1989 and 1995. Over half of young sexually active Ugandans report using condoms in their last sexual contact; this rate was close to zero at the outset of the epidemic. In Bali, Indonesia, USAID's peer education project with sexually active 15- to 25-year-olds led to an increase in consistent condom use, from 22 percent to 72 percent.

USAID's HIV/AIDS-Assisted Countries			
Africa Regional	Asia Near East Regional	Eastern Europe/Newly Independent States Regional	Latin America/Caribbean Regional
Benin	Bangladesh	Russia	Bolivia
Congo (Kinshasa)	Cambodia	Ukraine	Brazil
Ethiopia	Egypt		Dominican Republic
Ghana	India		El Salvador
Kenya	Indonesia		Guatemala
Madagascar	Laos		Haiti
Malawi	Morocco		Honduras
Mali	Nepal		Jamaica
Niger	Philippines		Mexico
Nigeria	Vietnam		Nicaragua
Senegal			Peru
South Africa			
Tanzania			
Uganda			
Zambia			
Zimbabwe			

Zimbabwe			
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U.S. Information Agency

Agency Mandate Relevant to HIV/AIDS

The U.S. Information Agency's (USIA) mission is to promote the national interest and national security of the United States through understanding, informing, and influencing foreign publics regarding U.S. foreign and domestic policies (including HIV/AIDS policies). It acts to broaden dialogue between American citizens and institutions and their counterparts abroad. USIA's public diplomacy strategy regarding USAID's policies extends throughout the year and employs a full range of public diplomacy tools. These include:

- Distributing policy information to foreign media, academics, and other government and civic opinion-makers through U.S. Information Service (USIS) posts at U.S. embassies abroad;
- Arranging speaking tours and programs/seminars abroad for U.S. experts on AIDS issues.
- Broadcasting policy information on Voice of America (VOA) radio and USIA television services and providing foreign publics with language-version news clips, editorials, and interactive dialogues featuring prominent U.S. experts and "best practices" of American individuals and communities meeting the challenge posed by AIDS and other infectious diseases. For example, VOA gave worldwide coverage to World AIDS Day last December 1 in all 52 languages in which VOA broadcasts.
- Publishing policy statements and analysis on the USIA International Homepage, which includes frequently updated information for USIS field officers to use to alert foreign leaders, NGOs, journalists, and healthcare specialists to the threat of AIDS-related health issues and responsibilities of the international community. This information is supplemented with timely reports highlighting American and foreign achievements and cooperative efforts in combating AIDS.
- Publishing a USIA electronic journal on "Infectious Diseases/The Global Fight." The 40-page journal features commentaries by Dr. Anthony Fauci, U.S. Surgeon General Dr. David Satcher, and USAID Director J. Brian Atwood, among other articles.
- Organizing briefings by senior U.S. AIDS experts for foreign journalists at USIA's Foreign Press Centers in Washington D.C., New York, and Los Angeles, as appropriate.
- Developing U.S. programs for international visitors, including discussions and briefings on AIDS policies and issues, such as treatment, prevention, and research efforts.

Funding

The funding level dedicated to HIV/AIDS programs by USIA is difficult to assess. Much of the programming conducted by the Agency is electronic, e.g., VOA broadcasts, WORLDNET TV programming, and the electronic journal (published in November 1996). There is no specific budget for these programs, other than staff salaries and overhead

expenses. However, in addition to these programs, USIA exchanges under the Fulbright, International Visitor, and U.S. Speaker programs budgeted \$655,200 in FY-1998 on HIV/AIDS programs. This figure has been relatively constant since 1995.

Agency Strategy for Specific Issues

The U.S. Information Agency is a multifaceted public diplomacy organization that uses its multilingual electronic and print media outlets and its educational and exchange programs to give broad support to policies aimed at combating HIV/AIDS.

U.S. Peace Corps

Agency Mandate Relevant to HIV/AIDS

Peace Corps' efforts in HIV/AIDS education and prevention is divided into three spheres of activities: (1) education efforts targeting Peace Corps employees; (2) education efforts targeting Peace Corps Volunteers (hereinafter "Volunteers"); and, (3) prevention efforts conducted by Peace Corps Volunteers targeting the people in the countries in which the Volunteers are serving. The focus of this document is on the third sphere--the work that the Volunteers do in the communities in which they serve. To date, the Peace Corps' HIV/AIDS prevention and education activities are being conducted in 48 countries around the world.

Peace Corps does not earmark any of its appropriated budget to a technical area such as HIV/AIDS. Rather, the agency funding is used to recruit, place, and support Volunteers--many of whom then work in HIV/AIDS efforts. Peace Corps does receive funding from USAID through an interagency agreement to support some of its HIV/AIDS activities. In FY-1999, these resources will total \$450,000.

Agency Strategy for Specific Issues

Prevention

The focus of Peace Corps work is in prevention, specifically, targeting women and youth. Since the mid-1980s when HIV/AIDS was first identified, Volunteers have been working to help individuals and communities understand the disease and to collectively develop solutions for ways communities can protect themselves and care for those who become ill. In December 1988, the Peace Corps and the Government of the Central African Republic negotiated the first formal agreement to place Volunteers in HIV/AIDS education. Since then, the pace of Volunteers' involvement has increased dramatically, both in number of volunteers engaged in HIV/AIDS work and in the range of activities.

Peace Corps Volunteers work in some health projects focused solely on HIV/AIDS; community health projects that also have an HIV/AIDS prevention component; projects that are not primarily involved with health, e.g., education projects; and community outreach activities undertaken by the Volunteers in addition to their main assignment.

The four major programmatic areas that the Volunteers work in are:

- NGO and community-based organizations (CBO) development in HIV/AIDS;
- Integrated community health approaches to HIV/AIDS prevention and care;
- Programs for women and girls; and
- Programs for youth, both in and out of school.

The Peace Corps meets these objectives largely through training and educational activities that build host-country capacity in project planning, monitoring/evaluation, and organizational management.

An example of the kind of work that Volunteers do is illustrated in the participatory development of a unique, low-cost, content-based approach to English-language instruction, "Teach English, Prevent AIDS" project in Cameroon. Education Volunteers, Cameroonian educators, and public health specialists worked together to draft 50 hours of lesson plans. To date the program has provided behavior change education to 300 teachers and 10,800 students, all of whom were also engaged in community-based HIV/AIDS prevention campaigns through the learning process. The manual, published with private-sector support, and the curriculum development process itself are being considered by UNAIDS as an international model for student and community education. The program is sustained as a part of the curriculum and has been adapted by multiple Peace Corps posts to use throughout Africa and the rest of the world.

Volunteers have a viable role to play in HIV/AIDS prevention and education overseas. Most importantly, Volunteers are successful in accessing communities that are often not reached by National AIDS Programs and in introducing new innovative education methods to achieve their outreach.

Although not quantified, there are a growing number of Volunteers who, based on their experiences overseas, return to the United States and continue to work in HIV/AIDS prevention in their communities. Bringing the lessons home is a valuable contribution that the Peace Corps makes to the domestic efforts in HIV/AIDS work.

U.S. Department of Health and Human Services

National Institutes of Health

Agency Mandate Relevant to HIV/AIDS

The National Institutes of Health (NIH) supports a comprehensive program of basic, clinical, and behavioral research on HIV infection and its associated opportunistic infections and malignancies. Each of the 24 NIH Institutes and Centers is involved in some HIV/AIDS-related research activity consistent with its individual mission. NIH is the world's leading biomedical research institution, supporting more than 5,000 individual HIV/AIDS research projects at more than 500 research institutions across the nation and around the world. NIH has played a leadership role in the discovery and characterization of HIV and continues to lead research to determine the pathogenesis of AIDS. Findings from NIH-sponsored studies have resulted in significant advances in the treatment of HIV infection and its related illnesses and prevention of the opportunistic infections that cause morbidity and mortality of HIV-infected individuals.

The NIH AIDS program supports biomedical and behavioral research necessary to identify therapeutic regimens, behavioral interventions, and vaccine candidates to treat and prevent HIV infection and its associated illnesses in the United States and internationally. The global nature of the AIDS epidemic underscores the critical need to identify interventions for developed and developing nations that prevent HIV transmission, disease progression, and mortality. Continued collaboration with international organizations and other nations is required to achieve these priorities. Research capacity-strengthening in foreign countries is a critical element to NIH's efforts to address HIV/AIDS, and in this regard, NIH supports a strong research training program with partners in 100 countries.

The NIH AIDS program includes collaborations with numerous international organizations. Ongoing and planned efforts include collaborations with the following organizations: UNAIDS, in planning for the initiation of international vaccine clinical trials; the Pan American Health Organization (PAHO) for studies on heterosexual transmission of HIV infection and tuberculosis prophylaxis; the World Health Organization (WHO) in the Antibody Serologic Project; WHO as one of three AIDS reagent centers; and WHO for support of several international workshops and conferences.

In addition, since its inception in 1996, NIH has collaborated with UNAIDS through mutual representation on advisory and coordinating bodies, frequent exchange of information, and collaboration on specific efforts, such as vaccine development, ethical issues related to clinical trials, and research training and infrastructure in developing countries. In this regard, the National Institute of Allergy and Infectious Diseases (NIAID) and the Fogarty International Center (FIC) have been designated UNAIDS Collaborating Centers. Additionally, NIAID and the National Institute of Child Health and Human Development (NICHD) have collaborated with UNAIDS on the Working Group on Prevention of Mother to Child Transmission of HIV.

The NIH Office of AIDS Research (OAR) is located within the Office of the Director of NIH and is responsible for the scientific, budgetary, legislative, and policy elements of the NIH AIDS research program. Congress provided in the NIH Revitalization Act of 1993 broad authorities to the OAR to plan, coordinate, evaluate, and fund all NIH AIDS research. The OAR is responsible for developing an annual comprehensive plan and budget for all NIH AIDS research. The OAR supports trans-NIH Coordinating Committees to assist in these efforts in the following areas of program emphasis: Therapeutics, Vaccines, Natural History and Epidemiology, Behavioral and Social Sciences, Etiology and Pathogenesis, Training and Infrastructure, and Information Dissemination.

The OAR promotes collaborative research activities in both domestic and international settings. These research studies are conducted by the Institutes and Centers of the NIH, including the NIAID, National Cancer Institute (NCI), NICHD, National Institute of Mental Health (NIMH), National Institute on Drug Abuse (NIDA), and FIC.

A report by a group of non-government scientists and AIDS community representatives who were convened to evaluate the NIH AIDS research program, has had a significant effect on almost every aspect of the AIDS research program--in setting the scientific agenda, refocusing priorities, and shaping the AIDS research budget. The recommendations in the "Report of the NIH AIDS Research Program Evaluation Working Group of the Office of AIDS Research Advisory Council" (also known as the "Levine Report") helped frame the OAR's final distribution of the NIH AIDS appropriations for fiscal years (FY) 1997 and 1998. In addition, the Levine Report significantly influenced the priority setting that occurred in the development of the FY-1999 NIH Plan for HIV-Related Research and Budget, which the OAR is congressionally mandated to develop in concert with the annual NIH AIDS research budget request. The priorities established by the Levine Report will have an impact not only on government-supported research but on the research agendas of industry and private research organizations in the United States and abroad.

The report articulated the importance of coordinating international HIV/AIDS research efforts with other agencies, international organizations, and other governments. Further, it listed as one of several high priorities "domestic and international studies testing the efficacy of joint behavioral and biomedical strategies for combined control of HIV and other sexually transmitted diseases and combined control of HIV and other adverse health consequences of injection drug use."

The FY-1998 and FY-1999 NIH AIDS research priorities include the following:

- A continued increased emphasis on fundamental science, particularly investigator-initiated research;
- A comprehensive effort, including several important new research initiatives, to develop new vaccine candidates and bring them to clinical trials as soon as possible, including a refocusing on the importance of international collaboration at the earliest stages of vaccine development and testing;
- An augmentation of research efforts to better understand the human immune system; and
- An emphasis on prevention science research, including enhanced domestic and international studies of risk-taking behavior and the development on strategies to avert infection, such as microbicides, female-controlled barriers, and STD treatment and prevention.

National Institutes of Health					
International AIDS Funding					
(in thousands of dollars)					
	FY-1995 Actual	FY-1996 Actual	FY-1997 Actual	FY-1998 Estimate	FY-1999 Estimate
NCI	5,876	3,415	5,641	5,674	5,775
NIDCR	--	--	782	816	901
NINDS	2,103	1,923	973	973	973
NIAID	21,112	21,691	24,892	26,958	29,958
NIGMS	--	--	92	89	84
NICHD	2,263	3,302	4,151	4,400	4,700
NIMH	4,301	3,894	3,512	3,656	3,912
NIDA	1,839	140	--	500	500
NCRR	677	590	418	499	588
FIC	9,108	9,694	10,312	10,611	11,305
Totals	\$47,279	\$44,649	\$50,773	\$54,176	\$58,696
Source: National Institutes of Health					

Agency Strategy for Specific Issues

Prevention

NIH-sponsored programs targeting the development and evaluation of various preventive interventions have resulted in marked changes in sexual and drug-using behaviors associated with HIV transmission among at-risk populations, including difficult-to-reach and socially disenfranchised populations in the U.S. and abroad. NIH programs have demonstrated that behavioral interventions targeting behaviors can be developed and implemented, including those designed to delay or prevent initiation of sexual activity and drug use. These studies have demonstrated that multifaceted risk-reduction programs, including those providing drug treatment, outreach, and education on HIV risk, and sterile injection equipment, can produce significant and sustained decreases in HIV risk behavior among injection drug users. Prevention research has shown that interventions must be culturally and ethnically directed in order to successfully reach targeted populations. NIH also is studying community-level interventions as an important way to effect behavioral change on a larger scale.

Preventing vertical transmission from HIV-infected mother to child is a priority of NIH intervention research. Implementing the ACTG 076 protocol has significantly reduced the incidence of maternal-fetal HIV transmission in the United States. Ongoing efforts are designed to identify and test other interventions that can effectively and easily be used globally to further reduce the incidence of vertical transmission of HIV. NIH-funded scientists are actively studying the timing and mechanisms by which HIV is transmitted from mother to baby so that more effective interventions can be developed to block mother-to-child transmission.

NIH also has sponsored several international conferences on the prevention of perinatal transmission. The second Global Strategies Conference on Prevention of HIV Transmission from Mother to Infant will be held in September 1999 in Montreal Canada. It will bring investigators from developing countries together with investigators from more developed countries to plan future collaborative strategies for the prevention of mother to infant HIV transmission.

NIH international efforts in prevention research and related training and research capacity-building include the following:

- Studies of the role of viral shedding in infectivity for both sexual transmission and mother to child transmission;
- Studies in several developing countries in Africa, Asia, and Latin America to evaluate interventions for reducing mother-to-child transmission of HIV that may be used in diverse cultural and economic settings, such as the use of short courses of treatment with zidovudine, nutritional supplements, HIV-1 hyperimmune intravenous immune globulin, vaginal cleansing, and studies of breastfeeding;
- Development of safe, effective, and acceptable condoms, microbicides, and other female-controlled barriers;
- Studies in Africa on the efficacy of STD treatment and prophylaxis on reducing sexual transmission of HIV; and
- Development of behavioral interventions to reduce the risk factors associated with HIV transmission, including injection drug use and various sexual behaviors.

In response to the Levine Report recommendation for developing a Prevention Science Agenda that combines behavioral and biomedical intervention research, the NIH sponsored several agenda setting activities, including a 1998 Workshop on International HIV/AIDS Prevention Research Opportunities. The goal of the Workshop was to encourage research that would be feasible and relevant for developing countries with limited resources. Representatives from 37 countries severely affected by the epidemic participated in the workshop to develop a "Basic Prevention Package," a list of HIV prevention interventions that would be important in developing countries, and a listing of "Priorities for International HIV Prevention Research." Another outcome of the workshop was a better understanding of the HIV prevention planning process. More information on this workshop may be found at <http://hivinsite.ucsf.edu/ari>.

Behavioral Research/ Behavioral Change Interventions

NIH supports an extensive portfolio of behavioral and social science research on HIV infection and AIDS. These studies have demonstrated the important interaction of biological, psychological, and social factors that contribute to HIV prevention, transmission, and disease progression among individuals and population groups. Findings from these studies have significantly contributed to the understanding of human behaviors that affect HIV transmission risk and to the development of successful interventions to encourage sustained behavioral change. NIH-sponsored behavioral and social science research includes research related to the following goals:

- Developing, implementing, and evaluating behavioral and social interventions to reduce HIV transmission;
- Strengthening the understanding of the determinants, trends, and processes of HIV-related risk behaviors and the consequences of HIV infection;
- Developing and evaluating behavioral strategies for preventing or ameliorating the negative physical, psychological, and social consequences of HIV infection; and
- Improving the research methodologies employed in behavioral and social science research.

NIH-supported studies are ongoing, either independently or linked with biomedical studies, in countries in Africa, Asia, and Latin America.

Vaccine Research

The development of a safe and effective HIV vaccine is of the highest priority for the NIH, and NIH has pledged to work with the other G-8 nations on vaccine efforts. NIH supports a broad program of basic, preclinical, and clinical research on the discovery and development of HIV vaccine candidates. Basic research on HIV and the immune system provides crucial information for developing potential vaccines. Various strategies for stimulating a protective immune response against HIV infection are being explored through basic research, animal model research, and clinical trials. In recognition of the need to develop vaccines that are efficacious against a variety of strains found around the world, NIH supports studies analyzing genetic and antigenic variation of HIV and targeted toward eliciting cross-reactive immune responses. While the goal of preventive vaccines is to end the HIV pandemic by protecting individuals from HIV infection, vaccines also may serve as immunomodulators to improve immune function and slow disease progression in infected individuals and may prevent them from infecting others.

To accelerate the development of NIH's AIDS vaccine effort, the AIDS Vaccine Research

Committee (AVRC), chaired by Dr. David Baltimore, was established. Specific areas of basic research relating to HIV vaccines efforts have been identified by the AVRC and a new, special initiative supporting innovative research in these scientific areas has been funded during the last 2 years to advance this research field. To further HIV vaccine research in the NIH intramural programs, the Vaccine Research Center is being constructed with completion targeted for 2000.

The NIH supports an AIDS Vaccine Evaluation Group (AVEG), which consists of six sites nationwide that are actively evaluating potential HIV vaccines in phase I and II clinical trials. To date, the AVEG has conducted or initiated more than 46 trials with 24 different HIV vaccine candidates. All vaccine candidates to date in AVEG phase I trials have been shown to be safe and well tolerated. In preparation for phase III clinical trials, NIH supports a domestic and international network of sites that are currently identifying the cohorts of populations at risk for HIV infection and building the infrastructure necessary to conduct large-scale efficacy trials of potential HIV vaccine candidates when they become available. These efforts involve strengthening in-country research capacity by training foreign scientists and health professionals. NIH collaborates with UNAIDS, host country governments, and in-country scientists in vaccine development and preparation for efficacy trials. Eleven sites have been established in Africa, Asia, and Latin America.

Treatment Equity

In an effort to identify options for clinical management of HIV-infected patients that would be useful in resource-poor settings, NIH is supporting studies on the use of isoniazid and rifampin to prevent active tuberculosis in PPD-positive, HIV-infected patients in Uganda. In addition, NIH-supported scientists in Thailand are studying risk factors for infection with *Penicillium marneffei*. These NIH-trained scientists also are working with the pharmaceutical industry in Asia on developing therapeutics for *P. marneffei* infection.

Women and Health

NIH supports an extensive portfolio of basic, clinical, and behavioral research focusing on women and HIV/AIDS. HIV-infected women experience some complications of HIV disease that are unique or more prevalent in them than in men, such as vaginal and esophageal candidiasis, chronic herpes simplex infections, other STDs, and cervical dysplasia. NIH-sponsored programs target studies on the natural history and epidemiology of the disease in women through a number of studies in Africa, Asia, and Latin America.

Studies on the etiology and pathogenesis of HIV infection and disease progression in women are ongoing. These studies focus on the role of STDs and other factors in acquiring HIV infection and the pathogenic mechanisms associated with HIV disease progression. Studies on biologic determinants of infectiousness and susceptibility are important areas under investigation. Specific attention is being given to the possible correlation between the level of cell-free or cell-associated HIV in blood, semen, urine, cervical/vaginal secretions or oral fluids, and the probability of transmission. In addition, NIH-funded researchers are investigating the cellular and molecular aspects of mucosal immunity and other infectious diseases as cofactors, as they impact HIV susceptibility and transmission. Results from these studies are critical to developing safe and efficacious AIDS vaccines and microbicides.

A critical area of concern is the impact of HIV on cervical cancer. Co-infection with human papilloma virus (HPV) is common in HIV-infected women, and HPV has been shown to act synergistically with HIV to increase expression of individual viral genes. A study in Africa is examining the natural history of cervical neoplasia in women infected with HIV-1 and HIV-2 and the role of HPV as a risk factor.

Of similar critical importance is a current NIH-sponsored multi-site international trial to determine any possible increase in risk acquisition of HIV through heterosexual contact by uninfected women who use hormonal contraceptives. Other studies are planned to examine the possible effects of steroidal hormones on early, acute HIV infection and later progression to AIDS among hormonal contraceptive users, and on the possible effect of steroidal hormone use on the infectiousness of HIV-infected women.

NIH-supported behavioral and social science research that relates to or focuses on women include studies on (1) determinants of HIV risk and prevention; (2) specific elements of social and cultural life that contribute to HIV risk and protective behaviors; (3) the development of appropriate interventions to reduce risk behaviors; (4) community-level interventions; (5) acceptability of both biomedical and behavioral interventions among different individuals and communities; (6) the behavioral aspects of the adoption of new HIV prevention technologies, such as microbicides and the female condom; and (7) social and psychological factors influencing treatment adherence and compliance as well as participation in clinical trials.

Microbicide Development

NIH sponsors a comprehensive biomedical and behavioral program for the discovery, development, preclinical testing, and clinical evaluation of topical microbicides and other female-controlled barrier methods for prevention of HIV transmission. Population-based research is essential to ensure both the efficacy and acceptability of these interventions to decrease or eliminate HIV transmission. It is an NIH priority to develop a safe, inexpensive, reliable, and acceptable microbicide for the prevention of HIV and other STDs.

The development of screening assays to test compounds and agents for their microbicidal/spermicidal activity, as well as developing suitable animal models for safety and efficacy-testing of potential microbicides, are vital parts of the developmental efforts supported by NIH in this field of research. Close collaboration with industry is important in conducting the important phase I through III clinical testing of these agents in various populations and to ensure their eventual availability. While a number of microbicidal substances have been clinically tested in phase I and II studies to date, a safe, effective, and acceptable microbicide has yet to be identified. NIH has placed a high priority on developing an efficacious microbicide and continues to look at new compounds, as well as other barrier interventions. In FY-1999, NIH will establish a Prevention Trials Network that will focus on the testing at U.S. and international sites of various interventions, including microbicides, the expansion of the Topical Microbicide Program Projects involving multidisciplinary research to develop and test new agents and the expansion of programs targeting the developing and clinical testing of spermicidal microbicides and other female-controlled barrier methods.

Other Activities

Basic biomedical and behavioral research has significantly contributed to advances in AIDS research. Findings from basic research have provided the scientific basis for developing potential AIDS drugs, vaccine candidates, and effective behavioral interventions to halt the AIDS epidemic.

The NIH has the primary responsibility for the Federally-supported clinical trials evaluating potential treatment regimens against HIV infection and its associated opportunistic infections and malignancies. NIH supports an extensive network of more than 100 clinical trial sites, including adult and pediatric units in major domestic medical centers and community-based primary care settings. More than 50,000 patients have been enrolled to date in these studies that have involved evaluating more than 200 different drugs. The enrollment and accrual in these clinical trials of women, minorities, children, adolescents, injection drug users, and other populations is a high priority for the NIH.

Centers for Disease Control and Prevention

Agency Mandate Relevant to HIV/AIDS

The U.S. Department of Health and Human Services (DHHS) is committed to working in partnership with others to reverse the toll that HIV/AIDS is taking on millions of lives by halting the further spread of HIV and mitigating its effects on those already infected through research, prevention, service delivery and education efforts. Scientists at DHHS have contributed significantly to international progress in understanding how HIV infection is transmitted, how it affects the body, and how to treat and prevent it. As new information becomes available, increased knowledge about this disease and better ways to treat and prevent it should be forthcoming to address this critical health problem.

As the Nation's prevention agency, CDC integrates prevention science, research and practice. Through basic and laboratory research, epidemiologic research, and surveillance, behavioral, communications, and social science research, CDC supports a comprehensive approach to issues which impact prevention. CDC collaborates with governmental and non-governmental organizations, international and domestic, awarding grants to national organizations, state and local health departments, community-based organizations and other institutions to support prevention activities based on science. This integration of science and practice is consistent across all of CDC's Centers, Institutes, and Offices supporting prevention science activities. These include the National Center for HIV, STD and TB Prevention (NCHSTP), the National Center for Infectious Disease (under which falls the Division of AIDS, STD, and TB Laboratory Research), the National Center for Chronic Disease Prevention and Health Promotion (under which falls the Division of Adolescent and School Health and the Division of Reproductive Health), the Office of Women's Health and the Public Health Practice Program Office (which ensures the quality of laboratory testing).

Funding

In FY-1998, DHHS received more than \$6.8 billion dollars for HIV/AIDS activities. The majority of these funds (nearly two-thirds) were distributed for care and treatment of Americans through the Health Care Financing Administration (HCFA) authorized under Medicaid and Medicare programs and through the Health Resources and Services Administration (HRSA) authorized under the Ryan White Care Act. Funding for international collaborative HIV/AIDS activities is limited within the offices and agencies within DHHS, with no formal budget allocation for international activities. Therefore, only a tiny percentage of HIV/AIDS funds are allocated for international HIV/AIDS activities.

Agency Strategy for Specific Issues

Prevention

CDC has two programmatic approaches to international collaboration in HIV/AIDS prevention: field-based research collaborations and limited CDC-based technical assistance, training, and project management.

Field-Based Research

Epidemiology of HIV. Field-based research provides collaborative assistance to Côte d'Ivoire, Uganda, South Africa and Thailand. Studies are designed to increase the understanding of the epidemiology of HIV and to evaluate intervention methodologies in the host country and the United States. Because of the variation in the virus itself throughout the world, CDC, through two of its centers in Côte d'Ivoire and Thailand, conducts international surveillance of the genetic diversity of HIV research collaborations in numerous countries throughout the world.

Perinatal Transmission. Earlier this year, researchers from CDC and the Ministry of Public Health in Thailand announced dramatic findings that offer real hope for extending perinatal prevention successes to many developing nations. Researchers found that a short course of AZT given late in pregnancy and during delivery reduced the rate of HIV transmission to infants of infected mothers by half and is safe for use in the developing world. CDC is continuing collaborative research in West Africa to establish the longer term efficacy of short course zidovudine for populations in whom safe alternatives to breast feeding may not be available.

Microbicide Development. CDC has also supported international collaboration on the development of microbicidal products, as well as international studies in acceptability of microbicides in Zimbabwe and Thailand. In addition, a number of domestic and international activities have included research about the potential impact of including information on microbicides, once available, as part of the prevention messages about condoms. CDC participates with NIH and FDA in the International Working Group on Microbicides, which also includes UNAIDS, the Population Council and some industry representatives.

Prophylaxis of Opportunistic Infections. In Côte d'Ivoire, a placebo controlled trial of cotrimoxazole in patients in treatment for tuberculosis showed a significantly reduced mortality in immuno-suppressed patients taking the active drug. The recently completed trial of preventive therapy for tuberculosis in Uganda, conducted by Case Western Reserve University in collaboration with Ugandan colleagues was supported by CDC as well.

Vaccine Research. CDC has a number of research activities related to the development of HIV vaccines. This includes participation in efficacy trials in the United States and Thailand, as well as in the development of novel candidate vaccines in collaboration with academic centers. In addition, behavioral research and communication efforts about vaccine related issues are ongoing. CDC expertise in vaccine implementation will be a valuable resource once candidates become available.

Technical Assistance

In addition, CDC provides both long and short term technical assistance internationally. Long-term technical assistance and management capacity has been established by CDC field assignees to Uganda and South Africa, working in conjunction with USAID, as well as India and Vietnam. In addition to these field-based staff, CDC provides short-term technical assistance and training to numerous countries including Brazil, Russia, The Republic of South Africa, and Mali, and to international organizations including UNICEF, UNAIDS, and WHO.

Training

In conjunction with these technical assistance activities, CDC provides training in the areas of epidemiology, evaluation, prevention methodologies and other technical areas through an extensive program of training based in Atlanta as well as at field sites in Thailand and Côte d'Ivoire. CDC has also designed a program, in collaboration with USAID, to link U.S.-based community organizations and their prevention interventions with counterparts in developing countries. This was established in order to provide a mechanism to share

relevant experiences, provide materials and resources, and training opportunities across countries. Other activities will support USAID-assisted countries with access to CDC epidemiologic and surveillance expertise.

Other Activities

Although not specific to HIV/AIDS, it is important to note that CDC's international work focuses heavily on strengthening public health infrastructure, and such work can contribute to sustainable HIV/AIDS control. For example, the CDC established field epidemiology training programs in developing countries. Epidemiology is the cornerstone of public health science, and trained epidemiologists are valuable countries to detect, monitor and help control their key public health programs. Secondly, CDC has established a sustainable management development program to provide practical training in management of public health programs in developing countries.

Recognizing the urgency of the epidemic and its impact on many domestic issues, CDC is committed to HIV/AIDS research within, as well as outside of, U.S. borders. To understand HIV/AIDS at a global level, research must address issues and conditions unique to different countries and communities within countries. Many developing countries severely affected by the epidemic lack the research capacity, public health infrastructure, and financial and human resources to respond to the epidemic. CDC's international research underscores the importance of developing and implementing diverse interventions to address issues among varied populations and to do so quickly and cost-effectively.

Food and Drug Administration

Agency Mandate Relevant to HIV/AIDS

The Food and Drug Administration (FDA) is the only agency within the U.S. Public Health Service whose responsibilities are regulatory in nature. Its purview is product-driven and encompasses products worth approximately 25 percent of the U.S. gross national product. FDA activities respond to product applications--the agency reviews what is brought to it.

FDA's level of commitment to prevention, diagnosis, and treatment of HIV/AIDS is broad-based. FDA, like all of its component agencies in the U.S. Public Health Service, is committed to finding more and better ways to prevent, diagnose, and ultimately cure HIV/AIDS. FDA performs research and review involving AIDS therapeutic and diagnostic vaccine products. Major research priorities include: (1) new more sensitive blood safety testing for HIV; and (2) methods, standards, and studies on mechanisms of action of new AIDS therapeutics and vaccines.

Funding

FDA and its budget is organized around the products within its regulatory framework and is not, generally, a grant-making institution nor an entity organized in terms of line items for particular diseases or disease groups. FDA does not have a specific international budget allocation.

Agency Strategy for Specific Issues

Prevention

Medical Devices. FDA has an ongoing responsibility to help ensure the safety and effectiveness of AIDS-related medical devices through its regulatory activities. This includes sampling and testing of medical gloves and latex condoms; reviewing submissions to market devices that reduce the risk of HIV transmission, including donor screening tests; conducting HIV-related regulatory research involving medical devices; and evaluating the role of devices in the transmission of bloodborne infections.

FDA has cleared for marketing over 280 needle and intravenous cannulas with safety features that reduce the risk of sharps injuries to healthcare workers. Among sharps containers FDA has recently cleared for marketing are devices that electrically oxidize all types and sizes of needles immediately after use, further reducing the risk from used needles.

As condoms remain the best means of protection against the transmission of HIV and other sexually-transmitted diseases, FDA must be vigilant in its regulation. FDA is working to develop better tests for condom strength and is investigating the barrier capability of condoms manufactured of different materials.

Blood and Blood Products. FDA is responsible for ensuring the safety of the U.S. blood supply. Regulatory mechanisms designed to ensure blood safety include establishing policies; approving authority for blood products and establishments; and surveilling and enforcing blood safety standards. The blood safety system FDA has established consists of five layers of overlapping safeguards that start at the blood collection centers and extend to the manufacturers and distributors of the blood products made from donated blood.

The first level of precautions seeks to eliminate high-risk donors by encouraging those whose blood may pose a health hazard to exclude themselves, and by evaluating their behavioral and medical history as a basis for deferral. The second safeguard entails constant updating of a list of unsuitable donors and checking donors' names against the list to prevent using their blood. The third consists of testing the blood for such bloodborne agents as HIV, hepatitis, and syphilis. The fourth safeguard FDA enforces is a quarantine of donated blood until tests and other control procedures establish its safety. Finally, the blood collection centers are obligated to investigate incidents, audit their systems, and correct deficiencies. FDA also sets quality and safety standards for blood-derived products such as viral inactivation of clotting factor concentrates and immune globulins.

Treatment Equity

Therapeutic Agents. FDA is responsible for approving safe and effective drugs and biologics used in the United States for treating HIV infection, AIDS, and AIDS-associated opportunistic infections. FDA is also responsible for regulating the investigation of new drugs. It places special emphasis on ensuring the most timely and efficient premarketing review possible of products that offer promise for diagnosing, treating, or preventing HIV and HIV-related illnesses. FDA has approved 37 applications for products to treat HIV/AIDS. Twelve drugs are antiretroviral agents that are used to treat the virus, and the remaining 25 are used to treat opportunistic infections that can complicate HIV infection. In addition, FDA is responsible for monitoring the safety of the drugs and biologics post marketing and places special emphasis on ensuring that new safety information is disseminated widely and in a timely manner.

Vaccine Research

Within the framework of the Public Health Service-wide vaccine program for prevention and therapy, FDA is continuing its efforts to guarantee that any promising products for immunization against HIV will receive expedited regulatory review, and when appropriate, will be approved in the shortest possible time.

Diagnostic Capability

Diagnostic Reagents and Test Kits. FDA conducts a variety of regulatory, testing, and research activities to approve for marketing satisfactory test methodologies for detection of HIV. FDA has approved 2 HIV-1 Antigen tests; 20 anti-HIV-1 assays; 3 anti-HIV-2 assays; 1 anti-HIV assay on urine; 1 anti-HIV testing service using home collection; 1 anti-HIV-1 oral specimen collection device; and 1 HIV-1 viral load assay. FDA currently is facilitating development of gene-based screening tests.

U.S. Department of Commerce

Agency Mandate Relevant to HIV/AIDS

The mission of the Department of Commerce is to foster, serve, and promote U.S. economic development and technological advancement. Data collection and analysis programs conducted by the Bureau of the Census and the Bureau of Economic Analysis affect the distribution of funds and other resources for private and public health initiatives, including HIV/AIDS research, treatment, and service programs. The Bureau of the Census maintains the broadest and most current numeric database in the world on HIV prevalence and incidence information for sub-Saharan Africa.

Scientific standards, methodologies, and technologies developed through the programs of the National Institute of Standards and Technology (NIST) affect laboratory procedures and equipment calibration at HIV/AIDS research facilities. The Patent and Trademark Office Biotechnology Examining Groups review and research patent applications for immunological testing apparatus and processes, apparatus for chemical and clinical analysis, immunoassay and pharmaceutical compositions, and apparatus and processes related to sterilization, cell biology, and blood and blood products.

Agency Strategy for Specific Issues

Vaccine Research and Other HIV/AIDS-Related Research

Patent Database. On its homepage on the World Wide Web, the U.S. Patent and Trademark Office provides a searchable database containing the full-text and images of patents related to AIDS research. This free service is available to anyone with access to the Internet, in the United States or internationally. Currently, there are almost 3,000 U.S. patents available for searching, as well as almost 800 Japanese patent documents and approximately 700 European patent documents in this database. This project was coordinated by the Patent and Trademark Office and the National Science Foundation and developed in cooperation with private and nonprofit organizations.

Advanced Technology Program. The Department has funded biotechnology development projects through NIST's Advanced Technology Program (ATP). The ATP is a unique partnership between government and private industry to accelerate the development of high-risk technologies that promise significant commercial payoffs and widespread benefits for the economy. The ATP encourages a change in how industry approaches R&D, providing a mechanism for industry to extend its technological reach of what can be attempted. The ATP supports enabling technologies that are essential to developing new

products, processes, and services across diverse application areas. Private industry bears the costs of product development, production, marketing, sales, and distribution.

ATP awards are made strictly on the basis of rigorous peer-reviewed competitions designed to select those proposals that are best qualified in terms of the technological ideas, the potential economic benefits to the nation, and the strength of the plan for eventual commercialization of the results. One project currently being funded through the ATP is a project on the Evolution of a Murine Model for AIDS: Applications to Discovery of Small Molecule and Vaccine Therapeutics. This project aims to provide a small-animal model for research on AIDS therapies and vaccines by developing a variant of HIV-1 that will replicate in mice. This approach will be less expensive than the current practice of using primates and has the potential to accelerate discovery and improve the quality of new AIDS therapies and vaccines.

Accelerated Processing of Patent Applications. The Patent and Trademark Office offers accelerated processing of applications for inventions related to HIV/AIDS.

Trade. The Department of Commerce works closely with the U.S. pharmaceutical and biotechnology sectors in the battle against HIV/AIDS. Commerce is proud that the U.S. industry is one of the leaders in research and development that produces new medical products to combat HIV/AIDS. Through Commerce trade missions and seminars, the Department works with industry to spread information about new medical products and discoveries in the pharmaceutical and biotechnology areas. Commerce will work with industry and other governments to create a trade environment that maximizes the exposure of new HIV/AIDS treatments. It will continue to combine efforts with industry, non-governmental organizations (NGOs), and other government agencies in a coordinated effort against the HIV/AIDS epidemic.

HIV/AIDS Surveillance. The U.S. Bureau of the Census, International Programs Center, compiles, evaluates, and analyzes selected health and related data for all countries overseas. With funding from USAID through an interagency agreement, the Health Studies Branch maintains and updates the HIV/AIDS Surveillance Data Base, which is a compilation of information on HIV prevalence and incidence from all available studies from Africa, Asia, Latin America, and some select countries in Europe. Using this information, the Bureau of the Census tracks patterns and trends in HIV infection among subpopulations within countries. This information is then used to estimate AIDS mortality and is incorporated into our world population estimates and projections. These estimates are available from the Bureau of the Census' International Data Base.

The International Programs Center has been designated a UNAIDS Collaborating Centre and contributed to the development and production of the UNAIDS Epidemiological Fact Sheets.

U.S. Department of Defense

Agency Mandate Relevant to HIV/AIDS

The threat that HIV/AIDS poses to the capabilities and readiness of the U.S. military forces is of great concern. In response to that threat, the military research program was initiated in 1986 to minimize the impact of HIV on military readiness by monitoring the spread of HIV infection in military forces and developing methods to prevent infection. The Tri-Service effort, which includes the Army, Navy, Air Force, and Marines, is a highly targeted

research program that addresses the military concerns of HIV. This includes surveilling infection rates and HIV subtypes around the world; developing vaccines and education strategies to prevent infection; and originating clinical studies to slow progression and prevent immune deficiency.

The Military HIV Research Program has as its primary goal the prevention of HIV infection in the fighting force. Once infected, the soldier, sailor, airman, or Marine is, irrevocably, a casualty, and that service member and his or her family and the country will feel the effects--physically, emotionally, and economically. Knowledge that HIV infection is possible and that HIV is present in the environment can have deleterious effects on unit morale and cohesion of deployed forces. Preventing HIV decreases casualties and improves unit effectiveness; helps protect the replacement blood supply; and preserves the available recruitment population in the civilian community.

Agency Strategy for Specific Issues

Vaccine Research

The Military HIV Research Program's preventive vaccine strategy involves developing several vaccine candidates in concert with industry, academia, and collaborators in Thailand. An initial Phase I safety trial of an HIV recombinant protein vaccine was successfully completed in Thailand in 1997. The vaccine was safe and well tolerated, with immunogenicity similar to that observed in U.S. trials. This current trial is the first of its kind to match the HIV vaccine to the HIV subtype of the population. The Program is conducting the first Phase II vaccine trial with a vaccine prepared from HIV subtype E, which is prevalent in the population of Thailand. The Military Program has a comprehensive vaccine development strategy with clear milestones leading to a large-scale efficacy evaluation of candidate vaccines in the year 2001.

The military research program is highly leveraged through cooperative development initiatives with private industry. In 1998 alone, three new cooperative research and development agreements were established, and two new HIV candidate vaccines have entered Phase I trials at the Walter Reed Army Institute of Research (WRAIR) and the Army overseas laboratory in Thailand.

Cooperation and coordination with other Federal agencies (including NIH/National Institutes of Allergy and Infectious Diseases and the Centers for Disease Control) and international agencies (WHO and UNAIDS) and a strategic alliance with the Royal Thai Government has resulted in an unprecedented opportunity to conduct advanced development and testing of protective vaccines.

Regarding vaccine testing, an initial Phase I vaccine trial of an HIV DNA vaccine began in 1998 with volunteers at WRAIR. Another protocol for an HIV vaccine involving unique boosting strategy with a novel envelope protein also began at WRAIR. The Military Program has secured a commitment from several of its industrial partners to produce large batches of these vaccines and plans to proceed with a large-scale multiple-arm efficacy vaccine trial in Thailand. The possibility of conducting vaccine trials in east Africa is also being investigated where it would be possible to test the effectiveness of vaccines against the subtypes of HIV found in Africa. Continued development and testing of second-generation vaccines with significantly improved biological properties generates optimism for the rapid advancement of vaccines effective against the various HIV subtypes found throughout the world.

In the area of diagnostic and clinical research, the Program is working on post-exposure prophylactic measures to deal with mass casualty situations in HIV-endemic areas overseas.

involving U.S. military personnel. These emergency situations require using rapid, sensitive diagnostic field tests for HIV, which are currently being developed and evaluated. In a clinical study, the Program has assessed using an HIV gp160 vaccine as therapy for persons already infected with HIV. The results of this long-term, Phase II study involving over 600 volunteers demonstrated that the amount of virus-- a patient's viral load--predicts disease progression. In addition, certain antibody responses altered disease progression so that the production of these antibodies will be the target of future vaccine development. In another clinical research project, there is an ongoing effort to monitor the development of resistance to antivirals in patients receiving triple drug therapy. This will assure the most effective use of these drugs while extending the lives and health of HIV-infected military healthcare beneficiaries.

Finally, DOD representation and numerous presentations of DOD conducted research have occurred at HIV/AIDS international meetings.

National Intelligence Council

Mandate Relevant to HIV/AIDS

The intelligence community and its various components produce analyses on the scope and impact of HIV/AIDS in response to Presidential decision directives, the needs of their associated agencies, and ad hoc requests from senior policymakers.

Strategy for HIV/AIDS Issues

The National Intelligence Council will produce an assessment on the global threat from infectious diseases, including HIV/AIDS; the capacity of foreign governments and international organizations to deal with such diseases; and the implications for the United States.

The Defense Intelligence Agency's Armed Forces Medical Intelligence Center (AFMIC) will continue to assess systematically worldwide HIV/AIDS incidence and prevalence. AFMIC also will forecast the impact of HIV/AIDS and other infectious diseases on U.S. national security interests and deployed forces. It will also examine the impact of such diseases on foreign military force readiness, military and civilian healthcare infrastructures and transnational health trends.

Other intelligence community collection and analytical components will focus on HIV/AIDS issues as necessary and upon authorized request.

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456-2439

Author: GlobalAIDS@aol.com at INTERNET
Date: 11/5/98 1:06 AM
Priority: Normal
TO: Margaret Scarlett at -OPHS_DC
Subject: USG Global AIDS response memo

Friends and Colleagues-

The Department of State has released a final draft version of the "1999 US International Response to HIV/AIDS". We urge you to look at this document and consider responding. You can find it at the department's web sit-
www.state.gov

This could be an important document, providing a unified strategy for US global AIDS efforts at a time when the pandemic is exploring and the US leading the world response. GAAN has not had time to review in-depth this report since we were given the 100+ page document over the weekend. However we note two things missing from the report:

1. The first document of this sort written in 1995 by Undersecretary Wirth was called a strategy; this document is labeled a "response", and is more accurately described within the text as a "compellation of USG policies". The Department of State appears to be abandoning its responsibility to lead the US strategic planning in response to AIDS.

2. Cooperation among the various agencies engaged in US global AIDS programs is so poor that several agencies actually refused to allow their comments to be part of the draft report. Quote "At the request of the Department of Health and Human Services, the section on the National Institutes of Health is not being made available for public review of the draft document."

The Department of State has missed all of its own deadlines in drafting and releasing this compilation. As a result they will not meet with US AIDS groups on this draft. They also have shortened the response time for your comments to a few days. It was announced at the US Conference on AIDS this weekend that the Department of State needed all responses to this draft by 5 PM Wednesday November 5, 1998.

All of this hurry appears to be so the document, such as it is, can be released by the Secretary of State on World AIDS Day- December 1.

The many month fiasco around this report has discouraged deeply those of us involved in global AIDS issues. Many groups have abandoned efforts to make this document meaningful as clearly no one at higher levels of the Department of State cares about the global AIDS pandemic.

None-the-less I wanted to call the release of the draft document "1999 US International Response to HIV/AIDS" by the Department of State to your attention ASAP. We urge you to respond as you are able.

GAAN will review this report in depth and seek to respond. We will not give up on making the Department of State a meaningful participant in US global AIDS policies. If you or your organization would be willing to be involved in this ongoing issue please let us know.

And share this information with those you think may be interested.

Paul Boneberg
Global AIDS Action Network

1999 U.S. INTERNATIONAL RESPONSE TO HIV/AIDS

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U.S. INTERNATIONAL RESPONSE TO HIV/AIDS

PREFACE

The 1999 U.S. International Response to HIV/AIDS is part of a continuing effort by the USG to create positive change in the international fight against HIV/AIDS. It is designed to foster political commitment, assist in the development of appropriate international partnerships, and provide a directory of public programs which can serve as a model of government policy and resource investments made by the U.S. Government to more effectively meet the challenges posed by the global HIV/AIDS pandemic.

The 1999 response, like the 1995 strategy, is the product of an interagency effort and provides a framework of programs and strategies that have proven effective in the past and which can be used as a model to guide future efforts in the continual battle against HIV/AIDS. It contains a set of USG priorities for combating the worldwide spread of HIV/AIDS. Participating agencies include the White House Office of National Aids Policy, the U.S. Department of State, the U.S. Agency for International Development, the U.S. Information Agency, the U.S. Peace Corps, the U.S. Department of Health and Human Services (National Institutes of Health, Centers for Disease Control And Prevention, and the Food and Drug Administration), the U.S. Department of Commerce, the Department of Defense, the National Intelligence Council and the U.S. Department of Justice.

The 1999 response reviews the objectives of the 1995 strategy and the USG accomplishments and difficulties in meeting those objectives. It then examines the remaining challenges confronting the USG and other members of the international community in meeting the many challenges of the HIV/AIDS epidemic. The goals of the 1999 response are to:

- Raise awareness to the issue of international HIV/AIDS;
- Promote collaboration between governments, international organizations, and the private sector in the development of international partnerships to leverage investments of capital and expertise into sustainable programs to fight HIV/AIDS.
- Encourage political and economic commitment by foreign

- leaders to more appropriately meet human needs;
- Encourage and support the efforts of UNAIDS and other international organizations;
- Promote greater human rights for those afflicted with HIV/AIDS; and
- Highlight the growing needs of women and children infected with HIV/AIDS.

This document is not to be viewed as a funding directory or as a manual for eradicating the HIV/AIDS epidemic for this would be an oversimplification of the problem and its solution. Rather, we provide this compilation of USG policies and the programs and priorities in an effort to better coordinate and share our collective expertise in the hopes of expanding the beneficiaries of the lessons learned and goals accomplished through successful, responsible partnerships at home and abroad.

No member of the global community can afford, either in terms of human suffering or economic costs, to recognize and to act to forestall the impending devastation which has already begun to ravage national economies, security and social infrastructure. It threatens the very fabric of society, regardless of race, creed or spiritual belief. Disease is the equalizer, touching all nationalities, all genders, and ages but which preys hardest on those least able to meet its economic costs, and in the case of HIV/AIDS, those in their most productive stage of life-- between the ages of 20 and 45.

The one-world nature of life as we know it, where people change address and transportation routes, and exchange goods and services over vast distances links us all in this battle. We must approach the solutions to our collective dilemma in a universal and collaborative way that brings to bear the most fervent action and the most specialized resources we each have to offer.

We look forward to each nation joining this initiative at the highest levels bringing sustainable commitments to see this fight through to its successful conclusion. Our tools are effective, multi-sectored national policies and programs underpinned by strong public health infrastructures with effective preventative health care as a global priority.

The target audience of this document includes governments of both developing and developed nations,

international organizations, non-governmental organizations, industry and the public at large. We at the State Department will take the charge by initiating high-level foreign policy discussions by our ambassadors and other embassy representatives with host country counterparts to disseminate and discuss the strategy and by encouraging leaders to expand HIV/AIDS prevention and mitigation programs. Our goals are to raise the level of priority by all governments accorded to stemming the spread of HIV/AIDS and infectious diseases of all kinds, and to collaborate on disease surveillance and response of infectious disease threats. We will continue to work with international organizations, governments, non-governmental organizations, industry, and others in the private sector to effect this goal as a global priority to reduce human suffering, and to safeguard all peoples from the devastation of HIV/AIDS.

INTRODUCTION: WORLD AIDS SITUATION

A Rapidly Expanding Epidemic

Dire predictions from the 1980s have become the reality of the 1990s, as HIV moves from the latent state to active disease in an increasing number of people around the world. HIV/AIDS is insinuating itself into communities previously little troubled by the epidemic and strengthening its grip on areas where AIDS is already the leading cause of death in adults. The cumulative number of those infected has nearly tripled from the 10 million infections estimated in 1990. UNAIDS and the World Health Organization estimate that over 30 million people are infected with HIV and 16,000 new infections are acquired every day. An estimated 2.3 million in 1997 alone and 11.7 million people around the world have already lost their lives to the disease. Given the current rate of infection as well as the sheer number of those already infected, the death toll from HIV/AIDS is projected to increase exponentially in the years to come.

AIDS is a global problem touching virtually every country and every family around the world. It does not recognize nationality, gender, age, or sexual preference. Globally, one in every 100 adults 15 to 49 years of age is HIV-infected; at least 80 percent of these infections are due to heterosexual transmission.

Regional Assessment

AIDS ignores international borders, cultural practices, and religious beliefs. HIV/AIDS is resident in humans in every region of the globe, from Sub-Saharan Africa to Asia, the Americas, Eastern and Western Europe to the Middle East. However, most HIV infections are concentrated in the developing world, largely in countries least able to afford the care for infected people. In fact, nearly 90 percent of people with HIV live in the developing world. .

AIDS is now threatening development gains that local and donor governments, citizens, non-governmental organizations, and international agencies have worked for decades to achieve. Sub-Saharan African, with 67% of the world's people living with HIV, has less than 10 percent of the world's population. In many sub-Saharan African countries, AIDS has increased infant mortality and reduced life expectancy to levels not seen since the 1960s. By the

year 2010, life expectancy in some sub-Saharan countries could decrease by 30 years or more. In just the last three years, 27 countries have seen their HIV infection rates double. AIDS is doubling, or even tripling, death rates among young adults in countries in southern Africa. In Botswana and Zimbabwe, prevalence among young adults has reached 25 percent - one person in four, a historic new high. In South Africa, it is estimated that three million people are now living with HIV, and 700,000 were infected in 1997 alone.

Globally, the number of children under 15 who have lived or are living with HIV since the start of the epidemic in the late 1970s has reached approximately 3.8 million - 2.7 million of whom have already died. Nearly 600,000 children were infected with HIV in 1997, most were infected before or during birth or through breastfeeding by HIV infected mothers. From the beginning of the epidemic until the start of 1998, some 8.2 million children around the world lost their mothers to AIDS. In 1997 alone, it is estimated that HIV orphaned 1.6 million children and 90 percent of the orphans live in sub-Saharan Africa. In some sub-Saharan African nations, infant and child mortality rates are expected to double and even triple early in the next century if the HIV infection rates are not reduced.

An important trend of the 1990s has been the beginning of the shift of the global AIDS epicenter from Africa to Asia, which will soon have more new HIV infections than any other region of the world. Though the HIV epidemic was a latecomer to Asia and the Pacific, its spread has been swift. Since 1994, almost every country in Asia and the Pacific region has seen HIV prevalence rates increase by more than 100 percent. Nearly 6.2 million people in the region are now believed to be living with HIV. In years to come, that number may grow dramatically. India and China, the two most populous countries on earth, have experienced exponential growth. India, with a population of over 900 million, had 3-5 million people infected in just the last three years, making it the nation with the most HIV/AIDS infected individuals. China, the world's most populous nation, will need to act quickly and effectively to avoid following a similar course.

In some, such as Senegal and the Philippines, HIV has remained at roughly the same low levels for a number of years. It is these countries that have the greatest potential to avert epidemic spread by acting quickly.

Infection rates are rising rapidly in much of Asia, Eastern Europe and southern Africa.

The situation in Latin America is mixed, with prevalence in some countries: mainly Mexico, Brazil, Guyana, and Haiti rising rapidly and in other countries, as in many industrialized nations, infection rates have stabilized or are falling. The level of damage sustained by developing nations varies with the maturity of the epidemic and the response of national authorities and local communities to the threat of its spread throughout the population.

In Eastern Europe, though the absolute numbers are lower, many countries have experienced a doubling or tripling of their infections since 1994. Before 1995 the incidence of HIV/AIDS in the former Soviet Union and Eastern Europe was negligible. However, in 1996, 8,000 new HIV cases were reported. In Russia 2,223 cases of HIV were reported in the first six months of 1997 alone and by the year 2000, without appropriate interventions to eliminate illegal IV drug use and to curb high risk behaviors, as many as one million Russians could be infected with HIV.

The long lag time between HIV infection, AIDS and death - which is 4-5 years in developing countries and 10 years, on average, in industrialized countries - helps explain why most countries have yet to see the damage the epidemic can do to their social and economic fabric. By the year 2000, the estimated direct (medical) and indirect (loss of labor force and family impact) costs of the disease will exceed \$500 billion. In South African, President Mandela has stated that the South African economy will shrink by 1% a year because of AIDS.

II. ASSESSMENT OF U.S. INTERESTS

In the face of HIV/AIDS, the USG aims to reduce human suffering in the face of HIV/AIDS and stem further disease transmission. We must remind ourselves that the world looks to and depends on the United States, both for financial support and for the technical expertise to reduce HIV/AIDS transmission and to take a leadership role in mitigating its devastating individual and social impact. Focusing our considerable technical and human resources on this pandemic confirms our national ethos to help those in need. Fulfilling this trust, however, is also in the interest of the citizens of this country. This pandemic is the silent enemy of economic growth, national well-being, and stability around the globe, without distinction to borders, nationality, gender, or religion. Further, our hopes of new markets and stable democracies could be threatened by an unbridled HIV epidemic in our partner countries. The new epidemics in Russia and the Ukraine are sobering reminders that this applies worldwide.

The number of AIDS cases worldwide will continue to rise in the next millennium and will increasingly undermine other projects intended to foster key U.S. policy goals, including democratization, economic development, conflict resolution and peacekeeping, and promotion of individual and political rights. The AIDS pandemic will overwhelm underfunded and inadequate health delivery systems in much of the developing world and could undo hard-won health, social, and economic gains by nations around the world.

Security and Political Concerns

Although not an issue of strategic security in the classic sense, the growing incidence of HIV/AIDS internationally and its pervasive impact must reshape U.S. thinking about definitions of security and about U.S. leadership in a changing world. The security implications are due to the fact that the increase in HIV-infected military personnel is gradually weakening the capacity of militaries to defend their nations and maintain civil order, to provide qualified personnel for overseas training and to have access to a healthy conscription pool.

The high HIV/AIDS infection rate in military personnel of many countries will result in national security threats as militaries are diminished and depleted by the disease. According to a 1996 UNAIDS report, it was found that an

astounding 50% of Zimbabwe's 50,000 military personnel were infected with the virus. In this instance, a strong correlation found between rank and prevalence rates indicated that as the disease progresses militaries would suffer from debilitated leadership and an inability to meet military needs and commitments.

AIDS has also emerged as a significant political destabilizing factor. The virus' infiltration into the middle class, ruling elites and military personnel of developing countries poses unique security threats. By the year 2000, the estimated direct (medical) and indirect (loss of labor force and family impact) costs of the disease will exceed \$500 billion.

In many instances, the spread of HIV/AIDS creates a crippling cycle. Civil strife, refugee flows, urbanization and poverty all play a role in creating conditions for the rapid spread of HIV. When economies and governments fail, or are chronically enfeebled, health systems rapidly falter, leaving populations more prone to illness and the potential ensuing economic decline. As an example, political instability and disease have reinforced each other in Rwanda and the countries of the Former Soviet Union.

Developed countries are not immune to the destabilizing effects of HIV infections. HIV blood test scandals in Germany, France, and Switzerland have resulted in national outcries and triggered the dismissal or prosecution of government and other officials.

Social and Economic Impacts

Like the spread of the disease, the economic impact of HIV/AIDS is pervasive and devastating. Severely affected countries will experience large impacts on their health sector and on the poor. AIDS will affect the health sector in two ways: by increasing demand and by reducing the supply of a given quality of care at a given price. As a result, some HIV-negative people who would have obtained treatment had there been no epidemic will be unable to do so, and total national expenditure on health care will increase, both in absolute terms and as a proportion of national product. The net effect will be to increase the price and reduce the availability of health care for everyone, which will tend to affect the poor the most. Governments, therefore, will confront tradeoffs along at least three dimensions: treating AIDS versus preventing HIV infection;

treating AIDS versus treating other illnesses; and spending for health versus spending for other objectives.

Regionally, a severe HIV/AIDS epidemic will tend to worsen poverty and increase inequality because low-income households will be more adversely affected by an AIDS-related death. Decisions made at the household level to reallocate resources (such as time, labor, housing, and land) to meet costs related to the disease may alter the distribution of income in society and create new groups of poverty. Because HIV is predominantly transmitted sexually, AIDS kills many people in their 20s, 30s and 40s - their economically most productive as well as child bearing years.

One important way in which AIDS is likely to exacerbate poverty and inequality is the increase in the number of children who lose one or both parents. Embattled populations are becoming progressively less productive and are burdened with increasing numbers of children orphaned by AIDS. As a result, development in these countries is adversely affected, and they will require increased economic and medical assistance from the community of developed nations. The problems posed by HIV/AIDS will generate additional pressure on North-South transfers of resources, cooperation, and bilateral relations.

AIDS also affects the workplace both because of reduced productivity and because HIV-related illnesses can cause increased absenteeism among employees and increased employee costs. Employee turnover related to the disease requires increased training and recruitment costs. In addition to soaring medical costs, corporations incur expenditures related to death benefits and funerals.

The full social and economic costs to a nation from HIV/AIDS are almost incalculable. Most prevalent among adults in their years of greatest productivity, economic well being, particularly of developing nations, will be drastically affected by the presence and spread of HIV/AIDS in the country.

The loss of so many working-age adults to illness and death undermines previous achievements in extending life expectancy, and increases the burden placed upon the gamut of government and social systems: the education system, healthcare systems, business and industry, communities and families. Already the HIV/AIDS epidemic is taking a toll on the education systems. Children are being forced to leave

school to care for ailing parents who themselves have fallen prey to the disease. When orphaned, children usually abandon schools in more immediate need of a livelihood as a means of self-support. That livelihood all too often becomes commercial sex work, selling themselves to survive or to support their remaining siblings or other extended family. This situation already worsened by the growing international financial crisis in Asia, Russia and Latin America, portends an even greater likelihood of increased transmission of HIV/AIDS and other STI's.

The pool of uneducated and undereducated people due to HIV/AIDS related causes further threatens to undermine critical economic investment for business which needs a stable, well-educated, and healthy laborpool for production of goods for domestic and international commercial markets. The increased costs of doing business due to increased turnover of employees and additional training and other employee related benefits and costs could raise the costs of doing business and discourage international investment critical to stabilizing regional and national economies. This would also mean a reduction in taxes and other production-related revenues generated from tourism and other inputs in a healthy economic climate, at the same time increased healthcare needs and associated costs for treating HIV/AIDS victims strain national healthcare budgets.

Poorly trained and educated girls and women, with few opportunities for employment in the business sector may resort to or be sold into commercial sex work by impoverished family members in an effort to cover family expenses in times of economic hardship. Not only does this lead to an erosion of society, and a further undermining of the roles and status of women, but also leads to the increased transmission of HIV/AIDS, and an exacerbation of the poverty/HIV/AIDS cycle of suffering. With fewer healthy people, and the healthy needed to support the sick, there will be fewer persons available to care for the growing numbers requiring care. They will likely look to the formal healthcare system, in whatever state it may exist, for care and support. And the ever-growing numbers of sick and dying will severely burden inadequate healthcare infrastructures, increase fear and intolerance, which could lead to increased violations of human rights.

Of all the economic and social costs incurred due to HIV/AIDS, healthcare costs are the most easily quantifiable. The World Bank estimates that in the average country, the

annual treatment cost of AIDS is about 2.7 times GNP per capita. Spending on AIDS treatment increases with GNP; on average, treating an AIDS patient for one year costs about the same as educating 10 primary school students for one year. If India maintains its current level of health care subsidies, a severe AIDS epidemic would increase government health care expenditure by about \$2 billion per year by 2010. If subsidies are increased to the 50% level, the same size epidemic would increase annual government health expenditures by an additional \$30 billion.

HIV/AIDS is not simply about mustering resources, technological know-how, and collective will to manage and eventually halt the spread of AIDS. The political and economic reverberations of HIV/AIDS demand a far broader response. Its increased incidence among military populations, its transforming of the debates about both North-South issues and gender equity, and its challenges to the central tenets of human rights are all inextricable elements of policy development and implementation.

III. ASSESSMENT OF 1995 STRATEGY

The July 1995 US International Strategy on HIV/AIDS was structured around three broad categories of goals: 1. Prevent New HIV Infections; 2. Reduce Personal and Social Impact; and 3. Mobilize and Unify National and International Efforts. The following is a brief review of the progress made on these goals since that time. This review does not constitute an exhaustive analysis of the activities of each agency, rather it is simply intended to highlight areas of success and to identify areas where more action needs to be taken.

Prevent New HIV Infections

There is not yet a cure for HIV/AIDS and existing treatment regimens are costly. As such, the bulk of USG efforts and achievements since 1995 have been in the area of prevention. Under the heading of preventing new HIV infections, the 1995 Strategy laid out several points for action:

- Take diplomatic initiatives to promote more active involvement on HIV/AIDS issues by national governments;
- Develop behavioral prevention strategies;
- Augment research;
- Safeguard the blood supply;
- Provide access to health services and technologies;
- Address the adverse impact of poverty and other factors on prevention efforts.

Take Diplomatic Initiatives to Promote More Active Involvement on HIV/AIDS Issues by National Governments

As a result of the 1995 U.S. International Strategy on HIV/AIDS, the Department of State, in conjunction with other agencies, has taken numerous diplomatic initiatives to promote more active involvement on HIV/AIDS by national governments. For example, the Department of State has: initiated senior staff briefings and high level directives to engage host government counterparts; placed the issue of HIV/AIDS on multilateral agendas; promoted positions at the IVth World Conference on Women; included a discussion of HIV/AIDS in Agenda 21 for the International Conference on Environment and Development; placed HIV/AIDS on the G-7 agenda of Finance and Foreign Ministers in 1996 in Lyon; and supported consensus on HIV/AIDS related Human Rights

Commission Resolutions.

On December 1, 1997 - World AIDS Day - Secretary of State Madeleine Albright issued a statement in which she called on nations, private institutions, local and international business, communities and families to intensify the fight to curb the HIV/AIDS epidemic. In addition, U.S. ambassadors and other embassy representatives were instructed to meet with host country counterparts to brief them on the 1995 U.S. International Strategy on HIV/AIDS and to encourage leaders to expand HIV/AIDS prevention and mitigation programs.

USAID has been successful in identifying effective prevention strategies and, through USAID missions and U.S. embassies, publicized successes to government and community health workers so that they may be duplicated elsewhere. Dissemination activities have included production of training curricula; convening of workshops; "lessons learned" documentation (electronically, hard copy, CD-ROM, etc.) has been distributed, and most importantly, these best practices have been incorporated into all USAID assisted programs.

Develop Behavioral Prevention Strategies

CDC has supported an ongoing portfolio of behavioral research to identify and monitor risk behaviors and their psychosocial and environmental determinants. CDC scientists have also completed and are disseminating information from several large, multi-site intervention trials evaluating one-on-one, small group, and community level behavioral intervention strategies. In addition, approximately 6 trials evaluating interventions for young gay and bisexual men, young men about to be released from prison, serodiscordant couples, and HIV infected persons are now in the formative or implementation phase. Ongoing research also includes HIV risks to postpartum women and perception and behaviors that influence acceptance of HIV counseling and testing. Finally, CDC established an ongoing database of HIV intervention research literature to facilitate ready identification of scientifically credible intervention models for use by HIV prevention programs.

In the past 5 years, USAID, through work with host country governments and community groups, has provided

behavior change services for over 22 million specially vulnerable men, women and youth helping them to reduce their risk of HIV infection. To accomplish this task USAID has trained over 180,000 new dedicated counselors and educators. In addition, with our partner organizations we have improved the clinical management of sexually transmitted diseases (STD) in over 22 countries as a significant way to reduce the efficiency of HIV sexual transmission, as well as to restore and protect their health.

Building on this investment in behavioral research, the USAID funded AIDS Control and Prevention Project (AIDSCAP) project supported ten studies ranging from an intervention trial to define cost-effective approaches to HIV/AIDS education for vocational students in Sao Paulo, Brazil, to a collaborative, UNAIDS/AIDSCAP multi-site efficacy study of the impact of personal risk reduction counseling and HIV testing on sexual risk behavior. AIDSCAP also built new tools for behavioral research related to HIV/STI. They adapted rapid ethnographic assessment procedures to the STI field. The resulting Targeted Intervention Research (TIR) manual was developed and applied in nine countries in Africa and southeast Asia to develop locally meaningful health education message, and to enable developing country researchers/providers to include improve doctor-patient communication by using local language and concepts in STI screening and case management.

USAID's Women and AIDS Research Program, a cooperative agreement with the International Center on Research on Women, supported 17 small behavioral studies on the perceptions and experiences of women and girls around sexuality, HIV/AIDS, and risk reduction. This research has resulted in a dramatic increase in the quality and quantity of knowledge regarding the behavioral, socio-cultural, and economic factors that influence women's vulnerability to HIV infection throughout the world. It has brought to the forefront the need to incorporate women and a gender perspective into AIDS prevention programs; has built local NGO and government capacity to deal with gender issues, and in the second phase of the project, has turned the research findings into eight HIV/AIDS interventions focusing on the special needs and circumstances of women.

USAID social and behavioral research at the macro level has developed and applied epidemiological and economic projections for HIV/AIDS for improved policy-making. In the Dominican Republic, policy research involving

epidemiological models and projections stimulated the President to sign into law legislation to enhance HIV/AIDS prevention efforts in the country. In Brazil, a study of the economic losses associated with high consumer prices for condoms was used successfully by local advocates to convince the Federal government to reduce taxes on condoms. In South Africa support to research on the social and economic impact of HIV/AIDS has provided crucial data for policy dialog about the need for private and public investment in HIV/AIDS prevention and care. USAID-funded projects have established formative behavioral research as a prerequisite of technically sound intervention development. Thus most of our future interventions will contain data collection components that enrich the knowledge base for understanding HIV risk behavior and opportunities for prevention and care.

Finally, behavioral research is one of the core mandates of Horizons, USAID's new global leadership and operations research project managed by the HIV/AIDS division. Through mechanisms under USAID's HIV/AIDS strategic objective, USAID is initiating intervention research on a range of behavioral topics, including: improving risk reduction interventions for women and girls; promoting effective STI care seeking behavior by men as well as women; supporting culturally appropriate counseling and testing; strengthening community mobilization and empowerment for HIV prevention, care and support; improving methods for personal HIV risk assessment, and understanding the economic and societal pressures that increase sexual risk behavior.

Augment Research

The USG has made large strides towards improving HIV prevention research in the area of developing behavioral prevention strategies and providing access to health services and technologies for the prevention of mother to infant, or vertical, transmission. CDC has pledged to enhance emphasis on prevention of perinatal HIV transmission through research, training and pilot projects. CDC is actively involved in ongoing research on the use of AZT therapy in pregnant women to prevent perinatal HIV transmission. In 1995 NIH pledged to place a high priority on following up initial studies which could lead to methods for preventing HIV transmission from mother to fetus, including anti-viral therapy (AZT) and micro-nutrient treatment (vitamin A) during pregnancy and on further defining the context of their use. To this end, it is

notable that the results from the U.S. AIDS Clinical Trials Group 076 in 1994 and the recent Thailand trial findings in 1998 highlight the dramatic success of AZT in reducing the risk of perinatal HIV transmission.

NIAID is supporting additional perinatal prevention trials in Malawi, Zambia, South Africa, Zimbabwe, Uganda, Ethiopia and Thailand. These trials address questions about breastfeeding transmission, STD treatment, microbicides and promising new antiretroviral immune agents to decrease perinatal transmission to as low rates as possible in international settings. NICHD (National Institute of Child Health and Human Development) has also been instrumental in that between 1995-1997 they increased their support for international perinatal transmission studies by more than 90%. With support from the Office for AIDS Research (OAR), NIAID, NICHD investigators and Fogarty International Center grantees are undertaking pilot studies directed at implementation of short course AZT therapy in a number of developing countries.

DOD continued in its cooperation with other countries in the quest for the identification of an HIV/AIDS vaccine and the identification of "best practice" for the treatment of HIV/AIDS. The Department of Commerce US Patent and Trademark office developed a homepage that provides a searchable database containing the full-text and images of patents related to AIDS research.

Safeguard Blood Supply

FDA has worked with manufacturers to facilitate the development of new testing methodologies and other approaches to help assure the safety of the blood supply. FDA is also collaborating with international organizations such as WHO and ICH to harmonize biological standards on blood safety and is actively involved in training others in their specialty. Additionally, USAID has directly supported improvements in health care infrastructure by providing advocacy and leadership in the area of blood safety and universal precautions.

Provide Access to Health Services and Technologies

Toward the goal of providing greater access to health services and technologies, USAID is supporting female condom distribution and market research in over 15 countries. The USAID Population, Health and Nutrition (PHN) Center has

developed a global research agenda for determining the net public health value of providing the female condom through public and private sector outlets. USAID supports several grants to non-governmental organizations, as well as epidemiological and biomedical research administered by the NIH, CDC, and the Global Programme on AIDS of the WHO. Specific areas of research include female-controlled vaginal spermicides and microbicides, female condoms, the economic impact of HIV/AIDS, inexpensive STD diagnostics, and novel testing and counseling strategies.

FDA has also been instrumental in securing greater access to health services and technologies. FDA has worked with manufacturers to facilitate the rapid development of new agents for prevention and treatment of HIV related conditions, and medical devices for the prevention of transmission, through streamlining the FDA review and drug certification process for HIV/AIDS therapies. FDA has approved 12 distinct drugs for the treatment of HIV/AIDS and 25 drugs for the treatment of infection related to HIV.

Address the Adverse Impact of Poverty and other Factors on Prevention Efforts

In 1996, USAID redesigned its HIV/AIDS strategic objective to better reflect the experience gained to date in prevention activities and to respond more effectively to the growing and changing worldwide epidemic. Representatives of host governments, international development organizations, NGOs, the private sector, affected communities, people living with AIDS, and USAID Mission and Regional Bureau staff participated in a series of activities resulting in recommendations to expand the scope of USAID's response to the epidemic. The revised Strategic Objective (SO) states: to increase the use of improved, effective and sustainable responses to reduce HIV transmission and to mitigate the impact of the HIV/AIDS epidemic. This new strategy is based on the need for continued and expanded efforts to prevent HIV transmission, and a new focus on mitigating the disease's impact on people and their communities, while more closely studying its social, economic and policy impacts.

Included in the 1999 document is a directive to "develop and promote approaches that address key contextual constraints and opportunities for prevention and care interventions." HIV/AIDS prevention and management efforts are often hampered by the policies, norms, and financial

constraints under which they operate. USAID will address these environmental constraints by: effectively communicating the economic, social and health costs of HIV/AIDS to key policy-makers and budgetary and decision makers; promoting the elimination of barriers that inhibit the flow of HIV/AIDS prevention and management information and services to youth, women, people living with AIDS (PLWA) and other vulnerable groups; developing and promoting effective strategies for providing basic care and support services for PLWA; and, supporting initiatives to dedicate increased resources for HIV/AIDS prevention and management.

Reduce Personal and Social Impact

The 1995 Strategy called for a greater consideration of the problems HIV/AIDS poses that go beyond the medical and health implications. The strategy stipulated that in order to mitigate the impact of HIV/AIDS on the individual and society, the following broader issues must be taken into consideration:

- Provide Care and Support;
- Guarantee Human Rights;
- Protect Politico-Military Structures at Risk;
- Place HIV/AIDS on the Sustainable Development Agenda

Provide Care and Support

In an effort to provide greater care and support, USAID was active in advocating a strategy of "prevention to care," which included: access to counseling and testing, reducing stigma, improving psychosocial and basic medical support for HIV positive persons and selected interventions for survivors. NIH has studies underway to find ways to limit progression of HIV disease in infected children and to increase childhood survival in developing countries, particularly Africa and Asia.

Providing care and support to those afflicted with HIV/AIDS reaches beyond the health sector. As such, increased attention has been given to the social and economic impact of HIV/AIDS. The USAID Regional Missions support a range of studies on the social, economic and community impact of HIV/AIDS in Africa, Asia and Latin America, ranging from studies on the social and economic impact of HIV/AIDS in Southern Africa, to studies of collaboration between traditional and biomedical healers' in

management of HIV/AIDS in Zambia and Senegal. At the request of Leon Fuerth, Assistant to the Vice President for National Security Affairs, the NIC Office of Transnational Issues recently published a study assessing the social and economic impact of AIDS in the sub-Saharan Africa region.

Guarantee Human Rights

In the area of human rights, the State Department and other USG representatives took diplomatic initiatives to promote and safeguard protection under the law for persons living with HIV/AIDS with regard to access to health care, employment, education, travel, housing and social welfare in all appropriate fora. Further, the USG supported consensus on the UN Commission on Human Rights' biennial Resolution "The protection of human rights in the context of the human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS)." The resolution sets out guidelines states may follow in dealing with the health crisis and human toll of AIDS and HIV. The resolution also asks the Secretary General to solicit input from countries, specialized agencies, and related governmental and non-governmental organizations in order to provide a progress report to the Commission on follow-up. The next session of the Commission at which the AIDS/HIV resolution will be considered will take place in March, 1999. In addition, the Department of State continues to include HIV/AIDS-related discrimination and human rights abuses in regular embassy reporting.

Protect Politico-Military Structures

DOD furthered its efforts to protect politico-military structures at risk by continuing to conduct military to military educational programs on HIV/AIDS, which are expected to contribute to changes in high-risk behavior and an overall decrease in rates of infection in foreign militaries. Additionally, the National Intelligence Council prepared a national estimate on the impact of HIV/AIDS on military establishments.

Place HIV/AIDS on the Sustainable Development Agenda

The Department of State is directly responsible for placing health and HIV/AIDS on the international agenda as elements of sustainable development. Health - including a discussion of HIV/AIDS - was a part of the discussions for Agenda 21 for the International Conference on Environment and Development and continues to be a part of the USAID

programs for development assistance. The Department of State also placed HIV/AIDS on the agenda of Finance and Foreign Ministers in 1996 in Lyon.

Mobilize And Unify National And International Efforts

The 1995 International Strategy called for increased collaboration and unification of USG HIV/AIDS prevention and mitigation efforts, and stated that "strengthened collaboration within and among countries is an essential component to improving efforts to combat global HIV/AIDS."

In this vein, the Department of State has been active in diplomatic prevention efforts. In particular, at the Fourth World Conference on Women, the Department of State successfully promoted major tenets of the 1995 International Strategy on HIV/AIDS. U.S. positions in support of the strategy were adopted at the Beijing conference. In addition, the Department of State, USAID and others continue to work with UNAIDS, UNICEF, UNFPA, UNESCO and UNDP on the goal of unifying international efforts to mitigate and prevent HIV/AIDS.

Through public diplomacy, USIA continues to share with foreign publics key policies and a variety of American Federal and local government and non-government organizational activities that contribute to HIV awareness, prevention and treatment programs in the US and abroad. An example of USIA efforts is the campaign mounted to bring attention to the December 1997 World AIDS Day.

The White House Office of National AIDS Policy (ONAP) took further steps toward unifying national efforts. Representatives from State, USAID, ONAP Director's Office, DHHS and others worked together collaboratively and met several times to develop a National AIDS Strategy.

Areas for Continued or Future Action

- Strengthening public health infrastructures;
- Making AIDS treatment more accessible and affordable;
- Addressing the adverse impact of poverty and other factors on prevention efforts;
- Protecting human rights; and
- Improving collaboration and donor coordination through sharing both technical and financial resources.

IV. ISSUE OVERVIEW

An Interagency Working Group of the U.S. Government agreed to the following issues as those most relevant for USG action through agency programs. They are HIV transmission prevention, vaccine research, and the mitigation of the impact of HIV/AIDS. Within these larger issues are several issues of importance including treatment equity; behavioral research/ behavioral change intervention; AIDS-orphaned children; women and health; microbicide development; and donor coordination. This section provides an overview of these issues.

In Section V, the Action Strategy identifies specific objectives to effectively address the targeted problems presented in the issue overview. The Action Strategy's programs, policies and activities represent commitments by each agency and have been adopted by the highest level of agency authority.

EFFECTIVE INTERVENTIONS, TEMPORARY SUCCESSES

Antiretroviral Drugs

New breakthroughs in the development of multi-drug therapies and antiviral use to reduce the perinatal transmission of the disease from mother to fetus or newborn are providing a larger arsenal of weapons with which to fight the HIV/AIDS epidemic. The demonstration that potent new combinations of antiretroviral drugs reduce viral load in patients proved to be one of the major scientific advances of 1996. However, the relative short-term success of potent three-drug combinations due to the development of drug resistance and the extreme costs and difficulty in the treatment regimen undermines the long-term prospects for continued success and their widespread availability beyond the developed world.

While the drug therapies may extend and improve the quality of life for HIV/AIDS patients, they are not a cure for the HIV/AIDS virus and are not available to all who need them. The costs of antiretroviral therapy ranges from US \$10,000 to US \$15,000 per person per year and requires an established public health infrastructure which can assure compliance with a continuous, comprehensive and vigorous treatment regimen, making the treatments impractical and unwise for much of the developing world.

In addition to cost, drug resistant strains of HIV emerge if an individual's viral replication is not completely suppressed by antiviral treatment. As a result, the viral load increases and disease progression may occur. The therapies have not been proven successful for everyone, and they often cause severe negative side effects. The misconception that antiretroviral therapy is a cure may work against prevention of transmission if individuals believe they are no longer contagious and continue high-risk behavior. And although antivirals can prevent mother-to-child transmission of the disease, they provide no protection to the mother carrying both the unborn and the HIV/AIDS virus. The potential emergence of drug resistant strains combined with the emergence of mutated strains of the virus and the need for more widespread availability of prevention and treatment measures demand that all efforts for vaccine research and transmission prevention be redoubled immediately.

HIV TRANSMISSION PREVENTION

HIV transmission can be reduced and the socio-economic impact of AIDS alleviated with effective development and implementation of improved policies, strategies and coordinated programs underscored by strong commitment and involvement from national, state, provincial and local governments.

Now, as more accurate numbers are tabulated to show the presence and rate of infection, it is evident that the fight to end HIV/AIDS will be long and will require the sustained partnerships of all effected. HIV/AIDS is a multi-sector problem that can only be solved with interventions comprised of well-planned sustainable programs, which address legal, social and economic inequities as well as a new array of problems unique to HIV/AIDS. The effort requires the collaborative expertise of international organizations, governments, industry, and non-governmental organizations.

There exists no single, standardized set of interventions in HIV/AIDS prevention programming. Specific regional strategies must include an appropriate mix of programs proven to be effective for the vulnerable populations being addressed. These strategies must take into account available resources and local risk behaviors and be tailored to cultural attitudes and belief systems.

Preventing sexual transmission requires comprehensive

and persuasive education to convince people to change deeply ingrained sexual behaviors, a difficult and complex task that can cause examination of cultural, religious and personal beliefs. But prevention works.

There is good evidence that HIV infection rates are stabilizing or decreasing in places where focused and sustained prevention programs have brought about significantly safer behavior. This is not just the case in developed countries in Europe and the Americas. It is true around the world. For example, surveillance testing in urban areas of Uganda over the past five years reveals a 40% drop in HIV prevalence among pregnant women. This decline in HIV infection is particularly striking in young women and is associated with delayed first sexual intercourse, increased condom use, and fewer sexual partners.

In Thailand, annual surveys in young men showed both substantial reductions in risk behavior and decreases in HIV infection levels. Between 1991 and 1995, visits to sex workers reported by these men were cut by almost a half; and those who reported not using a condom on the last visit dropped from nearly 40% in 1991 to slightly over 5% in 1995. As a result, HIV prevalence among this group has decreased from 8% in 1992 to less than 3% in 1997. The first signs of an HIV turnaround are also being seen among young people in northern Tanzania. In areas with active prevention programs, prevalence in young women fell by 60% over a period of six years.

Other methods of preventing HIV transmission also may have an important impact on slowing the pandemic. For example, researchers are developing and testing topical microbicides, substances that a woman could use in her vagina before sex to prevent the transmission of HIV and other sexually transmitted diseases. USAID, UNAIDS and others also have facilitated more widespread use in Africa of the female condom. These interventions may help empower women to protect themselves in situations where they are unable to avoid sex with partners who are HIV-infected or to persuade their partners to use a condom.

However, to prevent HIV transmission it is no longer sufficient to focus solely on sexual transmission as the only route of HIV infection. While sexual transmission, both heterosexual and homosexual, is still the primary means of transmission there are many other routes which, if ignored, will continue to raise transmission rates resulting

in further spread of the deadly virus. A continued emphasis on a full range of effective, low-cost tools of HIV prevention is crucial to slowing the epidemic.

Researchers have shown that several approaches to HIV prevention can reduce the number of new infections when properly executed including: education and behavior modification; the social marketing and provision of condoms; treatment of other sexually transmitted diseases; drug abuse treatment (for example, methadone maintenance for injection drug users); and the use of antiretroviral drugs to interrupt the transmission of virus from mother to infant.

Integration of the use of proper procedures for blood safety and universal infection control is effective in reducing blood-borne HIV transmission in health programs. Development and application of intervention strategies, within existing health programs, to decrease transmission by other routes such as perinatal and by blood is absolutely integral to the decrease of HIV transmission rates.

The case of mother-to-child transmission is estimated to be the source of 5-10 percent of the total of new HIV infections each year in many developing countries, with more than 500,000 children infected each year. Over 1.5 million HIV infected women become pregnant each year, the majority in Africa and Asia; projections to the year 2000 indicate between 5-10 million children are expected to be infected.

A recent clinical trial conducted by the Centers for Disease Control and Prevention with the Ministry of Thailand found that HIV transmission from mother to child could be reduced by 50 percent by giving the drug AZT to mothers during the last four weeks of pregnancy and during labor and delivery. A recent trial, completed in 1998 in Thailand, showed that antiretroviral pills given to pregnant women during the last week prior to and during labor combined with safe alternatives to replace breastfeeding cut overall vertical transmission of HIV to 9 percent. This compares with the norm in developing countries of up to 35 percent.

While prevention of HIV transmission is necessary to curb the ever growing epidemic, countering the increasing rates of opportunistic infections is also essential. HIV-related increases will occur in the progression of dormant Tuberculosis infection to infectious TB diseases in individuals infected with both diseases. Programs to address other STI's which exacerbate or are exacerbated by

HIV/AIDS must be implemented along with more comprehensive, accurate and inexpensive diagnostic testing and counseling. In Tanzania, the groundbreaking "Mwanza study," showed that using simple, realistic syndromic management to treat sexually transmitted infections within a study population reduced the number of new infections by an impressive 42 percent.

Prevention of and reduction in transmission rates is key to slowing the HIV/AIDS epidemic, however, it is important to note that should HIV transmission cease tomorrow, the continual impact of AIDS cases following the natural course of HIV will remain great for many years to come. Therefore, tailored combinations of programs designed to mitigate the devastation wreaked by HIV/AIDS as well as prevention of transmission are needed for an effective sustainable response to the deadly epidemic.

HIV Drug and Vaccine Development

A number of new research advances indicate progress against AIDS and open new areas of investigation. Protease inhibitors, a new class of drugs, used in combination with other antiretroviral therapies, have been shown to remarkably diminish the amount of HIV in an infected individual. Receptors for molecules called chemokines have been identified as critical cofactors for HIV infection, providing us with an entirely new set of targets for anti-HIV therapies and new approaches for vaccine development. The challenge now is to develop more effective drugs and to prepare for the possible emergence of drug-resistant strains of the virus.

Despite these advances, the end of the pandemic is not in sight. The new drugs, while promising, are not a panacea. It is not known how long the benefits of the drugs will last. There are many for whom the new drug regimen s have not been effective or for whom the side-effects are not tolerable. The challenge now is to develop more effective drugs and to prepare for the possible emergence of drug-resistant strains of the virus.

Developing a vaccine or vaccines that are safe and effective in preventing HIV infection in exposed individuals is a major public health priority in the national and international effort to combat this epidemic. The development of a safe and effective vaccine for HIV infection remains the "holy grail" of AIDS research, and an

important step toward bringing the HIV epidemic under control. The goal is a preventive vaccine is to slow and eventually end the HIV pandemic and to protect the individual from HIV infection and/or disease. Developing a vaccine or vaccines that are safe and effective in preventing HIV infection in exposed individuals is a major public health priority in the national and international effort to combat this epidemic.

Without a vaccine, AIDS will soon overtake tuberculosis (TB) as the leading infectious cause of death in the world. Vaccines may be the cost-effective way to prevent HIV infection worldwide. Therefore, an affordable, safe and effective vaccine that is also easily delivered and acceptable to various populations at risk is urgently needed. President Clinton called for the development of an HIV/AIDS vaccine by 2007, inviting international scientific collaboration to meet this goal.

MITIGATING THE IMPACT OF HIV/AIDS

Mitigation of HIV/AIDS impact will need to focus primarily on three main areas, while maintaining adequate surveillance and flexibility to address other issues as they may arise. Programs for mitigation should address care and support for HIV infected individuals, dependency and orphanhood resultant of HIV/AIDS deaths and the pandemic's affect on women and health.

Due to investments in biomedical research, steady progress has been made in improving the care of people with HIV or AIDS. For example, the usefulness of a tuberculosis prophylaxis has been confirmed that will now allow more effective action against this co-epidemic. Widespread access to highly effective antiretroviral therapy has significantly prolonged life and improved the quality of life for people living with HIV in the Western world and has resulted in a spectacular decline in AIDS death in these countries. But because of the high cost and complexity of these drug regimens, most infected individuals in the developing world have no access to these latest therapies - and often not even to simple treatments to fight their infections and diminish their pain. The absence of affordable therapies in developing countries, where 90% of the epidemic is concentrated, will only exacerbate the already enormous human and economic costs of AIDS. It also risks becoming a major contributing factor to social and political instability in those countries with hundreds of

thousands to millions of infected and affected citizens.

More needs to be done to document and improve understanding of the nature, magnitude, and prevention and mitigation of HIV/AIDS-related adverse socio-economic impacts in the different levels and sectors of society. Surveillance of the disease itself as well as tabulation of infection rates is absolutely necessary to ensure that programs are implemented and that funds are used adequately. HIV/AIDS sentinel surveillance inclusion into regional and national surveillance for emerging and re-emerging disease will serve both to better follow the epidemic as well as strengthening surveillance systems worldwide. Linkages of surveillance systems will not only serve to better understand the path of the disease but it will also ensure that all information is available and encourage information sharing of effective strategies worldwide.

Care and Support for HIV Infected Individuals

With 30.6 million people infected with HIV and with infection rates on the rise, the need to create comprehensive care systems is great. The numbers of HIV infected individuals and people living with AIDS-related illnesses will be so large that governments and donor agencies will have to have developed cost-effective intervention strategies to improve the accessibility and quality of care and support services for HIV-infected individuals. They will also have to have strategies to reduce the adverse socio-economic consequences of AIDS. Health care for HIV/AIDS infected individuals must be designed and administered in an equitable manner. It must also be in agreement with Human Rights as stipulated by the International Guidelines for HIV/AIDS and Human Rights: that vulnerability to HIV/AIDS be reduced, that those infected with HIV/AIDS live a life of dignity without discrimination and that the personal and societal impact of HIV infection is alleviated.

AIDS-Orphaned Children

During the 12th World AIDS Conference in Geneva, the problems posed by this issue were referred to as a "massive social time bomb" as the number of children affected by AIDS, including those who are orphans or caring for sick parents, continues to escalate. By the year 2000, 15.6 million will have lost their mothers or both of their parents in 23 countries heavily affected by HIV/AIDS.

Largely as a result of the HIV/AIDS pandemic, that number will increase to 22.9 million by 2010. When paternal orphans are included, the total number of orphans from all causes is projected to increase from 34.7 million in 2000 to 41.6 million in 2010 in these 23 countries.

HIV has often caused huge increases in death rates among younger adults - just the age when people are forming families and having children. This inevitably leads to an increase in orphans. In rural areas of East Africa, 4 out of every 10 children who have lost one of their parents by age 15 have been orphaned by HIV/AIDS.

The loss of a parent poses tremendous challenges for a child. These children may suffer from depression, malnutrition, lack of immunizations or health care, increased demands for labor, loss of schooling, forfeiture of inheritance, forced migration, homelessness, vagrancy, starvation, crime and increased exposure to HIV infection.

The growing number of children who will lose parents will, in turn, have a profound impact on their societies. With children who have lost parents eventually comprising up to a third of the population under age fifteen in some countries, this outgrowth of the HIV/AIDS epidemic will create a lost generation - a sea of youth who are disadvantaged, vulnerable, undereducated and lacking both hope and opportunity. The creation of such a large and disaffected demographic "youth explosion" could propel some of these societies to significant unrest and destabilization over the long term. The threat to the prospects for economic growth and development in the most seriously affected countries is considerable.

Women and Health

One of the most striking trends in the HIV/AIDS pandemic during the past decade has been its rapid spread among women. Worldwide, women are becoming infected at faster rates than men, and the total number of HIV-positive women is fast approaching that of men. Young women are particularly vulnerable and it is estimated that 70 percent of women infected with HIV are between the ages of 15 and 24.

Women and girls face greater biological vulnerability than males. The female reproductive tract is more susceptible to infection with HIV and other STDs, a

susceptibility that is particularly great in young girls. Sexual transmission of the virus is four times more efficient from men to women than from women to men; the immaturity of the sex organs of girls and younger women raises their biological vulnerability even higher. Nine in ten women are becoming infected through heterosexual intercourse.

But social and economic forces can play an even greater role in increasing women's risk of acquiring HIV infection. The imbalance of power between men and women in most cultural settings limits women's ability to protect themselves. Many women and young girls are forced to accept sexual partnerships that put them at high risk of contracting the virus and are unable to insist on condom use by their partners. More than half the young women in a Malawi study reported coercion; over 20% of young women surveyed in Nigeria reported being forced to have sex. The reasons for forced sexual intercourse range from social pressure through coercion by older men in authority to having sex with virgins prescribed as a remedy for a range of "illnesses" to outright violence. Young girls are often targeted because they are believed "safe" and uninfected with HIV. Rape has become lethal with the advent of HIV. Adolescent girls face the greatest threat, as their extreme biological vulnerability is amplified by their psychological and cultural subordination and their lack of access to reproductive health information and services.

Topical microbicides are chemical barriers that women can apply topically to inhibit HIV infection. Although none have been shown to be effective now, microbicides are needed due to the high prevalence of non-consensual sex, lack of condom use and need for reproductive choices. Products also are needed to allow conception while preventing infections with HIV and other STDs.

Collaboration is important in addressing both common and individualized concerns for women addressing HIV/AIDS issues. Such collaboration should include the public and private sectors, international organizations, NGOs, the media, and women.

Donor Coordination

While the HIV/AIDS pandemic continues to grow, it is apparent that current worldwide programs and financial resources available to combat this disease are insufficient.

An improved worldwide response to the pandemic in the developing world will require enormous increases in resources. Regardless of increases, it is unlikely that there will ever be adequate resources available to effectively meet all the needs associated with HIV/AIDS.

There will be a critical need for the development of effective coordination mechanisms within the donor community, multilateral coordinating bodies, the private sector and host country governments to ensure that available resources meet the most urgent program needs. The coordination of donor efforts for HIV/AIDS will assure that the limited resources currently available will maximize the comparative advantage donors have in various program areas. For example, some bilateral donors such as USAID may have strength in service delivery programs while other bilateral donors may play important complementary roles in other areas such as policy dialogue and training. Similarly, multilateral donors such as UNAIDS and the World Bank would play important roles in coordinating the efforts of other U. N. agencies or organizations.

Donor coordination will become even more important in the future as efforts increase to identify additional resources needed to combat HIV/AIDS. Increasingly HIV/AIDS is recognized not only as a health problem but as a development problem which adversely impacts all sectors of a developing country-education, finance, agriculture, other labor sectors. Therefore, the search for additional financial resources must extend to funds which may be available within the budgets of these other sectors. In addition, it may be possible through effective donor coordination/collaboration to mobilize increased private sector resources for HIV/AIDS prevention and mitigation efforts. In addition, there is a critical need for improved collaboration and coordination between those organizations that are performing biomedical research and those who are implementing programs and delivering services. Improved collaboration will allow better exchange of information about the current status, effectiveness, cost, and availability of potentially useful technologies. Likewise, organizations that implement service delivery may be able to contribute critical insights during research design to assure that key operational questions can be addressed during initial research endeavors.

To effectively prevent transmissions and mitigate impacts, there must be coordination of various programs

designed to address the entire spectrum of the epidemic. It has been shown that the key to any effective program or strategy is the full commitment by all involved, particularly the involvement and commitment of government officials at the highest levels. Serious information gaps and lack of leadership and sustained commitment on the part of government and donors have significantly slowed efforts to advance and sustain HIV/AIDS prevention and mitigation programs throughout the world.

In the protracted battle against HIV/AIDS, two of the greatest factors inhibiting effective program planning and implementation are cost and sustainability. Sustainability plays a major role in cost due to the fact that need for repeated creation, implementation and staffing of effective programs requires great investment. Therefore, the development of programs that are self-sustaining and easily administered at all levels of implementation is absolutely integral to countering the epidemic.

In order to design sustainable systems for effective prevention and mitigation, a foundation must be laid for local training of technical workers along with locally planned, managed and implemented programs. The development of linkages between various institutions and international research centers and the development of regional networks of health and non-health experts involved in fighting HIV/AIDS who can assist in the review and improvement of regional training curricula will prove highly beneficial in the fight against HIV/AIDS. The planning of future programs must involve national and local investment in building professional and institutional capacity to ensure sustainability at all levels of administration. Working with the international community the collective efforts of all concerned are needed to effectively address the myriad issues involved in addressing this pernicious epidemic.

The USG calls upon all nations, international organizations, the public and private sectors to work together in effective partnerships to advance vaccine research efforts and to promote more effective use of limited technical and financial resources in the fight against HIV/AIDS.

WHITE HOUSE OFFICE OF NATIONAL AIDS POLICY

Role and Structure

The Office of National AIDS Policy was created in 1993 by President Clinton to provide the Federal government with a greater focus on the issues related to the pandemic of HIV/AIDS. Creation of the office was suggested by numerous national and community-based AIDS organizations. The office provides broad direction for Federal AIDS policy and fosters interdepartmental communication on HIV/AIDS. The Office Director is a member of the President's Domestic Policy Council. The Office also works closely with the AIDS community both in the United States and around the world.

In addition, the Office of National AIDS Policy created the Interdepartmental Task Force on HIV/AIDS to help better facilitate communication among the various departments and agencies of the Federal government involved in HIV/AIDS.

The Office of National AIDS Policy also functions as a liaison with Presidential Advisory Council On HIV/AIDS. The Council was established by Executive Order, to provide advice, information and recommendations to the President, the Administration, and particularly, the Secretary of Health and Human Services, regarding programs and policies affecting or affected by HIV/AIDS. Its mission is to advise the President on what the Administration can and should do to stop the spread of the pandemic; to find a cure and vaccine for HIV; to provide the best possible treatment and care to those who are infected; and to end HIV-related discrimination and intolerance.

The Council is uniquely positioned to play a leadership role in raising unpopular issues, ensuring that no affected populations are forgotten, and keeping HIV/AIDS issues in the forefront of Administration priorities.

U.S. DEPARTMENT OF STATE

Agency Mandate Relevant to HIV/AIDS

The Department of State is the lead U.S. foreign affairs agency. It advances U.S. objectives and interests through formulating, representing, and implementing the President's foreign policies. The United States maintains diplomatic relations with some 180 countries and also maintains relations with many international organizations. The State Department has more than 250 diplomatic and consular posts around the world: country mission components - including embassies and consulates; and delegations and missions to international organizations.

The State Department carries out its mission through overseas posts; in Washington, D.C. headquarters; and other offices in the U.S. In addition to representing U.S. policy and interests at these posts, the State Department is the primary provider of foreign affairs information used by the U.S. Government in policy formulation. Information received from U.S. posts - including in-depth analyses of the politics, economic trends, and social forces at work in foreign countries - is provided to some 60 federal agencies.

In the area of international health, the role of the State Department is to develop and coordinate a sustained effort to enlist support from other nations and international bodies to raise the level of priority accorded HIV/AIDS and infectious diseases. The State Department, through the coordinating efforts of the Bureau of Oceans and International Environmental and Scientific Affairs/Emerging Infectious Diseases and HIV/AIDS Program (OES/E/EID), works with USAID and other federal agencies to develop the bilateral and multilateral partnerships for international collaborations to address the unique implications of HIV/AIDS and other infectious diseases. OES/E/EID seeks to negotiate cooperative agreements with other nations to promote the establishment of a global surveillance and response network, and to work with other agencies to enhance awareness and national capacities around the world to prevent, diagnose, report, and respond to the threat of disease.

Other bureaus play a key role in international health matters. The Bureau of Population, Refugees and Migration (PRM) is at the center of a cooperative effort among the State Department, other USG agencies, private voluntary

organizations, and international agencies to implement a more comprehensive international population policy. It includes broadening population assistance programs to cover a wider range of reproductive health services, including family planning. PRM also provides assistance to refugees in first-asylum countries. The Bureau of Democracy, Human Rights, and Labor (DRL) oversees initiatives and policies to promote and strengthen civil society and respect for human and worker rights. DRL ensures that human rights in foreign countries are taken into account in the U.S. policy-making process and submits an annual report to Congress extensively reviewing human rights practices in each country.

The President's Interagency Council on Women, which is chaired by the Secretary of State, is charged with coordinating the implementation of the Platform for Action adopted at the UN Fourth Conference on Women. The Platform recommends actions to increase women's access to appropriate, affordable and quality health care, information and related services; encourage both women and men to take responsibility for their sexual and reproductive behavior; and undertake gender-sensitive initiatives that address sexually transmitted diseases, HIV/AIDS and sexual and reproductive health issues.

Agency Strategy for Specific Issues

U.S. Role in Promotion of Active Involvement on HIV/AIDS by National Governments

The State Department hopes to bring the message to leaders around the world that HIV/AIDS and infectious diseases are the silent enemies of economic and social development, political stability and economic productivity. No member of the global community can afford, either in terms of human suffering or economic costs, to fail to recognize or to act to forestall the impending devastation which has already begun to ravage national economies, security and social infrastructure. Political commitment at the highest level of national government makes the critical difference in stemming the spread of HIV/AIDS. Where such commitment is present, such as Uganda and Thailand, the transmission rates are being effectively reduced.

Working through regional bureaus and embassies and missions abroad, the goal of the State Department is two-fold: to enhance U.S. diplomatic efforts to raise the level of priority by all governments to more effectively meet the

challenges of HIV/AIDS and infectious diseases of all kinds; and to enhance international collaboration on disease surveillance and response threats to reduce human suffering and to safeguard all peoples from the devastation of HIV/AIDS as a global priority.

HIV/AIDS will be introduced to a greater extent in the U.S. diplomatic and policy dialogue in order to underscore the recognition of HIV/AIDS as an international problem with political, social, and economic impacts which go well beyond the boundaries of the traditional health sector. Nations should address HIV/AIDS as a pandemic fueled by socio-economic inequities, human rights issues and questions of gender status.

The State Department and senior officials must play a central role in raising HIV/AIDS in international fora and is redoubling efforts to put the full weight of the U.S. diplomatic infrastructure behind enhanced political commitment for overseas national action.

Recognition of the problem and promotion of AIDS education and prevention programs by high-level government officials is vital to the success of AIDS prevention. Posts through our mission planning process will be charged and held accountable for their active interventions to raise awareness with host government officials. Ambassadors and other foreign policy officials at posts are directed to:

- Urge foreign leaders to openly address the HIV/AIDS pandemic in their own countries;
- Urge other governments to consider the adverse economic and social impact of HIV/AIDS in their countries;
- Urge other governments to increase spending or to reallocate funds to prevent the spread of HIV/AIDS and strengthen AIDS research efforts;
- Emphasize the importance of National AIDS Action Plans which involve all relevant governmental agencies, ministries, NGOs and the private sector;
- Encourage foreign leaders to support the Joint U.N. Programme on AIDS (UNAIDS); and
- Incorporate AIDS issues into foreign policy interactions with all government and international organizations.

The State Department, through formalized briefings as part of our National Foreign Affairs Training Center curricula and by country specific regional briefing to senior officials, is working to heighten the awareness of the foreign policy implications of HIV/AIDS to the foreign policy community through all available mechanisms.

The State Department will convene regular interagency meetings to discuss the international calendar and to develop common approaches on HIV/AIDS and other infectious disease issues.

The State Department seeks to enhance diplomatic support for HIV/AIDS programs in developing countries and HIV/AIDS vaccine research and policy collaborations with international partners.

Using the HIV/AIDS component of the Common Agenda with Japan as a model, the State Department and USAID will pursue agreements with other donors to work more closely on HIV/AIDS in priority countries.

Human Rights Issues

The U.S. regularly supports UN resolutions before the Commission on Human Rights' for the protection of human rights in the context of the human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS). The resolutions set out guidelines nations may follow in dealing with the health crisis and human toll of AIDS and HIV. The resolution also asks the UN Secretary General to solicit input from countries, specialized agencies, and related governmental and non-governmental organizations in order to provide a progress report to the Commission on follow-up. The next session of the Commission at which an HIV/AIDS resolution is expected for consideration will take place in March 1999.

The State Department will continue to include HIV/AIDS-related discrimination and human rights abuses in regular embassy reporting and in its annual "Country Reports on Human Rights Practices" and represent these interests before the Human Rights Commission.

Information from post reporting has been correlated with increased requests for asylum and are used in U.S. Government consideration of asylum requests. The Department

works closely with the Department of Justice on these issues.

The U.S. helped to negotiate a partnership arrangement between the Office of the High Commissioner for Human Rights (OHCHR) in Geneva and UNAIDS. The U.S. strongly supports the efforts of the OHCHR to mainstream human rights into the activities of other UN departments and agencies and especially the cooperation this partnership represents on combating the devastating worldwide crisis of HIV/AIDS.

U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

Agency Mandate Relevant To HIV/AIDS

The U.S. Agency for International Development (USAID) is the global leader in developing and implementing international HIV/AIDS/Sexually Transmitted Infections (STI) prevention and control programs. USAID's HIV/AIDS/STI mandate is to achieve a sustainable reduction in HIV/STI transmission among key populations in developing countries and to reduce the impact of the epidemic on individuals, communities and societies in general. This mandate fits within the broader Agency goal of stabilizing world population and protecting human health in a sustainable fashion.

USAID's regional and bilateral programs are the core of the Agency's HIV/AIDS/STI prevention activities, while the central programs provide complementary technical and programmatic support. The Global Bureau, Office of Health and Nutrition, HIV/AIDS Division (G/PHN/HN/HIV-AIDS) is the Agency unit charged with the primary responsibility for developing program interventions designed to accomplish the Agency's HIV/AIDS/STI mandate. In collaboration with USAID field missions and other partners and stakeholders, the HIV/AIDS Division has developed a detailed strategic framework that is consistent with the overall Agency mandate and lays out a future-oriented HIV/AIDS/STI program for the next 7-10 years.

USAID's strategy continues to focus on three key approaches to HIV/AIDS prevention, each of which, over time has had demonstrable impact in multiple country settings:

- Reducing high risk sexual behavior through behavioral change interventions (BCI). These include not only mass and interpersonal communication strategies, but also policy and legislative reforms that enhance communication strategies and campaigns;
- Increasing demand for and access to condoms, mainly through condom social marketing (CSM) programs;
- Treating and controlling sexually transmitted infections (STI) and sexually transmitted diseases (STD).

The first decade of HIV/AIDS programming has revealed that effective, individually focused approaches must be complemented or supplemented by services more attuned to the environment in which individuals live and make sexual and health decisions. This implies greater emphasis on interventions that address couples, parents and children, social networks, religion, worksites; the interaction of sexual and health beliefs; and the norms, values, and policies that determine the social and sexual context in which people live.

In addition to continuing the three major interventions stated above, the expanded strategy now includes selected basic care and psycho-social support for HIV infected individuals and their survivors. This will enhance the prevention agenda, and slow the deterioration of economic and social development. The expanded strategy includes increased emphasis on supporting HIV/STI surveillance systems that will assist in our understanding of the growth of the epidemic, as well as allow the assessment of the impact of interventions. There are now innovative initiatives to perform operations research to identify best practice; to expand policy dialogue to include issues such as discrimination and resource allocation; to increase PVO/NGO capacity building; and to conduct targeted biomedical research.

The expanded strategy responds to concerns raised by many observers (field Mission staff, stakeholders, other donors, PVO/NGO representatives, program evaluators and auditors) that USAID's HIV/AIDS/STI program interventions should concentrate on achieving well-defined program targets and results at country, regional and G/PHN levels, and should be closely coordinated with, and provide technical support to, regional bureau and field mission programs.

To operationalize the strategic framework presented above, the HIV/AIDS Division developed a results-oriented program of grants, cooperative agreements, interagency agreements and contracts that will continue the Agency's focus on the prevention of sexual transmission of HIV. This program is accomplished through the following ten activities:

- **HORIZONS:** This Cooperative Agreement with the Population Council (and collaborating partners: International Council for Research on Women, Program for Appropriate Technology in Health, International HIV/AIDS Alliance,

University of Alabama, and the Futures Group) will develop and disseminate the most effective ways of combating HIV/AIDS, through operations research, field testing of program interventions, and the review of scientific studies and publications.

- **IMPACT:** This Cooperative Agreement with Family Health International (and collaborating partners: Program for Appropriate Technology in Health, Population Services International, Management Sciences for Health, University of North Carolina, Institute of Tropical Medicine in Brussels) offers opportunities for field support (technical assistance, training, materials production, support for HIV/AIDS/STI programs including the development of communication campaigns, and delivery of STD clinical services) to Missions and countries for the implementation of prevention and mitigation programs.
- **AIDSMark:** This Cooperative Agreement with Population Services International (and collaborating partners: Program for Appropriate Technology in Health, Management Sciences for Health, International Planned Parenthood Federation, International Council for Research on Women, DKT International and Family Health International) provides support for developing regional and country HIV/AIDS social marketing program interventions. AIDSMark will focus on the social marketing of critical public health products that are appropriate and timely for the setting (male and female condoms, STI treatment drugs, STD diagnostics, etc.)
- **DMELLD:** (To be awarded in November, 1998) This contract will offer field missions access to technical assistance for program design, monitoring, and evaluation. It will also collect technical lessons learned from all components of the portfolio and disseminate these to field missions, cooperating agencies, governments and international donors.
- **UNAIDS:** (WHO, UNICEF, UNDP, UNICEF, UNFPA, World Bank) USAID is the lead donor to the Joint Coordinated UN Programme on HIV/AIDS (UNAIDS). UNAIDS coordinates UN activities at country level, supports national strategic planning, generates best practice recommendations, and advocates for increased resources to combat the pandemic.
- **PVO/NGO Capacity Building:** USAID supports this activity through four separate agreements: National Council for

International Health, International HIV/AIDS Alliance, CDC, Peace Corps. These organizations focus on building indigenous PVO/NGO capacity through technical assistance, training, technology exchange, and institutional partnering.

- **Operations Research for Implementing the Prevention to Care Continuum:** This activity supports focused operations and applied research and provide selected technical assistance to Missions and selected service delivery projects in order to address key questions regarding the prevention to care continuum.
- **Biomedical Research:** USAID provides support for biomedical research for the development of selected technologies, including an effective vaginal microbicide to reduce sexual transmission of HIV/STIs; rapid, simple, inexpensive STI diagnostic tests; realistic interventions to reduce mother to child HIV transmission.
- **Policy Reform:** USAID supports policy initiatives that focus on increasing commitment to prevention/care interventions, assisting with resource allocation decision making, discrimination, and other key policy areas which enhance and facilitate prevention and mitigation activities.
- **Strengthening Surveillance Systems:** Through agreements with CDC, the U.S. Bureau of Census, and UNAIDS, consensus guidelines will be finalized on minimum surveillance packages for developing countries based on phase of the epidemic. Technical assistance to Missions and host governments will be available to Missions to establish and maintain credible surveillance systems and operations research will develop and refine methodologies to estimate HIV incidence.

In addition to the strategic framework of the Global Bureau, outlined above, USAID's regional bureaus have also developed HIV/AIDS programs which are tailored to meet the needs of each region and are consistent with the Agency's overall HIV/AIDS strategic objective. These programs also strengthen central and bilateral program efforts. What follows is a brief description of USAID regional program approaches.

Africa Bureau - USAID's Africa Bureau provides leadership in the area of integration of HIV/AIDS activities into ongoing

maternal-child health programs. Also this bureau has been in the forefront for its strong support for developing a solid research and analytical agenda for HIV/AIDS. Agenda topics include information, education and communication strategies for behavioral change; evaluation of integration strategies; analysis of HIV/AIDS inputs from other development sectors; STD service delivery system strengthening; and monitoring/evaluation. The Africa Bureau also is a strong proponent of sensitizing policy makers to the adverse impact of HIV/AIDS on other development sectors such as education and agriculture.

Latin America/Caribbean Bureau (LAC) - The LAC Bureau's HIV/AIDS strategy focuses on countries where the majority of HIV/AIDS infections occur, e.g., Brazil, Haiti, Mexico. The LAC HIV/AIDS program approaches vary by country depending upon the country's experience level with the epidemic. In some countries such as those in Central America, USAID's HIV/AIDS efforts stress improving the policy environment, NGO strengthening and condom promotion. In other countries such as Brazil and Haiti, HIV/AIDS activities focus on targeting high risk groups such as women, youth, commercial sex workers and men who have sex with men.

Eastern Europe/Newly Independent States (ENI) - HIV/AIDS programs in this region are just beginning as policy makers become increasingly aware of the significance of the skyrocketing HIV/AIDS problem in this region. HIV/AIDS specific interventions currently are being developed in Russia and Ukraine. HIV/AIDS assessment activities have been completed and initial program plans have been developed. The focus of these early program efforts will be on policy formulation, public education regarding HIV/AIDS prevention, STD/diagnosis and treatment, NGO capacity building, condom promotion and targeting high risk groups such as youth and injecting drug users. USAID financed HIV/AIDS interventions in other countries of the region remain to be developed. There are some beginning HIV/AIDS education and counseling activities in countries such as Romania where HIV/AIDS information is integrated within an overall women's health strategy.

Asia Near East (ANE) - This region has been identified as the site of the next wave of the HIV/AIDS epidemic. The ANE Bureau has developed a regional strategy that includes the funding of an Asia Regional Office in Bangkok which provides critical technical support to many USAID mission bilateral programs. The ANE regional strategy depends heavily on the

services provided by cooperating agencies through agreements managed by the HIV/AIDS Division of the Global Bureau PHN Center. Many countries such as Bangladesh, Cambodia, India, Indonesia, Nepal and the Philippines have developed full scale USAID-financed bilateral HIV/AIDS prevention programs. Other countries will rely on USAID assistance provided through the ANE regional bureau in close cooperation with the G/PHN/HIV-AIDS Division. The focus of these regional efforts will be on limiting cross border and seafarer's HIV/AIDS transmission routes, developing prevention programs in low prevalence countries, upgrading surveillance systems to improve capacity to analyze HIV/AIDS regional trends, targeting high risk groups such as commercial sex workers and working on specialized issues such as the trafficking of women, condom social marketing, HIV/AIDS/STI case management, behavioral change communications and policy advocacy. Other regionally supported activities include building and strengthening local NGO programs and identifying local sources of HIV/AIDS technical assistance.

Funding

Since 1986 USAID has committed nearly \$1 billion for HIV/AIDS/STI prevention and mitigation programs in developing countries, where over 90% of the current and new infections occur. The Agency has maintained an HIV/AIDS annual funding level of approximately \$121 million since 1993. These resources are distributed within geographic regions in a pattern which reflects the severity of the pandemic. Approximately 45 percent of the total HIV/AIDS/STI funding goes to Sub-Saharan Africa; 17 percent to Asia/Near East; 12 percent to Latin America/Caribbean; and the remaining 26 percent is provided for worldwide programs including UNAIDS. If, as experts predict, the severity of the pandemic shifts towards Asia, USAID will need to reconsider resource allocations to reflect the new situation. USAID provides approximately 25 percent of the UNAIDS budget (\$15 million of a total \$60 million annual budget).

In spite of the fact that USAID is a major international funder for HIV/AIDS/STI prevention programs in the developing world, the financial resources available to combat the pandemic clearly are inadequate to mount an effective truly global response in view of the steadily increasing HIV/AIDS/STI infection rates. Approximately \$550 million is currently expended per year for HIV prevention and care in the developing world. This includes funding

from the international donor community, loans through the World Bank and expenditure by host country governments. By comparison, the annual U.S. expenditure for HIV/AIDS/STI prevention activities domestically is approximately \$700 million! In order to deal with the implications of this funding inadequacy, USAID has strategically focused its efforts on key countries and targets its programs to those most likely to transmit or acquire HIV infection. The emphasis countries for USAID prevention and mitigation programs are listed in the attachment.

STRATEGY FOR SPECIFIC HIV/AIDS/STI ISSUES

Prevention

While HIV infection is deadly, it is also preventable. In the developing world, where costly, complex antiretroviral therapies are only accessible to a few, primary prevention remains the best, most cost-effective response to the pandemic. Some 80% of infections world-wide are attributed to sexual transmission. Over the past 10 years, in over 70 countries world-wide, USAID's prevention strategy has focused first on promoting and facilitating sustained reduction in sexual risk behavior and, more recently, on modifying environmental conditions, such as poverty and the subordination of women, that provoke or facilitate risk behavior.

The behavioral outcomes that increase protection against sexual transmission of HIV and STI are clear: abstinence, long-term mutual monogamy among sero-concordant partners (HIV testing status for both partners is the same, i.e. both partners are seronegative or both partners are seropositive. Unfortunately, only approximately 10% of persons in the developing world currently have access to accurate and confidential HIV testing), reduced rates of partner change (reduced number of partners), and correct, consistent condom use. However, no two countries and target audiences are alike, and USAID has learned that there is no single blueprint for prevention programs to achieve these outcomes. Rather, the Agency has established a process for developing and implementing HIV prevention programs in partnership with host-country governments, non-governmental organizations, technical experts and intended beneficiaries. This enables USAID-funded services to reach the people at the grass roots level and are shaped to meet the needs of specific target audiences and their cultural, economic and political environments.

The three pillars of USAID's HIV/AIDS prevention strategy respond to the principle determinants of sexual risk behavior. The first is behavior change communications, which is used to transmit information and to engage people in dialog about HIV/AIDS, STI, reproductive health, gender power and sexual norms - because people must understand the risks and means of protection, and must be motivated to act to protect themselves and others. The second is condom social marketing, which uses private sector advertising and commercial distribution approaches to make condoms more widely and sustainably accessible to people who know and are motivated to use them. The third is improved STI services - including improved and more accessible curative care, partner referral, and prevention counseling, because STI infections are health threats in their own right, and because they significantly increase the risk of HIV transmission and acquisition.

Our three core prevention strategies are supported by policy dialog, behavioral research, and monitoring and evaluation. Improving policy dialog, for example, through assisting community based organizations and government officials to consult and work together, helps to shape policy and normative environments so that they facilitate rather than impede risk reduction. Behavioral research is essential for identifying and understanding risky behaviors and the populations who practice them, the characteristics and preferences of key audiences, the language and content of messages that will appeal and "speak" to particular audiences, and other site-specific details. (Behavioral research is discussed in more detail below). Transferring skills in monitoring and evaluation enables USAID and our partners to track our programs, test assumptions, make mid-course corrections, and document the successes and shortcomings of our activities to inform future programming.

In nascent and concentrated epidemics, our programs prioritize work with so-called "high frequency transmitters," or, most accurately, Those Most Likely To Contract and Transmit (TMLCT) HIV/STI, such as sex workers and their clients, other men whose work takes them away from home for long periods (e.g. military, long-distance truckers), or women and men with large, open sexual networks. USAID programs have developed an array of methods and innovative models for reaching and serving even hard to reach populations at risk of HIV, who often include poor, marginalized groups such as street children or people living

with HIV/AIDS. Key to their success are procedures for defining specific audiences and tailoring interventions to their needs, which have been shared among AIDS and reproductive health researchers world-wide. The AIDSCAP program alone supported over 450 projects in over 40 countries, reaching urban university students to rural traders, secondary school students to factory employees, legions of women attending antenatal care clinics to fledgling networks of people living with HIV, and private medical practitioners and pharmacists to traditional healers.

Whether focused services for localized groups or national programs reaching the general population, behavior change interventions strive for both consistency and dynamism. The most effective programs deliver not one, but an array of consistent messages through multiple, mutually reinforcing channels (e.g. newspaper, radio, billboards, community theater). And while coherent, these messages need to move with the public ethos, the stage or readiness of the audience to change, and evolution of the epidemic itself. Thus, new to our programs in the second decade, is a more balanced set of messages about HIV/STI prevention, HIV/AIDS care, and clarifying and defending the human rights of people already HIV positive. USAID and our partners across the globe have found that people living with HIV or AIDS are the most convincing educators and advocates in prevention programs, and in high prevalence settings, communities need help in devising ways to care for families and orphans devastated by HIV/AIDS.

Creating environments where Persons Living with HIV and AIDS (PLHA) can come forward safely to serve as HIV/AIDS educators and community mobilizers requires confronting and overcoming HIV/AIDS stigma, and combating discrimination and oppression of people with or associated with HIV. This has become an important new focus in USAID's strategy for prevention. In addition, the sustainability of programs hinges upon local participation and ownership, and upon resources that require local private sector and political support. Overcoming HIV/AIDS stigma both facilitates and follows community and policy-maker support for HIV/AIDS prevention and care. In short, while carrying forward the successes of the three "pillars" (BCI, CSM, and STI interventions) plus policy dialog, behavioral research and monitoring and evaluation activities, USAID's HIV/AIDS prevention strategy has been expanded based on a decade of field experience that shows the importance of preparing

communities and service providers to respond to a range of individual, family, and community needs along the prevention-care continuum.

Care and Support

USAID supports care activities because they improve our efforts to achieve sustainable development, enhance overall public health, and support our efforts to prevent further spread of HIV. Rather than take a narrow biomedical view of care, USAID advocates care and support activities which are broad in nature, and are critical to the continued efforts of communities, governments, and donors to promote sustainable development in the face of the HIV/AIDS epidemic. Care and support activities include:

- Protection of basic human rights
- Psycho-social care of persons infected and affected by HIV/AIDS.
- Palliative care for persons with HIV related symptoms such as pain, fever, or diarrhea.
- Prevention and treatment of common opportunistic infections.
- Supporting programs which provide economic support to those communities hard hit by HIV/AIDS.
- Supporting foster and extended families for the millions children who have been orphaned thus far by AIDS.

HIV/AIDS care and support activities enhance sustainable development by shoring up fragile infrastructures. For example, community-based care, and retraining of key personnel, are essential to preserve the health and education sectors where, in some east African countries, up to 40% of these workers are already infected with HIV.

HIV/AIDS care and support activities contributes to decreasing secondary epidemics most notably Tuberculosis. The global HIV pandemic is driving a secondary explosion of TB, which is responsible for 35% of the deaths of HIV infected persons in the developing world.

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HIV/AIDS care and support enhance all of our primary prevention efforts. Presenting information and education messages to include everyone in the community increases the acceptance, credibility, ownership and ultimately the response to behavior change messages. In addition, programs to protect the basic human rights of HIV infected individuals and those most at risk for infection, open the door for the implementation of far more effective behavior change campaigns. Prevention efforts, to be effective must mobilize those living with HIV/AIDS as spokes people for change. Ultimately, the person who is carrying the virus, particularly one with multiple sexual contacts, is the single most important recruit for prevention programs promoting reduced risk behavior. If programs appear to abandon people living with HIV/AIDS and their families, or to ignore their needs and concerns, we cannot expect them to help.

USAID is also supporting operational research to determine the most cost effective ways to provide care and support to persons infected. USAID does not at this time support the large scale procurement of anti-retroviral drugs for developing countries. The use of antiviral drugs in treatment regimens similar to those used in the U.S. would cost approximately \$35 billion per year to treat those infected in the developing world. In addition to the enormous cost, these treatments require sophisticated health provider and laboratory infrastructure which does not exist in most of the developing world, where the average health expenditure per person per year is about \$10.00.

AIDS Orphans

The number of children affected by AIDS, including those who are orphans or caring for sick parents, continues to escalate. There has been growing recognition and concern for these children. In a study funded by USAID, "Children on the Brink, Strategies to Support Children Isolated by HIV/AIDS," the U.S. Census Bureau estimated that 15.6 million children will have lost their mothers or both of their parents by 2000 in 23 countries heavily affected by HIV/AIDS. That number will increase to 22.9 million by 2010, largely as a result of the HIV/AIDS pandemic. During the 12th World AIDS Conference in Geneva, the problems posed by this issue were referred to as a "massive social time bomb". In 1996, USAID expanded its HIV/AIDS strategic objective to include issues related to care and support of

those affected by the disease.

More recently, the Division has supported the development of a series of discussion papers focusing on issues related to care and support of persons affected by HIV/AIDS. Included among these papers is a document entitled "Responding to the Needs of Children Orphaned by HIV/AIDS", specifically focusing on the affect of the disease on youth. These papers provide background information which will be used to develop the HIV/AIDS strategy on care and support. The strategy will influence future related projects conducted by USAID Cooperating Agencies and Missions. In addition, "HORIZONS", the HIV/AIDS operations research project, is currently exploring avenues for conducting research to contribute to the development of "best practices" for setting up community based methods of providing care and support to people affected by HIV/AIDS, including children. Representatives of the HIV/AIDS Division have been actively involved in meeting with other donors and organizations that are working with children and families affected by HIV/AIDS. They are also working on the establishment of an electronic network as a forum for exchange of technical information among a wide variety of donors and other organizations regarding programs related to orphans and other children affected by the disease. These activities contribute toward identifying the scope of the problem, sharing information about how to address it, and coordinating activities to do so.

Women and Health

USAID recognizes that women and girls are at the epicenter of the HIV/AIDS epidemic in every community, both as positive agents of change and as individuals in need of services and support. Though not recognized as a key audience for HIV interventions until the early 1990s, in most regions women and girls represent the fastest-growing segment of the HIV+ population.

The impact of HIV/AIDS on women is not solely a function of their greater biological and social vulnerability to infection. It is also because, when family members become ill with HIV disease, the burden of care falls disproportionately on women and girls. Data from a wide range of studies on health and nutrition have confirmed the critical role women can play in improving the health of their families when they have access to information, skills, and some control over resources. USAID's HIV/AIDS programs

aim to alert and mobilize communities to respond to the care needs of people living with HIV/AIDS (PLWH) without sacrificing the progress achieved in women's education and economic participation, because that progress is beneficial for all.

Finally, as noted previously, the ability of a relatively low-cost antiretroviral treatment regimen to decrease the risk of mother-to-child transmission (MTCT) has focused attention on another situation where a woman's own health and welfare may be given lower priority than the health of her children and family. By aiming to have all USAID programs examined through a gender lens, and by listening to and involving women at all stages of project identification, design, implementation and evaluation, the USAID strategy acknowledges the complexity of women's lives and roles, and gives priority to programs and approaches that respond to their expressed concerns.

Vaccine Research

While USAID lacks the resources to independently fund vaccine research we have a strong interest in the vaccine development process and we are uniquely positioned to facilitate the implementation of vaccine trials in developing countries. Because of the tremendous genetic diversity of HIV, one of the greatest challenges facing vaccine developers is to produce a vaccine that can protect against infection with diverse viral isolates. This avoids the need for many isolate-specific vaccines. However because this type of vaccine may not be developed in the near future, there is concern that initial vaccines will be effective only against those strains of virus found predominantly in North America and Western Europe.

It is the USG view that vaccine candidates should have broad activity against the most common genetic subtypes of virus for two reasons. First is the issue of impact on the epidemic. Approximately 90% of all new HIV infections occur in sub-Saharan Africa and Asia while about 1% occur in North America and Europe. In order to have an impact on the growth of the epidemic, candidate vaccines should be targeted to those strains responsible for the most new infections.

The second reason to advocate for vaccines with the broadest possible coverage is to prevent selective pressure for new epidemics. A vaccine which provides protection for

only the viral subtypes currently prevalent in a community will reduce transmission of those types of virus while leaving the community vulnerable for a new epidemic caused by subtypes not covered by the vaccine.

USAID can assist the vaccine development processes in the following ways:

- USAID can take the lead in educating stakeholders in developing countries. This task entails explaining the importance of clinical trials, making accurate information widely available, responding to questions, ensuring ethical designs, countering misinformation and lining up high-level support from both host country and U.S. officials.
- USAID is uniquely positioned to assist in developing the methodology of community-level interventions; fostering long-term, sustained relations with local communities; measuring indirect effects; and doing impact modeling. By working closely with local communities, USAID could ensure that they are ready to participate in clinical trials.
- Policy advocacy for research on broad activity vaccines.

Behavioral Research/Behavioral Change Interventions

HIV/AIDS prevention and care hinges upon changes in patterns of risky behavior -- be they relating to sex, illicit drugs, or exposure to infected blood through medical waste or unsterile needles, razor blades and other instruments. Even improvements in STI services will not fulfil their potential impact unless people with STI symptoms and signs change their help seeking behavior, and unless allopathic and traditional practitioners improve their diagnostic and therapeutic practices to recruit people at risk of STI and to satisfy them with their services. Thus USAID supports behavioral research in our partner countries both to develop new intervention models and to adapt and apply existing models for new settings. USAID's cooperating agencies conduct behavioral research:

- in diagnostic studies to define the specific behaviors that put people at risk in a given setting;
- in defining the distribution of risky behaviors in a population, so as to identify sub-groups or target audiences for intervention development;

- in formative research to build understanding of the causes and meanings of risky practices, from the actors' points of view, and to pre-test intervention ideas and messages with the intended audience;
- and in testing and documenting the effectiveness of interventions, where changes in behavior are key outcomes of intervention trials.

Under the AIDS Technical Support Project, completed in 1997, USAID's investment in behavioral research comprised a major increase in the resources available for studying the interactions of culture, health, gender and sexuality in the developing world. The AIDS Behavioral Research Grants program, funded jointly with NIH, supported partnerships between US and developing country NGOs (including universities) to revise and adapt theoretical models of health behavior to strengthen HIV/AIDS behavioral interventions in non-Western settings. The nine studies have provided baseline data for local policy and intervention development. They are also helping to build a more representative, international base for evaluating the roles of culture, society and behavioral biology in human sexuality and health behavior, and for guiding the design of behavior change interventions appropriate for particular audiences and settings.

USAID-funded projects have established formative behavioral research as a prerequisite of technically sound intervention development. Thus most of our future interventions will contain data collection components that enrich the knowledge base for understanding HIV risk behavior and opportunities for prevention and care. In addition, the HORIZONS Project, discussed in the previous section, will extend these achievements through a program of developing research to answer selected research questions in nine thematic areas: 1) STI prevention and management; 2) HIV care and support services; 3) Stigma and discrimination; 4) Risk assessment and behavior change; 5) Policy analysis and change; 6) Social marketing and private sector involvement; 7) NGOs and community mobilization; 8) Integration of HIV/STI, Family Planning, and Maternal and Child Health services; and 9) Community mobilization.

In addition to pursuing some relatively new topics in developing countries (e.g. HIV/AIDS stigma), USAID has mandated all projects under the Global Bureau's HIV/AIDS strategic objective, to document and develop knowledge about the following cross-cutting issues: gender inequalities and

their effects on risk reduction and program success; the vulnerability of youth; involvement of PLHA in HIV/STI intervention programs; building local NGO and CBO capacity; links between prevention and care services; sustainability of services; costs and cost-effectiveness of service modalities and models; and methods and costs of taking successful pilot projects to scale.

Microbicide Development

USAID has been a major contributor to the search for a vaginal microbicide. Vaginal microbicides are products which ideally can be used by a woman herself, without the cooperation or consent of her sexual partner, to protect herself from the possibility of acquiring HIV and other sexually transmitted diseases (STDs). The agency has supported laboratory work to identify and test promising compounds, as well as the Women's Health Advocates for Microbicides (WHAM), an innovative group providing advocacy for the product, and promotion of international collaboration and involvement of women at all stages of product development.

Most products which have been developed and tested in the past several years have been based on a product known as Nonoxynol-9 (N-9) which, unfortunately, has not proved effective as of this date. In collaboration with the Research Division in the Office of Population, the HIV/AIDS Division is currently supporting a trial of a new microbicide, developed with support from USAID, which has a unique mechanism of action and has been shown to be safe in preliminary studies. The study is expected to continue for approximately two years and provide information on safety and effectiveness of the product.

Donor Coordination

Donor coordination is key to the success of the U.S. response to the HIV/AIDS global pandemic. USAID's G/PHN Strategic Objective 4 "to increase the use of improved, effective, and sustainable responses to reduce HIV transmission and to mitigate the impact of the HIV/AIDS pandemic," includes donor coordination and partnership at global, regional, and country levels. USAID has been an active partner with the United Nations in providing financial support for international HIV/AIDS program efforts. Since 1986, USAID has been a major contributor to the WHO Global Program on AIDS. As that program terminated

in 1995, USAID support shifted to a new United Nations HIV/AIDS endeavor which officially began in January, 1996.

Also, in countries where USAID Missions include HIV/AIDS as part of their country strategy, PHN offices coordinate closely with the Joint United Nations Programme and other donors which may be in country. In addition, there are a series of specific donor coordination activities including the U.S. Japan Common Agenda, collaboration with DFID, the EU, and a number of other selected partners. There are also excellent examples of strong coordination, through funded activities with national governments, PVOs/NGOs, and local organizations.

Capacity Building

Effective HIV/AIDS programs work to sustain changes in behaviors that contribute to the risk of HIV infection and to establish, improve and maintain systems and practices to appropriately manage the effects of HIV and AIDS. As HIV/AIDS becomes endemic in many countries, the need for programs to achieve and sustain these results over the long term is heightened. The time period to achieve sustained changes in risk behaviors and manage the effects of HIV will exceed the time frame of many external technical inputs and donor contributions. Therefore, a programming strategy that prioritizes building local capacity within the public and private sector is essential.

The USAID HIV/AIDS program works to build the local public and private sector response to HIV/AIDS by increasing political awareness and commitment in local government, and by increasing the technical and managerial capacity of local public, commercial and non-profit entities to provide services and commodities required for sustainable HIV/AIDS programs. Within the public sector, the USAID and its partners work with government ministries of health and other sectors to increase:

- Political awareness of the effects of HIV and the importance of preventing HIV infection and appropriately caring for those who are infected,
- Technical quality and use of surveillance information in monitoring the epidemic, and in program management and evaluation,
- Quality and reach of public sector services needed

in HIV programming, such as STI diagnosis and treatment, logistical systems for commodities (i.e. essential drugs and condom), and training in counseling and home-based care,

- Collaborations between the public and private sector.

USAID and its partners strengthen the technical and managerial capacity of indigenous NGOs so that they have greater competence in, impact on, and influence over the design, implementation, and evaluation of sustainable HIV/AIDS prevention and care programs. USAID also works to build and improve regional and local networks and coalitions. The networks provide technical support and improve advocacy efforts by building relationships across public and private sector institutions.

USAID works to strengthen commercial sector involvement in HIV by increasing the awareness of the potential impact of HIV on various areas of the commercial sector and by building HIV prevention programs for the business environment. In addition, some USAID programs work to leverage local commercial markets for condoms and other commodities, such as essential drugs for STI treatment. Sustained local responses to HIV will depend upon public and private sector involvements which supplement and complement each other. As we enter the second decade of the HIV/AIDS pandemic it is clear that the populations requiring HIV prevention and care and support services are changing and increasing. Building the capacity of local institutions to recognize these changes and respond to these increasing demands is critical in order to stem the impact of this pandemic.

Reducing Mother to Child HIV Transmission

Mother to child transmission (MTCT) is the second leading route of transmission of HIV in the world. Annually over 500,000 infants are infected by their mothers. This transmission takes place during one of three times: before birth, during labor and delivery, or during breast feeding.

In February 1998, researchers from the U.S. Centers for Disease Control announced the results of a randomized placebo controlled study in Thailand. This study demonstrated that a short course of AZT given to HIV infected women in the last trimester of their pregnancy,