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U.S. International Response to HIV/AIDS

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Contents

Executive Summary

The 1999 U.S. International Response to HIV/AIDS (human immunodeficiency virus/ac-quired immune deficiency syndrome) is part of a continuing effort by the U.S. Government to create positive change in the international fight against HIV/AIDS. It will be used to foster political commitment and to develop international partnerships. It also provides a framework of effective programs and strategies that can serve as a model of government policy and resource investments to more effectively meet the challenges posed by the global HIV/AIDS pandemic.

The 1999 report examines the present world AIDS situation and assesses the U.S. foreign policy interests presented by the HIV/AIDS pandemic. It then reviews the objectives and accomplishments of the 1995 U.S. International Strategy on HIV/ AIDS, and identifies the HIV/ AIDS challenges confronting the United States and other members of the international com-munity. The report includes agency strategies that identify specific objectives to effectively address HIV/AIDS issues. The programs, policies, and activities represent commitments by each agency and have been adopted at the highest level of agency authority. To underscore the global battle against HIV/AIDS, the report also identifies the respective roles of the phar-maceutical industry, international non-governmental organizations, and international organi-zations.

The 1999 report, like the 1995 report, is the product of an interagency effort. Participating agencies include the 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 U.S. Department of Defense, the National Intelligence Council, and the U.S. Department of Justice.

The goals of the 1999 U.S. International Response to HIV/AIDS are to:

- Raise awareness of the issue of international HIV/AIDS;
- Raise the level of priority accorded to stemming the spread of HIV/AIDS by all govern-ments;
- Promote collaboration between governments, international organizations, and the pri-vate sector in developing international partnerships to leverage investments of capital and expertise into sustainable programs to fight HIV/AIDS;
- Encourage and support the efforts of UNAIDS and other international organizations;
- Promote respect of human rights for those afflicted with HIV/AIDS; and
- Highlight the special and growing needs of women and children infected with HIV/AIDS.

The target audience of the report includes governments of both developing and developed nations, international organizations, non-governmental organizations, industry, and the pub-lic at large. The 1999 report should not be viewed as a funding directory or as a manual for eradicating the HIV/AIDS epidemic. Rather, it is a compilation of government policies, pro-grams, and priorities to further coordinate and share our collective expertise. Through suc-cessful, responsible partnerships at home and abroad, the global community can realize the benefits of the lessons learned and accomplish greater goals.

No member of the global community can afford, either in terms of human suffering or development and economic costs, to ignore the impending devastation that has already be-

gun to ravage national economies, security, and social infrastructure. It threatens the very fabric of society, regardless of race,

economic means, or spiritual belief. HIV/AIDS has hit hardest those least able to meet its economic costs and those in their most productive stage of life.

The dynamic global environment, where people change addresses and transportation routes, and exchange goods and services over vast distances, links all nations in this battle. We must approach the solutions to our collective dilemma in a universal and collaborative way. Only then can we bring to bear the most fervent action and the most specialized resources we each have to offer. We look forward to each nation making a political commitment at the highest levels and bringing sustainable commitments to see this fight through to its successful conclu-sion.

This report will be used as a foreign policy tool to foster political commitment by other governments and to assist U.S. efforts in establishing or strengthening international partner-ships to address the pressing challenge of HIV/AIDS. We will disseminate and discuss U.S. Government programs and activities and encourage leaders to establish or strengthen na-tional plans against HIV/AIDS, and expand the broad range of relevant activities - including education for prevention, improved access to treatment, and strengthened research efforts to develop new tools against HIV/AIDS. And finally, we will continue to work with international organizations, governments, non-governmental organizations, industry, and others in the pri-vate sector to reduce human suffering, mitigate the impact that HIV/AIDS is having around the globe, and to work towards the day when HIV/AIDS is eradicated.

Introduction: World AIDS Situation

A Rapidly Expanding Epidemic

Dire predictions from the 1980s have become the reality of the 1990s. HIV/AIDS is insinuating itself into communities previously little troubled by the epidemic and is strengthening its grip on areas where AIDS is already the leading cause of death in adults. The cumulative number of those infected has more than tripled from the 10 million infec-tions estimated in 1990. UNAIDS and the World Health Organization estimate that more than 33 million people are infected with HIV and that 16,000 new infections are acquired every day. Worldwide, an estimated 13.9 million people have lost their lives to the disease - 2.5 million in 1998 alone. Given the current rate of infection as well as the sheer number of those already infected and the limited availability of state of the art care, the death

toll from HIV/AIDS is projected to increase expo-nentially in the years to come.

HIV/AIDS is a global problem touching virtually every country and every family around the world. It does not recognize boundaries of nationality, gen-der, age, occupation or sexual preference. Globally, 1 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

HIV/AIDS is resident in humans in every region of the globe, from sub-Saharan Africa to Asia and the Pacific, the Americas, Eastern and Western Eu-rope, to the Middle East (figure 1). However, HIV infections are concentrated largely in countries least

able to afford the care for infected people. In fact, more than 95 percent of people with HIV live in the developing world. It is estimated that by the year 2020 HIV will be responsible for 37 percent of all adult deaths from infectious diseases in the developing world.

HIV/AIDS is now threatening development gains that local and donor governments, citizens, non-governmental organizations, and international agen-cies have worked for decades to achieve. In many

sub-Saharan African countries, AIDS has increased infant mortality and reduced life expectancy to lev-els not seen since the 1960s. Infant and child mor-tality rates are expected to double and even triple early in the next century. By the year 2010, life expectancy in some sub-Saharan countries could decrease by 30 years or more. AIDS is doubling, or even tripling, death rates among young adults in countries in southern Africa. In Botswana and Zim-babwe, prevalence among young adults has reached

25 percent—one person in four, a historic new high. In South Africa, it is estimated that 3 million people are now living with HIV, and 700,000 were infected in 1997 alone. Deputy President Mbeki, speaking for President Mandela, has stated that South Afri-can economic growth could slow by 1 percent a year because of AIDS.

Globally, the number of children under 15 who have lived with or are living with HIV/AIDS 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 1998; 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, it is estimated that HIV/AIDS orphaned 1.6 million children. At present, 90 percent of the orphans live in sub-Saharan Africa.

An important trend of the 1990s has been the beginning of a shift of the global AIDS problem from Africa to Asia, which will soon have more new HIV infections than any other region of the world. The recent spread of the HIV epidemic in Asia and the Pacific has been swift. Since 1994, almost every country in Asia and the Pacific region has seen HIV prevalence rates increase by more than 100 per-cent. Nearly 7.2 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 3 years, making it currently the nation with the greatest number of

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 countries—such as Indonesia and the Philippines—HIV has remained at roughly the same low levels for a number of years. The situation in Latin America is mixed, with prevalence rising rap-idly in Mexico, Brazil and Guyana. In other coun-tries, as in many industrialized nations, infection rates have stabilized or are falling. The level of dam-age sustained by developing nations varies with the maturity of the epidemic and the response of na-tional authorities and local communities to the threat of its spread throughout the population.

In Eastern Europe, though the absolute num-bers 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 negli-gible. However, in 1996, 8,000 new HIV cases were reported. The bulk of the spread has been in in-jecting drug users and the sex partners of injecting drug users (IDU), which may provide a bridge for the virus into the general population. In Russia 2,223 cases of HIV were reported in the first 6 months of 1997, and by the year 2000, without appropriate interventions to eliminate illegal injec-tion drug use and to curb high-risk behaviors, as many as 1 million Russians could be infected with HIV.

The long lag time between HIV infection, devel-opment of AIDS symptoms, 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.

Assessment of U.S. Interests

In the face of HIV/AIDS, the U.S. Government aims to reduce human suffering and stem further disease transmission. The U. S. has a critical lead-ership role to play in assisting the global effort to address the growing threat of HIV/AIDS. We must continue to take a leadership role in mitigating the devastating individual and social impacts of the dis-ease. Focusing our considerable technical and hu-man resources on this pandemic confirms our na-tional ethos to help those in need. Fulfilling this trust, however, is also in the interest of U.S. citi-zens. This pandemic is the silent enemy of eco-nomic growth, national well-being, and stability around the globe. Further, our collective hopes of new markets, foreign investment and stable democ-racies could be threatened by the unbridled spread of HIV. The recent outbreaks in Russia and the Ukraine are sobering reminders that this danger ap-plies worldwide.

The number of AIDS cases worldwide will con-tinue to rise in the next millennium and will increas-ingly undermine other projects intended to foster key U.S. policy goals, including democratization, economic development, conflict resolution and peacekeeping, and the promotion of individual and political rights. The AIDS pandemic will overwhelm underfunded and inadequate health delivery sys-tems in much of the developing world and could undo hard-won health, social, and economic gains by nations around the world and represent a sig-nificant increase in government costs.

HIV/AIDS is not simply about mustering re-sources, technological know-how, and collective will to manage and eventually halt the spread of dis-ease. The political and economic reverberations of HIV/AIDS demand a far broader response. Its increased incidence among military populations, its impact on the debates about both North-South is-sues and gender equity,

and its challenges to prin-ciples of human rights are all inextricable elements of policy development and implementation.

Security and Political Concerns

Although not an issue of strategic security in the classic sense, the growing prevalence of HIV/AIDS internationally and its pervasive impact must re-shape 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 gradu-ally weakening the capacity of militaries to defend their nations and maintain civil order, to provide qualified personnel for peacekeeping, and to have access to a healthy conscription pool.

The high HIV/AIDS infection rates in military per-sonnel of many countries, including officers as well as enlisted personnel, will result in national secu-rity threats as military command structures are di-minished and depleted by the disease. A 1998 UNAIDS report entitled “AIDS and the Military” states that military HIV infection rates in Zimbabwe and Cameroon are three to four times higher than in the civilian population. A strong correlation found between rank and prevalence rates indicated that as the disease progresses, militaries will suffer from debilitated leadership and an inability to meet mili-tary needs and commitments.

HIV/AIDS has potential implications for political stability. In many instances, the spread of HIV/ AIDS is part of a crippling cycle affecting leader-ship and governance. Civil strife, refugee flows, urbanization, and poverty all play a role in creating conditions conducive to the rapid spread of HIV. When economies and governments fail, or are chronically enfeebled, health systems falter rapidly. This leaves populations more prone to illness and at greater risk of economic decline. As an example, political instability and disease have reinforced each other in Rwanda and the countries of the former Soviet Union.

Industrialized countries are not immune to the destabilizing effects of HIV infections. HIV blood test scandals have resulted in national outcries. Special considerations for the needs of HIV-infected persons (e.g., anti-discrimination, compensation, funding of care) also have been socially divisive issues.

Social and Economic Impacts

Like the spread of the disease, the economic impact of HIV/AIDS is pervasive and devastating. A 1993 study by DRI/ McGraw estimated that by the year 2000, the direct (medical) and indirect (loss of labor force and family impact) costs of the dis-ease will exceed $500 billion. Severely affected countries will experience large impacts on their health sector and on the poor. According to the World Bank, 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. In the case of an HIV/AIDS epidemic, the number of patients that will overwhelm healthcare systems will lead to an increase in total national expendi-ture on healthcare, both in absolute terms and as a proportion of national product. The net effect will be to increase the price and reduce the avail-ability of healthcare for everyone, which will tend to affect the poor the most. Governments, there-fore, will confront trade-offs along at least three di-mensions: treating AIDS versus preventing HIV in-fection; 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 af-fected by an HIV/AIDS-related illness and death. De-cisions 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 afflicts many people in their 20s, 30s, and 40s—their most economically productive as well as child-bearing years.

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

Impact on the Workplace

Most prevalent among adults in their years of greatest productivity, the economic well-being, par-ticularly of developing nations, will be drastically affected by the presence and spread of HIV/AIDS in the country. AIDS 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.

The loss of so many working-age adults to ill-ness and death undermines previous achievements in extending life expectancy and increases the bur-den 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 educational 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 school in more immediate need of a livelihood as a means of self-support. That livelihood all too often becomes com-mercial sex work, selling themselves to survive or to support their remaining siblings or other ex-tended family. This situation, already worsened by the growing international financial crises in Asia, Russia and Latin America, portends an even greater likelihood of increased transmission of HIV/AIDS and other sexually transmitted infections (STI).

The pool of uneducated and undereducated people due to HIV/AIDS-related causes further threatens to undermine critical economic and busi-ness investment. Critical to attracting investment, is a stable, well-educated, and healthy labor pool for production of goods for domestic and interna-tional commercial markets. Increased turnover of employees, additional training, and other employee-related expenses could raise the costs of doing busi-ness and discourage international investment criti-cal to stabilizing regional and national economies. This could also mean a reduction in taxes and pro-duction-related revenues generated as part of a healthy economic climate. At the same time, in-creased 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 busi-ness sector, may resort to or be sold into prostitu-tion by impoverished family members in an effort to cover family expenses in times of economic hard-ship. Not only does this lead to a further under-mining 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 accel-erated infection rates, there will be fewer persons available to support the growing numbers requir-ing care. They will likely look to the formal healthcare system, in whatever state it may exist, for care and support. And the ever-growing num-bers of sick and dying will severely burden inad-equate healthcare infrastructures and heighten fear and intolerance, which could lead to an increase in human rights violations.

Healthcare Costs

Of all the economic and social costs incurred by 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; and, on aver-age, treating an AIDS patient for 1 year costs about the same as educating 10 primary school students for 1 year. The simulated impact of a severe AIDS epidemic on healthcare expenditures, illustrated below, predicts that if India maintains its current level of healthcare subsidies, a severe AIDS epi-demic would increase government healthcare ex-penditure by about $2 billion per year by 2010. If subsidies are increased to the 50 percent level, the same epidemic would increase annual government health expenditures by an additional $30 billion (figure 2).

Figure 2. Simulated Impact of a Severe AIDS Epidemic on Health Expenditures, India, 1990–2010.

Assessment of 1995 Strategy

The July 1995 U.S. International Strategy on HIV/ AIDS was structured around three broad categories of goals:

- Prevent new HIV infections;
- Reduce personal and social impact; and
- 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 identify areas where more action might be taken.

Prevent New HIV Infections

Under the heading of preventing new HIV infec-tions, the 1995 Strategy laid out several points for action:

- Implement 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 tech-nologies; and
- Address the adverse impact of poverty and other factors on prevention efforts.

Implement Diplomatic Initiatives on HIV/AIDS Issues by National Governments

As a result of the 1995 U.S. International Strat-egy on HIV/AIDS, the Department of State, in con-junction with other agencies, has taken numerous diplomatic initiatives to promote more active in-volvement on HIV/AIDS by national governments. For example, the Department 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 Fourth World Conference on Women; placed HIV/AIDS on the G–7 agenda of Finance and For-eign Ministers in 1996 in Lyon; supported the G–8 agreement to work more closely on an AIDS vac-cine, made at the Denver Summit and reconfirmed at subsequent summits; and supported consensus on HIV/AIDS-related Human Rights Commission Resolutions.

On December 1, 1998, at President Clinton's World AIDS Day event, Secretary of State Madeleine Albright issued a statement to highlight the foreign policy implications of HIV/AIDS and initiate activity on a U.S. diplomatic initiative on HIV/AIDS. The 1998 statement builds on the Secretary of State's 1997 World AIDS Day statement, in which she called on nations, private institutions, local and interna-tional business, communities, and families to in-tensify the fight to curb the HIV/AIDS epidemic. In addition, U.S. ambassadors and other embassy rep-resentatives were instructed to meet with host coun-try counterparts to brief them on the U.S. Interna-tional Strategy on HIV/AIDS and to encourage lead-ers to expand HIV/AIDS prevention and mitigation programs.

The U.S. Agency for International Development (USAID) has been successful in identifying effec-tive prevention strategies and, through USAID mis-sions and U.S. embassies, publicized successes to government and community health workers so that they could be duplicated elsewhere. Dissemination activities have included producing training curricula; convening workshops; distributing "lessons learned" documentation (electronic, hard copy, CD-ROM, etc.); and most importantly, incorporating these best practices into all USAID-assisted pro-grams.

Develop Behavioral Prevention Strategies

USAID and the Department of Health and Hu-man Services (DHHS), primarily through the National Institutes of Health (NIH) and the Centers for Dis-ease Control and Prevention (CDC), have supported

an ongoing portfolio of behavioral research to iden-tify and monitor risk behaviors and their psychoso-cial and environmental determinants. CDC scien-tists have also completed and are disseminating information from several large, multi-site interven-tion trials evaluating one-on-one-, small-group-, and community-level behavioral intervention strategies. Approximately six trials evaluating interventions for young gay and bisexual men, young men about to be released from prison, serodiscordant couples (i.e., HIV status is not the same), and HIV-infected persons are now in the formative or implementa-tion phase. Continual research also includes HIV risks to postpartum women and perception and be-haviors that influence acceptance of HIV counsel-ing and testing. Finally, CDC established an ongo-ing database of HIV intervention research literature to facilitate ready identification of scientifically cred-ible intervention models for HIV prevention pro-grams to use.

NIH supports a range of behavioral research through a number of its component institutes and centers. These studies have demonstrated the important interaction of biological, psychological, and social factors that contribute to HIV preven-tion, 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 suc-cessful interventions to encourage sustained be-havior change.

In the past 5 years, USAID, through work with host country governments and community groups, has provided behavior change services for over 22 million men, women, and youth, helping them to reduce their risk of HIV infection. To accomplish this task, USAID has trained over 180,000 new dedi-cated counselors and educators. In addition, with partner organizations, the clinical management of sexually transmitted diseases (STD) has been im-proved in more than 22 countries as a significant way to reduce the efficiency of HIV sexual trans-mission.

Building on this investment in behavioral re-search, the USAID-funded AIDS Control and Preven-tion Project (AIDSCAP) supported over 250 studies ranging from an intervention trial to define cost-effective approaches to HIV/AIDS education for vocational students in Sao Paulo, Brazil, to a col-laborative, AIDSCAP/UNAIDS/WHO multi-site effi-cacy 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 and sexually transmitted infections (STI) and adapted rapid ethnographic assessment procedures to the STI field. The resulting Targeted Intervention Research (TIR) manual was tested and applied in nine countries in Africa and Southeast Asia. It was used to develop a locally meaningful health education message and to enable develop-ing-country researchers/providers to improve doc-tor-patient communication by using local language and concepts in STI screening and case manage-ment.

USAID's Women and AIDS Research Program, a cooperative agreement with the International Cen-ter for Research on Women (ICRW), 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, so-ciocultural, 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 HIV prevention programs; has built local non-gov-ernmental organization (NGO) and government ca-pacity to deal with gender issues, and in the sec-ond phase of the project, has turned the research findings into eight HIV/AIDS interventions, focus-ing on the special needs and circumstances of women.

USAID's social and behavioral research at the macro level has developed and applied epidemio-logical and economic projections for HIV/AIDS to improve policymaking. In the Dominican Repub-lic, policy research involving epidemiological mod-els and projections stimulated the President to sign into law legislation to enhance HIV/AIDS preven-tion efforts. In Brazil, a study of the economic losses associated with high consumer prices for condoms was used successfully by local advocates to con-vince the Federal Government to reduce taxes on condoms. In South Africa, support for research on the social and economic impact of HIV/AIDS has provided crucial data for policy dialogue concern-ing the need for private and public investment in HIV/AIDS prevention and care. USAID-funded projects have established formative behavioral re-search as a prerequisite of technically sound inter-vention development. Thus, most of our future in-terventions 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 leader-ship and operations research project managed by the Global Bureau's HIV/AIDS division. Through mechanisms under USAID's HIV/AIDS strategic ob-jective, 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 ap-propriate counseling and testing; strengthening community mobilization and empowerment for HIV prevention, care, and support; improving methods for personal HIV risk assessment; and understand-ing the economic and societal pressures that in-crease sexual risk behavior.

Augment Research

The results of research provide the foundation on which interventions are developed. Based on such research, the U.S. Government has made large strides toward improving intervention strategies such as new approaches to stem mother-to-child transmission and new behavioral interventions. To this end, it is notable that the results of studies supported by NIH and CDC in the U.S. and by USAID in Thailand highlight the dramatic success of anti-retroviral therapy (AZT) in reducing the risk of peri-natal transmission.

NIH has strengthened its overall program on HIV/ AIDS since 1995 (for a complete description, see NIH section, page 35). Through many of its Insti-tutes and Centers, a robust research and research training program is ongoing. NIH works with a range of national and international partners, including UNAIDS, WHO, other U.S. Government agencies, and industry to advance the research mission on HIV/AIDS. NIH continues to work with international partners to garner support for the G–8 AIDS vac-cine effort.

NIH is supporting additional intervention stud-ies in countries, including Malawi, Zambia, South Africa, Zimbabwe, Uganda, Ethiopia and Thailand. These studies address questions about the use of STD treatment and microbicides in reducing sexual transmission and about breastfeeding and the use of antiretroviral drugs to reduce mother-to-child transmission in international settings.

CDC emphasizes the eradication of perinatal HIV transmission in the U.S. through research, training, and pilot projects. CDC is actively involved in on-going research on using AZT in pregnant women to prevent perinatal HIV transmission. In 1995 NIH pledged to place a high priority on following up ini-tial studies on methods to prevent HIV transmis-sion from mother to fetus, including AZT and mi-cronutrient treatment (vitamin A) during pregnancy, and on further defining the context of their use.

The Department of Defense continued in its co-operation with other countries in the quest for the identification of an HIV/ AIDS vaccine and the iden-tification of “best practice” for the treatment of HIV/ AIDS. Further, the Department of Commerce, U.S. Patent and Trademark Office, developed a homepage that provides a searchable database with the full-text and images of patents related to AIDS research.

Safeguard Blood Supply

The Food and Drug Administration (FDA) has worked with manufacturers to facilitate the devel-opment of new testing methodologies and other approaches to assure the safety of the blood sup-ply. FDA is also collaborating with international organizations such as the World Health Organiza-tion (WHO) to harmonize biological standards on blood safety and is actively involved in training oth-ers in their specialty. Additionally, USAID and NIH, primarily through the National Heart, Lung and Blood Institute (NHLBI), have directly supported improve-ments in health care infrastructure and research on relevant diagnostics by providing advocacy and leadership in the area of blood safety, including the development of assays for detection of HIV, and in development of universal precautions.

Provide Access to Health Services and Technologies

Toward the goal of providing greater access to health services and technologies, USAID is support-ing 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. In addi-tion, USAID supports several grants for specific

areas of research, including female-controlled topi-cal spermicides and microbicides, the economic impact of HIV/AIDS, inexpensive STD diagnostics, and novel testing and counseling strategies.

FDA has worked with manufacturers to facilitate the rapid development of new agents to prevent and treat HIV-related conditions and medical de-vices to prevent transmission, through streamlin-ing the FDA review and drug approval process for HIV/AIDS therapies. FDA has approved 12 drugs as antiretroviral agents used to treat the virus and 25 drugs for the treatment of opportunistic infec-tions related to HIV.

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

In 1996, USAID redesigned its HIV/AIDS strate-gic 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 HIV/AIDS (PLWHA), and USAID Mission and Re-gional Bureau staff participated in a series of activi-ties 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 sus-tainable responses to reduce HIV transmission and to mitigate the impact of the HIV/AIDS epidemic.” This new strategy is based on the need for contin-ued and expanded efforts to prevent HIV transmis-sion 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 revised strategy is a directive to “develop and promote approaches that address key contextual constraints and opportunities for pre-vention and care interventions.” HIV/AIDS preven-tion and management efforts are often hampered by the policies, norms, and financial constraints under which they operate. USAID will work with the Department of State and other agencies to ad-dress these environmental constraints and effec-tively communicate the economic, social, and health costs of HIV/AIDS to key policymakers; pro-moting the elimination of barriers that inhibit the

flow of HIV/AIDS prevention and management in-formation and services to youth, women, people living with HIV/AIDS and other vulnerable groups; developing and promoting effective strategies for providing basic care and support services for PLWHA; and supporting initiatives to dedicate in-creased resources for HIV/AIDS prevention and management.

Reduce Personal and Social Impact

The 1995 Strategy called for a greater consider-ation of the problems HIV/AIDS poses that go be-yond the medical and health implications. The strat-egy stipulated that in order to mitigate the impact of HIV/AIDS on the individual and society, the fol-lowing broader issues must be taken into account:

- Providing care and support;
- Guaranteeing human rights;
- Protecting politico-military structures at risk; and
- Placing HIV/AIDS on the sustainable develop-ment agenda.

Provide Care and Support

In an effort to provide greater care and support, USAID was active in advocating a strategy of “pre-vention to care,” which included improving access to counseling and testing, reducing stigma, improv-ing psychosocial and basic medical support for HIV-positive persons, and implementing selected inter-ventions for survivors. USAID and NIH have studies underway to find ways to limit progression of HIV disease in infected children and to increase child-hood survival in developing countries, particularly Africa and Asia.

Providing care and support to those living with HIV/AIDS reaches beyond the health sector. As such, increased attention has been given to the social and economic impacts of HIV/AIDS. The USAID Regional Missions support a range of stud-ies on the social, economic, and community im-pacts of HIV/AIDS in Africa, Asia, and Latin America, ranging from studies on the social and economic impacts of HIV/AIDS in Southern Africa to studies of collaboration between traditional and biomedi-

cal healers in managing HIV/AIDS in Zambia and Senegal. At the request of the Office of the Vice President, the National Intelligence Council (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 Department of State and other U.S. Government representatives implemented diplomatic initiatives to promote and safeguard protection under the law for persons liv-ing with HIV/AIDS with regard to access to healthcare, employment, education, travel, hous-ing, and social welfare in all appropriate fora. The U.S. Government 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 Ac-quired 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-gov-ernmental organizations in order to provide a progress report to the Commission on follow-up. The next session of the Commission at which the HIV/AIDS resolution will be considered will take place in March 1999. In addition, the Department of State continues to include HIV/AIDS-related dis-crimination and human rights abuses in regular embassy reporting.

Protect Politico-Military Structures

The Department of Defense furthered its efforts to protect politico-military structures at risk by con-tinuing to conduct military-to-military educational programs on HIV/AIDS, which are expected to con-tribute to changes in high-risk behavior and an over-all decrease in rates of infection in foreign militar-ies. Additionally, the National Intelligence Council prepared a national estimate on the impact of HIV/ AIDS on military establishments. USAID also funded, through AIDSCAP, a global initiative called the Civil-Military Alliance on HIV/AIDS to provide network collaboration and information sharing op-portunities among civilian and military populations in Africa, Asia, Latin America, the Caribbean, and Eastern and central Europe.

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—con-tinues to be a part of the USAID programs for de-velopment assistance. The Department of State also placed HIV/AIDS on the G–7 agenda of Finance and Foreign Ministers in 1996 in Lyon and supported the G–8 agreement to work more closely on an AIDS vaccine or vaccines, made at subsequent summits. These efforts culminated in increased collaboration and President Clinton’s call for an HIV/AIDS vac-cine by 2007.

Mobilize and Unify National and International Efforts

The 1995 International Strategy called for in-creased collaboration and unification of U.S. Gov-ernment 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 actively forged international partnerships to promote HIV/ AIDS prevention. 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, the Office of National AIDS Policy (ONAP) and others continue to work with UNAIDS and other international organizations with the goal of unify-ing international efforts to mitigate and prevent HIV/ AIDS.

Through public diplomacy, the U.S. Information Agency (USIA) continues to share with foreign pub-lics key policies and a variety of American federal and local government and non-governmental orga-nizational activities that contribute to HIV aware-ness, prevention, and treatment programs in the United States and abroad. An example of USIA ef-forts is the campaign mounted to bring attention to the December 1, 1997 World AIDS Day issue of AIDS orphans.

Since 1995, the Office of National AIDS Policy has taken further steps toward unifying national ef-forts. Representatives from Department of State, USAID, ONAP Director’s Office, the Department of Health and Human Services (DHHS), and others worked together collaboratively and met several times to develop a National AIDS Strategy. In addi-tion, the Office of National AIDS Policy coordinates the Interdepartmental Task Force on HIV/AIDS, aimed at developing a coordinated response to the steps laid out in the National AIDS Strategy. ONAP also coordinates the federal response to World AIDS Day, and as a member of the President’s Domestic Policy Council, provides ongoing input into the de-velopment of the annual federal budget request.

Areas for Continued or Future Action

- Strengthening political commitment by govern-ments to more actively address HIV/AIDS and its impacts;
    - 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 coordina-tion through sharing both technical and finan-cial resources.

Issue Overview

A U.S. Government Interagency Working Group on International HIV/AIDS agreed to the following issues as those most relevant for action through agency programs. They are HIV transmission pre-vention, vaccine research, and mitigation of the impact of HIV/AIDS. Within these larger issues are several other issues of importance, including treat-ment equity, behavioral research/behavioral change intervention, AIDS-orphaned children, women and health, microbicide development, and donor coor-dination. This section provides an overview of these issues.

Effective Interventions

Antiretroviral Drugs

New breakthroughs in the development of multidrug therapies and antiretrovirals used to re-duce 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. Potent new combinations of antiretroviral drugs have reduced viral load in patients and have proven to be one of the major scientific advances in 1996. However, the relative short-term success of potent three-drug combinations, due to the de-velopment 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 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 avail-able to all who need them. Nor have they been proven successful for everyone and often cause severe negative side effects. The costs of antiretroviral therapy range from U.S. $10,000 to U.S. $15,000 per person per year and require an established public health infrastructure that can as-sure compliance with a continuous, comprehensive, and vigorous treatment regimen, making the treat-ments impractical and unwise for much of the de-veloping world.

In addition to cost, drug-resistant strains of HIV emerge if an individual’s viral replication is not com-pletely suppressed by antiretroviral treatment or

compliance with the treatment regime. As a result, viral load increases and disease progression may occur. The misconception that antiretroviral therapy is a cure may work against prevention of transmis-sion if individuals believe they are no longer conta-gious and continue high-risk behavior. And although antiretrovirals can prevent mother-to-child transmis-sion of the disease, they provide no protection to the mother. The potential emergence of drug-re-sistant 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 re-search and transmission prevention be redoubled immediately.

HIV Transmission Prevention

HIV transmission can be reduced and the socio-economic impacts of HIV/AIDS alleviated with ef-fective development and implementation of im-proved policies, strategies, and coordinated HIV prevention programs, underpinned by strong com-mitment and involvement from national, state, pro-vincial, 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 affected. HIV/AIDS is a multisectoral problem that can be solved only 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 inter-national organizations, governments, industry, and non-governmental organizations.

There exists no single, standardized set of inter-ventions in HIV/AIDS prevention programming. Spe-cific regional strategies must include an appropri-ate mix of programs proven to be effective for the vulnerable populations being addressed. Taken into account must be the available resources and local risk behaviors and approaches that would be tai-lored to cultural attitudes and belief systems.

Preventing sexual transmission requires compre-hensive and persuasive education to convince people to change deeply ingrained sexual behav-

iors and gender and power relations, a difficult and complex task that can challenge 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 engen-dered significantly safer behavior. This is not just the case in industrialized countries in Europe and the Americas. It is true around the world. For ex-ample, surveillance testing in urban areas of Uganda over the past 5 years reveals a 40 percent drop in HIV prevalence among pregnant women. This de-cline 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 of young men showed both substantial reductions in risk behav-ior and decreases in HIV infection levels. Between 1991 and 1995, visits to sex workers reported by these men were cut by almost one-half; and those who reported not using a condom on the last visit dropped from nearly 40 percent in 1991 to slightly over 5 percent in 1995. As a result, HIV preva-lence among this group has decreased from 8 per-cent in 1992 to less than 3 percent 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 percent over a period of 6 years.

Other methods of preventing HIV transmission also may have an important impact on slowing the pandemic. For example, NIH-sponsored research-ers 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 wide-spread use in Africa of the female condom. These interventions may help women to protect them-selves in situations where they are unable to avoid sex with partners who are HIV-infected or are un-able to persuade their partners to use a condom.

However, to prevent HIV transmission it is no longer sufficient to focus solely on sexual trans-mission as the only route of HIV infection. While heterosexual and male-to-male sexual contact are 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 (figure 3).

Injection drug use, for example, is another preva-lent mode of HIV transmission. In many countries,

drug injection accounts for more HIV infections than sexual transmission. According to UNAIDS, three-quarters of cases recorded in Malaysia, Vietnam, southwest China, northeast India, and Myanmar are among injecting drug users. In Western Europe, if one counts infections passed on to the sex part-ners and infants of drug users, drug injection ac-counts for 44 percent of AIDS cases. In the south-ern cone countries of Latin America it accounts for nearly a third. In Eastern Europe the picture is even more alarming. Some 87 percent of HIV infections in Belarus, for example, are among drug injectors. In the Russian Federation, most infections were spread sexually until 1995, and injection drug use was virtually unheard of. However, in 1996 and 1997 confirmed infections in drug users accounted for four out of every five newly-diagnosed infections.

Researchers have shown that several approaches to HIV prevention can reduce the number of new infections when properly executed, including: edu-cation and behavior modification; the social mar-keting and provision of condoms; treatment of other sexually transmitted diseases; drug abuse treatment (for example, methadone maintenance for injec-tion 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 ef-fective in reducing blood-borne HIV transmission in health programs. Developing and applying inter-vention 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 esti-mated to be the source of 5–10 percent of the total of new HIV infections in many developing coun-tries, with almost 600,000 children infected in 1998. Compounding the situation is the fact that over 1.5 million HIV-infected women become preg-nant each year. The majority of these pregnancies are in Africa and Asia.

A recent USAID-funded clinical trial conducted by the Centers for Disease Control and Prevention with the Thailand Ministry of Health found that HIV transmission from mother to child could be reduced by 50 percent by giving the drug AZT to mothers during the last 4 weeks of pregnancy and during labor and delivery. Trials show that antiretroviral pills given to pregnant women during the last week prior to and during labor, combined with safe alter-

natives to replace breastfeeding, cut overall verti-cal transmission of HIV to 9 percent. This com-pares with the norm in

developing countries of up to 35 percent.

While preventing 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 (TB) infection to infectious TB diseases in individuals infected with both diseases. People whose immune defenses are weakened by HIV infection are more vulnerable to microbes, including the bacillus that causes TB. The resulting infections are responsible for the re-curring illnesses which in their late stages are called AIDS, and which ultimately lead to death. Accord-ing to UNAIDS, about 30 percent of all AIDS deaths result directly from TB. The World Bank estimates that between directly causing AIDS deaths and in-directly facilitating the spread of TB, HIV will be responsible for up to half of all adult deaths from infectious disease in the year 2020 (see figure 4).

Programs to address other STIs, which exacer-bate or are exacerbated by HIV/AIDS, must be implemented along with more comprehensive, ac-curate, and inexpensive diagnostic testing and coun-seling. In Tanzania, the “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 are 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 com-binations of programs designed to mitigate the devastation wreaked by HIV/AIDS, as well as pre-vention of transmission, are needed for an effec-tive 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 in-vestigation. Protease inhibitors, a new class of drugs used in combination with other antiretroviral thera-pies, have been shown to remarkably diminish the amount of HIV in an infected individual. Receptors for molecules called chemokines have been iden-tified as critical co-factors for HIV infection, provid-

Figure 4. Causes of Death, by Percent, From Infectious Diseases Among People Ages 15 to 59, in the Developing World, 1990 and 2020.

ing us with an entirely new set of targets for anti-HIV therapies and new approaches for vaccine de-velopment. 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 ben-efits of the drugs will last. There are many for whom the new drug regimens 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. A safe and effective vaccine for HIV in-fection is a priority of AIDS research and an impor-tant step toward bringing the HIV epidemic under control. The goal is a preventive vaccine to slow and eventually end the HIV pandemic and to pro-tect the individual from HIV infection and/or dis-ease.

Without a vaccine, AIDS will soon overtake TB as the leading infectious cause of death in the world.

Vaccines may be the most cost-effective way to pre-vent HIV infection worldwide. Therefore, an afford-able, 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 the impact of HIV/AIDS will need to focus primarily on three main areas, while main-taining adequate surveillance and flexibility to ad-dress 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/AIDS. For example, the usefulness of a tuberculosis prophylaxis has been confirmed that will now allow more effective ac-tion against this coepidemic. Widespread access to highly effective antiretroviral therapy has signifi-cantly 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 deaths 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 the latest therapies—and often not even to simple treatments to fight their infections and to diminish their pain.

Despite advances in biomedical research, the absence of affordable therapies in developing coun-tries, where 90 percent of the epidemic is concen-trated, 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 im-prove understanding of the nature, magnitude, pre-vention, and mitigation of HIV/AIDS-related adverse socioeconomic impacts in the different levels and sectors of society. Surveillance of the disease it-self, as well as tabulation of infection rates, is ab-solutely necessary to ensure that programs are implemented and that funds are used adequately. Including HIV/AIDS sentinel surveillance in regional and national surveillance for emerging and reemerg-ing infectious diseases will serve both to better fol-low the epidemic and strengthen surveillance sys-tems worldwide. Linking surveillance systems will not only serve to better understand the path of the disease but will also ensure that all information is available and encourage sharing of effective strate-gies worldwide.

Care and Support for HIV-Infected Individuals

With 33.4 million people infected with HIV world-wide and with infection rates on the rise, the need to create comprehensive care systems is great. The numbers of HIV-infected individuals and people liv-ing 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 also will need strategies to reduce the adverse so-cioeconomic consequences of AIDS. Healthcare for HIV/AIDS-infected individuals must be designed and administered in an equitable manner. It must also be in agreement with human rights, as stipu-lated 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 al-leviated.

AIDS-Orphaned Children

During the Twelfth 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 mil-lion will have lost one or both of their parents in 23 countries heavily affected by HIV/ AIDS. Largely as a result of the 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 coun-tries.

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. UNAIDS estimates that, in rural areas of east Af-rica, 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 chal-lenges for a child. These children may suffer from depression, malnutrition, lack of immunizations or healthcare, increased demands for labor, loss of schooling, forfeiture of inheritance, forced migra-tion, homelessness, vagrancy, starvation, crime, and increased exposure to HIV infection.

The growing number of children who lose par-ents will, in turn, have a profound impact on their societies. With children who have lost parents even-tually comprising up to one-third of the population under age 15 in some countries, this outgrowth of the HIV/AIDS epidemic will create a lost genera-tion—a sea of youth who are disadvantaged, vul-nerable, undereducated, and lacking both hope and opportunity. The creation of such a large and dis-affected demographic “youth explosion” could pro-pel some of these societies to significant unrest and destabilization over the long term. The threat to the prospects for economic growth and develop-ment 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 be-coming infected at faster rates than men, and the total number of HIV-infected women is fast ap-proaching that of men. Young women are particu-larly 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 vulner-ability 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. Nine in ten HIV-infected women became infected through heterosexual intercourse.

But social and economic forces can play an even greater role in increasing women’s risk of acquir-ing 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 contract-ing 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 percent of young women surveyed in Nigeria reported being forced to have sex. The reasons for forced sexual intercourse range from social pres-sure 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 vul-nerability 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 to inhibit HIV infection. Although none have been shown to be effective now, microbicides are needed due to the high prevalence of nonconsensual sex, lack of condom use, and need for reproductive choices. Products also are needed to allow conception while preventing HIV infections 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, in-ternational 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 re-quire enormous increases in resources. Regard-less of increases, it is unlikely that there will ever be adequate resources available to effectively meet all the needs associated with HIV/AIDS.

There is a critical need for developing effective coordination mechanisms within the donor com-munity, 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 complemen-tary roles in other areas, such as policy dialogue and training. Efforts to enhance UNAIDS' activities and to enhance donor coordination should be sup-ported.

Donor coordination also will become even more important in the future as efforts increase to iden-tify additional resources needed to combat HIV/ AIDS. Increasingly, HIV/AIDS is recognized not only as a health problem but also as a development prob-lem that adversely impacts all sectors of a develop-ing country—education, finance, agriculture, and other labor sectors. Therefore, the search for addi-tional financial resources must extend to funds that may be available within the budgets of these other sectors. It may be possible through effective do-nor coordination/collaboration to mobilize in-creased private-sector resources for HIV/AIDS pre-vention and mitigation efforts. A critical need ex-ists for improved collaboration and coordination between those organizations that are performing biomedical research and those who are implement-ing programs and delivering services. Improved

collaboration will allow better exchange of infor-mation about the current status, effectiveness, cost, and availability of potentially useful technologies. Likewise, organizations that implement service de-livery may be able to contribute critical insights dur-ing research design to assure that key operational questions can be addressed during initial research endeavors.

To effectively prevent transmissions and miti-gate impacts there must be coordination of vari-ous programs designed to address the entire spec-trum 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 involve-ment 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 signifi-cantly slowed efforts to advance and sustain HIV/ AIDS prevention and mitigation programs through-out 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 the need for repeated cre-ation, implementation, and staffing of effective pro-grams requires great investment. Therefore, the

development of programs that are self-sustaining and easily administered at all levels of implemen-tation is absolutely integral to countering the epi-demic.

To design sustainable systems for effective pre-vention and mitigation, a foundation must be laid to locally train technical workers and to locally plan, manage, and implement programs. Developing link-ages between various institutions and international research centers and developing regional networks of health and nonhealth experts involved in fight-ing HIV/ AIDS, who can assist in the review and im-provement of regional training curricula, will prove highly beneficial in fighting HIV/AIDS. Planning fu-ture programs must involve national and local in-vestment in building professional and institutional capacity to ensure sustainability at all levels of ad-ministration. Working with the international com-munity, the collective

efforts of all concerned are needed to effectively address the myriad issues involved in addressing this pernicious epidemic.

The U.S. Government calls upon all nations, in-ternational organizations, and the public and pri-vate sectors to work together in effective partner-ships to advance vaccine research efforts and to promote more effective use of limited technical and financial resources in the fight against HIV/AIDS.

Agency Strategies

Office of National AIDS Policy

Role and Structure

In 1993, President Clinton created the Office of National AIDS Policy (ONAP) to provide a national focus and direction to the U.S. Government's re-sponse to HIV and AIDS. ONAP provides broad guidance for Federal AIDS policy and fosters inter-departmental communication and coordination. ONAP works closely with non-profit and for-profit organizations at the national, state, and commu-nity-based levels, as well as internationally, to en-sure the broadest input into policy development and implementation. The Director of ONAP is a member of the President's Domestic Policy Coun-cil, and provides ongoing input into the develop-ment of the Administration's annual budget request to Congress. She serves as the chair of the Inter-departmental Task Force on HIV/AIDS, an intra-gov-ernmental coordinating body working to develop a unified approach to HIV/AIDS in the Federal gov-ernment.

The ONAP director has taken a leadership role on international AIDS issues, having led delegations to Africa, Russia and India to study first-hand the impact that HIV/AIDS is having on developing coun-tries. In December 1998, the President directed the ONAP director to visit South Africa and report back with recommendations on additional mea-sures the United States could implement to assist South Africa in addressing the impact of HIV/AIDS in that country. The ONAP director also participates as an official representative of the United States to UNAIDS.

In 1997, ONAP developed "The National AIDS Strategy," a comprehensive, long-term plan to ad-dress the HIV/AIDS epidemic. The Plan contains detailed descriptions of the objectives, goals and budgets of all Federal agencies involved in the Fed-eral response to HIV in six major areas of HIV policy: prevention, research, care and services, civil rights, international activities, and translation of research advances into practices. The Plan identifies key areas for further effort. This Report was developed in consultation with many individuals and groups, public and private, both inside and outside the Fed-eral government.

ONAP also serves as a liaison to the Presidential Advisory Council on HIV/AIDS (PACHA), which was established by Executive Order to provide advice, information and recommendations to the President, his 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 his Ad-ministration can and should do to stop the spread of the epidemic; 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 dis-crimination and intolerance. The Advisory Council has adopted HIV/AIDS in racial and ethnic commu-nities as its primary focus for the remainder of its term. The Advisory Council also focuses on appro-priations, international issues, prison issues and discrimination.

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 in-terests 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 Depart-ment 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 or-ganizations.

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 informa-tion 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 Fed-eral agencies.

In the area of international health, the role of the Department of State is to develop and coordi-nate support from other nations and international bodies to raise the level of priority accorded HIV/ AIDS and infectious diseases. Through the coordi-nating efforts of the Bureau of Oceans and Interna-tional Environmental and Scientific Affairs/Emerg-ing Infectious Diseases and HIV/AIDS Program (OES/ E/EID), the Department works with USAID and other Federal agencies to develop the bilateral and mul-tilateral 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 Migra-tion (PRM) coordinates efforts among the Depart-ment of State, other U.S. Government agencies, pri-

vate voluntary organizations, and international agen-cies to implement a more comprehensive interna-tional 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 assis-tance to refugees in first-asylum countries.

The Bureau of Democracy, Human Rights, and Labor (DRL) oversees initiatives and policies to pro-mote and strengthen civil society and respect for human and worker rights. DRL ensures that hu-man rights in foreign countries are taken into ac-count in the U.S. policymaking process and sub-mits an annual report to Congress extensively re-viewing 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 Plat-form for Action adopted at the UN Fourth Confer-ence on Women. The Platform recommends ac-tions 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 reproduc-tive behavior; and undertake gender-sensitive ini-tiatives that address sexually transmitted diseases, HIV/AIDS, and sexual and reproductive health is-sues.

Agency Strategy for Specific Issues

Promoting Active Involvement by National Governments

The Department of State hopes to bring the mes-sage to leaders around the world that HIV/AIDS and infectious diseases are the silent enemies of eco-nomic and social development, political stability, and economic productivity. No member of the glo-bal community can afford, either in terms of hu-man suffering or economic costs, to fail to recog-nize or to forestall the impending devastation that has already begun to ravage national economies, security and social infrastructure. Political commit-ment 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, em-bassies 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 in-fectious diseases of all kinds, and to enhance in-ternational collaboration on international health.

HIV/AIDS will be introduced to a greater extent in the U.S. diplomatic and policy dialogue to un-derscore the recognition of HIV/AIDS as an inter-national problem with political, social, and eco-nomic impacts that go well beyond the boundaries of the traditional health sector. Nations should ad-dress HIV/AIDS as a pandemic fueled by socioeco-nomic inequities, human rights issues, and ques-tions 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 infra-structure 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 gov-

ernmental 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 in-teractions with all government and interna-tional organizations.

The Department of State, through formalized briefings as part of our National Foreign Affairs Train-ing 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 dip-lomatic support for HIV/AIDS programs in develop-ing 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 prior-ity countries.

Promoting Human Rights

The United States regularly supports UN resolu-tions before the Commission on Human Rights for the protection of human rights in the context of HIV/AIDS. The resolutions set out guidelines na-tions 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 Com-mission on follow-up. The next session of the Com-mission 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 an-nual “Country Reports on Human Rights Practices” and represent these interests before the Human Rights Commission.

The United States helped to negotiate a partner-ship 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 activi-ties of other UN departments and agencies and es-pecially 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 imple-menting international HIV/AIDS/sexually transmit-ted infections (STI) prevention and control pro-grams. 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 individu-als, communities, and societies in general. This mandate fits within the broader Agency goal of sta-bilizing 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 ac-tivities, while the central programs provide comple-mentary 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 devel-oping program interventions. In collaboration with USAID field missions and other partners and stake-holders, the HIV/AIDS Division has developed a de-tailed 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 mul-tiple country settings:

- Reducing high-risk sexual behavior through be-havioral change interventions (BCI). These in-clude not only mass and interpersonal com-munication strategies but also policy and leg-islative reforms that enhance communication strategies and campaigns and build awareness and support for health infrastructure change;

- Increasing demand for and access to con-doms, mainly through condom social market-ing (CSM) programs;

- Treating and controlling sexually transmitted infections (STI) and sexually transmitted dis-eases (STD).

The first decade of HIV/AIDS programming has revealed that effective, individually focused ap-proaches 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 inter-ventions that address couples, parents, and chil-dren, social networks, religion, worksites; the in-teraction of sexual and health beliefs; and the norms, values, and policies that determine the so-cial and sexual context in which people live.

In addition to continuing the three major inter-ventions stated above, the expanded strategy now includes selected basic care and psychosocial sup-port for HIV-infected individuals and their survivors. This will enhance the prevention agenda, and slow the deterioration of economic and social develop-ment. The expanded strategy includes increased emphasis on supporting HIV/STI surveillance sys-tems that will assist in our understanding of the growth of the epidemic, as well as allow the as-sessment 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 volun-tary organization (PVO) and non-governmental or-ganization (NGO) capacity-building, and to conduct targeted biomedical research.

The expanded strategy responds to concerns raised by many observers (field mission staff, stake-holders, other donors, PVO/NGO representatives, and program evaluators and auditors) that USAID's HIV/AIDS/STI program interventions should

concen-trate on achieving well-defined program targets and results at country, regional, and G/PHN levels. In-terventions should be closely coordinated with, and provide technical support to, regional bureau and field mission programs. Likewise, to expand glo-bal knowledge of the status of the regional and glo-bal HIV/AIDS epidemics, AIDS Control and Preven-tion Project (AIDSCAP) formed the Monitoring the AIDS Pandemic (MAP) Network of more than 120 HIV/AIDS specialists in 50 countries with its found-ing partners, UNAIDS and the Harvard School of Public Health.

To operationalize the strategic framework pre-sented 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 accom-plished through the following 10 activities:

- **Horizons:** This cooperative agreement with the Population Council (and collaborating part-ners: International Council for Research on Women; Program for Appropriate Technology in Health; International HIV/AIDS Alliance; Uni-versity of Alabama; and the Futures Group) will develop and disseminate the most effec-tive ways of combating HIV/ AIDS, through op-erations research, field testing of program in-terventions, and the review of scientific stud-ies 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 pro-grams.

- **AIDSMark:** This cooperative agreement with Population Services International (and collabo-rating partners: Program for Appropriate Tech-nology in Health; Management Sciences for Health; International Planned Parenthood Fed-eration; International Council for Research on Women; DKT International; and Family Health International) provides support for develop-ing regional and country HIV/AIDS social mar-keting program interventions. AIDSMark will focus on the social marketing of critical pub-lic-health products that are appropriate and timely for the setting (male and female condoms, STI treatment drugs, STD diagnos-tics, 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 col-lect technical lessons learned from all com-ponents of the portfolio and disseminate these to field missions, cooperating agencies, gov-ernments, 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 plan-ning; generates best-practice recommenda-tions; 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, technol-ogy exchange, and institutional partnering.

- **Operations Research for Implementing the Prevention to Care Continuum:** This activ-ity supports focused operations and applied research and provides selected technical as-sistance to missions and selected service de-livery projects in order to address key ques-tions regarding the prevention to care con-tinuum.

- **Biomedical Research:** USAID provides sup-port for biomedical research for developing selected technologies, including an effective topical microbicide to reduce sexual transmis-sion of HIV/STIs; rapid, simple, inexpensive STI diagnostic tests; and realistic interventions to reduce mother-to-child HIV transmission.

- **Policy Reform:** USAID supports policy initia-tives that focus on increasing commitment to prevention/care interventions, assisting with resource allocation decisionmaking, discrimi-nation, and other key policy areas that en-hance and facilitate prevention and mitigation activities.

- **Strengthening Surveillance Systems:** Through agreements with CDC, the U.S. Bu-reau of Census, and UNAIDS, consensus guide-lines will be finalized on minimum surveillance packages for developing countries based on the phase of the epidemic. Technical assis-tance to missions and host governments will be available to establish and maintain cred-

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 geo-graphic bureaus has its own approach.

ible surveillance systems, and operations re-search will develop and refine methodolo-gies to estimate HIV incidence.

In addition to the strategic framework of the Global Bureau, outlined above, USAID's regional

Africa Bureau—USAID's Africa Bureau pro-vides 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 in-clude information, education, and communica-tion strategies for behavioral change; evaluation of integration strategies; analysis of HIV/AIDS in-puts from other development sectors; STD ser-vice delivery system strengthening; and monitor-ing/evaluation. The Africa Bureau also is a strong proponent of sensitizing policymakers to the ad-verse impact of HIV/AIDS on other development sectors, such as education and agriculture.

Latin America/Carribean Bureau (LAC)— The LAC Bureau's HIV/AIDS strategy focuses on countries where the majority of HIV/AIDS infec-tions 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 ef-forts 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 prob-lem in this region. HIV/AIDS specific interven-tions 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 pro-gram efforts will be on policy formulation, pub-lic education regarding HIV/AIDS prevention,

STD/diagnosis and treatment, NGO capacity-build-ing, 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 coun-seling activities exist in countries such as Roma-nia, 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 pro-vides

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 as-sistance provided through the ANE regional bu-reau 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 commu-nications, and policy advocacy. Other regionally supported activities include building and strength-ening local NGO programs and identifying local sources of HIV/AIDS technical assistance.

Funding

Since 1986 USAID has committed nearly $1 bil-lion for HIV/AIDS/STI prevention and mitigation pro-grams in developing countries, where more than 90 percent of the current and new infections oc-cur. The Agency has maintained an HIV/AIDS an-nual 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 pat-tern that reflects the severity of the pandemic. Ap-proximately 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/Carib-bean; and the remaining 26 percent is provided for worldwide programs, including UNAIDS. If, as ex-perts predict, the severity of the pandemic shifts toward Asia, USAID will need to reconsider resource allocations to reflect the new situation. USAID pro-vides approximately 25 percent of the UNAIDS' bud-get ($15 million of a total $60 million annual bud-get).

In spite of the fact that USAID is a major interna-tional funder for HIV/AIDS/STI prevention programs in the developing world, the financial resources available to combat the pandemic clearly are inad-equate to mount an effective, truly global response in view of the steadily increasing HIV/AIDS/STI in-fection rates. Approximately $550 million is cur-rently expended per year for HIV prevention and care in the developing world. This includes fund-ing 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 ac-tivities domestically is approximately $700 million. In order to deal with the implications of this fund-ing inadequacy, USAID has strategically focused its efforts on key countries and targets its programs to those most likely to transmit or acquire HIV infec-tion. (The emphasis countries for USAID preven-tion and mitigation programs are listed on page 31.)

Agency Strategy for Specific Issues

Prevention

While HIV infection is deadly, it is also prevent-able. In the developing world, where costly, com-plex 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 facili-tating 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 protec-tion 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 part-ner change (reduced number of partners), and cor-rect, consistent condom use. Unfortunately, only approximately 10 percent of persons in the devel-oping world currently have access to accurate and confidential HIV testing. However, no two coun-tries and target audiences are alike, and USAID has learned that there is no single blueprint for preven-tion programs to achieve these outcomes. Rather, the agency has established a process for develop-ing 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

tar-get audiences and their cultural, economic, and political environments.

The three pillars of USAID's HIV/AIDS preven-tion 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 sec-

ond is condom social marketing, which uses pri-vate-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 coun-seling, 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 sup-ported by policy dialogue, behavioral research, and monitoring and evaluation. Improving policy dia-logue, 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 re-search is essential for identifying and understand-ing risky behaviors and the populations who prac-tice them, the characteristics and preferences of key audiences, the language and content of mes-sages that will appeal and "speak" to particular au-diences, and other site-specific details. Transfer-ring 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 pro-grams 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 truck-ers), 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 pro-cedures for defining specific audiences and tailor-ing interventions to fit the need, which have been shared among AIDS and reproductive health re-searchers 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 popula-tion, behavior change interventions strive for both consistency and dynamism. The most effective programs deliver not one but an array of consis-tent messages through multiple, mutually reinforc-ing 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 part-ners across the globe have found that people living with HIV or AIDS are the most convincing educa-tors 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 par-ticipation 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 car-rying forward the successes of the three "pillars" (BCI, CSM, and STI interventions), plus policy dia-logue, 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 pre-paring communities and service providers to re-spond to a range of individual, family, and commu-nity needs along the prevention-care continuum.

Care and Support

USAID supports care activities because they im-prove our efforts to achieve sustainable develop-ment, 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 oppor-tunistic 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 or-phaned by AIDS.

HIV/AIDS care and support activities enhance sustainable development by shoring up fragile in-frastructures. For example, community-based care and retraining of key personnel are essential to pre-serve 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 driv-ing a secondary explosion of TB, which is respon-sible 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 behav-ior-change messages. In addition, programs to pro-tect the basic human rights of HIV-infected indi-viduals and those most at risk for infection open the door for implementing far more effective be-havior 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 promot-ing reduced risk behavior. If programs appear to

abandon people living with HIV/AIDS and their fami-lies, or to ignore their needs and concerns, we can-not expect them to be of any help.

USAID is also supporting operational research to determine the most cost-effective ways to pro-vide care and support to persons infected. USAID does not at this time support the large-scale pro-curement of antiretroviral drugs for developing countries. Using antiviral drugs in treatment regi-mens 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 labora-tory infrastructures that do not exist in most of the developing world, where the average health expen-diture per person per year is about $10.

AIDS-Orphaned Children

The number of children affected by AIDS, includ-ing those who are orphans or caring for sick par-ents, continues to escalate. There has been grow-ing 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

stra-tegic objective to include issues related to care and support of those affected by the disease.

More recently, USAID completed a series of dis-cussion papers focusing on issues related to care and support of persons affected by HIV/AIDS. In-cluded 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 back-ground information that will be used to develop the HIV/AIDS strategy on care and support. The strategy will influence future related projects con-ducted by USAID cooperating agencies and mis-sions.

In addition, “HORIZONS,” the HIV/AIDS opera-tions research project, is currently exploring av-

enues for conducting research to develop “best practices” for setting up community-based meth-ods of providing care and support to people affected by HIV/AIDS, including children. AIDSCAP sup-ported 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 chil-dren and families affected by HIV/AIDS. They have also established an electronic network to exchange technical information among a wide variety of do-nors and other organizations. These activities con-tribute toward identifying the scope of the prob-lem, 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 seg-ment of the HIV-infected population.

The impact of HIV/AIDS on women is not solely a function of their greater biological and social vul-nerability to infection. It is also because, when fam-ily members become ill with HIV disease, the bur-den 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 par-ticipation, 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 po-tential 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 indepen-dently fund vaccine research, it has a strong inter-est in the vaccine development process, and it is uniquely positioned to facilitate the implementa-tion of vaccine trials in developing countries. Be-cause of the tremendous genetic diversity of HIV, one of the greatest challenges facing vaccine de-velopers 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 can-didates should have broad activity against the most common genetic subtypes of virus for two reasons. First is the issue of impact on the epidemic. Ap-proximately 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 epi-demic, candidate vaccines should be targeted to those strains responsible for the most new infec-tions.

The second reason to advocate for vaccines with the broadest possible coverage is to prevent selec-tive pressure for new epidemics. A vaccine that provides protection for only the viral subtypes cur-rently prevalent in a community will reduce trans-mission 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 pro-cesses in the following ways:

- Take the lead in educating stakeholders in de-veloping countries. This task entails explain-ing the importance of clinical trials; making accurate information widely available; re-sponding to questions; ensuring ethical de-

signs; countering misinformation; and lining up high-level support from both host country and U.S. officials.

- Assist in developing the methodology of com-munity-level interventions; fostering long-term, sustained relations with local communities; measuring indirect effects; and doing impact modeling. By working closely with local com-munities, USAID could ensure that they are ready to participate in clinical trials.
- Advocate for research on broad-activity vac-cines.

Behavioral Research/Behavioral Change Interventions

HIV/AIDS prevention and care hinges upon changes in patterns of risky behavior—be they re-lating to sex, illicit drugs, or exposure to infected blood through medical waste or unsterile needles, razor blades, and other instruments. Even improve-ments in STI services will not fulfill their potential impact unless people with STI symptoms and signs change their help seeking behavior, and unless al-lopathic 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 inter-vention models and to adapt and apply existing models for new settings.

USAID's cooperating agencies conduct behav-ioral research in:

- Diagnostic studies to define the specific be-haviors that put people at risk in a given set-ting;
- Defining of the distribution of risky behaviors in a population, so as to identify subgroups or target audiences for intervention develop-ment;
- 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 effective-ness of interventions, where changes in be-havior are key outcomes of intervention trials.

Under the AIDS Technical Support Project, com-pleted in 1997, USAID's investment in behavioral research comprised a major increase in the re-sources available for studying the interactions of culture, health, gender, and sexuality in the devel-oping world. The AIDS Behavioral Research Grants Program, funded jointly with NIH, supported part-nerships 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 representa-tive, 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 appropri-ate for particular audiences and settings.

USAID-funded projects have established forma-tive behavioral research as a prerequisite of tech-nically sound intervention development. Most of our future interventions will contain data collection components that enrich the knowledge base for un-derstanding 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 sup-port services; 3) stigma and discrimination; 4) risk assessment and behavior change; 5) policy analy-sis and change; 6) social marketing and private-sector involvement; 7) NGOs and

community mo-bilization; 8) integration of HIV/STI, family planning, and maternal and child health services; and 9) com-munity mobilization.

In addition to pursuing some relatively new top-ics 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 vulner-ability of youth; involvement of PLWHA in HIV/STI intervention programs; building local NGO and com-munity-based organization (CBO) capacity; links be-tween 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 co-operation or consent of a sexual partner, to protect from the possibility of acquiring HIV and other sexu-ally transmitted diseases (STD). The agency has supported laboratory work to identify and test prom-ising 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 ex-pected 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 re-sponses to reduce HIV transmission and to miti-gate the impact of the HIV/AIDS pandemic," in-cludes donor coordination and partnership at glo-bal, regional, and country levels. USAID has been an active partner with the United Nations in provid-ing financial support for international HIV/AIDS pro-gram efforts. Since 1986, USAID has been a major contributor to the WHO Global Program on AIDS. As that program terminated in 1995, USAID sup-port shifted to a new United Nations HIV/AIDS en-deavor that officially began in January 1996.

Also, in countries where USAID missions include HIV/AIDS as part of their country strategy, PHN of-fices coordinate closely with the Joint United Na-tions Programme and other donors that may be in-country. In addition, there are a series of specific donor coordination activities, including the U.S.-Ja-

pan Common Agenda, collaboration with the United Kingdom's Department for International Develop-ment (DFID), the European Union (EU), and a num-ber of other selected partners. There are also ex-cellent 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 main-tain systems and practices to appropriately man-age the effects of HIV and AIDS. As HIV/AIDS be-comes 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 con-tributions. 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 com-mitment in local government, and by increasing the technical and managerial capacity of local public, commercial, and nonprofit entities to provide ser-vices 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 in-fected;
- Technical quality and use of surveillance in-formation in monitoring the epidemic and in program management and evaluation;
- Quality and reach of public-sector services needed in HIV programming, such as STI di-agnosis 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 im-prove regional and local networks and coalitions. The networks provide technical support and im-prove advocacy efforts by building relationships across public- and private-sector institutions.

USAID works to strengthen commercial-sector involvement by increasing the awareness of the po-tential impact of HIV and by building HIV-preven-tion programs for the business environment. In ad-dition, some USAID programs work to leverage lo-cal commercial markets for condoms and other commodities, such as essential drugs for STI treat-ment. Sustained local responses to HIV will de-pend upon public- and private-sector involvements that supplement and complement each other. As we enter the second decade of the HIV/AIDS pan-demic, it is clear that the populations requiring HIV prevention and care and support services are chang-ing 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 sec-ond 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 la-bor and delivery, or during breastfeeding.

Following the ground breaking ACTG 076 study, in February 1998, researchers from the U.S. Cen-ters 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 per-cent reduction of transmission of HIV to their in-fants. Because this compared favorably to a much more costly and complex regimen used in devel-oped 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 an-swered 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 as-sociated with bottle feeding. Will HIV-nega-tive 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 avail-able at a scale large enough to have a broad impact without sacrificing the quality and con-fidentiality of the services?

- **Infrastructure and capacity:** Many antena-tal care settings in developing countries are struggling to provide basic

care for pregnant women. If MTCT programs are added to exist-ing activities, can they be carried out prop-erly? Will they achieve in practice what was seen in a clinical trial? Conversely, will the additional burden of MTCT programs compro-mise the quality of basic antenatal care?

- **Stigma and discrimination:** Stepped up VCT, special antenatal programs, and the use of in-fant 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, stigmati-zation 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 research-ers to conduct a series of operational research stud-ies 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 coun-tries (e.g., Senegal, Philippines, Indonesia), early, comprehensive HIV intervention programs, sup-ported by USAID and other donors, have helped curtail and prevent a major epidemic. For example, USAID-supported prevention campaigns that in-cluded policy dialogue, behavior change efforts, bet-ter 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, Thai-land) 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 in-

tervention 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 hu-man behaviors, sex. While it is impossible to at-tribute 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 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		

USAID's evaluation research in poor urban neigh-borhoods in the Dominican Republic where our program operates, found that rates of sexually ac-tive youth declined from 73 percent in 1993 to 30 percent in 1996, and rates of participation in "trans-actional sex" (exchanging food, money, school fees, etc., for sex)—declined from 27 percent to 7 per-cent among males. The proportion of Ugandan girls

who have ever had sex declined by almost half be-tween 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 con-dom use, from 22 percent to 72 percent.

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 secu-rity of the United States through understanding, in-forming, 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 coun-terparts 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 me-dia, 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/semi-nars abroad for U.S. experts on AIDS issues.

- Broadcasting policy information on Voice of America (VOA) radio and USIA television ser-vices and providing foreign publics with lan-guage-version news clips, editorials, and in-teractive dialogues featuring prominent U.S. experts and "best practices" of American in-dividuals and communities meeting the chal-lenge posed by AIDS and other infectious dis-eases. For example, VOA gave worldwide cov-erage 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 in-cludes 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 commu-nity. This information is supplemented with timely reports highlighting American and for-eign achievements and cooperative efforts in combating AIDS.

- Publishing a USIA electronic journal on “In-fectious Diseases/The Global Fight.” The 40-page journal features commentaries by Dr. An-thony Fauci, U.S. Surgeon General Dr. David Satcher, and USAID Director J. Brian Atwood, among other articles.

- Organizing briefings by senior U.S. AIDS ex-perts 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 pro-grams by USIA is difficult to assess. Much of the programming conducted by the Agency is elec-tronic, e.g., VOA broadcasts, WORLDNET TV pro-gramming, and the electronic journal (published in November 1996). There is no specific budget for these programs, other than staff salaries and over-head expenses. However, in addition to these pro-grams, USIA exchanges under the Fulbright, Inter-national Visitor, and U.S. Speaker programs bud-geted $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 multi-lingual 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 activi-ties: (1) education efforts targeting Peace Corps em-ployees; (2) education efforts targeting Peace Corps Volunteers (hereinafter “Volunteers”); and, (3) pre-vention efforts conducted by Peace Corps Volun-teers targeting the people in the countries in which the Volunteers are serving. The focus of this docu-ment is on the third sphere—the work that the Vol-unteers do in the communities in which they serve. To date, the Peace Corps’ HIV/AIDS prevention and education activities are being conducted in 48 coun-tries around the world.

Peace Corps does not earmark any of its appro-priated 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 fund-ing 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, Vol-unteers have been working to help individuals and communities understand the disease and to col-lectively develop solutions for ways communities can protect themselves and care for those who be-come ill. In December 1988, the Peace Corps and the Government of the Central African Republic ne-gotiated the first formal agreement to place Volun-teers in HIV/AIDS education. Since then, the pace of Volunteers' involvement has increased dramati-cally, 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 preven-tion component; projects that are not primarily in-volved 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 Vol-unteers 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, monitor-ing/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, Pre-vent AIDS" project in Cameroon. Education Volun-teers, Cameroonian educators, and public health specialists worked together to draft 50 hours of les-son plans. To date the program has provided be-havior 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, pub-lished with private-sector support, and the curricu-lum development process itself are being consid-ered by UNAIDS as an international model for stu-dent 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 impor-tantly, Volunteers are successful in accessing com-munities that are often not reached by National AIDS Programs and in introducing new innovative edu-cation methods to achieve their outreach.

Although not quantified, there are a growing number of Volunteers who, based on their experi-ences overseas, return to the United States and continue to work in HIV/AIDS prevention in their communities. Bringing the lessons home is a valu-able 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 asso-ciated opportunistic infections and malignancies. Each of the 24 NIH Institutes and Centers is involved in some HIV/AIDS-related research activity consis-tent 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 char-acterization 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 op-portunistic infections that cause morbidity and mor-tality of HIV-infected individuals.

The NIH AIDS program supports biomedical and behavioral research necessary to identify therapeu-tic 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 epi-demic underscores the critical need to identify in-terventions 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 ele-ment 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. Ongo-ing 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 infec-tion 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 work-shops and conferences.

In addition, since its inception in 1996, NIH has collaborated with UNAIDS through mutual represen-tation on advisory and coordinating bodies, frequent exchange of information, and collaboration on spe-cific efforts, such as vaccine development, ethical issues related to clinical trials, and research train-ing and infrastructure in developing countries. In this regard, the National Institute of Allergy and In-fectious Diseases (NIAID) and the Fogarty Interna-tional 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 re-sponsible for the scientific, budgetary, legislative, and policy elements of the NIH AIDS research pro-gram. Congress provided in the NIH Revitalization Act of 1993 broad authorities to the OAR to plan, coordinate, evaluate, and fund all NIH AIDS re-search. The OAR is responsible for developing an annual comprehensive plan and budget for all NIH AIDS research. The OAR supports trans-NIH Coor-dinating Committees to assist in these efforts in the following areas of program emphasis: Thera-peutics, Vaccines, Natural History and Epidemiol-ogy, Behavioral and Social Sciences, Etiology and Pathogenesis, Training and Infrastructure, and In-formation Dissemination.

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

A report by a group of non-government scien-tists and AIDS community representatives who were convened to evaluate the NIH AIDS research pro-gram, has had a significant effect on almost every

aspect ofthe AII~S research program-in setting the scientifıc agenda, refocusing priorities, and shap-ing the AIDS research budget. T'he recommenda-tions in the "Report of the NIH AIDS Research Pro-gram Evaluation WorkingGroup ofthe Offıce ofAII~S Research Advisory Council" (also known as the "Levine Report") helped frame the OAR's fınal dis-tribution of the NIH AIDS appropriations for fıscal years (F~ 1997 and 1998. In addition, the Levine Report signifıcantly influenced the priority setting that occurred in the development of the FY-1999 NIH Plan for HN-Related Research and Budget, which the OAR is congressionally mandated to de-velop in concert with the annualNIHAIDS research budget request. The priorities established by the Levine Report will have an impact not only on gov-ernment-supported research but on the research agendas of industry and private research organiza-tions in the United States and abroad.

The report articulated the importance ofcoordi-nating international HN/AIDS research efforts with other agencies, international organizations, and other governments. Further, it listed as one of sev-eralhigh priorities "domestic and international stud-ies testing the effıcacy of joint behavioral and bio-medicalstrategies forcombined controlofHNand

other sexuallytransmitted diseases and combined control of HN and other adverse health conse-quences of injection drug use."

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

- A continued increased emphasis on funda-mental science, particularly investigator-ini-tiated research;

- Acomprehensive effort, including severalim-portant 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 interna-tional collaboration at the earliest stages of vaccine development and testing;

- An augmentation of research efforts to bet-ter understand the human immune system; and

- An emphasis on prevention science research, including enhanced domestic and interna-tional studies of risk taking behavior and the development on strategies to avert infection, such as microbicides, female~ontrolled bar-riers, 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	21,1 12	21, 6 91	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	11,3OS
Totals	$47,279	$44,649	$50,773	$54,176	$58,696

Source: NationalInstitutes ofHealth

Agency Strategy for Specific Issues

Prevention

NIH-sponsored programs targeting the develop-ment and evaluation of various preventive inter-ventions have resulted in marked changes in sexual and drug-using behaviors associated with HIV trans-mission among at-risk populations, including diffi-cult-to-reach and socially disenfranchised popula-tions in the U.S. and abroad. NIH programs have demonstrated that behavioral interventions target-ing behaviors can be developed and implemented, including those designed to delay or prevent initia-tion 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 commu-nity-level interventions as an important way to ef-fect behavioral change on a larger scale.

Preventing vertical transmission from HIV-in-fected mother to child is a priority of NIH interven-tion research. Implementing the ACTG 076 proto-col has significantly reduced the incidence of ma-ternal-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 devel-oped to block mother-to-child transmission.

NIH also has sponsored several international conferences on the prevention of perinatal trans-mission. 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 infec-tivity for both sexual transmission and mother to child transmission;
- Studies in several developing countries in Af-rica, Asia, and Latin America to evaluate in-terventions for reducing mother-to-child trans-mission 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 accept-able condoms, microbicides, and other fe-male-controlled barriers;
- Studies in Africa on the efficacy of STD treat-ment 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 recommenda-tion for developing a Prevention Science Agenda that combines behavioral and biomedical interven-tion research, the NIH sponsored several agenda setting activities, including a 1998 Workshop on International HIV/AIDS Prevention Research Oppor-tunities. The goal of the Workshop was to encour-age research that would be feasible and relevant for developing countries with limited resources. Rep-resentatives from 37 countries severely affected by the epidemic participated in the workshop to de-velop 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 understand-ing 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 behav-ioral 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 preven-tion, 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 suc-cessful interventions to encourage sustained be-havioral 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 deter-minants, trends, and processes of HIV-related risk behaviors and the consequences of HIV infection;
- Developing and evaluating behavioral strate-gies for preventing or ameliorating the nega-tive physical,

psychological, and social con-sequences of HIV infection; and

- Improving the research methodologies em-ployed in behavioral and social science re-search.

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

Vaccine Research

The development of a safe and effective HIV vac-cine 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 dis-covery and development of HIV vaccine candidates. Basic research on HIV and the immune system pro-vides crucial information for developing potential vaccines. Various strategies for stimulating a pro-tective 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 pre-ventive 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 Commit-tee (AVRC), chaired by Dr. David Baltimore, was es-tablished. Specific areas of basic research relating to HIV vaccines efforts have been identified by the AVRC and a new, special initiative supporting inno-vative research in these scientific areas has been funded during the last 2 years to advance this re-search field. To further HIV vaccine research in the NIH intramural programs, the Vaccine Research Center is being constructed with completion tar-geted for 2000.

The NIH supports an AIDS Vaccine Evaluation Group (AVEG), which consists of six sites nation-wide that are actively evaluating potential HIV vac-cines 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 infrastruc-ture necessary to conduct large-scale efficacy trials of potential HIV vaccine candidates when they be-come available. These efforts involve strengthen-ing in-country research capacity by training foreign scientists and health professionals. NIH collabo-rates 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 man-agement of HIV-infected patients that would be useful in resource-poor settings, NIH is supporting studies on the use of isoniazid and rifampin to pre-vent active tuberculosis in PPD-positive, HIV-infected

patients in Uganda. In addition, NIH-supported sci-entists in Thailand are studying risk factors for in-fection with *Penicillium marneffei.* These NIH-trained scientists also are working with the phar-maceutical industry in Asia on developing thera-peutics 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 expe-rience some complications of HIV disease that are unique or more prevalent in them than in men, such as vaginal and esophageal candidiasis, chronic her-pes simplex infections, other STDs, and cervical dysplasia. NIH-sponsored programs target studies on the natural history and epidemiology of the dis-ease in women through a number of studies in Af-rica, Asia, and Latin America.

Studies on the etiology and pathogenesis of HIV infection and disease progression in women are on-going. These studies focus on the role of STDs and other factors in acquiring HIV infection and the pathogenic mechanisms associated with HIV dis-ease 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 addi-tion, NIH-funded researchers are investigating the cellular and molecular aspects of mucosal immu-nity and other infectious diseases as cofactors, as they impact HIV susceptibility and transmission. Results from these studies are critical to develop-ing safe and efficacious AIDS vaccines and microbicides.

A critical area of concern is the impact of HIV on cervical cancer. Co-infection with human papil-loma 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 ste-roidal hormones on early, acute HIV infection and later progression to AIDS among hormonal contra-ceptive users, and on the possible effect of steroi-dal hormone use on the infectiousness of HIV-in-fected women.

NIH-supported behavioral and social science re-search that relates to or focuses on women include studies on (1) determinants of HIV risk and preven-tion; (2) specific elements of social and cultural life that contribute to HIV risk and protective behav-iors; (3) the development of appropriate interven-tions to reduce risk behaviors; (4) community-level interventions; (5) acceptability of both biomedical and behavioral interventions among different indi-viduals and communities; (6) the behavioral aspects of the adoption of new HIV prevention technolo-gies, such as microbicides and the female condom; and (7) social and psychological factors influenc-ing 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 topi-cal microbicides and other female-controlled bar-rier methods for prevention of HIV transmission. Population-based research is essential to ensure both the efficacy and acceptability of these inter-ventions to decrease or eliminate HIV transmission. It is an NIH priority to develop a safe, inexpensive, reliable, and acceptable microbicide for the pre-vention of HIV and other STDs.

The development of screening assays to test compounds and agents for their microbicidal/sper-micidal activity, as well as developing suitable ani-mal models for safety and efficacy-testing of poten-tial microbicides, are vital parts of the developmen-tal efforts supported by NIH in this field of research. Close collaboration with industry is important in conducting the important phase I through III clini-cal testing of these agents in various populations and to ensure their eventual availability. While a number of microbicidal substances have been clini-cally 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 devel-oping an efficacious microbicide and continues to look at new compounds, as well as other barrier interventions. In FY–1999, NIH will establish a Pre-vention Trials Network that will focus on the test-ing at U.S. and international sites of various inter-ventions, 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 re-search. 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 poten-tial treatment regimens against HIV infection and its associated opportunistic infections and malig-nancies. NIH supports an extensive network of more than 100 clinical trial sites, including adult and pediatric units in major domestic medical cen-ters 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, minori-ties, 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 Ser-vices (DHHS) is committed to working in partner-ship 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, ser-vice delivery and education efforts. Scientists at DHHS have contributed significantly to international progress in understanding how HIV infection is trans-mitted, how it affects the body, and how to treat and prevent it. As new information becomes avail-able, increased knowledge about this disease and better ways to treat and prevent it should be forth-coming to address this critical health problem.

As the Nation's prevention agency, CDC inte-grates prevention science, research and practice. Through basic and laboratory research, epidemio-logic research, and surveillance, behavioral, com-munications, and social science research, CDC sup-ports a comprehensive approach to issues which impact prevention. CDC collaborates with govern-mental and non-governmental organizations, inter-national and domestic, awarding grants to national organizations, state and local health departments, community-based organizations and other institu-tions to support prevention activities based on sci-ence. This integration of science and practice is consistent across all of CDC's Centers, Institutes, and Offices supporting prevention science activi-ties. These include the National Center for HIV, STD and TB Prevention (NCHSTP), the National Cen-ter for Infectious Disease (under which falls the Di-vision of AIDS, STD, and TB Laboratory Research), the National Center for Chronic Disease Prevention and Health Promotion (under which falls the Divi-sion of Adolescent and School Health and the Divi-sion of Reproductive Health), the Office of Women's Health and the Public Health Practice Program Of-fice (which ensures the quality of laboratory test-ing).

Funding

In FY–1998, DHHS received more than $6.8 bil-lion 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 ac-tivities is limited within the offices and agencies within DHHS, with no formal budget allocation for international activities. Therefore, only a tiny per-centage of HIV/AIDS funds are allocated for inter-national HIV/AIDS activities.

Agency Strategy for Specific Issues

Prevention

CDC has two programmatic approaches to inter-national 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 pro-vides collaborative assistance to Côte d'Ivoire, Uganda, South Africa and Thailand. Studies are designed to increase the understanding of the epi-demiology of HIV and to evaluate intervention meth-odologies in the host country and the United States. Because of the variation in the virus itself through-out 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, re-searchers 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. Research-ers 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 sup-ported international collaboration on the develop-ment of microbicidal products, as well as interna-tional studies in acceptability of microbicides in Zim-babwe and Thailand. In addition, a number of do-mestic 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 tubercu-losis 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 re-search activities related to the development of HIV vaccines. This includes participation in efficacy tri-als 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 valu-able 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 coun-tries 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 methodolo-gies and other technical areas through an exten-sive 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 ac-tivities will support USAID-assisted countries with access to CDC epidemiologic and surveillance ex-pertise.

Other Activities

Although not specific to HIV/AIDS, it is impor-tant to note that CDC's international work focuses heavily on strengthening public health infrastruc-ture, and such work can contribute to sustainable HIV/AIDS control. For example, the CDC estab-lished field epidemiology training programs in de-veloping countries. Epidemiology is the cornerstone of public health science, and trained epidemiolo-gists are valuable countries to detect, monitor and help control their key public health programs. Sec-ondly, CDC has established a sustainable manage-ment 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 commit-ted to HIV/AIDS research within, as well as outside of, U.S. borders. To understand HIV/AIDS at a glo-bal level, research must address issues and condi-tions unique to different countries and communi-ties 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 im-portance of developing and implementing diverse interventions to address issues among varied popu-lations 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 prod-ucts 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, diag-nosis, 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 prod-ucts within its regulatory framework and is not, gen-erally, a grant-making institution nor an entity orga-nized 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 respon-sibility to help ensure the safety and effectiveness of AIDS-related medical devices through its regula-tory 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 in-volving medical devices; and evaluating the role of devices in the transmission of bloodborne infec-tions.

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 protec-tion against the transmission of HIV and other sexu-ally-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 dif-ferent materials.

Blood and Blood Products. FDA is respon-sible for ensuring the safety of the U.S. blood sup-ply. Regulatory mechanisms designed to ensure blood safety include establishing policies; approv-ing authority for blood products and establishments; and surveilling and enforcing blood safety stan-dards. 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 his-tory as a basis for deferral. The second safeguard entails constant updating of a list of unsuitable do-nors 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 un-til tests and other control procedures establish its safety. Finally, the blood collection centers are ob-ligated 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 investiga-tion 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-re-lated illnesses. FDA has approved 37 applications for products to treat HIV/AIDS. Twelve drugs are antiretroviral agents that are used to treat the vi-rus, and the remaining 25 are used to treat oppor-tunistic infections that can complicate HIV infec-tion. In addition, FDA is responsible for monitor-ing the safety of the drugs and biologics post mar-keting 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 Ser-vice-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 short-est possible time.

Diagnostic Capability

Diagnostic Reagents and Test Kits. FDA con-ducts a variety of regulatory, testing, and research activities to approve for marketing satisfactory test methodologies for detection of HIV. FDA has ap-proved 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 devel-opment and technological advancement. Data col-lection 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 ser-vice programs. The Bureau of the Census main-tains the broadest and most current numeric data-base in the world on HIV prevalence and incidence information for sub-Saharan Africa.

Scientific standards, methodologies, and tech-nologies 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 Exam-ining Groups review and research patent applica-tions for immunological testing apparatus and pro-cesses, apparatus for chemical and clinical analy-sis, immunoassay and pharmaceutical composi-tions, and apparatus and processes related to ster-ilization, cell biology, and blood and blood prod-ucts.

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 al-most 800 Japanese patent documents and approxi-mately 700 European patent documents in this da-tabase. This project was coordinated by the Patent

and Trademark Office and the National Science Foundation and developed in cooperation with pri-vate and nonprofit organizations.

Advanced Technology Program. The Depart-ment has funded biotechnology development projects through NIST's Advanced Technology Pro-gram (ATP). The ATP is a unique partnership be-tween government and private industry to acceler-ate the development of high-risk technologies that promise significant commercial payoffs and wide-spread benefits for the economy. The ATP encour-ages 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 essen-tial to developing new products, processes, and ser-vices across diverse application areas. Private in-dustry bears the costs of product development, pro-duction, marketing, sales, and distribution.

ATP awards are made strictly on the basis of rig-orous peer-reviewed competitions designed to se-lect 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 thera-pies 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 dis-covery and improve the quality of new AIDS thera-pies and vaccines.

Accelerated Processing of Patent Applica-tions. The Patent and Trademark Office offers ac-celerated processing of applications for inventions related to HIV/AIDS.

Trade. The Department of Commerce works closely with the U.S. pharmaceutical and biotech-nology sectors in the battle against HIV/AIDS. Com-merce 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 in-formation about new medical products and discov-eries in the pharmaceutical and biotechnology ar-eas. Commerce will work with industry and other governments to create a trade environment that maximizes the exposure of new HIV/AIDS treat-ments. It will continue to combine efforts with in-dustry, 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 com-pilation of information on HIV prevalence and inci-dence from all available studies from Africa, Asia, Latin America, and some select countries in Eu-rope. Using this information, the Bureau of the Census tracks patterns and trends in HIV infection among subpopulations within countries. This in-formation is then used to estimate AIDS mortality and is incorporated into our world population esti-mates and projections. These estimates are avail-able from the Bureau of the Census' International Data Base.

The International Programs Center has been designated a UNAIDS Collaborating Centre and con-tributed 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 capabili-ties and readiness of the U.S. military forces is of great concern. In response to that threat, the mili-tary research program was initiated in 1986 to mini-mize the impact of HIV on military readiness by monitoring the spread of HIV infection in military forces and developing methods to prevent infec-tion. The Tri-Service effort, which includes the Army, Navy, Air Force, and Marines, is a highly tar-geted research program that addresses the military concerns of HIV. This includes surveilling infection rates and HIV subtypes around the world; develop-ing 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 pri-mary goal the prevention of HIV infection in the fighting force. Once infected, the soldier, sailor, air-man, or Marine is, irrevocably, a casualty, and that service member and his or her family and the coun-try will feel the effects—physically, emotionally, and economically. Knowledge that HIV infection is pos-sible and that HIV is present in the environment can have deleterious effects on unit morale and cohesion of deployed forces. Preventing HIV de-creases 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 vac-cine 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 im-munogenicity similar to that observed in U.S. tri-als. This current trial is the first of its kind to match

the HIV vaccine to the HIV subtype of the popula-tion. The Program is conducting the first Phase II vaccine trial with a vaccine prepared from HIV sub-type E, which is prevalent in the population of Thai-land. The Military Program has a comprehensive vaccine development strategy with clear milestones leading to a large-scale efficacy evaluation of can-didate vaccines in the year 2001.

The military research program is highly leveraged through cooperative development initiatives with private industry. In 1998 alone, three new coop-erative 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 over-seas laboratory in Thailand.

Cooperation and coordination with other Fed-eral 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 vac-cine 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 Af-rica. Continued development and testing of sec-ond-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 prophy-lactic measures to deal with mass casualty situa-tions in HIV-endemic areas overseas involving U.S. military personnel. These emergency situations re-quire using rapid, sensitive diagnostic field tests

for HIV, which are currently being developed and evaluated. In a clinical study, the Program has as-sessed 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 dis-ease progression so that the production of these antibodies will be the target of future vaccine de-

velopment. In another clinical research project, there is an ongoing effort to monitor the develop-ment of resistance to antivirals in patients receiv-ing 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 pre-sentations of DOD conducted research have oc-curred at HIV/AIDS international meetings.

National Intelligence Council

Mandate Relevant to HIV/AIDS

The intelligence community and its various com-ponents produce analyses on the scope and im-pact of HIV/AIDS in response to Presidential deci-sion directives, the needs of their associated agen-cies, and ad hoc requests from senior policymak-ers.

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 for-eign 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 inci-dence 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 dis-eases on foreign military force readiness, military and civilian healthcare infrastructures and transnational health trends.

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

Role of the Pharmaceutical Industry

Agency Mandate Relevant to HIV/AIDS

In general, the role of the pharmaceutical indus-try is to find sustainable long-term solutions that will marshal the expertise and resources of all stake-holders to improve the health of those infected with HIV/AIDS, and to help establish balanced ap-proaches to education, prevention, and treatment of HIV/AIDS. Effective responses to the HIV/AIDS challenge must take into consideration all the rel-evant factors such as available therapies and their applicability for developing countries, medical in-frastructure, available resources, disease awareness and prevention initiatives, and national commitment and leadership to make HIV/AIDS a public health priority.

The principal role of the research-based U.S. pharmaceutical industry in confronting HIV/AIDS (in the developing world) is to continue to marshal the expertise and capacity in basic biomedical research and drug development to discover new and more effective treatments, make treatments more afford-able and, in the longer term, to develop an effec-tive HIV vaccine.

As corporate entities, the pharmaceutical indus-try seeks a return on the sizable investment for re-search and development of new drugs. Annually, the U.S. pharmaceutical industry spends approxi-mately $2 billion on research and development of HIV/AIDS-related drugs. As citizens of the larger global community, however, the industry has a com-mitment to bring to bear its vast resources to help those in need.

The research-based U.S. pharmaceutical indus-try is also well-positioned to provide input in the area of national health education and policy through contacts with government and health agencies around the world. This expertise should supple-ment the responsibilities and expertise of other members of the world health care community, both public and private.

Major U.S. companies are active across a broad front to try to improve the quality, delivery, and outcome of HIV/AIDS care in the developing world. The pharmaceutical industry has aggressively pur-sued prevention and treatment efforts for HIV and related illnesses. Although not uniformly available, the following is a summary of the pharmaceutical sector's efforts:

- A new class of drugs called non-nucleoside reverse transcriptase inhibitors became avail-able for use in combination therapy.
- There are more than 120 new medicines for HIV/AIDS in development, including:
  - 40 antiviral medicines, including new pro-tease inhibitors;
  - 23 medicines to fight AIDS-related cancers such as Kaposis sarcoma;
  - 12 vaccines;
  - 12 immunomodulators designed to stimu-late the patient's own immune system to fight the virus;
  - 11 anti-infective medicines to fight against such deadly diseases as Pneumocystis carinii pneumonia, a lung infection that affects eight out of ten AIDS patients;
  - 8 antifungal medications aimed at thwart-ing fungal infections that can prove deadly to people with compromised immune sys-tems; and
  - 5 gene therapies designed to genetically alter cells in patients' bodies to make them more resistant to the virus or to alter the virus itself.
- Two protease inhibitors have been approved to treat children with AIDS.
- A new medicine that combines two widely pre-scribed AIDS drugs in a single tablet has been approved by the FDA, a first important step toward simplifying the highly effective, but complex, combination drug therapy.
- The treatment of HIV-infected pregnant women with an antiretropviral drug has shown to be highly effective in preventing transmission of the virus to babies, even in women with ad-vanced AIDS.
- In 1997, a pharmaceutical became the first HIV therapy simultaneously cleared for use both in adults and in children 2 through 13 years of age.

Strategy for Specific Issues

Prevention

In light of the pharmaceutical industry's efforts, the most beneficial solution to the HIV/AIDS chal-lenge worldwide would be the prevention of new HIV infection via a safe and effective vaccine, es-pecially for those areas of the world where antiretroviral therapy is not yet feasible or practi-cal.

A vaccine, however, will require adequate distri-bution and supply programs. In some disease areas where vaccines exist, for example, there are insufficient mechanisms for funding and supplying vaccines. To increase the availability of needed pharmaceuticals, the pharmaceutical industry must work with nations and many others to build a coop-erative relationship and to develop appropriate ex-pertise and infrastructure to facilitate distribution.

Treatment Equity

The conventional view is that there needs to be greater equity in access to treatments between pa-tients in developed and developing countries. Al-though this is a straightforward and laudable goal, the issue is complex. In many developing coun-tries, the lack of medical infrastructure and a basic health care system undermine best efforts to make advanced AIDS therapies more widely available. Even if an unlimited amount of drugs were made available, access to HIV/AIDS therapies in the de-veloping world may be thwarted by the lack of ba-sic medical care, poor infrastructure, and the lack of political will and commitment at national levels. In addition to battling the complex HIV/AIDS prob-lem, developing countries are faced with the di-lemma of allocating scarce resources to effectively implement prevention, education, and treatment programs and effectively cope with the complex social, cultural, and economic factors involved in improving health.

In many respects, price is not the only issue. Even at a substantially lower price, many of the world's poorest regions still would not be able to obtain optimum clinical benefit from the new treat-ment drugs, like protease inhibitors or other antiretroviral therapy. This is due in part to the lack of properly trained medical personnel and sup-porting public health infrastructure, inadequate dis-tribution mechanisms, and other challenges. Using

protease inhibitors and other antiretroviral therapy under such circumstances would not only be im-practical and potentially ineffective, but even haz-ardous, as the combination therapies require strict dosage schedules and substantial HIV medical sup-port care to ensure ongoing and uninterrupted use. Inappropriate use of therapy increases the risk of emergence of drug-resistant virus, which exacer-bates the impact of HIV/AIDS in affected popula-tions.

To reduce the spread of HIV/AIDS there is a need for reduced treatment costs, better health infrastruc-ture and government commitment. Government action is required to provide incentives for private individuals and firms to pursue responsible devel-opment of new drug therapies and to develop the necessary public health infrastructure. This will per-mit the development of therapies that are consis-tent with internationally recognized rights and stan-dards and promote the distribution of safe and ef-fective medical supplies and services.

Improving Infrastructure for HIV/AIDS. The international community at large is working to strengthen public health infrastructures to address a wide array of disease problems. The pharmaceu-tical industry can and should play a part in address-ing infrastructure inadequacies. Clinical trials, with the support and agreement of national govern-ments, can be a vehicle for improvement if they are based on a commitment to make sustainable the infrastructure created for the purpose of con-ducting such trials. This will provide mutual ben-efits to both the sponsors and the participating entities.

An example of a successful private/public part-nership is the clinical trial of a new antiretroviral drug in Brazil. Brazil's medical community had con-siderable experience with clinical trials, but to date had not engaged in large-scale studies of HIV infec-tion. Merck & Co., Inc.'s medical department in Brazil worked closely with U.S. colleagues, Brazil-ian health and regulatory officials, clinical investi-gators, and their staffs to meet the challenges of finding personnel to serve as clinical monitors. They also trained the staff to collect and interpret the data on safety and clinical efficacy correctly; equipped the clinics with the necessary equipment to manage sophisticated clinical tests; expanded the capabilities of the local clinical laboratory to handle the thousands of blood samples from pa-tients; and recruited patients within the trial guide-

lines, ensuring both that their rights were protected and that their care was delivered appropriately.

As a result, the treatment program has gener-ated almost R$1 billion of savings for the govern-ment (R$l.05 equals approximately U.S. $1) and in Sao Paulo, the number of AIDS-related deaths fell by 35 percent in the first half of 1997, compared with the first half of 1996. In Rio de Janeiro, the number of deaths was 21 percent lower. Other ancillary effects include a 20 percent reduction, in 1998, on government spending for related medi-cation; in Sao Paulo, the use of emergency

facili-ties by AIDS patients fell by 40 percent and one entire floor of an AIDS wing in the city's largest hospital was closed due to insufficient demand; and patients receiving the antiretroviral drugs required less treatment for opportunistic diseases. Another indirect effect of the program is the increased abil-ity for HIV-infected individuals to retain the physi-cal vigor to continue in their jobs.

The successful findings from the clinical end-point trial played a vital role in making the new therapy available in the countries of the European Union, in Brazil, and elsewhere. For the Brazilian medical community, the completion of the trial was a significant accomplishment. The community had carried to successful completion a complex trial that generated massive amounts of data. The in-vestigators and their teams had solved a variety of logistical and organizational problems and devel-oped the kind of meticulous statistical data on which physicians in Brazil and around the world could, with assurance, base their decisions about HIV/AIDS therapy for their patients.

This example demonstrates the power of part-nerships among key stakeholders—the private and public sectors, the medical and patient communi-ties—to improve the framework for HIV/AIDS care in the developing world. Examples like this can set the stage for reallocation of government resources to address access to effective new medicines in a more comprehensive way, with confidence that the treatment algorithms will work in the local context.

The industry plans to continue to work in part-nership with governments, non-governmental or-ganizations, advocacy groups and academic insti-tutions to lead, support, or initiate projects on AIDS awareness. This can result in a better understand-ing of the patterns of HIV-related illnesses, care-

taking behaviors and determinants of such behav-iors among HIV positive individuals. Industry also stands ready to work with governments, interna-tional organizations and others to address public health infrastructure needs in developing countries.

At the Twelfth World AIDS Conference in 1998, Merck & Co., Inc., announced a $3 million grant from the Merck Company Foundation to underwrite the Enhancing Care Initiative, an initiative coordi-nated by the Harvard AIDS Institute and the Francois-Xavier Bagnoud Center for Health and Human Rights at the Harvard School of Public Health. The Enhancing Care Initiative will address the issue of HIV/AIDS in the developing world by bringing together the best possible expertise within specific countries, including representatives of the local HIV community. The goal is to customize con-crete, practical improvements that will help to ad-vance the quality, delivery and outcomes of HIV care for men, women and children living with HIV/ AIDS, not only in the initial countries selected (be-ginning with Senegal and Brazil), but in a broad range of developing world countries.

The kind of commitment that the pharmaceuti-cal industry is making to this type of responsible partnership is exemplified in industry's efforts in Africa. In South Africa and Botswana, the Bristol-Myers Squibb Company supports medical educa-tion activities for local HIV specialists. One project called AIDSFACT is designed to educate healthcare professionals on the management of HIV. It is authored by HIV experts in South Africa and was distributed to 10,000 general practitioners in 1998. To help improve the care that African physicians are able to give to their patients with HIV infection, Merck & Co., Inc., has worked with leading HIV/ AIDS treatment specialists at clinical centers in Paris, using a "train the trainer" approach to provide phy-sicians from Uganda, Côte d'Ivoire, and Senegal ex-perience with the best international standards of HIV care. The physicians then disseminate this knowledge to colleagues at home, which over time will improve the level of understanding and exper-tise in meeting the challenges of HIV/AIDS through-out the medical community in their countries. The information gained from these types of studies can then be used to guide government decisions on making additional resources available to expand programs of HIV/AIDS treatment.

These activities in the private sector complement the initiatives of other stakeholders—including the HIV community, governments, international orga-nizations, and non-governmental organizations—to help improve medical infrastructures and support the efforts to find long-term, sustainable solutions to the problems of HIV/AIDS faced by countries in the developing world.

Women and Health

Some gender analysis, though limited, has be-gun. An analysis of data from Merck, Sharp and Dohme's study 028 (the Brazil trial) shows compa-rable effects on disease progression among men and women as a result of treatment with a protease inhibitor. The study, a clinical endpoint trial of 996 previously untreated HIV patients in Brazil included 277 women (28

percent of total patients), which constitutes one of the largest representations of women in a long-term protease inhibitor study in the world. The objective of the analysis was to determine whether there was consistency of treat-ment effects across gender in the testing of vari-ous new therapies. This type of study is only a beginning. There is a strong need for more research on women's risks, prevention and care needs. Also, funding for women-specific interventions programs needs to be increased.

Related to the issue of HIV/AIDS and women is pediatric health care. The Bristol-Myers Squibb Foundation and Bristol-Myers Squibb Company - Mexico have jointly funded a pediatric AIDS initia-tive to address prevention and education, treat-ment, and access to care. Through community outreach and education of pregnant women and women of childbearing age, the program aims to reduce the incidence of pediatric AIDS. With the Baylor College of Medicine, the program provides medical training to pediatricians, infectious disease specialists, and nurses on the management and treatment of pediatric AIDS. A third component of the program provides anti-retroviral drugs for ap-proximately 200 pediatric AIDS patients in need and infant formula for approximately 100 infants. The program began in 1998 and the total commitment for this initiative will be U.S. $4.4 million over three years.

Vaccine Research

In November 1997, the Pharmaceutical Research Manufacturers of America (PhRMA) reported that 12 vaccines under development from member com-

panies, including the first AIDS vaccines, were in clinical trials or under review by the U.S. Food and Drug Administration (FDA). Currently, there are no FDA-approved vaccines for HIV.

Biopharmaceutical research and development companies are involved in the development of therapeutic and preventive vaccines that can induce protective immunity against HIV-1 subtypes preva-lent in different parts of the world.

Industry also must commit to make therapies available where clinical trials are performed. In research programs underway in Côte d'Ivoire and Thailand, one Merck & Co., Inc., designed its pro-tease inhibitor clinical trials so that patients in these trials will continue to get access to the therapy af-ter the studies are completed.

Vaccine research is difficult and expensive. The risk of failure is high. Of an initial five thousand compounds in basic research, only one will emerge from the laboratories and actually reach the mar-ket. According to PhRMA, promising new vaccines require an average of 10 to 15 years of intense study and development. Nonetheless, U.S. phar-maceutical companies active in the HIV/AIDS field remain committed to developing new and innova-tive vaccines as well as developing combination vaccines and multiple antigens in a single inocula-tion. For vaccine researchers, the ideal would be converting multidose vaccination regimens into a single time-released shot.

Vital to the continued progress in developing new pharmaceutical defenses against HIV/AIDS is strong intellectual property protection. Intellectual prop-erty protection provides the indispensable incen-tives to invest in pharmaceutical research, which leads to the discovery and development of better treatments for patients with AIDS all over the world. Strong worldwide patent protection is essential to spur pharmaceutical innovation.

Behavioral Research/Behavioral Change Interventions

As part of its ongoing effort to work with partners to improve environments through which health care is delivered in developing countries, PhRMA under-wrote AIDS education work in Africa, in partnership with Africare.
In Nigeria, Merck & Co., Inc., joined forces with the World Health Organization (WHO) in Geneva, Women's Health & Action Research Centre in Be-

nin, Nigeria, the Ford Foundation in Beijing and three U.S. Universities (University of Pennsylvania Medical School, Princeton University, and Harvard School of Public Health) in a project aimed at iden-tifying choices made by Nigerian youth to treat symp-toms of sexually transmitted diseases (STDs) and identify targets for improving treatment of STDs. The findings will guide an intervention to reduce the prevalence of STDs and incidence of HIV among Nigerian youth.

Microbicide Development

Pharmaceutical companies are working to de-velop topical microbicides that women can apply to inhibit HIV infection.

Although none have been shown to be effective to date, a potential microbi-cide that is spermicidal is in later stages of efficacy testing against HIV. Other formulations of microbicides are still in early development and test-ing.

The pharmaceutical industry realizes that women need microbicides that allow conception, but pre-vent infection with HIV and other STDs.

Donor Coordination

The pharmaceutical companies sponsor billions of dollars of research and development into new treatments as well as donate products. To facili-tate product donations, U.S. research-based phar-maceutical companies created the Product Dona-tions Steering Committee (steering committee), an organization of innovative companies and key U.S.-based voluntary organizations. The Committee was organized to facilitate experience-sharing regarding obstacles to donations and to formulate guidelines for responsibly managing donations.

The Steering Committee has forged a “Statement of Principles” and has taken other actions such as educational meetings and seminars to help ensure that donations are carried out and coordinated be-tween the donor company, private voluntary orga-nizations and recipients in a way that assures the highest level of quality and ethics.

Donor coordination requires consideration of what is needed for a successful donation in gen-eral. The need for coordination goes far beyond the donors, it extends to all of those involved in the donation process—donors, private voluntary and/or non-governmental development organiza-tions, local ministry of health, governments, field staff, and patients. In addition, coordination of organizations working in any one particular area is needed to avoid overlap, duplication of efforts, and to ensure appropriate coverage.

Sustainability of treatment is crucial and must be considered when planning donor coordination. Sustainability of treatment is contingent on a num-ber of factors: available product supply, program funding, government/minister of health involve-ment, and recipient fatigue. For diseases like AIDS that require long term treatment and medicines with complex administration protocols, a reliable medi-cal staff is needed to administer the medicines. Failure to ensure proper and continued administra-tion could actually harm the patient. Other require-ments for a successful donation include a reliable delivery system on the ground in the recipient coun-try; assurances of adequate and appropriate stor-age of the medicines; and a system for recording adverse reactions and monitoring patients.

Role of International Non-governmental Organizations (NGOs)

Mandate Relevant to HIV/AIDS

Progress in halting the spread of the HIV/AIDS pandemic and its consequences can only be made if public sector efforts are supplemented by private sector involvement in HIV/AIDS prevention and miti-gation. Over the past decade, selected non-govern-mental organizations (NGOs) have demonstrated that they are often in the best position to mobilize communities worldwide for HIV/AIDS prevention and care. Their close relationship with target com-munities and their experience in community devel-opment enables NGOs to work with community members to develop responsive, cost-effective pro-grams. To build effective and sustainable HIV/AIDS programs, it is essential to improve and enhance the performance of these local organizations to provide appropriate HIV prevention and care ser-vices.

The functions of NGOs in a democratic society are many: they monitor the action of governments in meeting the needs of poor and disenfranchised populations; are instrumental in building commu-nity awareness and support for efforts by interna-tional organizations and government agencies; and help to provide a seamless transition from exter-nally sponsored immediate assistance to long-term, domestic assistance.

Strategy for Specific Issues

Prevention

NGOs work to educate the media, private sec-tor, development organizations, multilateral and bilateral institutions, domestic and international AIDS organizations, the U.S. Government, and oth-ers about the importance of international HIV/AIDS prevention efforts.

International NGOs in the HIV/AIDS movement also work to create linkages with other health pro-grams, domestic AIDS organizations, and advocacy institutions. The NGO-coordinated strategy for im-proving and creating linkages with other health pro-grams includes: educating domestic AIDS service

organizations on global HIV/AIDS issues to ensure that they will create linkages with indigenous NGOs, and the creation of a working group dedicated to looking at development issues, health, and HIV/ AIDS.

NGOs engage in HIV/AIDS behavioral prevention strategies that traverse several levels of impact, highlighting best practices and exemplary behav-ior change programs. Conference workshops are organized to feature behavior change issues and specific interventions designed on the premise that personal behavior is profoundly influenced by broad contextual factors, including service accessibility and social norms, and that sustained individual be-havior change is unlikely unless there is also a change in relevant contextual factors.

Interventions targeting individuals include activi-ties such as peer counseling, couples counseling and testing, and small group interventions. Initia-tives at the societal level, such as mass media cam-paigns and school and workplace interventions, mo-bilize communities to provide a supportive envi-ronment for reducing risk, and support individu-ally-based interventions. Advocacy activities target-ing environmental or structural constraints contrib-ute as well. In short, accurate knowledge and sus-tained behavior change at the community level is directed at the demand side to create understand-ing and awareness and to spur the adoption of ap-propriate HIV/AIDS behaviors at the community level.

NGO prevention programs target the population as a whole, as well as groups most vulnerable to HIV, including adolescents, women, refugees, mi-grant workers, miners, commercial sex workers, and intravenous drug users. For instance, NGO HIV/ AIDS prevention projects target young adults with information and services that address their specific issues. Communication material targeting young adults promotes safer sexual behavior, encourag-ing abstinence as a viable alternative to early sexual activity, and making condoms the right choice for protection when sexual activity does take place. Advice, information, and products are made readily available where youth spend their leisure time. Additionally, NGOs collaborate with traditional con-

dom outlets (e.g., pharmacies) to make them youth-friendly. Call-in radio shows in India, Zambia, and South Africa invite and respond to young people’s questions about sex and send out additional, youth-oriented information booklets to interested callers. A comic book is used in Haiti to encourage teens to discuss sexual matters with their parents. Youth-oriented “photonovellas” in Bolivia capture in print the same stories portrayed in popular TV miniseries on unwanted pregnancies, STIs, and HIV/AIDS.

Over the last 15 years, NGOs have targeted women in their prevention strategies as well. NGO initiatives encourage women to purchase condoms and to insist on their use with partners. Women in Cameroon and Côte d’Ivoire can purchase condoms in self-service shops where the anonymity of a checkout counter is preferred over direct interac-tion with sales staff. In Burkina Faso, the Griottes, an organized union of female historians and story-tellers, go door to door to talk about AIDS with women. Women street vendors do the same in Haiti, where free samples are included in boxes of fe-male hygiene products.

Further, international NGOs have worked collabo-ratively to open markets for female condoms in developing countries, and to create a video train-ing program on their benefits and use. NGOs have also collaborated with UNAIDS to communicate with local governments, NGOs, and health providers in developing countries about this product and to as-sess their demand and technical assistance needs for starting or sustaining female condom projects.

Recognizing that injecting drug use has played a critical role in fueling the epidemic in various re-gions, particularly in some countries in Asia, East-ern Europe, and the Commonwealth of Indepen-dent States, NGOs support at least three major pre-vention components, including: early implemen-tation of prevention initiatives while HIV prevalence is low; community outreach to injecting drug users (IDUs) to provide HIV/AIDS information and help develop trust between IDUs and healthcare provid-ers; and widespread provision of sterile injection equipment.

Workplace Interventions

For over 5 years, labor unions have conducted an ongoing effort in the U.S. to combat the scourge of HIV/AIDS and STDs through unique programs of workplace peer education. Despite vast cultural differences, two things nearly all people the world over share in common are the need to work and the need to receive medical care. People, rich or poor, uneducated or educated, active in commu-nity organizations or not, are best reached where they work. This is particularly true in developing countries and among workers who are most at risk of contracting HIV/AIDS. Truckers, transit workers, miners, and others whose jobs require them to travel through porous borders are the ones most often associated with the spread of HIV/AIDS. Few ways exist to reach these people other than through their jobs and at their place of employment.

What began as a practical effort to cope with issues of occupational safety and health at the be-ginning of the AIDS pandemic has now become a deep commitment to share the special strengths of labor movements worldwide to open a new front in a global war against this tragic disease. Now more than ever, a mounting body of evidence suggests that the workplace peer education strategy can re-spond to program needs with practical low-technol-ogy methods to help arrest the explosion of HIV/AIDS infection rates in developing nations.

Social Marketing

An example of a specific HIV/AIDS prevention and mitigation methodology utilized by NGOs to make condoms available to low-income people in developing countries is a technique called social marketing. Condom social marketing involves the distribution of condoms to lower-income persons by marketing through the existing local commer-cial and NGO infrastructures. NGOs procure prod-ucts using donor funding or obtain them directly from donors; establish an office and a distribution system in the developing country, often acting as its own distributor; and sell the products, through the existing wholesale and retail network in the country. Products are branded and attractively pack-aged, and sold at low prices, making them afford-able to the poor. Since this retail price is often lower than even the manufacturing cost, donor con-tributions are a vital element of the social market-ing process.

A key ingredient to successful social marketing is effective communications to stimulate demand and encourage the adoption of appropriate health practices. This is done in a culturally and linguisti-cally appropriate manner through both brand ad-vertising and generic educational campaigns, us-ing a mix of strategies and channels, such as mass

media and interpersonal communications, to reach the targeted audience. Activities range from brand advertising informing the public that a quality prod-uct is available and where it can be purchased, to generic educational efforts that help people under-stand why changing behavior is necessary and im-portant.

A project in Côte d'Ivoire provides an illustra-tion of communications initiatives designed to ef-fect behavioral change. Saturation-level brand pro-motion informs the public about condoms and that their use protects against contracting HIV/AIDS. That activity is complemented by producing and broadcasting a popular and award-winning televi-sion soap opera, *SIDA dans la Cité* (AIDS in the City). The multipart program engages viewers in a gripping drama about a family in which the father is diagnosed with AIDS because he was unfaithful and did not use protection. This dual approach, based on research and testing, recognizes that people learn in different ways and a variety of mes-sages will more effectively reach a larger audience.

In Guinea, local religious leaders now use their mosques to preach messages on marital fidelity and abstinence—all part of the national campaign in Guinea to prevent HIV/AIDS. In seven countries, mobile video units, equipped with camcorders and large screens, take health messages to the rural countryside. In Tanzania, these video-equipped vehicles show films that educate about AIDS, en-courage fidelity, and promote condoms. These mul-timedia presentations are extremely popular among entertainment-starved populations; in Pakistan and Bolivia mobile video units have attracted audiences of thousands of people.

Some of the other communications activities used by NGOs include point-of-sale material; radio call-in shows, soap operas, documentaries, profiles and other programs; television documentaries, de-bates, and other informational programs; musical

songs and videos; cinema ads and trailers; theater troupe presentations and puppetry; product dem-onstrations and information distribution at work places, community meeting places, and special events; print materials, posters, brochures, car-toons, and inserts; informational kiosks and peer education activities at special and sporting events, and in high traffic areas throughout communities; and providing information to and training to those with the ability to reach larger, affected populations.

Treatment Equity

The international NGO community recognizes that very few people living with HIV in the develop-ing world have access to many life prolonging drugs, including basic antibiotics. As the number of people living with HIV/AIDS continues to reach alarming levels, programs dedicated to providing services to these individuals are drastically needed. Recogniz-ing that prevention has been a priority for most multilateral, bilateral, and private voluntary organi-zations (PVOs), NGOs advocate for the development and inclusion of programs focused on care that address the needs of people living with AIDS and their family members. Care programs should in-clude access to appropriate life-saving therapeutic treatments, development of counseling and related services, and the development of human rights projects to curb discrimination against persons af-fected by HIV/AIDS.

The coordinated NGO strategy that emphasizes the necessity of creating care projects and moni-tors the development of these projects includes: offering seminars and workshops on the preven-tion to care continuum and arranging meetings with PVOs and multi- and bilateral institutions. NGOs can also be advocates and work to broaden the policy dialogue on issues such as drug pricing, call-ing for price reductions, and aggressively working through all available private and public networks to engender an informed and supportive policy en-vironment to effect change.

An example of a strategy to improve treatment equity is the use of mechanisms such as private sector leveraging to help communities and govern-ments tap into additional financial resources.

AIDS-Orphaned Children

Currently, the future of millions of children is threatened because of HIV/AIDS. In addition to the 1.2 million children that UNAIDS estimates are infected with HIV, a growing number of children are being orphaned as a result of AIDS-related adult mortality. Young people whose family controls are lacking may seek emotional support and security through sexual relations, thereby increasing their risk of HIV infection. In addition, they may be abused and forced into prostitution. Children liv-ing in the streets are forced to fend for themselves, with few options for survival. With an estimated

100 million street children alive today, the implica-tions for the spread of HIV are alarming.

To avoid infection, children need a supportive, enabling environment that provides them not only with knowledge about how to protect themselves, but also with the motivation and the power to do so. Care is also essential for the survival of chil-dren. NGOs have worked with local collaborators to develop a methodology for orphan assessment, which identifies priority needs of orphans and their caretakers. Activities are also focused on orphan care and support, which include care, counseling services, and vocational training. In addition, in-come-generating activities with NGOs, mobilization of local resources, and psychosocial support and training are supported by NGOs at the country level. Finally, in response to the growing number of chil-dren left parentless due to HIV/AIDS, NGOs have made efforts to highlight this crisis through confer-ence workshops, briefings, and media articles.

Women and Health

The international NGO community works to bring attention to the growing vulnerability of women to HIV/AIDS through: workshops at domestic and in-ternational conferences, briefings for government leaders, media articles, and monthly E-mail broad-casts.

NGOs have worked tirelessly to:

- Promote access to reproductive health ser-vices, such as family planning and antenatal care, that protect the health of women and their families.

- Encourage earlier access to treatment through the development of voluntary HIV counseling and testing services.
- Promote improved treatment by encouraging early management of symptoms and treatment of opportunistic infections.
- Improve STI case management at the clinic level and to make services, including drugs, more accessible to populations at risk.
- Promote dialogue between men and women.
- Expand women's prevention efforts through female condom studies.
- Educate younger women about reproductive health, providing the information they need

to make informed choices about abstinence, the initiation of sexual activity, selection of partners, and the use of condoms and other available protection methods.

Vaccine Research

NGOs advocate the development of vaccines for global use. Although spending allocated to research in both the public and private sector has increased over the past few years, NGOs point out that issues concerning the allocation of funding and the ethics surrounding some of the clinical trials being con-ducted require continuing attention. The interna-tional NGO community provides a venue for de-bate on the ethics of individual clinical trials and monitors and reports on spending and profits gen-erated by the development of vaccine, antiretrovirals, therapeutic interventions and prophylaxsis by private pharmaceutical companies.

Microbicide Development

NGOs are involved in clinical trials of vaginal microbicides to evaluate efficacy and acceptability in preventing STIs, HIV, and pregnancy. More than 200 scientific publications on barrier methods have been produced, including a monograph for the 1994 International Conference on Population and Development in Cairo.

Three existing trials are Phase I safety and ac-ceptability studies of candidate products taking place both in the United States and at seven inter-national sites in six countries. A fourth trial, a Phase III non-Oxynol (N–9) efficacy study in Zimbabwe and Malawi (two sites), is currently in the final planning stages and the first phase of study enrollment is expected to get underway in early 1999.

A randomized control trial evaluating the impact of N–9 film on the transmission of HIV and STIs in Cameroon has been completed. Results showed N–9 film was safe but did not protect against HIV/ STI. Methodological and operational lessons learned from this study have influenced directions of new microbicide development. Other related research includes a number of clinical trials of vaginal microbicides with STI infection as the primary study endpoint, and HIV infection as a secondary end-point.

Donor Coordination

NGOs play a role in facilitating dialogue among multilateral donors, such as UNAIDS, bilaterals, in-cluding USAID, and private funding bodies in order to maximize donor effectiveness and minimize over-lap.

In addition, at the country level, NGOs develop programs that complement those of other donors. For instance, NGOs collaborate with the World Bank on specific technical areas such as STI research, and work jointly with UNAIDS and the World Health Organization (WHO) on the development of guide-lines for behavioral data collection needs of national HIV/ AIDS/STI programs.

Role of International Organizations

Mandate Relevant to HIV/AIDS

Where possible, the U.S. Government works closely with international organizations to leverage both human and financial resources for the greater benefit of those in need. International organiza-tions are uniquely positioned to provide support for HIV/AIDS prevention and mitigation efforts worldwide. The U.S. Government provides direct assistance to these important institutions and sup-ports the critical role international organizations play in the international fight against HIV/AIDS. The role of international organizations is characterized as follows:

- International organizations have a wide fund-ing base and are able to provide significant financial backing and multisectoral support.
- International organizations are able to effect cooperation without political ramifications or restrictions that bind local and national gov-ernmental actors.
- International organizations are nonpartisan.
- International organizations are able to bridge gaps between countries and donor nations and provide a fora to bring various international players together on issues.

UNAIDS

The Joint United Nations Programme on HIV/ AIDS (UNAIDS), an international organization cre-ated specifically to address the HIV/AIDS pandemic, was established as an independent UN agency on January 1, 1996. UNAIDS brings together the ef-forts of five UN organizations: United Nations Inter-national Children's Emergency Fund (UNICEF), United Nations Development Programme (UNDP), United Nations Population Fund (UNFPA), United Nations Educational, Scientific, and Cultural Orga-nization (UNESCO), World Health Organization (WHO), and the World Bank. The primary focus of UNAIDS is to strengthen the capacities of national governments for an expanded response to HIV/ AIDS. UNAIDS will achieve this objective through work at national, regional, and global levels in the following four mutually reinforcing areas: policy development and research, technical support, ad-vocacy, and coordination.

Prevention

Testament to the multisectoral reach of UNAIDS are its numerous prevention efforts, ranging from collaboration with the religious sector to assess-ment of the cost-effectiveness of HIV prevention strategies. Examples of the range of UNAIDS pre-vention strategies are detailed below.

Recognizing that truly effective prevention efforts must begin at a young age, UNAIDS activities target school-aged children through outreach and preven-tion efforts. In 1997, UNAIDS published a position paper on integrating HIV/STD prevention in the school setting; produced a technical update on learning and teaching about AIDS at school; and participated in the organization of seminars on school-based AIDS education at the three regional conferences on AIDS held in Côte d'Ivoire, Peru, and the Philippines.

Within the religious sector, UNAIDS employs a two-pronged prevention approach. The first is to promote the exchange of ideas and training for com-munity-based prevention and care programs. The second is to encourage religious institutions to strengthen life-skills training approaches for HIV education in schools operated by their congrega-tions. UNAIDS also collaborates with the Roman Catholic organization CARITAS International and is supporting a forum of religious leaders in Africa.

UNAIDS' efforts to reduce risk and vulnerability in institutional settings, such as prisons and work-places, have largely focused on strengthening na-tional and regional networks and facilitating infor-mation exchange on effective programming. A joint undertaking with the Civil-Military Alliance to Com-bat HIV/AIDS, and its regional affiliates, helps to establish and strengthen AIDS programs with mili-tary services in Africa, Asia, and Latin America.

To prevent intravenous transmission, UNAIDS works to strengthen regional HIV/injecting drug use harm reduction networks, focusing on exchanging lessons learned and sharing technical resources. In the area of sexual transmission, UNAIDS' princi-pal efforts in 1997 and 1998 have been identifica-tion and dissemination of best practices in HIV pre-vention and care, strengthening of regional net-works, and development of tools and guidelines to

facilitate project development. UNAIDS has sup-ported specific initiatives in the Asia-Pacific region, central and Eastern Europe, and west and central Africa. With regard to men who have sex with men, UNAIDS is building several regional networks of ex-perts in HIV prevention.

Finally, to assess the efficiency and effectiveness of HIV prevention efforts, UNAIDS has initiated a number of studies evaluating the cost-effectiveness of HIV prevention strategies. The studies have led to the preparation of costing guidelines for such strategies; a UNAIDS' point-of-view document on cost-effectiveness analysis; and three computerized models covering blood safety, prevention programs for sex workers, and school education, all of which will be published in 1998.

Treatment Equity

Recognizing that there are often insurmountable barriers to obtaining access to available HIV/AIDS treatment, UNAIDS and the WHO Action Program on Essential Drugs are developing an operational plan to improve access to drugs for HIV infection. UNAIDS supported several consultations on this subject in Senegal and during the AIDS conference in Abidjan. UNAIDS also is supporting preparation of case studies on treatment equity and access to care and drugs in Asia, Latin America and the Car-ibbean, and West Africa; and, in collaboration with the Ministries of Health and a number of pharma-ceutical companies, UNAIDS is initiating pilot projects to improve access to drugs of interest to people living with HIV/AIDS, in Chile, Côte d'Ivoire, Uganda, and Vietnam.

Further, UNAIDS is currently collaborating with local partners to document case studies on the pro-cess of introducing antiretrovirals in Argentina, Bra-zil, Colombia, and Mexico, where the drugs have been made available despite resource constraints. The objective of the studies is to assess the extent to which their introduction was successful, and to learn about difficulties encountered in introducing the new technology. These lessons can serve as a learning tool for other countries.

Women and Health

UNAIDS coordinates the Informal Working Group on Mother-to-Child Transmission of HIV, which fo-cuses on the coordination and design of clinical trials on the prevention of HIV transmission from

mothers to their children. UNAIDS also supports the Ghent International Working Group on Perinatal Transmission of HIV, sponsored by the European Union, which conducts studies on the acceptability of prenatal voluntary counseling and testing in the context of ongoing clinical trials in Africa, as well as cost-effectiveness studies related to the use of AZT and alternatives to breastfeeding.

Vaccine Research

In collaboration with the WHO Global Program for Vaccines and Immunization, UNAIDS is support-ing a project to promote the development of a novel vaccine approach—the International AIDS Vaccine Initiative (IAVI)—whose mandate is to accelerate progress toward an AIDS vaccine for use in devel-oping nations where the epidemic is spreading most rapidly. IAVI is designed to complement, not com-pete with, existing AIDS vaccine programs, which have emphasized basic research. IAVI's strategy consists of accelerated product development and human testing through international collaboration. In addition, UNAIDS, WHO, and the Council for In-ternational Organizations of Medical Sciences are developing a guidance document for ethical stan-dards in the conduct of HIV vaccine trials.

Behavioral Research/Behavioral Change Intervention

In the area of behavioral prevention, UNAIDS, USAID, and WHO collaborated to assist in the mul-ti-site voluntary counseling and testing (VCT) study carried out from 1995 to 1997 in Kenya, Tanzania, and Trinidad and Tobago. The study concluded that VCT significantly reduces sexual risk-taking behav-ior and does not increase such negative life events as disintegration of relationships and discrimina-tion.

Another behavioral intervention project com-bined the efforts of UNAIDS, UNESCO, UNICEF, and the World Bank in the development of communica-tion strategies and regional networks for national AIDS and health-promotion programs.

Microbicide Development

UNAIDS advocates for the development of vagi-nal microbicides and serves as the Secretariat for the International Working Group on Microbicides. In 1996–1997, UNAIDS launched a multicenter

study on the efficacy of COL–1492 in preventing HIV infection and sexually transmitted diseases among female sex workers in Benin, South Africa, and Thailand. In addition, preparatory work is pro-ceeding in Côte d'Ivoire and Senegal. A first interim analysis is expected in 1999 but final results will not be available before the end of 2001. It is hoped that microbicides will also be useful in preventing HIV infection in men.

UNAIDS' Cosponsors

Although the majority of HIV/AIDS activities on the part of UNAIDS' cosponsors fall under the ru-bric of UNAIDS, there are continuing independent cosponsor efforts to prevent and mitigate the im-pact of HIV/AIDS:

- UNESCO is developing curriculum and teacher training in India, and planning seminars in Nepal and Cambodia;
- UNFPA is focusing on integration of HIV/STD prevention in family life/reproductive health programs in more than 150 countries;
- WHO is integrating school-related health ser-vices for adolescents with action-research projects in six African countries, as well as integrating HIV/STD prevention into the "Health-Promoting Schools Network" in six regions. WHO also supports the Government of China in extending HIV/STD education in all schools in the most-affected southern prov-inces;
- UNICEF is developing youth-friendly health ser-vices and promoting life-skills education which integrate AIDS information;
- UNDP is preparing a series of issue papers on gender and the HIV epidemic;
- UNICEF is developing resource materials for integrating gender awareness into adolescent sexual health programs;
- UNESCO is implementing a project to reduce the rate of HIV transmission among women by empowering them with awareness, knowl-edge, and skills;
- WHO is providing technical support to an In-ternational Center for Research on Women (ICRW) project on reproductive-health rights of HIV-infected women.

In addition, since 1995, WHO, joined later by UNAIDS, has supported the PETRA study, in South Africa, Tanzania, and Uganda, to test the efficacy of a short-term regimen of AZT and 3TC for reduc-ing the risk of mother-to-child transmission of HIV.

Finally, after the results of the Thai/CDC trial on mother-to-child transmission, UNICEF-WHO-UNFPA-UNAIDS set up an international initiative to demon-strate the feasibility of prevention of mother-to-child transmission of HIV in some of the countries worst-affected by HIV infection. Under this initiative, pi-lot interventions are being implemented in the fol-lowing countries: Zimbabwe, Zambia, Uganda, Côte d'Ivoire, Burkina, Honduras, Vietnam, Cambodia, Thailand, Botswana, and Rwanda.

The World Bank

The World Bank—one of the six UNAIDS cospon-sors—is an example of an international organiza-tion that provides direct assistance to client gov-ernments in the form of loans, technical assistance, and policy guidance. The World Bank's compara-tive advantage lies in its ability to engage in dia-logue with client governments, enabling the cre-ation of an environment for the development of sustainable and multisectoral prevention and care programs, and in its capacity to finance large na-tional programs to combat HIV.

Most of the World Bank's loans for HIV/AIDS are provided on highly concessionary terms through the World Bank's concessionary lending arm, the Inter-national Development Association (IDA). While the approval of new loans for HIV/ AIDS fluctuates con-siderably from year to year, the World Bank is con-tinuing to expand its portfolio of HIV/AIDS projects and loan disbursements, which reflect efforts to implement AIDS control activities. The World Bank has committed over $800 million to HIV/AIDS projects over the past decade, and there are indi-cations that the pace of lending will rise in the next 3–5 years as more clients turn to the World Bank for financial assistance to address HIV/AIDS in their countries.

Additionally, the World Bank incorporates HIV/ AIDS components into other loans such as repro-ductive health and rural development programs. The World Bank's commitment to HIV/AIDS is also reflected in its technical and operational assistance. Further, the World Bank attempts to ensure that HIV/ AIDS strategies are effective and appropriate for

the specific challenge facing each country. Although individual governments are ultimately responsible for project implementation, the World Bank works closely with government officials in designing, moni-toring, and evaluating HIV/ AIDS projects. The World Bank is also increasingly focusing on capacity build-ing as part of country specific responses to HIV/ AIDS.

Prevention

The World Bank regularly funds regional preven-tion projects. For example, in collaboration with UNAIDS, the World Bank is providing grants for ini-tiatives which tackle the AIDS epidemic at the re-gional level, dealing with cross-border issues such as migration and transport, that are central to the spread of HIV. These regional problems, covering western Africa, southern and eastern Africa, South-east Asia, and Latin America and the Caribbean, are managed by UNAIDS on behalf of the World Bank. They aim to strengthen regional cooperation and improve the capacity for neighboring countries to consult and work jointly on policy and imple-mentation issues.

The World Bank is also working closely with UNAIDS at the country level in developing programs in a number of nations. Country-level projects are ongoing in India, China, Zimbabwe, and Brazil.

AIDS-Orphaned Children

In the area of AIDS-orphaned children, the World Bank supports the production of public service an-nouncements, picture exhibits, and video documen-taries to bring attention to the millions of children orphaned by AIDS. In 1997, the World Bank devel-oped a Public Service Announcement, which has been aired on CNN and many other international outlets to highlight the theme of the 1997 World AIDS Campaign: Children Living in a World with AIDS. On World AIDS day 1997, the World Bank hosted a picture exhibit titled: "Dying Branches: The Impact of HIV/AIDS on the Villages of Mpondas, Malawi." The goal of the exhibition was to portray both the vulnerability and resiliency of grandpar-

ents who are forced to provide for children who have lost one or both parents in a community dev-astated by HIV/AIDS. Finally, the World Bank, with UNAIDS, developed an MTV documentary on the 1998 theme for World AIDS Day, entitled "Youth— a Force for Change."

Vaccine Research

The World Bank recognizes that the HIV/AIDS epidemic in many of the World Bank's client coun-tries has increased the priority for developing a pre-ventive vaccine that will be effective and afford-able in the developing world. As such, a World Bank task force is exploring the market failures lead-ing to under investment in an HIV/AIDS vaccine and examining the feasibility and optimal design of in-novative financing instruments. This would stimu-late private investment. The task force also is re-sponsible for developing new World Bank instru-ments that will increase private incentives to in-vest in related

research and development.

Further, the World Bank is part of a global col-laboration of organizations that has created and funded the International AIDS Vaccine Initiative (IAVI).

UN Commission on Human Rights

The UN Commission on Human Rights regularly considers resolutions for the protection of human rights in the context of HIV and AIDS. The resolu-tions set out guidelines nations may follow in deal-ing with the health crisis and human toll of HIV and AIDS. Resolutions also ask the UN Secretary Gen-eral to solicit input from countries, specialized agen-cies, and related governmental and non-governmen-tal organizations in order to provide a progress re-port 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.

Conclusion

The 1999 U.S. International Response to HIV/ AIDS represents the continued commitment by the United States Department of State working with other Federal agencies, our partners in the interna-tional community, non-governmental organizations, and industry to stem the spread of HIV/AIDS. Al-though this report highlights the U.S. response to the international situation, it serves to intensify U.S. resolve to maintain its leadership role in initiating needed action to forestall unnecessary human suf-fering and related socioeconomic impacts from HIV/ AIDS. The U.S. has made the battle against HIV/ AIDS a national and international priority and calls upon other governments of the world to do the same.

We have defined some of the impending prob-lems which will confront us as a result of the HIV/ AIDS pandemic. It is up to all nations to structure solutions in anticipation of their occurrence, know-ing that many unavoidable deaths will occur unre-lated to our collective actions. Unfortunately, our initial lack of knowledge about HIV/AIDS and in-ability to acknowledge and address it swiftly has given temporary advantage to the disease. Yet new tools for prevention, growing knowledge, and the collaborations of governments, non-governmental entities, industry, and international organizations are making effective interventions possible. While maintaining a strong emphasis on other prevention interventions, it is critical that concerted efforts be focused on the development of a safe and effec-tive vaccine or vaccines against the many strains of HIV. President Clinton has placed the develop-ment of an HIV vaccine on the international agenda

and efforts to garner partnerships to meet the 2007 goal will be a priority for our domestic and interna-tional research.

Undermining primary prevention, research and vaccine and drug development efforts is the prob-lem of inadequate or non-existent public health in-frastructure in many parts of the world. Address-ing this problem can be part of the solution for HIV/ AIDS and other infectious diseases. Inadequate national and international political commitment to fully address HIV/AIDS around the world has con-tributed to the escalation of the global pandemic that now threatens the health and security of every nation. Any weak link in the global health chain, which binds the nations of the world, weakens us all. We all benefit from enhancing public health infrastructures around the globe. The United States and the international community must strengthen partnerships with all entities that can bring needed resources and expertise to expedite improvement.

The magnitude of the worldwide HIV/AIDS pan-demic calls for strong political commitment at the highest levels of government and collaborative sup-port from the full range of in-country technical ex-pertise and the greater international community. This multi-partite approach can leverage the vital resources to effectively bring practical solutions to the HIV/ AIDS epidemic. Stemming the continued global spread of HIV/AIDS requires developing and industrialized nations, international organizations, the pharmaceutical industry, and non-governmen-tal organizations to work effectively together for the sake of all concerned.

Secretary for

Secretary

Appendix A

U.S. Government Contact List for International HIV/AIDS Issues

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Appendix B

List of Acronyms

AFMIC	Armed Forces Medical Intelligence Center
AIDS	Acquired Immune Deficiency Syndrome
AIDSCAP	AIDS Control and Prevention Project
ANE	Asia/Near East Bureau (USAID)
ATP	Advanced Technology Program
AVRC	AIDS Vaccine Research Committee
AZT	Antiviral Therapy
BCI	Behavioral Change Intervention
CAPS	Center for AIDS Prevention Studies
CBO	Community-based Organization
CDC	Centers for Disease Control and Prevention
CSM	Condom Social Marketing
DFID	Department for International Development, United Kingdom
DHAP/IRS	Division of HIV/AIDS Prevention-Intervention Research and Support (CDC)
ENI	Eastern Europe/Newly Independent States Bureau (USAID)
EU	European Union
FDA	Food and Drug Administration
FIC	Fogarty International Center (NIH)
G–7	Group of Seven
G–8	Group of Eight
HIV	Human Immunodeficiency Virus
IAVI	International AIDS Vaccine Initiative
ICH	International Council for Harmonization
ICRW	International Center for Research on Women
IDA	International Development Association
IDU	Intravenous Drug User
IO	International Organization
HCFA	Health Care Financing Administration
HRSA	Health Care Resources Administra-

DHAP/SE	Division of HIV/AIDS Prevention - Surveillance & Epidemiology (CDC)
DHHS	Department of Health and Human Services
DOC	U.S. Department of Commerce
DOD	U.S. Department of Defense
DOJ	U.S. Department of Justice
DOS	U.S. Department of State
DRL	Bureau of Democracy, Human Rights and Labor (State)
	tion
LAC	Latin America/Caribbean Bureau (USAID)
MTCT	Mother-to-child Transmission
N–9	Non-Oxynol–9
NCHSTP	National Center for HIV, STD and TB Prevention (CDC)
NCI	National Cancer Institute (NIH)
NCIH	National Council on International Health

NCRR	National Center for Research Risks (NIH)
NGO	Non-governmental Organization
NHLBI	National Heart, Lung and Blood Institute (NIH)
NIAID	National Institute of Allergy and Infectious Diseases (NIH)
NIC	National Intelligence Council
NICHD	National Institute of Child Health and Human Development (NIH)
NIDCR	National Institute of Dental and Craniofacial Research (NIH)
NIDA	National Institute on Drug Abuse (NIH)
NIGMS	National Institute of General Medical Sciences (NIH)
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
PHS	U.S. Public Health Service
PLWHA	People Living with HIV/AIDS
PRM	Bureau of Population, Refugees and Migration (State)
R&D	Research and development
SO	Strategic Objective
STD	Sexually Transmitted Disease
STI	Sexually Transmitted Infection
TB	Tuberculosis
TIR	Targeted Intervention Research
UNAIDS	United Nations Joint Programme on AIDS
UNDP	United Nations Development Programme
UNESCO	United Nations Educational, Scientific and Cultural Organizations
UNFPA	United Nations Population Fund

	(NIH)
NINDS	National Institute of Neurological Disorders and Stroke (NIH)
NOAA	National Oceanic and Atmospheric Administration
OAR	Office of AIDS Research (NIH)
OES/E/EID	Office of Emerging Infectious Diseases and HIV/AIDS, Bureau of Oceans and International Environmental and Scientific Affairs (State)
OHAP	Office of HIV/AIDS Policy (DHHS)
OHCHR	Office of the High Commission for Human Rights
ONAP	Office of National AIDS Policy
PHN	Population, Health and Nutrition (USAID)
PhRMA	Pharmaceutical Research Manufacturers of America
UNICEF	United Nations International Children's Emergency Fund
USAID	U.S. Agency for International Development
USG	United States Government
USIA	U.S. Information Agency
USIS	U.S. Information Service
VCT	Voluntary HIV Counseling and Testing
VOA	Voice of America
WHAM	Women's Health Advocates for Microbicides
WHO	World Health Organization
WRAIR	Walter Reed Army Institute of Research