

December 1, 2000

CLINTON ADMINISTRATION RECORD ON HIV/AIDS

Overview: *An estimated 800,000 to 900,000 Americans are believed to be living with HIV, the virus that causes AIDS. Since the epidemic began in 1981, more than 700,000 Americans have been diagnosed with AIDS, and more than 420,000 men, women, and children have lost their lives to this disease.*

The Clinton Administration has responded aggressively to the significant threat posed by HIV/AIDS with increased attention to research, prevention, and treatment. Overall funding for AIDS-related programs within HHS has increased by 150 percent under the Clinton Administration, with funding for HIV/AIDS care under the Health Resources and Services Administration's Ryan White CARE Act increasing by 358 percent. The proposed FY 2001 budget includes \$9.2 billion in total HIV/AIDS funding within HHS.

At the same time, the Administration has sharpened the focus of its AIDS programs, establishing a new Office of National AIDS Policy at the White House, and signed legislation creating a permanent Office of AIDS Research at the National Institutes of Health (NIH). The Administration also convened the first-ever White House Conference on HIV and AIDS in December 1995, released the first National AIDS Strategy in December 1996, and prepared the first federal biomedical research plan for HIV/AIDS in 1997. In May 1997, President Clinton announced a comprehensive AIDS vaccine research initiative designed to lead to the development of an AIDS vaccine within 10 years, and in 1998, the Food and Drug Administration approved the nation's first large-scale trial of an AIDS prevention vaccine. In addition, the President announced the Millennium Vaccine Initiative on May 31, 2000 which calls for sharp increases in vaccine research at the National Institutes of Health, new investments for the purchase and delivery of existing vaccines and a substantial tax credit for the private sector to speed the development of new vaccines.

Today, HIV research efforts are making real inroads. New drugs are providing vast improvements in the treatment of HIV and AIDS, and new treatment guidelines released by HHS are giving health professionals much needed guidance to help standardize the care of individuals living with HIV/AIDS. As a result, the National Center for Health Statistics announced on October 5, 1999, that HIV/AIDS mortality has declined more than 70 percent since 1995, and that AIDS cases are no longer among the top 15 causes of death in national statistics, a fall from eighth place in 1996. Overall, the age-adjusted death rate from HIV infection is the lowest since 1987. This reflects the impact of powerful new anti-HIV drugs, and increased access to health care for those living with HIV/AIDS. However, transmission of the disease continues, and effective prevention efforts are still crucially important, as is the search for a vaccine.

The trends in AIDS death rates are uneven across racial and ethnic groups. In October 1998,

President Clinton declared HIV/AIDS to be a severe and ongoing health crisis in racial and ethnic minority communities and announced a comprehensive new initiative in collaboration with the Congressional Black Caucus to improve the nation's effectiveness in preventing and treating HIV/AIDS in the African-American, Hispanic and other minority communities. Through the Minority AIDS Initiative, targeted funding and technical assistance helps minority organizations and coalitions become stable, ongoing sources of HIV prevention, HIV care and treatment services, and substance abuse and mental health services within their communities. In June 1999, the Administration also announced that Crisis Response Teams would provide special technical assistance to 11 U.S. metropolitan areas to combat the spread of HIV/AIDS among racial and ethnic minority populations. The Crisis Response Teams are meeting with local officials, public health personnel and community-based organizations that work with racial/ethnic minority persons living with HIV/AIDS to help them develop targeted strategies to curb the rapid spread of HIV/AIDS among minority populations in their communities and to encourage those affected to enter care.

HHS Spending on HIV/AIDS

Under the Clinton Administration, discretionary spending for HIV/AIDS research, prevention, and treatment has increased dramatically. Altogether, discretionary AIDS-related spending by HHS in FY 2000 totaled \$4.6 billion, up from \$2.1 billion in FY 1993. In addition, at least \$3.9 billion is estimated to have been expended in FY 2000 for AIDS care under Medicaid and Medicare, up from \$1.6 billion in FY 1993. It is estimated that more than 50 percent of Americans living with AIDS rely on Medicaid for their health coverage.

The President's FY 2001 budget proposes an increase of \$66 million, for a total of \$795 million, for programs focused in two areas -- domestic HIV prevention and global AIDS. This increase in funding for HIV activities at the Centers for Disease Control and Prevention (CDC) will be used to encourage individuals at risk to avoid behaviors that can result in the transmission of the disease. Funding for CDC HIV prevention efforts in the U.S. have increased by \$297 million, or 60 percent during the Clinton Administration. Internationally, the President's budget includes \$61 million for CDC, an increase of \$26 million, or 74 percent, to continue efforts to prevent the spread of HIV in developing nations. It is estimated that currently there are 22 million adults and 1 million children living with HIV/AIDS in the sub-Saharan region of Africa, and 34 million persons living with HIV infection globally.

The FY 2001 budget will also invest an additional \$125 million, for a total of \$1.72 billion, in the Ryan White CARE Act Program, an increase of almost 8 percent over last year's funding level, to provide primary medical care and other crucial support services for people living with HIV and AIDS among increasingly vulnerable populations. This increase will allow an additional 2,900 persons to receive drug therapy through the AIDS Drug Assistance Program (ADAP). These drugs have helped to decrease the progression of HIV to AIDS as well as to improve the quality of life for people living with HIV/AIDS. During the Clinton Administration, the funding for the Ryan White CARE Act has increased 358 percent from \$348 million in FY 1993 to \$1.595 billion in FY 2000.

The FY 2001 budget also requests a total of \$2.1 billion for AIDS-related research at the NIH. This is an increase of \$105 million, or 5.2 percent over the FY 2000 level. It represents a 97 percent increase in funding for NIH AIDS-related research since FY 1993.

Further, the FY 2001 budget requests \$128.4 million for the Substance Abuse and Mental Health Services Administration (SAMHSA) to address substance abuse and mental illness specifically as they relate to HIV/AIDS. This is an increase of \$14.8 million, or 13 percent, over the FY 2000 level. The majority of this funding will be used for the HIV set-aside of the Substance Abuse Block Grant and Targeted Capacity Expansion programs for substance abuse treatment, prevention, and HIV/AIDS services focused on building infrastructure in racial and ethnic minority communities highly impacted by the HIV/AIDS epidemic.

HHS Accomplishments on HIV/AIDS

Stepping Up HIV Prevention

HIV prevention efforts in the United States have significantly reduced the incidence of HIV infections. Prevention initiatives have helped slow the rate of new HIV infections in the U.S. from more than 150,000 per year in the late 1980's to approximately 40,000 per year today. Specifically, the number of U.S. infants who acquire AIDS from mother-to-child transmission dropped by 75 percent from 1992 to 1998. In 1996, for the first time in the history of the AIDS epidemic, the number of Americans diagnosed with AIDS, a late manifestation of HIV disease, also declined. AIDS deaths dropped 42 percent between 1996 and 1997 and the rate of decline was 20 percent from 1997 to 1998.

HIV Prevention – Helping Communities

CDC provides local communities with extensive financial support and technical guidance to implement effective strategies to prevent HIV transmission. Each year, CDC delivers more than \$450 million in financial support for HIV prevention activities to 65 state, territorial and local health departments, multiple national and regional minority organizations, and more than 100 local community-based organizations. Altogether, this assistance accounts for 76 percent of CDC's spending on HIV prevention for high-risk communities.

In 1993, CDC revised the way funds were distributed from health departments, adopting "community planning" to improve the effectiveness of its prevention funding to local communities. Under this approach, special committees, including health department and community representatives, collaborate to determine local priorities for HIV prevention based on data on the local epidemic, existing community resources, and science on the most effective prevention interventions.

In addition to community-based prevention programs, CDC's grants to health departments also support the public HIV counseling and testing programs that serve as a gateway to HIV

prevention and treatment for both at-risk and infected individuals. CDC also funds and provides technical assistance to state and city education departments throughout the country to help them provide HIV prevention education for young people.

Publication of *Compendium of HIV Prevention Interventions with Evidence of Effectiveness* - CDC developed the *Compendium of HIV Prevention Interventions with Evidence of Effectiveness* to help prevention service providers, planners, and others to implement science-based interventions that work. The *Compendium* provides state-of-the-science information about interventions with evidence of reducing sex- and/or drug-related risks, and the rate of HIV/STD infections. These interventions have been effective with a variety of populations, including heterosexual men and women, high-risk youth, incarcerated populations, injection drug users, and men who have sex with men. All interventions included in the *Compendium* came from behavioral or social studies that had both intervention and control or comparison groups and had positive results for behavioral or health outcomes.

Implementation of *Know Now!* Campaign - Of the estimated 800,000- 900,000 people living with HIV in the United States, as many as one-third don't know it. Experience with, and formal evaluations of previous public health social marketing and communication campaigns consistently demonstrate the value of communication approaches in increasing awareness and promoting specific behaviors, such as HIV testing. In addition, campaigns can play a significant role in addressing HIV related stigma. For these reasons, CDC has developed *Know Now!*, a social marketing campaign that will utilize various communication channels in multiple targeted efforts to reach those at greatest risk of HIV with HIV testing and referral messages.

Surveillance CDC works with state and local health departments to track the number of HIV and AIDS cases in different areas. In December 1999, after extensive work with state health departments and community HIV/AIDS organizations, CDC released guidelines to assist states in designing and implementing effective HIV surveillance systems. These guidelines include specific standards for both quality and confidentiality, reflecting CDC's responsibility to balance the need for better data with legitimate concerns about confidentiality and security. They also stress the continued importance of anonymous testing as an essential component of any surveillance system.

Collaboration for Incarcerated Populations - The prevalence rates for AIDS are significantly higher among inmates and releasees, especially women and adolescents, than in the total U.S. population. Of the estimated 229,000 persons living with AIDS in 1996, almost 39,000 (17%) passed through a correctional facility that year. The confirmed AIDS case rate among prisoners (0.51%) was more than 5 times the US rate. Racial and ethnic minorities are disproportionately represented in incarcerated populations, and approximately 80% of prisoners have a history of substance abuse, including alcohol use. To begin to address these issues, in FY 99, CDC and the Health Resource and Services Administration (HRSA) jointly developed and funded a corrections demonstration project with 7 State health departments to design and implement innovative HIV prevention, care, and continuity of care programs for inmates in jails, prisons, or juvenile detention centers. Projects were also funded to provide technical support for these

demonstrations and help highly impacted communities develop capacity to address HIV/AIDS prevention in correctional settings.

Progress With Associated Conditions

Syphilis infections increase the risk of HIV transmission among adults at least 3 to 5-fold. Since 1990, syphilis rates have declined 88 percent. In 1999, CDC launched the *National Plan to Eliminate Syphilis in the United States* and initiated new efforts targeting 33 States and cities with either a heavy burden of syphilis or a high potential for re-emergence of syphilis. CDC has also increased tuberculosis (TB) prevention and control activities and subsequently reported a 34 percent decrease in new TB cases in the U.S. from 1992 to 1999. Persons with weakened immune systems, especially those infected with HIV, are at higher risk of developing active TB once infected with TB.

New Testing Technologies

CDC developed a cutting-edge laboratory tool, the detuned assay, which allows identification of recent HIV infections. This new technology has enhanced our ability to characterize the epidemic and allows us to ensure prevention programs are directed to those most in need.

Engaging States in Prevention

The Substance Abuse and Mental Health Services Administration (SAMHSA) has encouraged state and community efforts to link and coordinate substance abuse treatment, mental health services, and HIV/AIDS prevention and treatment efforts. SAMHSA surveys, conducted with the three national state mental health, alcohol and substance abuse organizations identified gaps in service coordination and ways to enhance service integration at the State level. These data are informing States on ways to bridge the three communities to improve outcomes for people with or at risk for substance abuse, mental illness and/or HIV/AIDS.

Reducing Risk-Taking Behavior

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Mental Health Services funds Project Shield, the HIV/AIDS High-Risk Behavior Prevention/Intervention Model for Adolescents/Young Adults and Women Program. Project Shield is a four-year, multi-site effort which is developing, implementing and evaluating a community-focused intervention to reduce high-risk behaviors among individuals at high risk for HIV infection.

Syringe and Needle Exchange Scientific research supported by NIH has shown that needle exchange programs can be an effective component of a comprehensive strategy to prevent HIV and other bloodborne infectious diseases in communities that choose to include them, and do not encourage the use of illegal drugs. The Clinton Administration has communicated what has been learned from the science so that communities can construct the most successful programs possible to reduce the transmission of HIV, while not encouraging illegal drug use.

Substance Abuse Treatment Services to Reduce HIV/AIDS Risk More than one third of all AIDS cases are directly or indirectly attributable to substance abuse. Current evidence indicates

that substance abuse treatment greatly reduces risk behaviors associated with the transmission of HIV. Beginning in 1994, SAMHSA's Center for Substance Abuse Treatment (CSAT) has supported the AIDS Outreach Program (now called the Community-based Substance Abuse and HIV/AIDS Outreach Program) targeting high risk injecting drug users, designed to both increase the number of clients entering treatment and to reduce their risk for contracting HIV and other infectious diseases. In FY 1999, SAMHSA initiated a Targeted Capacity Expansion Program for Substance Abuse Treatment and HIV/AIDS Services in racial and ethnic communities with high AIDS case rates, expanding this effort to include a second group of grantees in FY 2000 with a total investment of \$32 million. In addition, SAMHSA's Substance Abuse Prevention and Treatment Block Grant HIV set-aside provides funds for HIV counseling and testing in states with high AIDS case rates.

Increasing Access to Care and Treatment

Ryan White CARE Act The Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau administers the Ryan White CARE (Comprehensive AIDS Resources Emergency) Act, first enacted in 1990 to provide primary care and supportive services for low-income, uninsured and underinsured individuals and families affected by HIV/AIDS. Since FY 1991, \$8.0 billion has been appropriated for CARE Act programs, with a 358 percent increase in funding during the Clinton Administration FY 1993-FY 2000. In 2000, the CARE Act is serving some 500,000 people, providing care for individuals affected by HIV/AIDS in every state, the District of Columbia, Puerto Rico, Guam and the Virgin Islands. The CARE Act also funds services to individuals in 51 major metropolitan areas hardest hit by the AIDS epidemic. More than 2,500 organizations are now receiving funding to provide care to individuals living with HIV disease in their communities.

The CARE Act has saved many lives by speeding delivery of new HIV/AIDS treatments to the many Americans who otherwise lacked access to these therapies and quality health care. In 1995, AIDS was the leading cause of death for Americans between the ages of 25 and 44. In 1996, highly effective new HIV/AIDS medications were introduced and the AIDS Drug Assistance Program (ADAP) began to assist the states in paying for the expensive new medications. The benefits of these therapies were seen in 1997, when a sharp drop in the AIDS mortality rate was reported. The President's FY 2001 budget proposal includes \$554 million for the ADAP program, which serves thousands of Americans who would otherwise go without life-sustaining HIV/AIDS medications.

On May 26, 1996, and again on October 20, 2000, President Clinton signed legislation reauthorizing the Ryan White CARE Act for another five years. In addition to the health care and pharmaceutical assistance provided through states and municipalities described above, the CARE Act supports 260 programs that provide community-based HIV early intervention services, including HIV testing and counseling, and treatment for HIV disease. Over 700,000 AIDS care providers have received state-of-the-art education and training through the AIDS Education and Training Centers Program.

By widely distributing the results of the 076 AZT Perinatal Transmission Study to CARE Act providers, HRSA has facilitated a dramatic nationwide reduction of mother-to-infant transmission of HIV, with the incidence of mother-to-child transmission dropping to nearly zero at many treatment centers funded by the CARE Act. Through the Special Projects of National Significance Program, more than 200 research and demonstration projects nationwide have been supported to develop and evaluate new and more effective ways to delivery HIV/AIDS care and services to hard-to-reach populations.

Mental Health Services Attention to the mental health needs of persons living with HIV, or those with high risk behaviors for HIV infection, is critical to HIV prevention and treatment efforts. SAMHSA's Center for Mental Health Services (CMHS) funded the Mental Health Services Demonstration Program from FY 1994 - FY 1998 to provide mental health services to people living with or affected by HIV, generate new knowledge about the role of mental health services in primary medical treatment for people living with or affected by HIV, and to identify characteristics of clients served and the types of services utilized. The CMHS now sponsors a collaborative effort with CSAT, HRSA and three NIH Institutes, known as the HIV Cost Study Grant Program, to determine the effectiveness of treatment adherence models, health outcomes, and costs associated with the provision of integrated mental health, substance abuse, and HIV/AIDS primary care services for people living with HIV/AIDS who have both a mental disorder and a substance abuse disorder.

Treatment Guidelines HHS regularly updates and releases clinical guidelines for treating HIV disease using antiretroviral drugs among adults and adolescents, women during pregnancy, and children and infants, and guidelines for the reduction of mother-to-child transmission of HIV. The guidelines, developed by panels of expert AIDS clinicians and researchers, reflect the current state of knowledge about HIV disease and antiretroviral drugs, and help to improve and standardize the quality of care for HIV-infected persons in the United States.

Maine Medicaid Demonstration Plan On February 24, 2000, HHS approved Maine's Medicaid demonstration plan to launch an early intervention and treatment program for individuals in need who are HIV-positive but do not yet have AIDS and who are not already eligible for Medicaid. Maine is the first state to offer a plan to enroll low-income HIV-positive individuals in the Medicaid program before they become disabled or impoverished. Recent research has shown that early intervention with AIDS-fighting drugs, including antiretroviral therapies, can slow the progress of the disease and increase life expectancy for many HIV-positive individuals. However, many people with HIV generally do not qualify for Medicaid -- the state/federal partnership that provides health insurance to low-income young, aged, blind and disabled Americans -- until they are considered disabled. This demonstration program will make drug therapies and treatment services available to HIV-positive people earlier in the course of their disease, helping them live longer, healthier lives.

Ticket to Work and Work Incentives Improvement Act of 1999 (TWWIIA) On October 25, 1999 HHS announced two new initiatives to enable people with disabilities to become and stay competitively employed. One of the grant programs will fund cutting-edge demonstrations

that enable people with chronic, disabling conditions to get medical benefits without having to quit their jobs to obtain needed care. The other will assist states to increase services and supports to those who work, as well as help others return to work without the fear of losing health coverage. Both the grants and the demonstrations help advance the goals of the Ticket to Work and Work Incentives Improvement Act of 1999, a law passed by the Congress and strongly supported by the Clinton Administration to encourage people with disabilities to work without fear of losing their Medicare, Medicaid or similar health benefits. For example, Mississippi is using its \$27.5 million grant award with additional state funds to cover 500 persons with a diagnosis of HIV/AIDS, who work or who plan to return to work. The state's program will mirror the full Medicaid benefits and services. The project is being implemented in nine counties in the Mississippi Delta where there is a relatively high rate of HIV/AIDS and limited health care resources for people with HIV/AIDS.

Accelerating AIDS Drug Approvals Since 1993, the Food and Drug Administration (FDA) has approved eleven AIDS drugs and twenty two new drugs for AIDS-related conditions, and accelerated approval to record times. Included in those approvals were the new class of drugs known as protease inhibitors, which have proven to be dramatically effective in the treatment of HIV disease. In March 1997 the FDA approved the first protease inhibitor with labeling for use in children. Also in 1997, the President signed into law the FDA Modernization Act that included important measures to modernize and streamline the regulation of biological products; increase patient access to experimental drugs and medical devices; and accelerate review of important new medications. These reforms build on the Administration's reinventing government initiatives which led U.S. drug approvals to be as fast, or faster than any other industrialized nation. Average drug approval times have dropped from almost three years at the beginning of the Clinton Administration to just over one year.

Ricky Ray Hemophilia Relief Fund In August 2000, HHS began notifying the first eligible families approved to receive payments from the Ricky Ray Hemophilia Relief Fund. The fund was authorized by Congress in 1998 to provide compensation payments of \$100,000 to individuals with blood-clotting disorders, such as hemophilia, who contracted HIV from contaminated anti-hemophilic blood products between July 1, 1982 and Dec. 31, 1987. Spouses and children who contracted HIV from these individuals and certain survivors may also be eligible. In 1999, the Clinton Administration worked with Congress to achieve a \$75 million appropriation for FY 2000.

Accelerating Research on HIV/AIDS

The National Institutes of Health (NIH) represents the largest single public investment in AIDS research in the world. NIH funding for AIDS research has nearly doubled during the Clinton Administration, increasing from \$1.1 billion in FY 93 to \$2.3 billion in FY 2000. The NIH supports a comprehensive program of basic, clinical, and behavioral research on HIV infection and its associated opportunistic infections and malignancies, including a growing portfolio of research conducted in collaboration with investigators in developing countries. This research

aims to better understand the basic biology of HIV, develop effective therapies to treat it, and design interventions to prevent new infections from occurring.

Office of AIDS Research In one of his first acts in office, President Clinton signed the National Institutes of Health Revitalization Act of 1993, placing full responsibility for planning, budgeting and evaluation of the AIDS research program at NIH in the Office of AIDS Research (OAR). Since 1993, the OAR has developed an annual comprehensive AIDS research plan and budget, based on the most compelling scientific priorities that will lead to better therapies and prevention for HIV infection and AIDS. These priorities are determined through a unique and collaborative process involving the 25 NIH Institutes and Centers and non-government experts from academia and industry, with the full participation of AIDS community representatives.

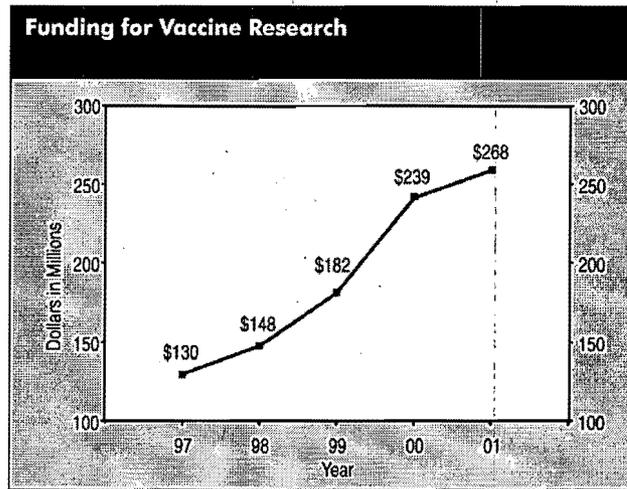
NIH-Wide Evaluation of AIDS Research The OAR initiated a major evaluation of the entire trans-NIH program in 1996, to assure that the most promising areas of science were being supported, that critical scientific questions were being addressed, and that the most effective use was being made of federal AIDS research resources. The review was of unprecedented scope and breadth across all the NIH Institutes and Centers. The Levine Report, as it was known, provided a blueprint for restructuring the NIH AIDS science program to streamline research, strengthen high-quality programs, eliminate inadequate programs, and ensure that the American people reap the full benefits of their substantial investment in AIDS research.

Prevention Research

- o ***AIDS Vaccine Initiative*** A safe and effective HIV preventive vaccine is essential for the global control of the AIDS pandemic. NIH has the largest single AIDS vaccine research program in the world. On May 18, 1997, President Clinton challenged the nation to commit itself to the goal of developing an AIDS vaccine within the next ten years. The President also announced a number of important initiatives to help fill this commitment, including high-level international collaboration, a dedicated research center for AIDS vaccine research at NIH, and outreach to scientists, pharmaceutical companies, and patient advocates to maximize the involvement of both private and public sectors in the development of an AIDS vaccine. As of May 2000, NIAID-supported researchers had evaluated 28 vaccine candidates and 12 adjuvants (substances incorporated into a vaccine that boost specific immune responses to vaccine) in more than 3,400 volunteers in Phase I/II clinical trials. On June 3, 1998, the FDA granted permission to VaxGen Inc. for the nation's first phase III clinical trial for an AIDS prevention vaccine. The trial of the vaccine, called AIDSVAX, will include at least 5,000 volunteers from the U.S., Canada and Europe and will last up to five years. A separate Phase III trial of AIDSVAX in Thailand will enroll 2,500 volunteers. In February 1999, NIH-supported investigators initiated the first AIDS vaccine trial in Africa.

CDC will play an important role in the AIDSVAX trials in the U.S., and continue to provide technical support to the Thailand trials. CDC's role in HIV vaccine research is to work to determine the behavioral approaches necessary to maintain prevention progress

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Consistent with the President's challenge, NIH funding for HIV vaccine research increased by more than 100 percent between FY 1997 and FY 2000, resulting in the award of new grants to foster innovative research on HIV vaccines, including vaccine design and development, and the invigoration and reorganization of the NIH vaccine clinical trials effort. Construction of the new intramural Vaccine Research Center is complete, and world-renown scientists have been recruited. The AIDS Vaccine Research Committee, chaired by Nobel laureate Dr. David Baltimore, continues to provide critical advice on all aspects of the NIH AIDS vaccine development program. To establish a global infrastructure for HIV vaccine trials, the NIAID has established a new comprehensive, clinically-based research and development network, the HIV Vaccine Trials Network (HVTN) with an expanded, integrated clinical research agenda that has both domestic and international components.

- o **Topical Microbicides Research** The vulnerability of women to acquiring HIV infection demands the development of effective and acceptable female-controlled chemical and physical barrier methods, such as topical microbicides, to reduce HIV transmission. To enhance and stimulate research in this area, the OAR co-sponsored the first international conference devoted to all aspects of microbicide research and development, including more than 600 participants from 45 nations. NIH is supporting Phase I, Phase II, and Phase III trials of various topical microbicides. NIH also supports behavioral and social research on the acceptability and use of microbicides among different populations. NIH has recently completed a strategic plan for microbicide research.
- o **Mother-to-Child Transmission** In the United States, regimens of antiretroviral drugs resulting from NIH-supported research have dramatically reduced HIV transmission from

infected mother to infant. NIH researchers first demonstrated the benefits of zidovudine (AZT) therapy for preventing mother-to-child transmission of HIV in 1994. However, the complexity of administration and high cost make this option impractical for much of the developing world.

In 1998, researchers from CDC and the Ministry of Public Health in Thailand 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 in non breast-feeding settings and is safe for use in the developing world. Studies in west Africa found that using this or a similar short course AZT regimen resulted in about a one-third reduction in the risk of perinatal transmission among breast-feeding women. Another important study in Africa using a AZT/3TC combination found a similar reduction in risk.

Most recently, in the summer of 1999, results from a NIH-supported clinical trial in Uganda showed that use of a single dose of another antiretroviral drug, Nevirapine, given to the mother at the onset of labor and another dose given to her baby reduced the risk of transmission by about 50% when compared to a very short course of AZT given only at labor and for one week to the infant.

The UNICEF/WHO/UNAIDS, with technical assistance from CDC, are now working with public health agencies around the globe to help make these short-course regimens available for as many women as possible and to continue to identify practical solutions for reducing the toll of the HIV epidemic on women and children worldwide.

Behavioral and Social Science Research

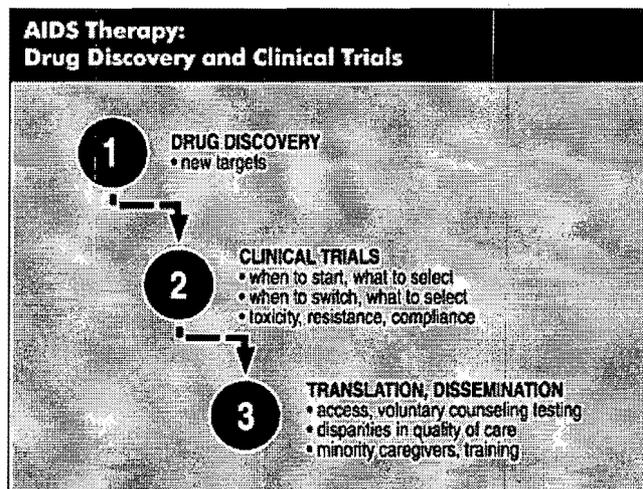
Both the CDC and the NIH conduct prevention research to assure that prevention efforts are based on sound behavioral and biomedical science. Studies have demonstrated that behavioral change can successfully prevent or reduce the spread of HIV infection in both domestic and international settings. Prevention programs resulting from such studies have reduced the risk of transmission in many communities and subgroups. NIH supports research to further understanding of how to change the behaviors that lead to HIV transmission -- including preventing their initiation -- and how to maintain protective behaviors once they are adopted in all populations at risk.

- CDC's research focuses on identifying the factors that influence risky behavior and transmission in different communities, and evaluating various approaches to reducing risk. For example, CDC researchers have recently examined the important role parental communication can play in reducing risk behavior among young African-American and Latino youth. Research also has focused on developing and evaluating new approaches to counseling and testing for women at high risk. Other behavioral research initiatives include examining the effectiveness of peer interventions for gay men, street outreach for injection drug users, community-level interventions for young Latino men who have sex with men, HIV education for youth, and faith-based programs for African-American communities.

- In June, 1998, the National Institute of Mental Health (NIMH) at the NIH announced that the NIMH Multisite HIV Prevention Trial found that even among persons considered hardest to reach, educational sessions that motivate and offer specific strategies to reduce high-risk sexual behaviors can cut those behaviors in half. The National Institute on Drug Abuse (NIDA) at the NIH has also conducted research on understanding the trends in HIV transmission among drug users and their sexual partners, as well as ways to reduce viral spread. As a result, innovative models of outreach have been developed to help stem the spread of HIV among this at-risk population.

Treatment Research

- o Advances in understanding HIV and how it causes AIDS have helped scientists to develop an effective arsenal of drugs that, when used in combination, can help many people with HIV disease live longer and healthier lives. These achievements highlight the pivotal contributions of both NIH-supported basic research and NIH collaborations with academia and industry to develop effective anti-HIV therapies. For example, NIH-supported research was pivotal to discovering and defining the importance of the HIV protease enzyme. NIH scientists helped determine the three-dimensional structure of HIV protease, a crucial step in designing drugs that block the enzyme. NIH also supported research on screening efforts by simple rapid tests to measure the activity of the protease. These accomplishments for NIH with the protease set the stage for collaboration with the pharmaceutical industry in developing the new class of anti-HIV drugs known as protease inhibitors. NIH worked closely with industry as they designed, produced, and clinically tested protease inhibitors. This collaboration helped speed product development.



- o NIH-supported investigators conclusively demonstrated that triple-drug combination therapy with a protease inhibitor and two other anti-HIV drugs was more effective than one- or two- drug regimens for long-term suppression of HIV. Basic researchers at NIH laboratories have helped explain why HIV can rebound in patients who discontinue combination therapy, and continue to open new avenues for drug development.
- o NIH clinical trials continue to study new anti-retroviral drugs and combinations of therapies to prevent disease progression and HIV-associated opportunistic infections and malignancies. NIH has also implemented guidelines requiring the inclusion of women and minorities in clinical trials.

Basic Research

- o Of paramount importance is maintaining a strong commitment to basic research. Tremendous progress has been made through groundbreaking research on basic HIV biology and AIDS pathogenesis, revolutionizing the design of drugs, the methodologies for diagnosis, and the monitoring for efficacy of antiviral therapies. Recently, NIH researchers identified a new genetic risk factor for HIV infection. A recently published study shows that a tiny variation in an immune system gene called RANTES can be a double-edged sword, substantially increasing one's susceptibility to HIV infection, but subsequently slowing down the disease's progress.

Women and AIDS

- o The NIH supports a number of epidemiologic cohort studies specifically focused on women and adolescents. These studies are designed to elucidate the pathogenic mechanisms more commonly observed in women, children and adolescents with HIV infection, and represent an important scientific link between epidemiology and basic research. Women also experience certain clinical manifestations of HIV infection that are unique and more prevalent than in men. The Women's Interagency HIV Study (WIHS), a major study conducted in collaboration with other PHS agencies, is identifying the nature and rate of HIV disease progression in women, characterizing clinical manifestations of HIV important to women, assessing the effects of therapeutic regimens, and identifying sociocultural and health care access factors that affect disease outcomes in women.

Eliminating Racial and Ethnic Disparities in HIV/AIDS

Although racial and ethnic minority groups account for only about 25 percent of the U.S. population, they account for more than 50 percent of all AIDS cases. While overall AIDS deaths are down, AIDS remained the leading killer of African-Americans ages 25-44 in 1998. In October 1998, President Clinton declared HIV/AIDS to be a severe and ongoing health crisis in racial and ethnic minority communities, and announced a comprehensive new initiative in collaboration with the Congressional Black Caucus to improve the nation's effectiveness in preventing and treating HIV/AIDS in African-American, Hispanic, and other minority communities.

In FY 99, \$165.7 million in new targeted funding was provided for the Minority AIDS Initiative, increasing to \$250.9 million in FY 2000. The HHS Crisis Response Team initiative has also provided intensive technical assistance to large metropolitan areas with high numbers of HIV/AIDS cases among racial and ethnic minority populations.

In October 2000, CDC awarded \$19 million to community coalitions in 15 states to help address racial and ethnic disparities in health in the United States. In addition, NIH contributed \$5 million dollars, for a total of \$24 million, and has pledged to sustain that level of support for 4 additional years. This is the second year that CDC has awarded the funds as part of its "Racial and Ethnic Approaches to Community Health (REACH 2010)" initiative, a demonstration project that targets HIV/AIDS and five other health priority areas.

In addition to appropriated funds directly targeted to HIV prevention, care and treatment, and substance abuse and mental health prevention and treatment in minority communities, the FY 1999 and FY 2000 Public Health and Social Services Emergency Fund provided \$50 million to address high priority HIV prevention and treatment needs of minority communities heavily impacted by HIV/AIDS. These resources were directed across three broad categories: technical assistance and infrastructure support; increasing access to prevention and care; and building stronger linkages to address the needs of specific populations. The Office of Minority Health and the Office of HIV/AIDS Policy have taken an active role in increasing the availability and effectiveness of technical assistance and capacity development initiatives to strengthen the community-based response to HIV/AIDS in minority communities. The Office of HIV/AIDS Policy has also conducted the Surgeon General's Leadership Campaign on AIDS to raise awareness and involvement of minority leaders and decrease the stigma associated with HIV/AIDS.

Research

- X Research to address the disproportionate impact of the HIV/AIDS epidemic on U.S. racial and ethnic minority communities continues to be a high priority. The OAR at NIH has established the Ad Hoc Working Group on Minority Research to advise NIH on the scientific priorities, and NIH is directing increased resources towards new interventions that will have the greatest impact on these groups. The NIH is also making significant

investments to improve research infrastructure and training opportunities for minorities. The NIH has provided additional funds to projects aimed at: increasing the number of minority investigators conducting behavioral and clinical research; increasing outreach education programs targeting minority physicians and at-risk populations; targeting the links between substance abuse, sexual behaviors and HIV infection; and expanding the portfolio of population-based research. The Training and Career Development Workshops for racial and ethnic minority investigators provide minority investigators with an opportunity to learn about available NIH funding mechanisms and to meet and network with senior minority investigators who receive significant levels of NIH funding.

- X The NIH has implemented a series of guidelines, policies, and programs to ensure that HIV-infected individuals from the most at-risk populations for HIV/AIDS are enrolled and accrued into federally-sponsored AIDS studies. In 1994, the NIH implemented revised Guidelines on the Inclusion of Women and Minorities in Clinical Research, requiring applicants to address the appropriate inclusion of women and minorities in clinical research. Applications that fail to meet these requirements, as evaluated by peer review, are barred from funding.

Care and Treatment

- X The Ryan White CARE Act is reaching minorities living with HIV disease. More than 60 percent of clients served are minority. The proportion of minority CARE Act clients mirrors the proportion of total AIDS cases that are among minorities. Minority women and children are the most heavily impacted groups; three out of five women newly diagnosed with HIV/AIDS are African-American, and one out of five is Hispanic; over 80 percent of AIDS cases among children are among racial and ethnic minorities. As part of the Minority AIDS Initiative, over 100 new planning grants have been awarded to help community-based organizations to develop primary health care services for HIV/AIDS in minority communities. The Targeted Provider Education Program has also directed new outreach efforts to minority providers of health and social services to increase their knowledge about HIV/AIDS.

Substance Abuse and Mental Health Services

- X SAMHSA has made both new and enhanced investments in substance abuse treatment services as part of the Minority AIDS Initiative, totaling \$73.6 million over the Fiscal Years 1999 and 2000. These include \$32 million for Targeted Capacity Expansion Programs for Substance Abuse Treatment and HIV/AIDS Services, \$13.5 million for Targeted Capacity Expansion for Substance Abuse Prevention and HIV Prevention, \$9.5 million for the Community-based Substance Abuse and HIV/AIDS Outreach Program, and other resources for integrated services planning grants, and developmental technical assistance for minority community-based organizations. SAMHSA has placed a special emphasis on addressing the needs of minority women around substance abuse treatment and prevention issues. In 1999, SAMHSA sponsored two policy forums focusing on

Coordination of HIV/AIDS, Substance Abuse and Mental Health Services for African American and Latina women. An interagency working group has also been established to address potential gaps in care and services for women infected and affected by HIV/AIDS.

HIV Prevention for People of Color

- The most effective prevention programs are targeted to specific needs of communities at risk for HIV transmission. CDC funding enables local community organizations to mount targeted prevention programs that are based on sound science. CDC's efforts to ensure that prevention programs are effectively directed toward those in greatest need have resulted in a substantial increase in HIV prevention funding targeted to African Americans and Latinos. The implementation of community planning has dramatically increased funds targeted to African-American and Latino communities, resulting in an increase from approximately \$17 million in 1993 to more than \$67 million in 1999. A

Additionally, recognizing the critical role of the faith community in mobilizing community leaders and reaching and serving those at risk, CDC established a collaboration with the faith community in 1987. By partnering with a small group of national faith organizations and schools of public health, CDC leverages relatively modest resources into remarkable programs for HIV prevention with communities of faith nationally.

International Efforts

Implementation of LIFE Initiative - In collaboration with USAID, HRSA, OPHS and other federal agencies, CDC has begun to work to combat the AIDS epidemic in India and 14 countries in Africa. CDC works in these countries to: (1) Provide technical assistance for primary HIV prevention activities (voluntary HIV counseling and testing, blood safety, behavior change and mother-to-child transmission); (2) Help countries develop surveillance programs to target prevention resources and assess the effects of HIV prevention interventions; and (3) Provide technical assistance for the care and treatment of opportunistic infections and STDs and for the provision of palliative care and psychosocial support to persons living with AIDS and their families.

International Research Priorities The exploding nature of the HIV pandemic globally, particularly in the poorest parts of the world, has escalated the urgency of improved intervention strategies. The NIH supports a growing portfolio of research conducted in collaboration with investigators in developing countries. For example, NIH collaborates with UNAIDS, host country governments, and in-country scientists for vaccine development and in preparation for efficacy trials. NIH-sponsored programs target studies on factors related to HIV transmission and the pathogenic mechanisms associated with HIV disease progression through a number of studies in Africa, Asia, and Latin America. NIH also supports international training programs and initiatives that help to build infrastructure and laboratory capacity in developing countries

where the research is conducted. Funding for international HIV/AIDS research has increased from \$34.6 million in FY 1993 to an estimated \$90.3 million in FY 2000.

IV (5)
AIDS

LEVEL 1 - 42 OF 51 STORIES

The Associated Press

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April 22, 1997, Tuesday, AM cycle

SECTION: Washington Dateline

LENGTH: 651 words

HEADLINE: Advocacy groups blasts U.S.-funded AIDS research overseas

BYLINE: By LAURAN NEERGAARD, Associated Press Writer

DATELINE: WASHINGTON

BODY:

The United States is paying for experiments in poor countries that could allow 1,000 babies to die of AIDS unnecessarily by withholding a protective drug from HIV-infected pregnant women, the patient advocacy group Public Citizen charged Tuesday.

The government says the studies are ethical because they are the only way to find new HIV protections that poor countries can afford. Pregnant women in developing countries today do not get the AZT therapy that American AIDS patients use to protect their unborn children.

But in a letter signed by prominent bioethicists and Dr. Wilbert Jordan, head of the Black Los Angeles AIDS Consortium, Public Citizen compared the U.S.-funded foreign research to the infamous "Tuskegee experiment" in Alabama in which the government withheld syphilis treatment from poor black patients.

Also, federal law says U.S. doctors cannot do experiments abroad that would not be tolerated here, the letter added in requesting a federal investigation.

"We are confident that you would not wish the reputation of your department to be stained with the blood of foreign infants," said the letter to Health and Human Services Secretary Donna Shalala.

Shalala did not immediately respond, but the National Institutes of Health and Centers for Disease Control and Prevention vigorously defended the studies.

"In the absence of identifying some regimen that is affordable, hundreds of thousands of kids are going to die," said the CDC's Dr. Phillip Nieburg.

Studies in 1994 studies on American women indicated that taking the drug AZT during pregnancy and labor - and giving it to infants for six weeks after birth - cuts by two-thirds babies' chances of catching HIV from mothers.



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The Associated Press, April 22, 1997

But that treatment costs about \$ 800 per person, too expensive for developing countries, so doctors are studying potential alternatives such as shorter courses of AZT or giving malnourished pregnant women vitamin A.

But nine of these U.S.-funded studies in Africa, Thailand and the Dominican Republic compare the possible new therapies with dummy pills, instead of giving the comparison women the U.S.-style AZT treatment.

The government insists a placebo comparison is the only way to prove potential new therapies are better than no treatment.

But Public Citizen's Dr. Peter Lurie accuses the researchers of a double standard by "conducting abroad experiments we would not condone here."

He estimated that 416 babies unnecessarily caught HIV in two just-completed foreign studies that gave their mothers placebos. An additional 600 babies are at risk in the continuing experiments, he said.

But ethics rules "also say you don't study a treatment that can't be used in the country where the study is being undertaken," countered NIH's Dr. Jack Killen, who noted each country agreed to these studies. "They look at it as a chance to deal effectively with the thousands of infants a day who are not in a study," by identifying affordable treatments.

The United Nations, South Africa and Europe are funding similar placebo-controlled studies in developing countries.

"We're doing this for their benefit," said Dr. Joseph Saba, head of the United Nation's AIDS study.

"We are informing the women that they have a ... risk of not getting any treatment," added Saba, who said the World Health Organization in 1995 declared placebo-controlled studies the best way to quickly find AZT alternatives.

But Jordan, who ships his California patients' leftover AZT to Africa, argues that researchers knowingly pass up a chance to save some infants in the studies.

"We are doing something overseas that we wouldn't be doing here," he said. "We've just continued to infect everyone."

Lurie noted that yet another study in Thailand, funded by Harvard University and the NIH, did compare "short-course" AZT to U.S.-style longer AZT therapy, proving experiments without dummy pills are feasible.

LANGUAGE: ENGLISH

LOAD-DATE: April 22, 1997



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Newsweek

January 17, 2000 \$3.50

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'SOPRANOS' IN
WAR OVER THE CUBAN

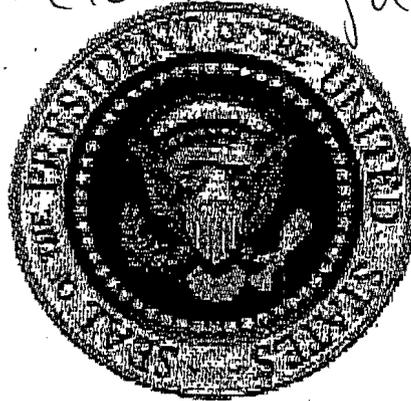
10

Million Orphan

The **AIDS epidemic** in Africa is leaving a generation of children without parents. Behind the plague—and what can be done



File Pelosi language



FACSIMILE

OFFICE OF NATIONAL AIDS POLICY EXECUTIVE OFFICE OF THE PRESIDENT

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TO:	Sarah Bianchi
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DATE:	October 17, 1997
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002/003

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(Labor/HHS Appropriations)

SUBSTITUTE OFFERED BY _____

At the appropriate place in the bill, insert the following:

1 Sec. ____ Notwithstanding any other provision of
2 this Act, no funds appropriated under this Act may be
3 used in a community to carry out any program of exchang-
4 ing sterile hypodermic needles and syringes for used hypo-
5 dermic needles and syringes (referred to in this section
6 as an "exchange project") unless the chief public health
7 officer of the State or of the political subdivision proposing
8 to use Federal funds for the exchange project notifies the
9 Secretary of Health and Human Services that all of the
10 following conditions are met:

11 (1) A program for the prevention of infection
12 with the human immunodeficiency virus (commonly
13 known as HIV) is operating in the community.

14 (2) The State or local health officer has deter-
15 mined that an exchange project is likely to be an ef-
16 fective component of such prevention program.

17 (3) The exchange project provides referrals for
18 the treatment of intravenous drug abuse and for
19 other appropriate health and social services.

20 (4) Such project provides counselling on reduc-
21 ing the risk of the transmission of HIV.

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(Labor/11115 Appropriations)

2

1 (5) The project complies with established stand-
2 ards for the disposal of hazardous medical waste.

3 (6) The State or local health officer agrees that,
4 as needs are identified by the Secretary, the officer
5 will collaborate with federally supported programs of
6 research and evaluation that relate to exchange
7 projects.

AIDS/HIV
NATIONAL STRATEGY
General Policy

AIDS-World File

DRAFT: PRESIDENT CLINTON JOINS INTERNATIONAL RELIGIOUS LEADERS IN CELEBRATING WORLD AIDS DAY
Announces First Ever National Institutes of Health Plan for International AIDS Research
December 1, 2000

Today, President Clinton joined international religious leaders at Howard University to celebrate World AIDS Day. At this event, he will unveil the first ever NIH plan for international AIDS research, a blueprint for establishing new funding approaches and research opportunities in over 50 countries. He will also release a new report from the White House Office of National AIDS policy detailing the Administration's successes in fighting the AIDS epidemic and providing a strategic blueprint of future challenges. The President will also urge the Congress to finish the job on the Labor-HHS appropriations bill and fund critical domestic and international HIV/AIDS funding priorities, including domestic and international AIDS prevention and treatment programs, the Ryan White CARE Act, and HIV/AIDS research.

THE CHANGING FACE OF THE AIDS EPIDEMIC CONTINUES TO PRESENT NEW GLOBAL CHALLENGES.

- **The spread of AIDS in the United States has slowed, but national challenges remain.** Each year, 40,000 Americans become infected with HIV – more than 110 a day. Half of new HIV infections in the U.S. are estimated to occur among young people under the age of 25, and the number of new AIDS cases among women, minorities, and adolescents has increased considerably since the early 1990s. Since the epidemic began in 1981, more than 700,000 Americans have been diagnosed with AIDS, and more than 420,000 men, women, and children have lost their lives to the disease. An estimated 800,000 to 900,000 Americans are now believed to be living with HIV.
- **The AIDS pandemic is a worldwide threat.** During nearly two decades of AIDS, HIV has infected 57 million men, women and children worldwide – and that number is projected to reach 100 million by 2005. Nearly 22 million people have died of AIDS, with 3 million deaths just last year. Over 13 million children under 15 have lost one or both parents to AIDS, and the total number of AIDS orphans is expected to exceed 40 million by 2010. HIV/AIDS is now the fourth leading cause of death worldwide and the single leading cause of death in sub-Saharan Africa. Over 36 million people around the world are living with HIV – often with little or no access to even basic care and support.

PRESIDENT CLINTON ANNOUNCES FIRST EVER NIH STRATEGIC PLAN FOR INTERNATIONAL AIDS RESEARCH. Today, the National Institutes of Health will release the first ever strategic plan for international AIDS research, a blueprint for establishing new funding approaches and research opportunities in over 50 countries. This plan, which invests over \$100 million in FY 2001, will:

- Establish new funding approaches and new research opportunities for researchers overseas;
- Provide support for long-term research infrastructure;
- Provide funding for development of new prevention strategies;

- Support international conferences and workshops with scholarships for scientists from developing nations;
- Help ensure that new research findings are applied in countries with the greatest need; and
- Address obstacles to conducting international research.

PRESIDENT CLINTON RELEASES A NEW REPORT DETAILING THE PROGRESS THAT HAS BEEN MADE AND THE WORK THAT NEEDS TO BE DONE. Today, President Clinton will release a new report describing the Administration's progress in addressing the AIDS epidemic, both nationally and abroad, and underscore that there is still more work to do. The report details the Administration's longstanding commitment to HIV/AIDS research, prevention, and treatment, including:

- **Strong steps to fight the spread of HIV/AIDS at home.** Since 1993, the Clinton-Gore Administration has more than doubled spending on research, prevention and treatment since 1993, to a total of \$12 billion in FY 2001; taken strong steps to eliminate racial and ethnic disparities in HIV and AIDS; strengthened the Ryan White Care Act, which provides treatment to 500,000 people with HIV and AIDS nationwide; led the search for an AIDS vaccine with the largest single vaccine research program worldwide; accelerated AIDS drugs approvals; and expanding access to health insurance for individuals with HIV and AIDS through the Work Incentives Improvement Act.
- **Committed domestic investment has shown dividends, but more work needs to be done.** The most recent data indicates that HIV/AIDS mortality has declined more than 70 percent since 1995, and new infections resulting from mother-to-child transmission have declined by 75 percent. In 1996, for the first time in the history of the AIDS epidemic, the number of Americans diagnosed with AIDS declined, and AIDS deaths dropped 20 percent between 1997 and 1998. However, the number of new AIDS cases among women, minorities, and adolescents has increased considerably, indicating the need for effective and well-targeted prevention efforts are still crucially important, and increased access to health care remains essential, as does the search for more and better treatments and a vaccine.
- **Serving as a strong international partner.** Under the leadership of the Clinton-Gore Administration, the United States has pioneered voluntary HIV testing and counseling in Africa; launched International HIV/AIDS Alliance and helped to create UNAIDS; taking executive action to make HIV/AIDS related drugs and medical technologies more affordable and accessible in sub-Saharan Africa; training all Peace Corps members as HIV/AIDS educators; accelerating the development of the public health infrastructure necessary to deliver critical medications for HIV/AIDS; and appointing a first-ever Presidential Envoy for AIDS Cooperation.
- **Laying the groundwork to fight HIV/AIDS internationally.** Through cooperation with our international partners, the Clinton-Gore Administration has made inroads on global fight against HIV/AIDS as well, including: the first decrease in the number of people infected with HIV in sub-Saharan Africa since the epidemic began three decades ago; reducing HIV prevalence in young adults in Uganda and Zambia; and maintaining low prevalence rates in Senegal, Philippines, and Indonesia.

**PRESIDENT CLINTON URGES THE CONGRESS TO ACT NOW TO FUND
CRITICAL HIV/AIDS RESEARCH, PREVENTION, AND TREATMENT PRIORITIES.**

Today, President Clinton urged the Congress to finish the job on the FY 2001 Labor-HHS Appropriations bill and fund critical international and domestic priorities on HIV and AIDS, including: an investment of \$460 million for international AIDS prevention and treatment, an increase of over 50 percent over last year's funding level; an investment of \$2.1 billion in AIDS related research at NIH; an investment of \$418 million in domestic HIV prevention activities at CDC; and a \$228 million increase in funding for the Ryan White Program, an increase of 14 percent over last year's funding level.

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Draft for Office Management and Budget Review: 6.28.96

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***Message from the Director of the
Office of National AIDS Policy***

The epidemic of HIV and AIDS constitutes a public health crisis of unprecedented proportions. In 1993, the Office of National AIDS Policy (ONAP) was created by President Clinton to provide a national focus and direction for the government's response to HIV and AIDS. More recently, President Clinton asked ONAP to develop a comprehensive National Strategy that would chart the Administration's direction in responding to the HIV/AIDS national and international pandemic. This was as a result of the President's commitment to promote efficient and collaborative policy and program efforts.

The development of a National Strategy for HIV and AIDS is an historic undertaking. No previous administration has undertaken so broad a planning effort that: (1) involves all Federal Departments and Agencies that engage in HIV-related efforts; (2) reaches out to communities and the private sector; and, (3) identifies areas where the Nation should place its most concerted efforts.

Combating HIV disease will require nothing less than the best innovative and cooperative efforts of State, local and federal governments, the private sector, and infected and affected communities and individuals. The urgency of the crisis requires that we build upon what we have already learned, joining together with one

another to develop a new, more unified and collaborative approach to addressing the epidemic.

The Strategy was developed through consultation with, and guidance from, many groups and individuals. I would like to thank, in particular, the members of the Interdepartmental Task Force on HIV and AIDS (IDTF) for the time and attention that they, and their staffs, contributed to the development of the Strategy. The IDTF is a group consisting of representatives from executive branch Departments and Agencies that conduct HIV-relevant work.

In developing the document, we depended heavily upon groups outside of government as well -- they, too, have been, and will continue to be, essential partners in developing solutions that capitalize on the opportunities for progress that are now before us. The recommendations provided by the Presidential Advisory Council on HIV and AIDS (PAC), the advocacy community, participants in the White House Conference on HIV and AIDS, service providers on the front lines of the epidemic, and many HIV-positive persons, their families, friends and care givers have been central to identifying areas for focused attention. The insights provided by the National Commission on AIDS, the Institute of Medicine and National Research Council, the General Accounting Office, and the reports of the Office of Technology Assessment have also been extraordinarily helpful in developing the National Strategy.

The National Strategy for HIV and AIDS
Draft for Office Management and Budget Review: 6.28.96

This document is a snapshot of where we are and where we think we need to go. Collaboration is one of the hallmarks of this Administration's approach to AIDS policy and Strategy serves as a reference point for lengthier dialogues and collaborative efforts between the public and private sectors.

It is important to remember that our efforts would not have been possible without leadership and direction at the highest levels of government. While the challenges of HIV/AIDS that are facing us cannot be solved by government or the private sector acting alone, more than ever in the history of this epidemic, we need innovative ideas, careful planning, and the strength of public-private partnerships to bring our strategy to fruition.

The epidemic challenges us on many fronts. Because the most common transmission routes are sexual activity and drug use, topics difficult for many Americans to confront directly, HIV has challenged this country to look at things that are difficult to face.

There is also fear -- fear of contracting this disease and unwarranted fear of those who are infected. Fifteen years into the epidemic, persons living with HIV still endure daily prejudice and discrimination based upon their HIV status. We are further challenged by the inadequacies of a social and health care infrastructure that is, in many ways, woefully unprepared to address the needs of HIV-infected persons. Moreover, the safety net provided by programs such as Medicaid and Medicare is

threatened with fundamental programmatic changes and reductions in funding. Scientifically, we have made much progress, but the virus continues to be a formidable adversary, challenging the best and brightest among us to find a cure and a vaccine.

Despite the many difficulties, AIDS has also brought forth an outpouring of compassion and caring. In my many meetings around the country with persons living with HIV, I have been inspired by numerous examples of great personal courage. I have been impressed by the dedication with which many communities and individuals have overcome obstacles in preventing infections and caring for those who are sick. By example, it demonstrates that, as a Nation, we, too, can collectively rise to meet the most difficult challenges placed in our path. Those Americans living with HIV, and others who are at-risk of infection, their families, and their communities, deserve a thoughtful, effective, and aggressive strategy to combat the disease.

Today we are facing great challenges, but we are also facing equally great opportunities. While AIDS is a terrible tragedy that has already affected far too many people around the world, I believe it is a disease that we can defeat -- just as we have eradicated polio from the western hemisphere and smallpox from the world. The National Strategy for HIV and AIDS lays a foundation for the public-private partnerships that are essential to our success. Together, with steadfast commitment, courage, and leadership, we will be able to win the battle against HIV and AIDS.

Preface

The Need for a National Strategy for HIV and AIDS

The National Strategy for HIV and AIDS has been developed to capitalize upon progress already made in fighting the epidemic and to catalyze collaborative efforts among Federal Departments and Agencies, communities, State and local governments, and the private sector.

Since the discovery of the first AIDS cases in the early 1980s, the epidemic of HIV and AIDS has posed a series of unique challenges. The challenges today are very different from those that we faced ten or even five years ago. We now know the risk factors and the etiologic agent, and we have tests to diagnose infection and protect the blood supply. We are developing new and more powerful therapies that offer hope for treatment and prevention. Scientists now believe that a vaccine is possible. Nonetheless, the epidemic continues. More people are infected every year, in every geographic area, and in every age range. Racial and ethnic minorities are disproportionately represented among existing and new cases of HIV infection. And youth are at increasing risk. Internationally, the epidemic is threatening the economic stability of a number of developing nations.

The changing face of HIV and AIDS, coupled with a period of overall fiscal restraint and a trend toward managed health care programs, require new approaches and

solutions. The National Strategy must incorporate innovative ideas, careful planning, and the strength of public-private partnerships.

The Strategy as a Catalyst for Change

The National Strategy is intended to serve the public, the President, the Congress, the members of the Interdepartmental Task Force on HIV/AIDS, and Presidential Advisory Council on HIV and AIDS. The text that follows will serve as a blueprint that will: document the baseline of current efforts government-wide; link goals to budget objectives; and, guide us in refining our goals and objectives in response to the changing face of the epidemic of HIV and AIDS.

The Strategy does not prescribe a fixed sequence of steps by which the entire plan, and its identified opportunities, are to be accomplished. The goals, common objectives, and opportunities for progress are intended to serve as a focus for our attention and efforts. The development of a functional implementation plan will be the responsibility of the Office of National AIDS Policy in partnership with the Interdepartmental Task Force on HIV/AIDS, the Presidential Advisory Council on HIV and AIDS, private sector organizations, and the community.

Executive Summary

== Place Holder ==

I. INTRODUCTION

Scope of the HIV/AIDS Pandemic

The pandemic of Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) presents unique social, economic, and public health challenges to governments and individuals here in the United States and worldwide. Unlike other infectious diseases that have arisen over the course of history, HIV is infectious for life and almost always fatal. [Awaiting revised language from NIE.] While we have made significant progress in understanding the disease and developing treatments since the first case was identified by the CDC in June of 1981, with this progress comes the challenge of preventing new infections, ensuring access to new treatments, and assuring that health care professionals know how to care for their patients. Still, HIV remains a deadly infection for which there is no vaccine, no cure, and for which there is an expanding, but still limited, inventory of available treatments.

An Expanding Public Health Threat

As of October 1995, the Centers for Disease Control and Prevention (CDC) reported 501,310 cases of AIDS among persons in the U.S.; 311,381 of these persons have been reported to have died as a result of complications related to HIV. Since 1987, AIDS has gone from being the 15th ranked cause of death among all Americans to the 8th. It is now the leading cause of death among Americans aged 25 to 44. (See

Figure 1.) In 1994 alone, approximately 81,000 new cases of AIDS and more than 45,000 AIDS-related deaths were reported to the CDC in 1994. The CDC estimates that between 40,000 and 60,000 Americans are becoming newly infected with HIV each year, and that between 800,000 and one million Americans are currently living with HIV.

As the epidemic in the United States has evolved, the demographics of the epidemic have been shifting. The early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers, such as New York, San Francisco, and Los Angeles; this group now represents less than half of all new cases. Among the populations being more heavily affected now are young gay men, women, and heterosexual injecting drug users. Although gay men no longer represent the majority of new cases, this group represents the majority of persons living with HIV and AIDS. In 1994, more than 14,000 women were reported with AIDS and now women comprise 14 percent of cumulatively reported AIDS cases. It is estimated that if this trend continues, 80,000 American children will have been orphaned as a result of AIDS by the end of this decade. In 1994 alone, more than 1,000 new pediatric AIDS cases were reported. As the geographic diversity of the disease has widened, the impact of the disease on the country as a whole has increased.

Adolescents are at special risk. The CDC estimates that one in four new HIV infections in the U.S. occur among people

under the age of 21. Under current trends, between 27 and 54 young people in the United States under the age of 21 are infected by HIV each day, or more than two young people every hour. Moreover, a significant number of young people are engaging in sexual intercourse as well as drug and alcohol use at earlier stages in their lives. This fact, coupled with the disturbing number of adolescents who are prone to high risk behavior due to homelessness, sexual abuse, and other circumstances, places young Americans in a situation that leaves them extremely vulnerable to HIV infection.

Communities of color have been more severely and disproportionately affected by the epidemic. As of October 1995, African-Americans accounted for 38 percent of newly reported AIDS cases, while representing approximately 12 percent of the general population. Hispanics represented 18 percent of new cases through October 1995, although this group represents only 9 percent of the general population. In 1982, Blacks and Hispanics represented 31 percent of all AIDS cases; however, as of October 1995 these groups comprised 51 percent of cumulative AIDS cases. Gay men of color in certain regions of the country account for approximately 39 percent of new AIDS cases.

AIDS is no longer just an urban problem. The HIV/AIDS pandemic is spreading to non-urban areas, including dramatic increases in certain regions of the South and Midwest. In fact, between 1993 and 1995 the largest numbers of AIDS cases (86,462)

were reported from the South.¹ While most cases are still reported from urban areas, the rate of reported cases in non-metropolitan areas is increasing faster than in urban areas. AIDS cases have now been reported in all 50 States, the District of Columbia, Puerto Rico, and each of the American Territories. (See Figure 2.)

Internationally, the toll of the epidemic is greater still. The World Health Organization (WHO) estimates that since the beginning of the epidemic, 4.5 million cases of AIDS have occurred worldwide. It has estimated that as of mid-1995, 18.5 million adults and more than 1.5 million children have been infected with HIV since the beginning of the pandemic. WHO also projects that by the year 2000 between 30-40 million people will have been infected with HIV.

The Social Impact

Prejudice and discrimination are still experienced by people living with HIV, their families, and their loved ones. Persons with HIV have been denied medical and dental services, emergency medical treatment, and health insurance. They have been discharged from their jobs and evicted from their homes. Unlike other persons with infectious diseases, many persons living with HIV have been the target of violence, rejected by their families, and suffered discrimination because of their HIV status.

AIDS is a disease that most often affects people in the prime of life. It

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Draft for Office Management and Budget Review: 6.28.96

disproportionately kills people during their most productive years. That it is the leading cause of death among Americans 25 to 44 is particularly significant since this is the age group that constituted 54% of the civilian labor force in 1992.² Premature deaths due to AIDS result in the loss of many productive years of life and in many cases deprive young children of their parents. In 1994, HIV infection was the fourth leading cause of potential life lost before age 65.

AIDS has consistently risen in the rankings as a cause of death, while rates for disease such as cancer and heart disease have been comparatively stable. Direct lifetime medical care after diagnosis for an HIV-infected person costs more than care for patients with cancer or heart disease, specifically: \$61,211 for heart disease³, \$25,000 to 84,000 for Cancer⁴, and \$119,000 for HIV/AIDS⁵ Overall HHS spending for research, treatment, prevention, and income supplements is significantly greater for cancer and heart disease than for AIDS. In FY 1995 DHHS spent approximately: \$38.0 billion for heart disease, \$17.5 billion for cancer, and \$6.0 billion for AIDS. [DHHS -- update figures.]

In developing countries, the pandemic threatens to reverse decades of progress in strengthening national economies and improving the health status and social well-being of millions of women, men, and children. In some African nations, 95 percent of hospital beds are occupied by AIDS patients. Moreover, the WHO estimates that 10 to 15 million children will be orphaned due to AIDS by the year 2000.

The human toll has been staggering and is likely to continue.

*The National Strategy for HIV and AIDS
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The Evolving Challenge of the HIV/AIDS Epidemic

The four decades prior to the report of the first AIDS case in the early 1980s encompassed a period of unprecedented success in controlling infectious diseases. The emergence of HIV, and the subsequent epidemic of HIV and AIDS, has posed an evolving series of unique scientific, economic, and social challenges, both domestic and international. Today the challenges we face with the epidemic are very different from challenges we faced previously.

In the early years of the epidemic, significant scientific resources were dedicated towards understanding how the disease was transmitted and identifying its underlying cause. Thanks to this work, we now know the risk factors and the etiologic agent for HIV, and we have a test to ascertain the serostatus of infected persons and can, therefore, protect the blood supply.

Building on the knowledge gained from those discoveries, more resources were subsequently directed towards achieving a deeper understanding of HIV-related immunology and pathogenesis, and, developing therapies for HIV primary infection and associated opportunistic infections. New and more powerful therapies that offer new hope for treatment and prevention have been developed. Scientists now believe that a vaccine is possible. Current day discoveries also create new challenges for the future. We

now face new scientific challenges in developing a vaccine and the new generation of therapeutics for primary and opportunistic infections.

Since the beginning of the epidemic, behavioral research designed to understand the behavioral, social, cognitive, and biological factors that place individuals at risk for acquiring HIV infection has provided important insights for prevention efforts. Practical experience has also taught us that prevention efforts can be effective. However, behavioral research remains a relatively young science and there are currently more questions than answers. The challenge before us now lies in expanding the scientific underpinnings that will allow us to design more effective prevention programs that will reach even more Americans at risk for infection.

The progress in developing therapies and prevention programs has also created new problems for the health care delivery system. As a result of improved therapies, people with AIDS now live twice as long as they did a decade ago. [Awaiting additional language from NIH.] Due to NIH-sponsored research we now have the ability to reduce the risk of perinatally acquired HIV infection by treating women with AZT during pregnancy. The recent approval of a new class of therapies, protease inhibitors, will again change the direction of HIV/AIDS treatment and prevention. Ensuring access to these therapies is the challenge that confronts us now. We need to improve our efforts in providing people with care earlier in their infection so they can receive the

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new treatments and we need, as well, to ensure that health care professionals are well-trained and know the best way to provide that care.

Ensuring access to prevention services and medical care for the growing number of people who need, or will need, health care is an enormous task. There are societal and economic changes that are influencing the ways in which the country addresses the issues of health care access and cost. There is a trend towards decentralizing the role of the Federal government in health care and placing more responsibility at the State and local levels, coupled with a movement to managed care systems. These changes will influence efforts to strengthen prevention efforts and ensure health care and services for people with HIV/AIDS.

From a societal perspective, while we have made tremendous progress in overcoming fear and discrimination, we still have a long way to go. There are no grounds for discriminating against persons with HIV infection and yet such action has thwarted access to health care, health insurance, housing, employment, and even funeral services. We must continue in our vigilance to ensure that the protections provided under the law are extended to all HIV-infected persons.

Goal of the National Strategy

The goal of the National Strategy for HIV and AIDS is to capitalize upon the progress which has been made in fighting the epidemic and to catalyze new and strengthened collaborative efforts among Federal Departments and Agencies, communities, State and local governments, and the private sector. To realize this ambition we will need innovative ideas, careful planning, and the strength of public-private partnerships to make these plans a reality.

The text that follows will serve as a blueprint that will: document the baseline of current efforts government-wide; link goals to budget objectives; and, guide us in refining our goals and objectives in response to the changing face of the epidemic of HIV and AIDS. This is intended to be a living document that will require regular updating and adjustment as goals are reached and as new challenges occur.

Development of the Strategy

The National Strategy for HIV and AIDS presented here is broader in scope than any prior planning efforts. To date, planning has been focused primarily in the Public Health Service (PHS)⁶, Department of Health and Human Services, as evidenced by a series of documents such as the Public Health Service Plan for the Prevention and Control of Acquired Immune Deficiency Syndrome⁷, the "Coolfont"⁸ and "Charlottesville"⁹ reports, and the PHS Strategic Plan to Combat HIV and AIDS in

the United States¹⁰. Recommendations have also been issued by a number of groups, including the National Commission on AIDS¹¹ and the Presidential Advisory Council for HIV and AIDS. There have also been significant planning efforts on the part of individual Agencies. However, until now there has not been a national plan that provides for a government-wide coordinated effort encompassing not just Public Health Service activities, but also that incorporates areas such as housing, health care, and civil rights.

Effective planning requires a genuine commitment from participants to work together toward clearly defined goals. Therefore, the strategy for HIV and AIDS has been developed by the Federal Departments and Agencies that support HIV-related activities along with the counsel of HIV-infected persons and their advocates, the private sector, and the Presidential Advisory Council on HIV and AIDS.

Through the Interdepartmental Task Force on HIV and AIDS (IDTF), a formal request went out for the executive branch Agencies to identify their activities, goals, and objectives. These pertinent data have been compiled uniformly and are contained within the appendices of the strategy. The IDTF members, with their specialized knowledge of a broad range of HIV-related issues, have been crucial in identifying areas requiring special attention.

There has also been a reliance on groups outside of government -- the same groups that have been and will continue to be

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essential partners in developing solutions and capitalizing on the opportunities for progress that lay before us now. The recommendations provided by the Presidential Advisory Council on HIV and AIDS (PAC) have been invaluable. The advice and counsel of the activist and advocacy communities, participants in the White House Conference on HIV and AIDS, individuals on the front lines of the epidemic, and many HIV-infected persons and their families, friends, and care givers have been essential in identifying areas for focused attention. And finally, the insights provided by the National Commission on AIDS, the Institute of Medicine of the National Research Council, the General Accounting Office, and the reports of the Office of Technology Assessment have also been extraordinarily helpful in developing this Strategy.

Common Objectives and Opportunities for Progress

Based on the consultations, the following national objectives are established:

- To provide strong support for research in order to find treatments and a cure for those currently infected, and a preventive vaccine to protect the uninfected;
- To provide solid support for effective prevention strategies so as to reduce the number of new infections each and every year until there are no new infections; and,
- To ensure that treatment of persons living with HIV is caring, ethical, and in accordance with legal standards.

Also through the consultations, it became clear that there was consensus regarding the major challenges facing us today, and that these challenges warranted focused attention. There was also a judgment that these challenges represent opportunities for progress -- opportunities to take steps today to find a cure and a vaccine, reduce the number of new infections, and care for those who are infected.

Based on this counsel, opportunities for progress are presented and discussed within each substantive section (i.e., prevention, research, care and services, international

activities, translation of research into clinical practice, and civil rights) of the Strategy. (See section on Organization of the Strategy below.) It is these opportunities that will require consideration and broad-based input in the development of implementation plans if we are to meet the challenges they present.

Implementation

First, it is important to realize that this document is a snapshot of where we are and where we think we need to go. The Strategy serves as a reference point for the lengthier dialogues and a foundation for future collaborative planning efforts between the public (i.e., Federal, State, and local governments), and private (i.e., persons living with HIV, AIDS service organizations, the advocacy and activist community, businesses, pharmaceutical and biotechnology companies, academia, health care providers, and insurers, etc.) sectors that will be absolutely essential.

Each issue raised in the Strategy will require specially tailored approaches and implementation plans. In some cases significant progress has already been made, in others much work remains. Some of these challenges can be resolved with the cooperation of a handful of people, while others will require extensive thoughtful effort on the part of many players in order to craft workable solutions. It will also be important to build on the less comprehensive planning efforts that have taken place and complement current planning activities.

Organization of the Strategy

The National Strategy is organized into the following substantive areas: prevention, research, care and services, international activities, translation of research into practice, and civil rights.

Information and discussion of Federal activities can be found in three locations within the document. First, discussion on each substantive area addresses broad policy issues and new Federal objectives in terms of the national goals and opportunities for progress. Second, each substantive section has a corresponding appendix that provides information on individual Agency goals, objectives, funding levels, constituency involvement, and unmet needs. And third, funding tables can be found in Appendix G.

Current Agency activities have not been arranged around administrative structures, but by area. In cases where a single Agency may have responsibility for more than one area, such as prevention and research, documentation of their activities will be found in the respective substantive sections. In some cases there are cross-cutting issues that could fall into several categories, such as internationally-based treatment and prevention efforts. In this case, programs that are specifically targeted towards geographic regions of the world are included in the international section.

The type of information provided in the appendices varies depending upon the type of efforts Departments and Agencies

sponsor. Support for HIV/AIDS activities falls into two general categories: in the first, HIV/AIDS activities are an essential part of the mission; in the second category, HIV-related activities are not an explicit part of the mission but are indirectly supported or receive collateral benefit from Agency supported work and/or policies. There are a number of Agencies for whom AIDS-specific activities are central to their mission (e.g., the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA)), while other Agencies maintain programs and activities that support a broad range of activities, of which HIV-related activities are one among many (e.g., the U.S. Agency for International Development (USAID) and the Department of Justice (DOJ)). Data are presented, therefore, in a manner consistent with an Agency's level of involvement.

II. OVERVIEW OF FEDERAL EFFORTS

Introduction

The scope and nature of the HIV/AIDS epidemic have brought State, local, and Federal involvement into many HIV-related activities. The Federal government, through its public health responsibilities in such areas as research, prevention, health care, and housing has seen a dramatic increase in its activities since the beginning of the epidemic. In 1985 the Federal government spent \$212 million for AIDS research, surveillance, and care. With the dramatic increase in cases, by 1995 that figure had reached \$6,848 million. (See Appendix G). Congress also took note of the rapid increase in cases of HIV and AIDS and passed legislation that sought to address the needs of HIV-infected persons and their families, and the Nation's need to find a cure and a vaccine, including the Ryan White Comprehensive AIDS Resources Emergency Act (CARE) Act and the NIH Revitalization Act of 1993.

Currently, Federally sponsored activities include direct support for research, prevention and education, housing, medical care, support services, information dissemination, enforcement of civil rights, and assistance to international organizations and other nations. While Federal Agencies are responsible for responding directly to the epidemic of HIV and AIDS, they also collaborate with and provide support for State and local governments, academic institutions, private foundations, health care

institutions and community-based organizations, which often have substantial surveillance, prevention, and health care responsibilities.

PREVENTION

The Nation's prevention goal is to develop effective prevention strategies that will reduce the number of new infections each and every year until there are no new infections. Achieving this goal will require a dedicated alliance between the Federal government, States, local governments, communities, businesses, non-governmental organizations, families, and individuals. Achieving this ambitious end will require a clear definition of the different roles and responsibilities of the Federal government, and an ongoing dialogue with its partners in the public and private sectors about the responsibilities each has in reaching this goal.

We know that HIV prevention works. We also know that the task of preventing HIV transmission faced by the United States in controlling the epidemic of HIV and AIDS has reached enormous proportions.¹² The Centers for Disease Control and Prevention (CDC) estimates that approximately 800,000 to 1 million Americans are presently HIV-infected, many of whom are unaware of their HIV status. Moreover, the CDC estimates that approximately 40,000 to 60,000 American will become infected each year. Many more Americans who are not presently infected are at risk for acquiring HIV. HIV infection is a unique prevention challenge because of the virus' virulence, the long period of time when people may not be aware they are infected, long duration of infectiousness, nearly always fatal prognosis, and potential for exponential spread. Moreover, HIV is transmitted

primarily as a result of personal and private individual behaviors -- sex and drug use. To be effective, HIV prevention programs must reach tens of millions of Americans who are characterized by a diversity of age, race, ethnicity, geographic locale, sexual orientation, and sexual and drug use behaviors.

Prevention activities are currently supported by several Federal Agencies. (See Appendix A.) Most Federal prevention efforts are funded by Department of Health and Human Services (HHS), although other Departments such as the Department of Defense (DOD), and the Department of Veterans Affairs (VA) also support prevention activities. These efforts reflect a continuum from surveillance to research to social marketing initiatives. Agency activities are also reflective of their respective missions. For example, the Centers for Disease Control and Prevention (CDC), the Agency with primary Federal HIV-prevention responsibilities, supports a wide range of surveillance and prevention projects, many in partnership with States, local governments, and community-based organizations. Other Agencies focus on specific aspects of prevention. For example, the National Institute on Drug Abuse (NIDA) and the Substance Abuse and Mental Health Services Administration (SAMSHA) support efforts to prevent HIV infection among drug users, while other Agencies support primary prevention efforts as part of medical care, such as at the veterans and military hospitals and clinics. The Health Resources and Services Administration (HRSA) also encourages

broader access to prevention information through the integration of prevention interventions into primary health care services and through support of early intervention services for low-income medically underserved persons. HRSA also has undertaken special initiatives designed to reduce perinatal transmission of HIV and has promoted primary prevention through the training of health professionals in the AIDS Education and Training Centers program.

The efforts of Federal Agencies as well as research conducted at universities and private organizations, have been instrumental in expanding our knowledge base about HIV prevention. However, significant gaps remain. We know from both formal research and community experience that developing prevention programs that are effective requires knowledge of who is becoming infected and of the behaviors that are enabling transmission, an understanding of the motivations for those behaviors, and an understanding of how best to reach people with messages that will ensure lasting behavior change.

Prevention priorities must be guided toward gaining knowledge that will improve our efforts to develop effective prevention programs. We need to improve our understanding of the major modes of transmission, close gaps in scientific knowledge, including identifying effective prevention models and strategies, and work towards eliminating gaps in program areas.

Opportunities for Progress

Modes of Transmission

An important part of strengthening prevention activities is to have a clearer understanding of who is being infected and what behaviors are placing people at risk for infection. Recent epidemiologic data show that the HIV epidemic continues to spread in the United States among people who engage in injection drug use and their sexual partners, young and minority men having sex with men, heterosexual transmission, and through perinatal transmission. Moreover, the youth of our country are becoming infected at an alarming rate -- 50 percent of new infections in the United States are in persons under 25 years of age. HIV is the leading cause of death in Americans aged 25 to 44 and it is likely that many of these people were infected while they were adolescents. Racial and ethnic minorities are also disproportionately represented among new HIV infections. As of October 1995, African-Americans accounted for 38 percent of newly reported AIDS cases and Hispanics represented 18 percent of new cases. These trends in the epidemic must be taken into consideration when prioritizing prevention research and service programs.

A crucial part of effective prevention strategies includes supporting adequate surveillance of HIV infection and related diseases in order to gauge future directions of the epidemic, and assess the effectiveness of prevention interventions. As previously

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noted, the CDC is the Federal Agency with primary responsibility for monitoring the epidemic. Seroprevalence surveys provide information on the level of HIV infections in "sentinel" populations. The CDC AIDS case and case death reporting system provides useful data for assessing AIDS prevalence and mortality by gender, race/ethnicity, age, and mode of exposure. This surveillance system also provides essential data on HIV-related opportunistic infections.

There are, however, opportunities for refinement. Effective prevention intervention programs begin with sound information on who is at risk. Current CDC surveillance systems do not capture sufficient "front-end" information on the incidence and prevalence of HIV (not AIDS) in the population, and trends in modes of transmission and new infections. Collection of these data are needed as part of an enhanced effort to link surveillance and epidemiological data to priority setting, in addition to the design and evaluation of prevention programs. (These data must be collected with the appropriate confidentiality protections.)

The CDC has recognized the value of this approach and has incorporated data collection design into its community planning process. These shifts in data needs coupled with fiscal restrictions may also require that the CDC reevaluate and reconfigure its data collection efforts. As part of the Agency's implementation of the recommendations set forth in the external review of CDC's HIV prevention

strategies¹³, the CDC has initiated efforts to evaluate current data collection efforts and implement necessary changes, and this work should continue.

Prevention Research¹⁴

Factors that place individuals at risk for acquiring HIV infection are a complex combination of behavioral, social, cognitive, and biological influences. Given this complexity we must not *assume* we intuitively know which interventions will work, but instead base our efforts on sound research findings and evaluation. Experience has taught us that prevention efforts can be effective, but when they are it is because the intervention incorporates findings from both experience and relevant research. Behavioral research is a relatively young science and there are currently more questions than answers. The three main areas where gaps in knowledge have been identified are basic behavioral research, intervention research, and social marketing research.

Basic Behavioral Research. Information provided by the conduct of basic behavioral research should serve as the foundation for prevention programs. Basic behavioral research, similar to basic research in other areas of scientific inquiry, seeks to explain the determinants and causes underlying biological, behavioral, and social processes. HIV-related risk-taking behavior is often complex and influenced by a host of individual and environmental factors.

To capitalize on what is known and improve

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HIV prevention programs that are targeted to reach a diversity of Americans, more information on the determinants of HIV-associated sexual and drug-using behaviors is needed. For example, although much has been learned about the basic biology of substance abuse, further elucidation of the mechanisms underlying addictive behavior may assist in the development of new therapeutic approaches to addiction, which may in turn reduce the number of new infections.¹⁵ And although we have some information on relevant risk-taking behaviors, more information about knowledge, attitudes, decision-making processes, and beliefs about AIDS and other sexually transmitted diseases (STDs) is much needed. Such data enable scientists to establish theories of behavioral change, which then provide researchers with tools for identifying what approaches may be most effective for an individual or a community.¹⁶ [Awaiting revised language from NIH.]

Intervention Research. A second major gap is research to improve prevention interventions, i.e., research that concentrates on modifying behaviors, such as those related to drug use and sexual practices. We know from other behavior-influenced diseases (such as hypertension) and practices (such as cigarette smoking and wearing seatbelts) that basic information about what motivates a person to exhibit these behaviors can be incorporated into intervention research to advance approaches to reducing unhealthy behaviors.

In HIV and AIDS, this intervention research

can focus on both individuals and communities, which often hold norms that influence personal behavior. Since the beginning of the epidemic we have made advances in our understanding of factors that are relevant to the design of intervention programs intended to reduce rates of HIV infection. This theoretically based intervention research has identified several significant predictors of changes in sexual and drug-using behaviors among gay men, adolescents, and heterosexual adults.¹⁷ Studies have shown that community-based HIV risk reduction programs that are gender relevant and culturally sensitive can be effective.¹⁸ A recent study has also provided a reason for optimism that the spread of HIV can be contained among injecting drug user populations when there is early community outreach and access to sterile injection equipment.¹⁹

However, despite this evidence of success, there is more that we need to know if we are to develop effective prevention programs for a diversity of Americans. We must incorporate findings from basic behavioral research into effective prevention interventions. One high priority area is research on interventions that lead to sustained behavior change and reduced recidivism. Another area for investment is research on cultural barriers and strategies to reach populations resistant to certain behavior interventions. A third area is research on the effectiveness of treatment for drug abuse, mental illness, and alcoholism in reducing HIV risk behavior.

Agencies supporting intervention and

behavioral research must include scientists from a broad range of disciplines in their planning activities and improve their data-sharing and collaborative efforts with Agencies responsible for implementing prevention programs. Enhancing the dialogue between researchers in these two related fields will invariably improve the development of effective prevention interventions.

Social Marketing Research. It is important that the findings from basic behavioral and intervention research be incorporated into prevention programs. Agencies supporting social marketing activities need to build on current knowledge in addition to strengthening efforts to understand barriers to the implementation and replication of promising prevention programs. Given the highly innovative nature of these endeavors, the CDC must consider providing broader technical assistance and training to community organizations. Moreover, a community-based effort that would test prevention models in a real-world setting should be carefully considered. [Awaiting additional language from NIH.]

We know from efforts in other countries that HIV-related social marketing efforts can be successful. However, we have not been as effective as we could be in disseminating information about effective strategies so that this knowledge can be employed in the design and implementation of prevention interventions. There *are* good models for prevention interventions that are not making their way to those on the front lines of the epidemic. Community-based organizations,

which are responsible for developing a large portion of the prevention programs often do not, or are not able to, take advantage of current knowledge about program effectiveness.

Prevention Programs

In order to stop new infections, the results of basic behavioral, intervention and social marketing research must serve as the foundation for prevention intervention programs that reach people at risk for acquiring or transmitting HIV. Presently, the Federal government supports a range of programs that address the disparate needs of a number of at-risk populations. However, the shifting demographics of the epidemic coupled with restricted resources has resulted in gaps in program areas that limit the Nation's ability to prevent new infections. It is therefore important that prevention planners carefully prioritize their efforts based on local epidemiology.

Community Involvement. For prevention interventions to be effective they must reach communities at risk and be responsive to their unique needs. And for individuals to take control of their own lives in fighting the spread of this virus, they must first have the information and skills to protect themselves.

One of the most important innovations in the prevention area is community planning. The community planning process is an outstanding model of a Federal-local partnership. Through this effort, it is possible to establish joint goals for the

prevention of HIV that will meet Federal standards while remaining responsive to local needs. However, this process is early in its development and requires significant, ongoing leadership and technical assistance from the CDC if it is to fulfill its potential for good priority setting and decision making.

Substance Abuse Prevention and Treatment. Injection drug use is one of the major forces driving the epidemic with one third of all new cases are directly or indirectly related to this mode of transmission. Limiting the impact of substance abuse on the epidemic will require efforts on several fronts.

First, we need to improve the integration of HIV prevention activities and substance abuse treatment and prevention programs. The epidemics of substance abuse and HIV in this country are overlapping and highly interrelated, however, care and prevention services for HIV and substance are not. It is vital to continue efforts to integrate HIV prevention into current substance abuse programs and integrate substance abuse prevention into HIV prevention.

A second avenue for controlling the spread of HIV among addicted persons is enrollment into drug treatment programs. Substance abuse treatment is a form of HIV prevention. Moreover, substance abuse problems that contribute to the spread of HIV are not limited to injecting drug use. There is substantial evidence that use of alcohol and other substances can adversely influence risk-taking behavior. In addition,

it is estimated that ~~x~~ percent of the population is affected by alcohol abuse and other non-injectable drugs.

Fundamental to the success of an integrated approach would be the continued expansion of educational activities to prevent substance abuse, and increased outreach efforts to encourage active substance users to seek treatment. We also need to ensure that drug treatment services are available in sufficient numbers for a range of addictions for those in need of such services. This would include services that accept pregnant women or women with children, indigent members of the community and adolescents.

Work on this issue has begun and will continue. The CDC has initiated State-by-State discussion, including meetings with State Legislators, regarding HIV prevention issues. The CDC is also working with the National Conference of State Legislatures to provide a forum for a broad spectrum of views on this important issues.

Treatment for Sexually Transmitted Diseases and Tuberculosis. Studies have shown that the presence of sexually transmitted diseases (STDs) can significantly increase the efficiency of HIV transmission, even by as much as 20 times. Studies have also shown that widespread treatment of STDs in certain communities has led to a 40 percent reduction in new HIV infections in these groups.^{20, 21} These data suggest treating STDs can be an effective HIV prevention strategy and points to a need for all clinicians to be vigilant in efforts to prevent and treat STDs.

Persons who are HIV positive are at significant risk for developing of *M. tuberculosis* (TB) disease. Studies suggest that the risk of developing TB disease is 7 to 10 percent each year for persons who are infected with both TB and HIV, whereas the risk is 10 percent over a lifetime for persons not infected with HIV.²² In addition to the health implications for infected persons, there is an increased risk of transmission of TB to household members, health care workers, and other persons having regular contact with the person with TB.

It is important that Federal and State efforts to reduce the incidence of sexually transmitted diseases (STDs) include an HIV prevention element, and, that HIV prevention programs incorporate STD prevention and treatment efforts. Moreover, the traditional model of targeting most STD prevention efforts towards individuals who have already contracted one STD is not necessarily effective for HIV prevention. Enhanced and innovative linkages between STD and HIV prevention need to be established. The newly organized National Center for HIV/STD/TB Prevention at CDC reflects the importance of integrating these inter-dependent aspects of the epidemic and illustrates our determination to integrate and coordinate HIV, STD, and TB programs.

Integration Into Primary Care. To reach our prevention goal, we must also improve the integration of prevention activities and messages into primary health care services. HIV counseling and voluntary testing often provide an important bridge between HIV prevention and care for many at risk

persons, including youth, women, and ethnic minorities. To assure that all persons seeking HIV testing can have access to such services, the CDC's counseling and testing guidelines should acknowledge and address the needs of persons seeking such services, and provide training for personnel at CDC-funded sites.

Incorporating a patient's sexual and drug using history when a medical history is taken, offering HIV-related counseling and voluntary testing, and working with HIV positive individuals so they do not infect others is also important. It also means offering pregnant women information about and access to AZT during pregnancy to reduce the risk of perinatal transmission. Training should be made available to improve primary care providers' skill, comfort level and sensitivity in these areas.

Achieving this level of integration will require active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to State, local, and Federal governments.

Prisoners. Populations in prisons are at high risk for both substance abuse and HIV disease. Moreover, there is often a high prevalence of both HIV and substance abuse behaviors in people entering prison.

Given that the incarcerated population is often at increased risk for HIV infection, offering educational programs during incarceration provides a unique opportunity

to reach these persons. Studies have found that programs using peer counselors have been effective in delivering HIV treatment and prevention messages. Research has also shown that individuals who are well informed about HIV and substance abuse issues do modify their risk-taking behaviors. It is important the Federal government build upon the knowledge and opportunity that currently exists and further improve HIV prevention efforts for incarcerated persons.

Evaluation. It is important to assess the effectiveness of the prevention interventions that have or will be implemented. Prospectively set performance measures can be used as a basis for evaluation and program improvement. Incorporating effectiveness measures must become a routine part of all Federally-funded programs. It is only through sound evaluations that we will be able to determine whether our efforts have been effective in slowing the epidemic. Achieving this will also require careful examination of what programs should be continued, what activities need to be initiated, and a awareness that a reconfiguration of some program priorities may be required.

RESEARCH

One of the Federal government's goals is to provide strong support for research in order to find treatments and a cure for those currently infected, and a preventive vaccine to protect the uninfected. It is research that will enable us to reach these goals and until they are a reality, the Federal government must provide solid ongoing support for basic and clinical research.

Achieving this goal will require committed collaborative efforts among the Federal government, universities, researchers, the advocacy community, persons living with HIV and those at risk for infection, communities where research is conducted, charitable organizations, pharmaceutical companies, biotechnology firms; and other parts of the private sector. It will also require an ongoing dialogue between the public and private sectors.

At present, a number of Federal Agencies play a significant role in U.S. AIDS research efforts. (See Appendix B.) These endeavors range from basic molecular research to clinical research to health services research. The National Institutes of Health (NIH) supports a significant portion of these efforts. NIH funds research on HIV-related natural history and epidemiology, etiology and pathogenesis, therapeutics, vaccines, and behavior. As part of its mission to protect and maintain a viable fighting force, the Department of Defense supports clinical vaccine and therapeutic research. The Agency for Health Care Policy and Research (AHCPR)

funds health services research to help determine which medical approaches are the most cost effective. The Department of Energy (DOE), through its support of technologically advanced equipment, provides the opportunity for Federal and private researchers to share resources and thereby analyze molecular structures that, without such equipment would not be possible. The Centers for Disease Control and Prevention (CDC) monitors and assesses modes of and risk factors for transmission through epidemiologic and laboratory studies. The Agency also supports facilities employing sophisticated methods for identifying viral variants.

Contributions of Research

[Awaiting revised language from NIH.] The Nation has already reaped some of the benefits of supporting research in general, and HIV-related research specifically. AIDS research has provided advances for treatment of other diseases. For example, HIV-related research has contributed to progress in treating breast cancer. Research revealed that by blocking cytokine receptors, tumor cell growth could be inhibited; this finding led to the development of new treatments for breast cancer.

Advances in treating conditions resulting from immunosuppression have come from HIV-targeted research. One of the most promising experimental therapies for advanced breast cancer is high-dose chemotherapy followed by bone marrow transplantation, but the treatment causes

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profound immunosuppression; AIDS-related research has provided valuable insights regarding the management of these patients.

HIV-related research has also accelerated study of the human immune system which has in turn improved our ability to understand and treat other conditions such as cancer and autoimmune diseases, including systemic lupus erythematosus, type I diabetes mellitus, rheumatoid arthritis, and multiple sclerosis.

Research involving the blood/brain barrier has led to a better understanding of the mechanisms by which infectious agents spread into the nervous system. These findings provide valuable clues for research on Alzheimer's disease, dementia, multiple sclerosis, neuropsychological disorders, encephalitis, and meningitis. Moreover, prior to the AIDS epidemic, little investment was made in research to treat viral diseases. Studies to develop anti-HIV therapies have improved our understanding of more viral diseases and led to development of treatments for many other diseases.

Research investments made before the advent of the AIDS epidemic produced a body of scientific knowledge that enabled researchers to more quickly pursue theories and avenues of investigation. For example, research previously conducted on the immune system in general, and CD4+ cells in particular, provided early insights into the pathogenesis of HIV. Research investments in retroviruses yielded invaluable information for identifying HIV as the etiologic agent of the emerging epidemic;

and advances in molecular biology provided researchers with the tools to understand HIV's structure and develop drugs based on that information.

Due in great part to Federally-sponsored research, persons with AIDS now live twice as long as they did a decade ago. Clinicians now have a growing array of medication to treat and in some cases prevent a variety of HIV-associated opportunistic infections. An NIH-sponsored study found that it is possible to dramatically reduce the chance of transmission of HIV from mother to infant. Data from federally-sponsored prospective epidemiological studies are helping scientists understand the factors that enable long-term non-progressors to live many years after infection without presenting clinical signs of progression to AIDS. [Awaiting revised language from NIH.] Understanding what happens in these non-progressors may help researchers develop better therapies and a vaccine.

And there is further reason for hope. Scientists now believe that a vaccine is possible. New classes of anti-retroviral therapies appear to be powerful in controlling the virus. Combination therapies are offer great potential promise in this area and in preventing perinatal transmission. In addition, the Food and Drug Administration, through its expedited review and accelerated approval programs, is now approving drugs faster than ever before and faster than any European nation.

However, despite these advances, many complex biomedical and behavioral

challenges remain. Identifying the most promising scientific avenues, and having the appropriate structures and processes in place to ensure that the Nation capitalizes on these opportunities, will require a considered and coordinated effort.

Opportunities for Progress

Coordinating Federal Research.

Developing and implementing the Federal government's AIDS research agenda presents both scientific and logistical challenges. Planning and overseeing this massive Federal effort requires coordination efforts at two levels -- one within NIH and the second among the Departments and Agencies supporting HIV research.

Within the NIH, the Agency with the largest portfolio, research is supported throughout 24 institutes, centers, and divisions (ICDs). In order to better plan, coordinate, and fund the AIDS research activities of these ICDs the Congress, through the NIH Revitalization Act Amendments of 1993, provided the Office of AIDS Research (OAR) with new oversight and budget authorities. As part of fulfilling the requirements of the law, the OAR develops a yearly NIH plan and budget for AIDS research and receives directly from the President and the Office of Management and Budget (OMB) a consolidated appropriation for AIDS activities at NIH. This single appropriation allows the OAR to effectively prioritize research resources on the basis of sound scientific judgment and provides flexibility for pursuing the most promising

research opportunities.

It is crucial that the authority granted OAR in the revitalization legislation, including the consolidated appropriation, be supported and maintained. With such a large research enterprise it is essential that there is oversight and accountability so the most promising approaches are vigorously pursued, gaps in research areas are identified, and the individual Institutes have both the scientific and administrative assistance they need to effectively collaborate with other NIH institutes.

It is also clear that while NIH supports a significant portion of HIV-related research, other Agencies and Departments support a broad spectrum of research related to HIV and AIDS. Multiple Federal Departments and Agencies have responded with research initiatives that bring to bear their unique capabilities and strengths. For the government to effectively support a diversity of promising approaches, these research efforts must also be well-planned and coordinated. To achieve this the Director of the Office of National AIDS Policy coordinated an inter-departmental working group, chaired by the Director of the Office of AIDS Research, whose charge it was to develop a coordinated plan and budget specifically for HIV and AIDS research across all Agencies Departments. [Awaiting additional language from NIH.]

The first Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS was completed in April 1996. The development of this plan brought together

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representatives from the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Department of Defense, the Department of Energy, and the Department of Veterans Affairs. This plan provides an initial blueprint to focus and coordinate existing Federal HIV/AIDS research initiatives and thereby utilize available resources more efficiently and effectively. It also serves as a foundation for continued planning and evaluation.

Vaccine Development. Several major challenges currently face the U.S. and the world in the HIV vaccine development effort. The first is to surmount the daunting scientific and social challenges, and the second is to ensure the development and testing of promising vaccine candidates.

On the scientific level, researchers presently hold two major views regarding the most promising approaches to vaccine development. Some scientists maintain that there is not sufficient information about the virus to warrant efficacy trials and there is a need to gather more basic science information to guide us. Others assert that only clinical efficacy trials in humans will provide the answers that will lead to the development of a successful candidate. This group believes that if a safe candidate is available, it is not necessary to resolve all of the scientific questions before proceeding, and, that in the face of a global emergency testing in people should begin immediately. Both groups have valid arguments.

The issues driving this debate are scientific

and social, and stem from the contrasting ways different parts of the world are experiencing the epidemic. Some regions of the world have already experienced the devastating consequences of the epidemic while, in other areas, the epidemic is in its early stages. Some governments have shown a greater interest than others in preparing for vaccine trials as a method of slowing the growth of the epidemic in their countries. [Awaiting revised language from NIH.] Both the social and scientific issues must be considered when planning trials. Given the State of scientific knowledge, there is some consensus that both the basic and empirical avenues can and should be pursued.

Both approaches face significant obstacles and it is clear that the developing a vaccine cannot be accomplished by the government or the private sector working apart -- a public-private partnership will be needed. In order to identify areas for fruitful collaboration and to accelerate the pace of development for vaccines, the Vice President convened a meeting of government scientists and leaders of the pharmaceutical and biotechnology industries to identify barriers to the development of these agents. Further dialogue involving key players regarding critical problems, and opportunities for development, and viable solutions has begun and will continue. [Awaiting revised language from NIH.]

In addition to effective collaboration with private sector partners, it is also vital that the Federal effort be well-coordinated. The Federal linkages that were strengthened

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during the development of the Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS should be utilized in furthering coordination. [Awaiting additional language from NIH.]

Microbicides. Many scientists believe that the prevention of sexually transmitted HIV infection will depend on the development of a safe, effective, female-controlled mechanical and chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections. [Awaiting revised language from NIH.] Worldwide over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. In the U.S., the infection rate among women is rising dramatically. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs²³. Microbicides could provide an easily available and inexpensive protection option for millions of women worldwide.

The barrier methods that are currently available have limitations. Most require consent, if not active participation of the male partner, and therefore cannot be independently used at the discretion of the female partner. Although epidemiological studies have demonstrated that the correct and consistent use of condoms will reduce the risk of acquiring HIV and other STDs there are many situations in which interpersonal, social, or cultural barriers interfere with a woman's ability to successfully negotiate condom use. The need for a method that can be employed by

women is based on the prevalence of non-consensual sex, sex without condom use, and risky behaviors that occur without partner knowledge. [Awaiting revised language from NIH.]

The development of this important prevention option will depend on strong support for basic and clinical research. Microbicides are a promising approach, but will require preliminary Federal support before they reach a stage where the pharmaceutical or biotechnology industries can assume a lead role. Discussions among Federal Agencies, the private sector, and advocacy groups have been ongoing and should continue in order to identify areas for worthwhile collaboration and hasten the pace of development. [Awaiting revised language from NIH.]

Examining the Impact of HIV on Youth. HIV-related research has made great strides on many fronts, however, adolescents have not received the full benefit of research discoveries. To date, HIV research efforts have primarily focused two specific populations: infants and adults.

But scientific information exists to indicate that HIV may behave differently in infected adolescents and that there are adolescent-specific health-care needs that must be addressed. Adolescent treatment approaches may vary from those used for adult or infants. Because little definitive research has been conducted to date with HIV-positive adolescents, the specific impact of puberty on the course of HIV infection has not yet been determined. Behavioral trends

that play a key factor in treatment and prevention have also not been sufficiently studied.

Adolescents must become a bigger part of the research process. The NIH and the Food and Drug Administration should examine options for lowering barriers to participation and continue to encourage sponsors to enroll adolescents, when feasible and appropriate, in HIV/AIDS clinical trials.

There is also need for adolescent-relevant information on the part of clinicians and researchers. Models of collaboration have been developed to improve our understanding of disease and health in adolescents; several PHS agencies have cooperatively established the Adolescent Medicine HIV/AIDS Research Network. The Public Health Service should continue to develop in collaboration with researchers, clinicians, and the infected and affected community, clinical practice guidelines and expeditiously disseminate the latest information on state-of-the-art therapies, options for trials and eligibility criteria for entry into them, and health care and prevention techniques to U.S. and international communities affected by HIV/AIDS.

Clinical Effectiveness Research. Due in part to the FDA's accelerated approval program²⁴, the Federal government is now approving new treatments in record numbers and at record speed, but it is not always known whether a treatment confers a clinical benefit for the person. Specifically, while some treatments have shown promise based

on surrogate markers and/or laboratory tests, data regarding clinical effectiveness are increasingly unavailable. For example, we do not know the optimal stage in the course of HIV disease to begin treatment, for which patient groups, with which regimen, or with single or combination therapy. We also do not know when it is appropriate to switch or add therapies.

If these studies are not done there will be little data describing which of the available treatments is more effective and for whom, and under what circumstances. As a result, patients may be receiving less effective treatments or combinations of treatments, and Federal programs such as Medicaid and Medicare and private insurers may be paying for treatment strategies that are not optimally effective.

With the advent of accelerated approval by the FDA it is incumbent on the government to ensure that post-marketing effectiveness studies, currently mandated through regulation are carried out. In order for the results to be relevant to as many persons as possible, it will be necessary that these studies include people representing a diversity of race, ethnicity, gender, age, and drug using behaviors. To develop a mechanism for conducting such studies, the Vice President has initiated discussions to examine possible options. Participants include pharmaceutical firms, public and private payors and insurers, researchers, the FDA, the NIH, and the advocacy community.

Public-Private Partnerships. As has been

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noted previously, a key role for the Federal government is to act in partnership with the private sector and support areas where there is a market failure, i.e., areas where industry is unlikely to pursue research that would be beneficial to the public health. Vaccine development is one such area, but there are others. The Department of Defense has been successful in developing partnerships in the conduct of vaccine trials and this effort should be strengthened. As noted previously, microbicides (i.e., chemical barrier methods for preventing HIV transmission) are a promising approach, but will require preliminary Federal support before they reach a stage where the private sector can assume a lead role. [Awaiting additional language from NIH.]

It is also unlikely that the free market system will push the implementation of head-to-head clinical trials of therapies that have been approved or are in development. However, information about these therapies is important to improving patient care and ensuring that the Nation's health dollars are wisely spent. The National Institutes of Health and Veteran's Administration have been successful in carrying out this type of valuable research in collaboration with the pharmaceutical industry and these efforts should continue. It is unlikely that the private sector would support research for therapies that are on the market but have not been tested in controlled clinical trials, such as alternative therapies. However, through collaborative partnerships including the NIH, studies of alternative therapies have been conducted; these are important efforts

that should continue. [Awaiting additional language from NIH.]

It is also cost effective for the government to provide access to sophisticated equipment and personnel that can be shared among many researchers in both the private and public sectors. For example, the Department of Energy has supported sophisticated imaging equipment that would be prohibitively expensive for individual researchers or companies to purchase. This shared resource that has accelerated our understanding of molecular structures in a number of research fields, including HIV research. Information gained from this research can form the basis for targeted drug design and development. [Awaiting additional language from NIH.]

Research: An Investment for the Future. And finally, research is an investment in our future. It must receive consistent and adequate funding if we hope to bring the best and the brightest to meet the research challenges that will lead to a cure, better therapies, and a vaccine.

At present, the NIH receives many more outstanding research applications than it is able to fund; these unfunded proposals represent a lost opportunity for scientific progress. Other Departments and Agencies, such as the Department of Defense and Veteran's Administration also support crucially important research that strengthens the overall U.S. research effort. Research has been key to improving lives and the Nation must continue this investment. [Awaiting additional language from NIH.]

CARE & SERVICES

One of the national goals is to ensure appropriate care for all persons living with HIV and AIDS. Achieving the goal of ensuring appropriate care of all Americans, including those living with HIV, will require a dedicated alliance among the Federal government, States, the private sector, local communities, community-based organizations, clinics, families, and individuals.

Background

Persons living with HIV finance needed health care services through a variety of mechanisms. Currently, nearly 50 percent of adult Americans and 90 percent of children living with AIDS receive their medical coverage through the Medicaid program and another 5 percent receive Medicare benefits. An estimated 15 percent of people living with AIDS have private health insurance and the remaining 30 percent are uninsured and must rely on personal payment or charity care. For the remainder, their lives often depend on the Federal health care safety net.

For those who qualify, care and services are provided through a number of Federal Agencies (See Appendix C), many in cooperation with local organizations and the AIDS community that have admirably served those living with HIV. Taken together, these efforts form a valuable if incomplete safety net for some of the most vulnerable people in our Nation.

After Medicaid, the centerpiece of this safety net is programs funded through the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, administered by the Health Resources and Services Administration (HRSA). It was established to fill gaps in coverage and build systems of care to create access to health care for people living with HIV/AIDS. Titles I and II of the CARE Act provide funds for outpatient care, support services, and case management that are given to cities and States primarily on a formula basis so the areas most affected by the epidemic receive a proportional share of available dollars. Title II also provides drug reimbursement funding for persons living with AIDS. Title IIIb of the Act provides early intervention services such as counseling and testing, medical care, and educational services for medically underserved persons with the goal reducing HIV-related illness. Title IV seeks to increase the availability of care and services for women, infants, children, and youth in a community-based family-centered system of care. HRSA also provides primary care to persons living with HIV through its Community Health Centers and Maternal and Child Health Programs.

Other sources of primary care supported by the Federal government include the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service/DHHS which provides health care for HIV-infected Native Americans and Alaska Natives. Additionally, the Bureau of Prisons within the Department of Justice provides care for HIV positive persons in

Federal prisons.

Housing assistance is provided by the Department of Housing and Urban Development (HUD) through their Housing Opportunities for Persons with AIDS (HOPWA) and other programs. These programs work in partnership with local initiatives incorporating housing assistance into a community's continuum of services.

Opportunities for Progress

The challenge before us today, especially in light of the restricted fiscal environment, is to ensure that persons living with HIV receive the care they need so they may have the opportunity to live productive lives. To achieve this, AIDS care and service programs must build upon past successes, continue to improve prioritization efforts, improve accountability, and increase the cost-effectiveness of services they provide.

The Health Care Safety Net. The cornerstone of care for people living with AIDS in the U.S. is Medicaid. Nearly 50 percent of all Americans living with AIDS -- including 92 percent of children with AIDS -- rely on Medicaid for their sole source of health coverage. Medicaid provides coverage for hospitalizations, physician visits, x-rays and laboratory tests, home health care, nursing home care, and outpatient prescription drugs. These services extend the length and the quality of life for people living with HIV and AIDS. In fiscal year 1996, Federal Medicaid spending for people living with AIDS is

estimated at \$1.8 billion, nearly six times the amount expended on the Ryan White CARE Act.

Maintenance of the Federal guarantee of Medicaid coverage for eligible individuals is essential to the continued ability of the Nation to respond to the health care needs of people living with HIV/AIDS. Of particular importance is the maintenance of a Federal definition of disability. The 30-year State partnership in Medicaid also must be maintained while the program is made more flexible for State innovations.

With a strong Medicaid program in place, it continues to be vital that the Ryan White CARE Act be maintained and expanded to fill the gaps in coverage. Many people with HIV and AIDS are too poor or too disabled to work yet they are not poor enough or disabled enough to qualify for Medicaid. For them, and for their families, the CARE Act provides essential protection.

Integrated Continuum of Care. Many health care providers believe that one of the most potentially effective approaches to treating HIV positive persons, in addition to reducing the spread of infection, lies in providing people access to an integrated continuum of health care services. This includes counseling and testing, comprehensive health care, home health care, and access to substance abuse treatment and prevention services.

One of the most powerful methods of recruiting people into primary care is knowledge of serostatus -- persons who

know they are HIV positive are more likely to seek health care. Counseling and testing services can serve as a gateway to this care. Unfortunately, the majority of Americans who may be at risk for HIV infection do not know whether or not they are HIV positive. There is a need to develop better outreach education in order to encourage people to come in for counseling and testing and link them to appropriate services as needed. Without the linkage of testing to medical care, the opportunity to prolong life is lost.

Linking an HIV-positive person with care also provides an opportunity for education about behaviors which may reduce their chances of infecting others. For example, this can mean offering addiction treatment or offering pregnant women information about and access to AZT during pregnancy to reduce the risk of perinatal transmission.

As noted in the Prevention Section, achieving this level of integration will require active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to State, local and Federal governments.

Housing Services. Housing is an important element in the effort to provide comprehensive care for persons living with HIV. It is the foundation upon which any program of care or services must be built. Without stable housing, a person with HIV/AIDS has diminished access to programs and services and a diminished opportunity to live a productive life. It is

estimated that up to 50 percent of persons living with HIV and AIDS will become homeless or are at risk for becoming homeless during the course of their illness.²⁵

Persons living with HIV face significant obstacles locating affordable housing. The private market alone does not consistently meet the basic housing needs of persons living with HIV and their families, as housing must often be provided in connection with specialized services that enhance an individual's or family's ability to live independently. In addition, persons living with HIV must also overcome reduced housing options due to unfounded fears and prejudice regarding AIDS.

Housing assistance is an area that requires significant community involvement and support if it is to be successful. Many communities are part of new efforts to comprehensively plan for the housing needs of their residents, including assessing and addressing the needs of residents living with HIV/AIDS.

The HOPWA program was created in 1992 to provide communities with a tool to meet the increased need for resources, effective planning, and coordination with existing public and private efforts. The program is representative of HUD's "Continuum of Care" approach to building local systems to address homelessness. Moreover, it is estimated that the cost of providing housing services in a HOPWA-funded residential facility is far less than the average day in the hospital.

To further foster community involvement, HUD has also established the Consolidated Planning process for communities that receive funds under the Department's economic and community development programs, including recipients of HOPWA formula allocations. In addition, the Community Development Block Grant (CDBG) and the HOME affordable housing program as well as Public Housing programs are key resources that are available to communities, contingent on eligibility, space availability and local priorities.

Providing consistent funding for the housing component of the safety net with programs such as community-oriented programs HOPWA must be a Federal priority. Moreover, integrating housing services into other programs and ensuring a shared responsibility between Federal, State, local governments and community organizations is another important step in assisting communities to build seamless systems of support for our most vulnerable citizens. Efforts are underway to improve inter-departmental coordination and should continue.

Prisoners. There are also groups of people, such as prisoners, who are not served by these traditional safety net programs. Most prisoners living with HIV are incarcerated in State and local prisons. Medical care for Federal prisoners is provided under the direction of the Department of Justice's Bureau of Prisons. Identifying the HIV positive prisoners and ensuring them access to quality care for incarcerated persons is

especially challenging. Prisoners do not have the choice of seeking care outside the prison setting and are dependent upon the prison staff to ensure that appropriate care is provided. They also may have difficulties regarding confidentiality, trust, and less access to research opportunities.

Improving access to appropriate HIV-related care in prisons must be a priority. At the Federal level significant advances are being made in the quality of care, improved coordination, and developing models of care. Improving the quality of care at non-federal prisons will require improving the knowledge and skill of the health care teams in the prisons, strengthening linkages between prisons and outside public health Departments and Agencies, and improving discharge planning. These efforts can serve to improve discharge planning for HIV positive prisoners at the time of their release from prison.

Program Coordination. For care and services to have the most beneficial impact they should be offered as part of a continuum of care. For organizations on the front lines of the epidemic, building a comprehensive integrated program requires applying to numerous Federal Agencies. For example, Creating a community program that integrates primary care with substance abuse treatment and prevention, and sexually transmitted disease screening, prevention, access to clinical trials, and housing assistance would require separate applications to SAMSHA, HRSA, CDC, NIH, and HUD.

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Efforts to simplify federal funding applications to facilitate improved integration of service programs have already begun. For example, HRSA and SAMSHA have issued joint announcements and the HUD and HRSA have issued a joint announcement for the Special Projects of National Significance (SPNS) program. These efforts to improve integration should be continued and expanded.

Evaluation. Strong Federal support for these safety net programs must go hand-in-hand with improved accountability and priority setting. Evaluating current activities can provide valuable information for planners and those on the frontlines of the epidemic. It can assist us in providing better care to persons living with HIV. In an era of limited resources coupled with a demand for cost effective services of high quality, we must use all the tools available to us if we are to help those persons living with HIV.

Quality of Care. Federally supported programs can and should consistently provide quality care. Through the efforts of researchers and clinicians, it has been proven that quality care for HIV positive persons is possible, but quality care is not consistently available throughout the health care system. Establishing a standard-of-care and ensuring consistency in care delivery will require increased training for health care professionals and more accountability through the use of performance measures for quality care.

A Federal program that has achieved success

in improving the knowledge and skills of clinicians is the AIDS Education and Training Centers (AETCs) effort sponsored by the Health Resources and Services Administration. A major goal of the AETC program is to train health care professionals in the prevention, early diagnosis, and treatment of HIV infection.

However, this program alone cannot ensure that all health care providers have the knowledge and skills required to provide satisfactory care for HIV positive persons. Achieving this goal will require the cooperation of Federal Agencies, States, professional organizations, professional and medical schools, and individual clinicians.

INTERNATIONAL ACTIVITIES

AIDS is a global pandemic. In the United States it is estimated that between 800,000 and 1 million people are currently infected with HIV. The World Health Organization (WHO) estimates that 18.5 million adults and over 1.5 million children are currently infected worldwide and there will be 10 to 15 million orphans worldwide attributable to HIV/AIDS by the year 2000. WHO also estimates that two to three million new HIV infections can be expected annually, and by the year 2000, thirty to forty million people will have been infected around the globe.

The pandemic jeopardizes decades of economic and social advances in many developing nations. In Africa and Asia, economic advances are threatened, and in some cases, may be reversed due to the pandemic of HIV and AIDS. Socio-economic studies have shown a decrease in overall domestic savings and investment levels, negative effects on foreign investments, reductions in the volumes of imports and exports, and a reduction in receipts from tourism.²⁶ In many countries, governments will be forced to cope with increasing numbers of cases, weakened health care systems, a deleterious economic impact on the most productive segments of society, and the reduction in the number of healthy men and women able to serve in the government and the military.

At present several Federal Agencies are working at slowing the AIDS epidemic internationally. (See Appendix D.) The Department of State has worked with other

Departments, Agencies, and non-governmental organizations to develop a framework to guide U.S. foreign policy in the global efforts against HIV and AIDS. The major areas identified for U.S. leadership are: preventing new infections; reducing the personal and social impact of the pandemic; and mobilizing and unify national and international efforts. The U.S. Agency for International Development (USAID) also has a leadership role in the global HIV effort through development assistance, research and policy formation. USAID focuses its strategy on developing prevention programs based on proven interventions, addressing social, cultural, regulatory and economic issues related to HIV/AIDS and other sexually transmitted infections, and developing and testing new interventions and methods to prevent transmission and mitigate the impact of the epidemic. The U.S. Information Agency (USIA) supports programs that promote dissemination of U.S. policies and information related to HIV and AIDS; and the Peace Corps trains a portion of its volunteers to directly address HIV-related concerns in their countries of placement. In addition, several Agencies support research overseas, including the National Institutes of Health, the Centers for Disease Control and Prevention, and the Department of Defense (DOD). The DOD is conducting clinical trials of candidate HIV vaccines in Thailand and NIH (working in collaboration with USAID), supports basic scientific studies on social and behavioral aspects of AIDS in developing countries. [Awaiting additional language from NIH.] The results of the studies ultimately will be used to develop

interventions to reduce behaviors that place individuals at risk for contracting HIV infection.

Opportunities for Progress

International Leadership. The United States has established a global leadership role in combatting the epidemic. This leadership must continue. The U.S. strongly supports the newly established Joint and Co-sponsored United Nations Programme on AIDS (UNAIDS).²⁷ Moreover, the U.S. is a member of the governing body of UNAIDS.

The U.S. also supports efforts to more effectively make use of available resources as well as to encourage non-traditional donor countries to provide much needed contributions. Supporting UNAIDS and its innovative programmatic efforts, and its goal of working to increase the availability of therapeutics (and vaccines when developed) to the residents of developing countries is not only morally correct, but also furthers U.S. interests by promoting economic and social stability worldwide.

Sharing Technology and Bringing Lessons Home. In addition to financing the development of large scale, comprehensive AIDS prevention programs in many countries, USAID has gained valuable insights and lessons from experiences from these countries and is applying them to U.S. populations.

Based on the Vice President's "Lessons without Borders Project" initiative to bring

lessons learned abroad home to inner city and rural areas with problems similar to those experienced overseas, this initiative creates linkages between U.S. community organizations and international projects. The U.S., through its various Agencies will continue to build and strengthen networks that will facilitate leadership, coordination and transnational approaches to AIDS prevention and control programs and AIDS related research; exchange culturally and linguistically appropriate educational and training materials; and demonstrate the bidirectionality of USAID international programs and its potential impact on US based programs, and U.S. based non-governmental organizations.

Program Coordination. One of the most challenging aspects of the U.S. effort is effective coordination among a host of Agencies with varied missions and activities. The State Department and Agencies such as USAID and USIA are primarily focused on country-specific activities, that include many HIV-related objectives. Other Agencies, such as NIH and CDC, also support international activities. [Awaiting additional language from NIH.]

These differences in focus present challenges in effectively planning, coordinating, and evaluating the overall U.S. international effort. Therefore, in order to improve this endeavor, the Agencies supporting international activities must develop a mechanism for identifying and coordinating this effort.

TRANSLATION OF RESEARCH INTO PRACTICE

An important element in our fight against AIDS is ensuring that hard won research advances are translated into practice (i.e., ensuring that new knowledge is incorporated into the standard practice of clinicians, service providers, and health educators caring for persons living with HIV). The increasing presence of HIV in every community necessitates that all health care providers become knowledgeable about assessing risk, promoting prevention, and caring for persons with HIV.

Improving the translation of research advances into daily clinical practice will require an ongoing collaborative effort on the part of the Federal government, individual health care providers, medical schools, professional organizations, international organizations, health centers and hospitals, and other parts of the private sector.

Information dissemination activities fall under the missions of several Agencies. (See Appendix E.) The National Institutes of Health (NIH) supports a broad range of efforts including a "Clinical Alerts" mechanism for the dissemination of clinical trials results to health professionals, the media, and the general public. DHHS supports and directs the International HIV/AIDS Clinical Conference Call series which disseminates critical, state-of-the-art clinical care information to primary care providers via live worldwide audio teleconferencing. NIH also supports publicly

available computerized databases such as AIDS DRUGS, AIDSTRIALS, and AIDSLINE. In addition the toll-free 1-800 TRIALS-A AIDS Clinical Trials Information Service (ACTIS) is co-sponsored by NIH, CDC, and FDA. [Awaiting additional language from NIH.] The Centers for Disease Control and Prevention (CDC) disseminates information through hotlines such as its toll-free 1-800-HIV-0440 HIV/AIDS Treatment Information Service (ATIS) and the AIDS Information Clearinghouse.

The CDC also issues guidelines for health professionals through its *Morbidity and Mortality Weekly Report*; such guidelines have included The U.S. Public Health Service Recommendations for HIV Counseling and Voluntary Testing for Pregnant Women. The Agency for Health Care Policy and Research (AHCPR) has published a series of HIV-related clinical practice guidelines for clinicians and companion pamphlets for their patients; an example of these materials is clinician guidelines for the evaluation and management of early HIV infection. The Health Resources and Services Administration has also developed guidances for its CARE Act grantees, funds an AIDS warmline that responds to questions from clinicians across the country, and directs a nationwide system of AIDS Education and Training Centers that provide state of the art HIV clinical information to health care providers.

Opportunities for Progress

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Due in part to Federally-sponsored information dissemination activities, dramatic changes in the way HIV is treated have taken place over the last 15 years. However, despite these successes, there are still areas for improvement. For example, an AHCPR-supported study indicated that primary care physicians may miss significant HIV-related symptoms during patient examinations.²⁸ Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.²⁹

We are also at a stage, unlike in the beginning of the epidemic, where research advances are coming more frequently. In the case of the NIH study that demonstrated it is possible to block perinatal transmission by administering a specific AZT regimen to the mother and baby, it became clear that this scientific breakthrough required a change in the standard of care and action by a number of Federal Agencies. This change also required the development of new testing and counseling guidelines to reflect the new options available to women. And it meant that for patients enrolled in Medicaid and Medicare to receive access to this breakthrough, a policy change on the part of the Health Care Financing Administration (HCFA) was required.

State of the Art Guidelines. One of the most difficult tasks for clinicians and patients is interpreting the patchwork of data and articles regarding treatments and converting it into a therapeutic strategy. With every research breakthrough, this task becomes more difficult. It is essential that

practical information for practicing clinicians and their patients be provided in a timely manner.

The Federal government must develop a mechanism for ensuring periodic assessment of the state of the art, ensuring that essential information can be found easily, and disseminating that information widely. This will require collaboration with industry, government, and professional groups.

Coordination of Federal Activities. Enhancing coordination of information dissemination activities among Public Health Service Agencies is an important priority. Within the DHHS, the Office of HIV/AIDS Policy has the lead responsibility for coordinating the HIV-related activities of the Public Health Service Agencies. Ensuring that information about a research breakthrough is easily available, reaches the appropriate persons and organizations, and that policies and standard-of-care practices for Federally-sponsored programs are modified to reflect the new standard, will require a continued high level of cooperation and coordination among Public Health Service Agencies.

Improved information dissemination efforts are also needed in the area of primary prevention models. As noted in the prevention section, good models of effective prevention interventions have been developed, but often this valuable information is not reaching those persons developing, implementing, and evaluating prevention programs. Here again, the Public Health Service must take the lead in

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ensuring that information that can be used to stem the tide of new infections reaches those who can make a difference.

CIVIL RIGHTS

One of the Nation's common goals is to ensure that treatment of persons living with HIV is caring, ethical, and in accordance with legal standards. Discrimination based on HIV status is illegal and morally wrong.

Discrimination undermines the Nation's efforts to prevent and treat HIV infection and bring the epidemic under control. Because of fear of discrimination and stigma, many people do not voluntarily seek testing for HIV, remain unaware of their HIV status, consequently do not take advantage of care that could help them live longer, healthier lives. In addition, opportunities to educate people are lost. Discrimination can also wrongfully deny persons access to housing, employment, and health care.

The Federal government and some States have enacted laws that protect persons with HIV from discrimination on the basis of their infection. Many of the more common legal issues faced by people living with HIV and AIDS, such as family law issues, estate planning, landlord/tenant problems are regulated by State law.

The primary source of Federal statutory protection for people living with HIV is the Americans with Disabilities Act of 1990 (ADA). (Federal Agencies are prohibited from discriminating against people with disabilities under the Rehabilitation Act of 1973.) Title I of the ADA prohibits discrimination against qualified disabled

individuals in employment settings. The Equal Employment Opportunity Commission (EEOC) is responsible for enforcing Title I. Title II of the ADA prohibits discrimination on the basis of disability with regard to public services while Title III prohibits discrimination on the basis of disability in public accommodations. The Department of Justice (DOJ) is responsible for enforcing Titles II and III. The Health Care Financing Administration (HCFA) also enforces regulations regarding the treatment of HIV-infected persons.

Opportunities for Progress

Enforcement of Federal Laws. The Federal government has aggressively and successfully prosecuted private sector violations of the ADA. These efforts will continue. Under this provision the government has been extremely successful in prosecuting a range of cases, including clinicians who have refused to care for HIV-positive patients and employers who have dismissed persons based on their actual or perceived HIV status. In addition to ongoing efforts, a joint Department of Justice and Health and Human Services program will seek to combat nursing home discrimination against persons living with AIDS.

Federal Policies. The Federal government must also actively work to remedy any of its own existing discriminatory policies. The Director of the Office of National AIDS Policy is working with Federal Agencies to ensure that HIV testing programs follow the recommendations of public health

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professionals. The Administration will also continue to oppose Congressional attempts to force discharge of infected military personnel who are still able to serve their country.

Leadership. The United States has made progress in fighting discrimination. However, the enactment of laws is insufficient to end discrimination. As a Nation we need to be vigilant and vocal in our efforts to fight discrimination. This is a responsibility that must be shared among Federal Agencies, States, communities, and the citizens of this country.

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Footnotes

1. *Morbidity and Mortality Weekly Report*. U.S. Department of Health and Human Services, Public Health Service. November 24, 1995, vol. 44, No. 46.
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4. Depending on stage diagnosed -- early or late. Source: Swartz & Rollins, *Business and Health*, 1985, 85, 24-6.
5. *Journal of the American Medical Association*, July 28, 1993.
6. The Public Health Service Agencies within DHHS with responsibility for a range of activities and programs associated with the HIV epidemic are: the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMSHA), the Health Resources and Services Administration (HRSA), the Agency for Health Care Policy and Research (AHCPR), the Food and Drug Administration (FDA), and the Indian Health Service (IHS). Information regarding these agencies can be found in the Appendices.
7. Public Health Service Plan for the Prevention and Control of Acquired Immune Deficiency Syndrome (AIDS), Public Health Reports 100:453-455, September-October, 1985.
8. Coolfont Report. A PHS plan for the Prevention and Control of AIDS and the AIDS Virus. Public Health Reports 101:341-348, July-August 1986.
9. Report of the Second Public Health Service AIDS Prevention and Control Conference. Public Health Reports. Vol. 103 Supplement No.1 (Revised). 1988.
10. The Public Health Service Strategic Plan to Combat HIV & AIDS in the United States. U.S. Department of Health and Human Services. 1992.
11. AIDS: An Expanding Tragedy. The Final Report of the National Commission on AIDS. Washington, DC. 1993.

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12. This section will address primary prevention activities. Other aspects of prevention, such as secondary prevention (i.e., preventing complications of HIV infection), development of topical microbicides, the behavioral components of vaccine research, and international prevention activities will be discussed in the following research, care and services, and international activities sections.

13. External Review of HIV Prevention Strategies by the CDC Advisory Committee on the Prevention of HIV Infection. U.S. Department of Health and Human Services, Public Health Service. June 1994.

14. Information on NIH-supported behavioral and epidemiological research relevant to primary prevention can be found in Appendix B: Research.

15. *AIDS and Behavior: An Integrated Approach*. Judith D. Auerbach, Christina Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine, National Academy Press, Washington, D.C., 1994. p.79.

16. *AIDS and Behavior: An Integrated Approach*. Judith D. Auerbach, Christian Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine. National Academy Press. Washington, DC. 1994.

17. *AIDS and Behavior: An Integrated Approach*. Judith D. Auerbach, Christian Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine. National Academy Press. Washington, DC. 1994.

18. JAMA article used in PRIM&R speech

19. Don C. Des Jarlais, Holly Hagan, Samuel R. Friedman, Patricia Friedmann, David Goldberg, Martin Frischer, Steven Green, Kerstin Tunving, Bengt Ljungberg, Alex Wodak, Michael Ross, David Purchase, Margaret E. Millson, Ted Myers. Maintaining Low HIV Seroprevalence in Populations of Injecting Drug Users. JAMA, October 18, 1995 -- Vol. 274, No. 15. pp 1226-1231.

20. Heiner Grosskurth, Frankc Mosha, James Todd, Extra Mwijarubi, Arnould Clokke, Kesheni Senkoro, Philippe Mayaud, John Changalucha, Angus Nicoll, Gina ka-Gina, James Newell, Kokuugonza Mugeye, David Mabey, Richard Hayes. Impact of Improved Treatment of Sexually Transmitted Diseases on HIV Infection in Rural Tanzania: Randomized Controlled Trial. The Lancet, Vol. 346, August 26, 1995.

21. Maria Wawer, Science. 9.08.95, vol. 269, No. 5229

22. Personal communication from CDC Division TB Elimination.

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23. Alan B. Stone, and Penelope J. Hitchcock. Vaginal Microbicides for Preventing the Transmission of HIV. *AIDS* 1994, 8 (suppl 1):S285-S293.

24. The accelerated approval regulation permits companies to seek approval of drugs for serious or life-threatening diseases when the drug provides meaningful therapeutic benefit over existing therapies. Under these procedures, the FDA may approve drugs based on surrogate endpoints, such as CD4+ cell counts that reasonably predict that a drug provides clinical benefit. The company is then required to confirm this clinical benefit through additional human studies to be completed after marketing approval. The accelerated approval regulation provides for removal of the drug from the market if further studies do not confirm the clinical benefit of the therapy.

25. Housing and the HIV/AIDS Epidemic: Recommendations for Action. National Commission on AIDS. Washington, D.C. July 1992.

26. *HIV/AIDS Policy Guidance*. U.S. Agency for International Development. September 1995.

27. Until recently, the United Nations' response to HIV/AIDS was carried out primarily by the World Health Organization's Global Programme on AIDS. On January 1, 1996 the U.N. launched UNAIDS, co-sponsored by six U.N. agencies to strengthen coordination and focus support for HIV/AIDS activities at the global and country levels. UNAIDS has established three mutually reinforcing roles: to be a major source of policy development and research; provide technical support; and be an advocate for comprehensive, multisectoral responses to the pandemic.

28. Douglas S. Paauw, Marjorie D. Wenrich, J. Randall Curtis, Jan D. Carline, Paul G. Ramsey. Ability of Primary Care Physicians to Recognize Physical Finding Associated with HIV Infection. *JAMA*. 1995; 274:1380-1382.

29. Colombotos, J., Messeri, P., McConnell, M.B., et al: Physicians, Nurses, and AIDS: Findings From a National Study. Rockville, MD: Agency for Health Care Policy and Research; 1995. Grant No. HS06359. (NTIS Publication PB95-129185)