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"We must develop a clear, well-articulated national plan for confronting AIDS."
The Final Report of the National Commission on AIDS
June 1993

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 AIDS Strategy that would detail the Federal government's long-term approach in responding to this epidemic. The National AIDS Strategy has been developed by the Clinton Administration 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, businesses, schools, churches, families, and individuals.

The President has identified the following national goals to guide our efforts against HIV:

- **To provide strong continuing support for AIDS-related research in order to find additional treatments, a preventive vaccine to protect the uninfected, and a cure for those currently infected;**

- **To provide strong continuing support for effective AIDS prevention efforts to continue to reduce the number of new HIV infections in the U.S.;**

- **To ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs; and,**

- **To ensure that people living with HIV are not subject to discrimination.**

- **To provide strong continuing support for international efforts to address the HIV epidemic.**

- **To ensure that research advances are translated into improved HIV prevention programs and better care for HIV positive persons.**

This document is a snapshot of where we are as a Nation and where we need to go in achieving these national goals. It summarizes some of the key accomplishments of our Nation's scientific and public health professionals and identifies key areas for further effort. In addition, the appendices to this report lay out, for the first time, detailed descriptions of the objectives, goals, and budgets of all Agencies involved in the Federal response to HIV in

six +services
five major areas of HIV policy: prevention, research, care, civil rights, international activities, and translation of research into practice.

advances
The National AIDS Strategy is intended to be a working document that requires regular updating and adjustment as goals are reached and new challenges emerge. This Strategy provides a reference point for continuing dialogues and collaborative efforts between the public and private sectors that are necessary to meet our national goals and objectives.

In that light, the Office of National AIDS Policy is seeking direct input from the Presidential Advisory Council on HIV/AIDS, national and community-based organizations, state and local government, clinicians and researchers, members of the infected and affected community, and other individuals and organizations who can contribute to this historic document. This Strategy is being released, first, in draft form to allow for maximum input to the first of an ongoing national effort to chart and plan Federal efforts in response to the epidemic of HIV/AIDS.

The development of a National AIDS Strategy 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 Federal government should focus its efforts.

The National AIDS Strategy was drafted in consultation with, and with guidance from, numerous groups and individuals. Within the Federal government, this effort began at the Agency level. Members of the Interdepartmental Task Force on HIV and AIDS (IDTF) representing all Federal Agencies involved in the national response to HIV and AIDS, identified their HIV-related goals, objectives, and highlighted areas requiring special attention.

Individuals living with HIV and AIDS, their families, friends, loved ones, and care givers made vital contributions to this Strategy. Numerous non-governmental groups and organizations have also been consulted including the Presidential Advisory Council on HIV/AIDS, participants in the historic White House Conference on HIV and AIDS, the ONAP-sponsored regional briefings, patient and consumer advocates, health care professionals, community-based organizations, educators, religious leaders, and business leaders. The earlier insights provided by the National Commission on AIDS, the Institute of Medicine and National Research Council, the General Accounting Office, and the Office of Technology Assessment have also been extraordinarily helpful in developing the National AIDS Strategy.

As a Nation, we face great challenges, but we are also facing equally great opportunities. After fifteen years, AIDS remains a terrible national tragedy that has affected -- and will

continue to affect -- far too many people in this Nation and around the world. But we have made tremendous progress in our understanding of HIV and HIV disease, ways we can treat those who are infected, and means by which we can prevent infection. Ultimately, HIV is a disease that we can defeat -- just as we have eradicated smallpox from our planet and polio from the western hemisphere. The National AIDS Strategy provides a foundation for the continuing public-private partnerships that are essential to our success. Together, with steadfast commitment, courage, and leadership, we will win the battle against HIV and AIDS.

Patricia S. Fleming
Director, Office of National AIDS Policy

"For nearly every American with eyes and ears open, the face of AIDS is no longer the face of a stranger. Millions and millions of us have now stood at the bedside of a dying friend and grieved. Millions and millions of us now know people who have had AIDS and who have died of it who are both gay and heterosexual. Millions and millions of us are now forced to admit that this is a problem which has diminished the life of every American."

President Clinton, December 1, 1993, Georgetown University

I. INTRODUCTION

Goals of the National Strategy

The President has identified the following national goals to guide our efforts against HIV:

- To provide strong continuing support for AIDS-related research in order to find additional treatments, a preventive vaccine to protect the uninfected, and a cure for those currently infected;
- To provide strong continuing support for effective AIDS prevention efforts to continue to reduce the number of new HIV infections in the U.S.;
- To ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs; ~~and,~~
- To ensure that people living with HIV are not subject to unlawful discrimination;
- To provide strong continuing support for international efforts to address the HIV epidemic; and,
- To ensure that research advances are translated into improved HIV prevention programs and better care for HIV positive persons.

Scope of the HIV/AIDS Epidemic

The epidemic 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 around the world. While significant progress has been made in understanding the disease and developing treatments since the first case was reported in the U.S. in June 1981, 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 average of 100 Americans are diagnosed with AIDS every day and a similar number of men, women, and children become infected with HIV every 24 hours. **[Richard -- are you certain these numbers are correct?]** Globally, 7,500 people become infected each day.

8,500

An Expanding Public Health Threat

As of December 1995, the Centers for Disease Control and Prevention (CDC) had received reports of 513,486 cases of AIDS among persons in the U.S. and 319,849 of these persons have been reported to have died as a result of complications related to HIV. Since 1987, AIDS has risen from being the 15th cause of death among all Americans to the 8th. AIDS is now the leading cause of death among Americans aged 25 to 44 (See Figure 1). In 1995 alone, approximately 74,000 new cases of AIDS were reported in the U.S. and more than 46,000 AIDS related deaths were reported to the CDC in 1994. CDC estimates that between 40,000 and 60,000 Americans are becoming newly infected with HIV each year, and that between 650,000 and 900,000 Americans are currently living with HIV.

As the epidemic in the United States has expanded, the demographics of the epidemic have changed. The early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers (i.e., New York, San Francisco, and Los Angeles). Today, this group represents less than half of all new cases, although they still represents the majority of persons living with HIV and AIDS. Among the populations that are more heavily affected today are young gay men, women, and injecting drug users and their sexual partners as well as users of non-injecting drugs (i.e., crack cocaine and alcohol). In 1995, nearly 14,000 women were reported to CDC as having been diagnosed with AIDS. Women now comprise 14 percent of cumulatively reported AIDS cases. If this trend continues, it is estimated that 80,000 American children will have been orphaned as a result of AIDS by the end of this decade. In 1995, approximately 800 new cases of pediatric AIDS cases were reported. (Footnote a) OK

Adolescents (age 13-19) are at increased risk for HIV infection. CDC estimates that one-quarter of new HIV infections in the U.S. occur among people under age 21. A significant number of young people are engaging at earlier ages in sexual intercourse and drug and alcohol use. 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.

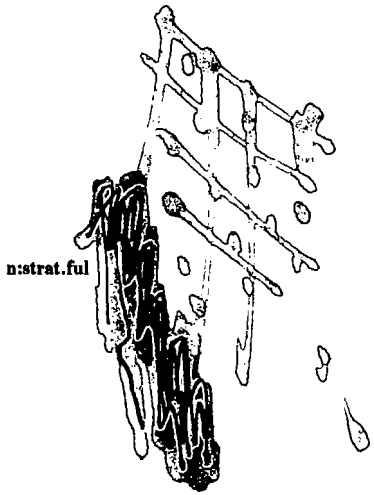
Racial and ethnic minorities have been disproportionately affected by the epidemic of HIV and AIDS. African-Americans, who represent approximately 12 percent of the U.S. population, accounted for 40 percent of newly reported AIDS cases in 1995. Hispanics, who account for about 9 percent of the general population, represented 19 percent of new cases reported in 1995. The number of African-Americans and Hispanics affected by HIV and

AIDS has risen dramatically. In 1982, Blacks and Hispanics represented 31 percent of all AIDS cases; however, as of December 1995, these groups comprised 52 percent of cumulative AIDS cases.

The HIV epidemic continues to spread into suburban and rural areas, with especially dramatic increases in certain regions of the South and Midwest. Between January 1993 and December 1995 the largest numbers of AIDS cases (86,462) were reported from the South. (Endnote 1)[1] While most cases are still reported from urban areas, the rate of reported cases in non-metropolitan areas is increasing more rapidly than in urban areas. AIDS cases have now been reported in all 50 States, the District of Columbia, Puerto Rico, Guam, and each of the U.S. territories (See Figure 2).

AIDS is an expensive disease. Average lifetime costs of medical care after diagnosis with HIV is $119,000 (Footnote b)[5] People living with HIV are disproportionately dependent on the public sector for their health care. Over 50 percent of people living with AIDS are enrolled in Medicaid, including more than 90 percent of children with AIDS. In FY 1996, the Federal government spent $1.8 billion on Medicaid benefits for people living with HIV and AIDS and another $690 million on Medicare benefits. Social Security benefits for people disabled by HIV/AIDS total $1.1 billion in FY 1996.

Globally, the toll of the epidemic is much greater and threatens to reverse decades of economic and public health progress in developing countries. The Joint United Programme on HIV and AIDS (UNAIDS) and the World Health Organization (WHO) estimate that 27.9 million people have been infected with HIV. Since the beginning of the pandemic, 6 million people, including 1.6 million children, have been diagnosed with AIDS. By the year 2000, WHO projects that between 30 million and 40 million people will have been infected with HIV and 10 million to 15 million children will be orphaned due to AIDS.



II. OVERVIEW OF FEDERAL EFFORTS

The scope and nature of the HIV/AIDS epidemic have drawn States, local governments, academic institutions, private foundations, health care institutions and community-based organizations and the Federal government 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 FY 1985 the Federal government spent $212 million for AIDS research, surveillance, and care. By FY 1995 that figure reached $6.8 billion. (See Appendix G).

In the past four years, under the leadership of President Clinton, spending for AIDS research, prevention, and care has increased by 47 percent. Funding for the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act alone has increased by 151 percent. Support for housing for people living with AIDS has increased by 91 percent. AIDS-related research funding has increased by 34 percent and AIDS prevention funding has increased by 24 percent. The National Institutes of Health Revitalization Act of 1993 provided the Office of AIDS Research with enhanced authority to prepare and carry out an annual AIDS research budget and plan. Approval of AIDS drugs by the Food and Drug Administration has been accelerated to record times. A community-based planning process has empowered local communities to develop innovative AIDS prevention programs. Eligibility for Social Security disability benefits for people with AIDS have been simplified and Federal laws prohibiting discrimination against people living with HIV and AIDS have been vigorously enforced.

As the epidemic continues, we must renew our vision for ending this epidemic. The sections that follow focus on six major policy areas: prevention, research, care and services, civil rights, international activities, and the translation of research advances into practice. They identify recent progress and future opportunities for further progress.

A. PREVENTION

"We have to set a goal. . .We have to reduce the number of new infections each and every year until there are no more new infections."

President Clinton, December 5, 1995, to the White House Conference on HIV and AIDS.

1. Record of Accomplishment

Since the epidemic began, there has been important progress in preventing HIV infection. Early in the epidemic, CDC estimated that more than 100,000 Americans were becoming infected with HIV each year; today, that total is between 40,000 and 60,000 people each year.

Sentinel accomplishments in prevention of HIV include:

- Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the first cases of AIDS;
- Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the risk factors associated with HIV infection; and
- Due in part to successful implementation of CDC-sponsored prevention strategies, a slowing in the growth of the epidemic.

Since President Clinton took office in 1993, efforts in HIV prevention have been accelerated. Actions include:

- Increasing funding for AIDS prevention by 24 percent;
- Launching the community planning partnership -- empowering local communities to make decisions about and develop innovative prevention efforts;
- Launching the Prevention Marketing Initiative, focusing on young adults (18 to 25) with frank public service announcements advocating sexual abstinence and, for the first time, the correct and consistent use of latex condoms; and,
- Reorganizing AIDS prevention efforts at the Centers for Disease Control and Prevention to foster greater coordination with efforts to reduce sexually transmitted diseases and tuberculosis.

Federal agencies have been instrumental in expanding our knowledge base about HIV prevention (see Appendix A). The CDC, the agency with primary Federal HIV surveillance and prevention responsibilities, has been pivotal in identifying risk factors associated with HIV transmission, seroprevalence of HIV in society, and trends in HIV infection. loud AIDS. CDC Helene

Federal efforts have shown that HIV prevention programs can be effective. CDC's prevention projects, many in partnership with states, local governments, and community-based organizations, have demonstrated that prevention programs are most effective when designed and implemented at a local level. Biomedical, behavioral, and social science prevention research conducted and supported by the National Institutes of Health (NIH) and CDC has expanded and will continue to expand our understanding of the determinants of HIV-related risk behavior.

The nation has also combatted the dual epidemics of HIV and drug abuse. The National Institute on Drug Abuse (NIDA), the Substance Abuse and Mental Health Services Administration (SAMHSA), and CDC support efforts to prevent HIV infection among drug users. The Office of National Drug Control Policy has pursued efforts to counter the problem of substance abuse and its devastating consequences.

There have been advances in integrating primary prevention into health care service systems. The Health Resources and Services Administration (HRSA) and the Department of Veterans Affairs (VA) have encouraged broader access to prevention information through the integration of prevention interventions into primary health care services and through support of early intervention services. HRSA and HCFA also have undertaken special initiatives designed to reduce perinatal transmission of HIV and HRSA has promoted primary prevention through the training of health professionals in the AIDS Education and Training Centers program.

2. Future Opportunities for Progress

To achieve the national goal of no new infections requires efforts in the prevention area on five fronts:

- o Improving understanding of trends in HIV transmission and seroprevalence
- o Improving scientific knowledge about effective prevention models and strategies
- o Strengthening community based programs
- o Integrating HIV and other prevention efforts
- o Targeting special populations

a. Improving Understanding of Trends in the Epidemic

Understanding who is becoming infected and through what behaviors is critical to designing effective prevention interventions, as well as targeting service resources. As discussed in the introduction, the demographics of the epidemic have shifted, and effective prevention depends on rapidly understanding these shifts and responding to them.

CDC's AIDS case and case death reporting system provides important data for assessing AIDS prevalence and mortality by gender, race/ethnicity, age, and mode of exposure. However, this approach does not capture sufficient "front-end" information on the incidence and prevalence of HIV prior to an AIDS diagnosis. We, therefore, miss critical warning signs about new trends in affected populations and increasing risky behaviors.

To address this shortcoming, the CDC will work to improve its surveillance of HIV infection and related diseases and surveillance of HIV behavioral risk factors, both to better monitor the course of the epidemic and to provide guidance to community planners for targeting prevention and service dollars. This can and will be undertaken without compromising the confidentiality of those involved.

b. Research on Effective Prevention Strategies

Effective interventions must be based on sound research findings and evaluations. Funding for prevention and behavioral research did not receive the same priority in the early years of the epidemic as biomedical research. In response to the recommendations from the Report of the NIH AIDS Research Program Evaluation Task Force, NIH is developing a comprehensive HIV prevention science agenda. NIH and CDC are both committed to increasing future support for basic research on behavior, interventions, social marketing and program evaluation.

Behavioral Research Basic behavioral research answers key questions about the determinants of HIV-associated sexual and drug using behaviors. We still lack key knowledge in this area, which is critical to developing effective interventions.

Intervention Research Intervention research focuses on individual and community level interventions that result in modified sexual and drug using behaviors. There have been significant accomplishments in this area, but, as this portfolio expands, it will be critical to assess intervention in real world settings that are relevant to the growing number of populations that must be reached by prevention programs. This research should be designed by a broad range of scientists, public health, and community experts to assure its relevance.

Social Marketing Research The use of social marketing techniques is a relatively new approach to HIV prevention. This promising area requires use of basic and intervention

research, as well as careful design and evaluation of social marketing efforts.

Evaluation To ensure that prevention programs are actually working -- and so scarce resources are spent on the most effective intervention -- all federally funded prevention activities will routinely include evaluation components. The funding agencies will share widely the knowledge gained about what works and what does not to ensure promotion of best practices in the field. In addition, as part of the federal government's compliance with the Government Performance and Results Act, CDC and SAMHSA will continue to work with its constituents to develop appropriate performance measures for HIV prevention programs.

c. Strengthening Community-based Programs

Community prevention planning is one of the key innovations in CDC's prevention programming over the last several years. This public/private partnership puts federal funds to work based on locally designed priorities. This three-year-old initiative is at a crucial stage of development, and ensuring its success is the third key element of this strategy's prevention agenda.

Community planning requires ongoing leadership from CDC and its partners as well as the resources to provide the technical assistance the community planning process needs to flourish. Successful HIV prevention often depends on small, new community based organizations, many serving minority populations. These organizations need assistance not just on how to plan and compete successfully for available resources, but also how to appropriately incorporate epidemiological and research information into community prevention programs.

d. Program Integration and Collaboration

The fourth of the prevention agenda is improving the integration of HIV prevention into other program areas that reach individuals at risk for HIV. HIV prevention programs cannot stand apart from other, related public health efforts.

Substance Abuse HIV transmission is directly related to substance abuse, both directly through needle sharing behaviors and indirectly as sex is traded for drugs or drug use impairs judgment and increases risk taking behaviors. Breaking that linkage will require:

- Integration of HIV prevention into substance abuse treatment and prevention programs. In August, 1996, at the request of President Clinton, the Public Health Service agencies jointly co-sponsored a national meeting of state and local officials, researchers, and community experts from the fields of HIV and substance abuse to develop an action plan to more effectively integrate HIV and substance abuse

prevention efforts. These agencies are committed to implementing this strategy in the year ahead.

- Enrolling more substance abusers into drug treatment. Substance abuse treatment is a major form of HIV prevention. This Administration will continue to press for increased funding for substance abuse treatment. Further, through outreach and demonstration programs, SAMHSA and CDC will work to enroll more people in treatment and to find more successful interventions to accomplish this end.

- Reducing the availability of illegal drugs. The Office of National Drug Control Policy (ONDCP) is leading the fight on two fronts: reducing demand for drugs through treatment and prevention programs, and reducing the availability of drugs through interdiction.

- Preventing HIV transmission through contaminated needles. Sharing of syringes among injecting drug users is the principal means of HIV transmission in this population. While abstinence from drug use is always the preferred means of prevention, the CDC has issued guidelines regarding the use of bleach to clean injection equipment. In addition, CDC-supported research showed that removal of restrictions on over-the-counter sale of needles results in decreased needle sharing. Current federal law prohibits the use of federal funds for needle exchange programs; however a number of communities across the country have successfully undertaken these programs with local resources.

Primary Care HIV prevention needs to be better integrated into primary care. New and promising medical interventions make it critical to improve our approach to HIV counseling and testing -- creating a critical bridge between prevention and primary care. CDC is committed to improving the return rate of those tested at publicly funded sites and the quality of referral to services for those who test positive.

The linkage must also go in the opposite direction: from primary care to prevention. Primary care providers must learn to incorporate a person's sexual and drug using history when a medical history is taken, offering HIV-related counseling and voluntary testing, and providing prevention education to HIV positive individuals as part of the provider- patient relationship. HRSA's AIDS Education and Training Centers (AETCs) have played a crucial role in giving providers the information and skills they need. The Administration is committed to restoring Congressionally-imposed cuts in the AETC program and giving it a renewed focus to support this goal.

Often primary care is a direct form of HIV prevention. The federally supported research that showed AZT could reduce perinatal transmission of HIV was a tremendous medical breakthrough. Realizing the promise of this advance requires a commitment to assuring that

all pregnant women are counseled and offered HIV testing -- and that AZT treatment is available for all who desire it. All federally funded programs reaching pregnant women -- from Medicaid to Ryan White CARE Act grantees to community and migrant health centers -- are required to take part in this effort. We are committed to expanding outreach and assuring appropriate care so that the Congressionally set goal of reducing perinatal transmission by 50 percent by the year 2000 is achieved.

Other STDs and TB Recent research has confirmed that treatment of sexually transmitted diseases (STDs) other than HIV can reduce the likelihood of HIV transmission -- making the need for collaboration between HIV and STD prevention efforts more compelling. Similarly, people living with HIV are at very high risk for developing active tuberculosis. Studies suggest that the risk of developing active TB is 7 to 10 percent per year for persons who are infected with both TB and HIV, as opposed to a 10 percent lifetime risk for persons not infected with HIV. [Footnote: Personal communication from CDC Division TB Elimination.]

To address the need to integrate work on these inter-related epidemics, CDC organized the new National Center for HIV, STD, and TB prevention. CDC has initiated -- and will aggressively pursue -- efforts to increase collaboration among these programs, including expanding the community planning experiment to cover STD programs.

e. Targeting Special Populations

As discussed above, the HIV epidemic continues to have a disproportionate impact on certain populations where infection rates are rising at a worrisome pace. A fifth and final challenge for prevention programming is to pay particular attention to groups which traditionally receive fewer services, but where the risk of infection is greatest. These include youth (especially young gay men), women, and minorities (especially young gay men of color), prisoners, and, as discussed above, substance abusers. Many federally funded HIV prevention activities already target these populations, but the President's increased funding request for CDC provides $35 million in new funds in FY 1997 specifically for programs and research targeting youth, women, and substance abusers.

B. RESEARCH

"Our common goal must ultimately be a cure, a cure for all those who are living with HIV, and a vaccine to protect us from the virus."
President Clinton, December 5, 1995, to the White House Conference on HIV and AIDS

1. Record of Accomplishment

Since 1981, the nation has made significant advances in HIV-related research including:

- Identification of HIV as the etiologic agent for AIDS,
- Development of a reliable test to determine exposure to HIV,
- Approval of zidovudine (AZT), the first treatment of HIV primary infection,
- Development by the Food and Drug Administration of a system of expedited review of treatments for life-threatening diseases, including HIV.
- Approval of by the FDA of 15 new drugs, 8 new indications, and three new diagnostics for HIV and related conditions, developed through public and private sector development efforts.

Since he took office in 1993, President Clinton has escalated our AIDS research efforts by:

- Increasing AIDS research funding by 34 percent,
- Signing the NIH Revitalization Act of 1993, granting the Office of AIDS Research at NIH new authority to plan and implement an annual AIDS research budget and plan,
- Accelerating AIDS drug approval to record times;
- Supporting research that led to finding that use of AZT during pregnancy, childbirth, and the first six weeks of life can reduce the transmission of HIV from mother to child by two-thirds,
- Launching a four-year, $100 million research effort to develop effective topical microbicides;
- Facilitating creation of the Forum for Collaborative HIV Research to identify opportunities for clinical effectiveness research to improve care for HIV-positive individuals.

Contributions of AIDS Research

AIDS research has provided significant benefits beyond the epidemic, in work on many other diseases. AIDS research has accelerated study of the human immune system, helping to better understand and treat diseases such as cancer; autoimmune diseases, including systemic lupus erythematosus; type I diabetes mellitus; rheumatoid arthritis; and multiple sclerosis. AIDS research advances have also contributed to the prevention of other infectious diseases and provided a new paradigm for treatment of viral diseases.

Progress in the treatment and prevention of HIV-related opportunistic infections have had an enormous impact on the care of patients with other immunodeficiency conditions who are susceptible to many of the same pathogens. This research effort has enhanced the care of cancer patients, patients who have received immunosuppressive therapy for transplants, and the treatment of diseases caused by elevated immune responses (i.e., allergies and lupus).

HIV research has assisted in identifying new infectious agents that may be responsible for malignancies, such as the recent discovery of the etiologic agent for Kaposi's sarcoma. These findings may help to identify other oncogenic agents. HIV research has led to a better understanding of the mechanisms by which infectious agents and inflammatory cells cross the blood/brain barrier, providing 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 additional viral diseases and led to development of treatments.

Efforts to develop drugs for the treatment of HIV have accelerated the development of methods of rational drug design using sophisticated techniques of structural biology and advanced computer imaging methods. These advances have implications for drug design for virtually all disorders. Comparative clinical trials of poxvirus vectors and vaccine adjuvants in HIV vaccine candidates have supported safety information for cancer vaccines. Research on HIV-related wasting has provided important information for research on nutritional disorders, metabolic abnormalities, and gastrointestinal dysfunctions.

2. Future Opportunities for Progress

While tremendous progress has been made in biomedical research, we cannot and will not diminish our effort until we have found a cure and a preventive vaccine. To accomplish this national goal, we must address four ongoing challenges:

o Provide leadership and coordination for the federal research effort

- o Develop biomedical interventions that prevent HIV infection, including both a vaccine and a microbicide

- o Develop new and more effective therapies for HIV and related conditions

- o Assure adequate funding for this research effort.

a. Leadership and coordination of research.

Developing and implementing the federal government's AIDS research agenda presents both scientific and logistical challenges that require leadership and coordination, first among the 24 institutes, centers, and divisions of the NIH, and second among the various Departments and Agencies throughout the government that support HIV research.

The strengthened authority and new leadership of the NIH Office of AIDS Research and the first Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS form the basis for better coordination of our research effort and provide the assurance that key questions are being answered systematically and without duplication. Over the next year, the Administration is committed to reauthorizing the OAR's authority and assuring that its budget powers are maintained throughout the appropriations process.

As part of the ongoing commitment to assess all aspects of our research effort, the OAR convened a panel of outside experts to evaluate the NIH AIDS programs. The Report of the NIH AIDS Research Program Evaluation Task Force included several key recommendations that will be implemented in the year ahead. These include:

[NIH: IS THIS THE RIGHT LIST OF KEY INITIATIVES RESULTING FROM LEVINE REPORT?]

- o increase the Nation's commitment to basic science advancement by expanding the resources available for investigator-initiated research;

- o improve coordination among all NIH-supported clinical trials groups;

- o give new and stronger leadership to the vaccine development programs; and

- o increase the commitment to behavioral research by developing a comprehensive NIH HIV prevention science agenda.

b. Biomedical Prevention of HIV infection

Vaccine Development The scientific community remains confident that, ultimately, an effective vaccine against HIV infection can be developed. This is our ultimate goal in the area of prevention and in FY 1997, the Federal government plans to increase its commitment to vaccine research by $xx million.

The federal government, through the NIH and the Department of Defense, will continue to support two approaches to vaccine development. The first approach is based on the belief that gathering additional basic science information offers the best hope in steering vaccine development and that many critical questions must be answered before human trials should begin. The second approach is guided by the belief that data gathered from clinical efficacy trials in humans can lead to the development of a successful candidate and that if a safe candidate is available, it is not necessary to resolve all of the scientific questions before proceeding with human trials. Both approaches will be pursued on a parallel and interrelated path.

Microbicides Many scientists believe that in the absence of a vaccine the development of safe and effective mechanical or chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections could dramatically reduce the sexual transmission of HIV. Worldwide, over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs. (Footnote: Alan B. Stone, and Penelope J. Hitchcock. Vaginal Microbicides for Preventing the Transmission of HIV. AIDS 1994, 8 (suppl 1):S285-S293.)

Condoms, the barrier methods that are currently available, have limitations. Most require the consent, if not the active participation of both partners and therefore cannot be independently used at the discretion of one partner. An easily available and inexpensive microbicide could provide a prevention option for millions of people worldwide.

To address this goal, the following steps will be taken:

o During FY 1997, the NIH and CDC will begin to implement the four-year, $100 million initiative on microbicides announced by Secretary of Health and Human Services Donna Shalala at the Eleventh International Conference on AIDS;

o The Vice President will continue a high-level dialogue designed to encourage private sector involvement in the development of microbicides;

o Through U.S. participation in UNAIDS, and in other forums, we will encourage international efforts to develop effective microbicides.

c. Developing New and More Effective Therapies.

Another challenge in the research arena is developing new and more effective therapies that allow us to transform HIV disease into a chronic, manageable condition. While the FDA is approving new treatments in record numbers and at record speed, the long-term clinical effectiveness of these new therapies remains unknown. There is no doubt that new drugs must be developed.

To accomplish this, federal support for drug development and clinical trials through NIH will increase by $xx million in FY 1997. In addition, several other initiatives will be undertaken or maintained:

- *Federal support for the Forum for Collaborative HIV Research will promote public-private collaboration in AIDS research.* This new group, formed at the behest of Vice President Gore, is designed to catalyze collaborations between the government research establishment, pharmaceutical companies, and third party payers for the purpose of capitalizing on recent scientific advances and learning how to optimally use available treatment regimens. The Federal government is committed to being an equal partner in this new effort as it begins its work later this year.

- *A federal commitment to continued access to sophisticated equipment and personnel that can be shared among researchers in both the private and public sectors.* The Department of Energy (DOE) has made available the use of sophisticated imaging equipment that would be prohibitively expensive for individual researchers or companies. This shared resource 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.

- *Increased focus in federal research on special populations.* Our research effort will increase its focus on the needs of special populations, including youth, women, minorities, and substance abusers who may not have received the full benefit of all research discoveries. The efforts of programs such as the Women's Interagency HIV Study (WIHS), the Terry Beirn Community Programs for Clinical Research on AIDS (CPCRA), and the Adolescent Medicine HIV/AIDS Research Network are important to improving our understanding of HIV disease in these populations and will continue.

d. Continued Support for Research

Research is an investment in our future. Already, it has helped prolong improve the quality of lives, and we must continue to make this investment. To unleash the talents of the best and the brightest in finding a cure, better therapies, and a vaccine will require a sustained commitment of funding to meet the research challenges. NIH currently receives many more outstanding research applications than it is able to fund -- representing a lost opportunity for scientific progress. Other departments and agencies, such as DOD and VA, also support

crucially important research that strengthens the overall U.S. research effort. Recognizing the importance of biomedical and AIDS research generally, the President has requested an increase of $xxx million for the NIH overall, an increase of $xx million for NIH-supported AIDS research, and an increase of $xx million for AIDS research government-wide.

C. CARE & SERVICES

"AIDS has taken too many friends and relatives and loved ones from everyone of us in this room. It has shaken the faith of many, but it has inspired a remarkable community spirit."
President Clinton, May 20, 1996
Signing of the Ryan White CARE Act Reauthorization

1. Record of Accomplishment

Since the epidemic of HIV and AIDS began in 1981, more than 500,000 Americans have been diagnosed with AIDS and required care. As the number of Americans living with AIDS increased, so did their needs. The demands on the U.S. health care system increased dramatically, but federal, state, and local governments along with community-based organizations and private clinicians have responded with compassionate, high-quality medical care. In 1985, Federal expenditures for HIV-related care and services were $xxx, by 1995 the Federal share reached $xxx.

In the early years of the epidemic, the health care infrastructure was particularly unprepared to accommodate the health care needs of persons with HIV. To meet their complex health care needs, HIV-positive persons were often forced to negotiate a fragmented system of care. There were few programs designed to meet the unique care needs of positive individuals. Moreover, available care services were often directed towards meeting the acute care needs of persons diagnosed with AIDS, rather than the early stages of HIV disease. While we still have far to go, the quality and availability of services for HIV-positive persons has improved significantly.

People living with HIV now access and finance necessary health care services in a variety of ways. Currently, over 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. JL cite.

In addition to Medicaid, the centerpiece of the national safety net for HIV positive people is the programs funded through the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, administered by the Health Resources and Services Administration (HRSA). The CARE Act programs were established to fill gaps in coverage and build systems of care to create access to health care for people living with HIV and AIDS. The first four titles of the CARE Act support direct services for people living with HIV:

- 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. Title II also provides drug reimbursement funding for persons living with HIV/AIDS under the AIDS Drug Assistance Program (ADAP).

- Title IIIb of the CARE Act provides early intervention services such as counseling and testing, medical care, and educational services for medically underserved persons with the goal of reducing HIV-related illness.

- Title IV seeks to increase the availability of research, 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 (IHS) which provides health care for HIV-positive Native Americans and Alaska Natives. Additionally, the Bureau of Prisons within the Department of Justice provides care for HIV-positive people in Federal prisons.

People living with HIV and their families face significant obstacles to locating affordable housing. Housing assistance for people living with HIV and AIDS is provided by the Department of Housing and Urban Development (HUD) through its Housing Opportunities for Persons with AIDS (HOPWA), enacted in 1990, and other programs, such as the Section 811 Supportive Housing Programs for Persons with Disabilities. These programs work in partnership with local initiatives incorporating housing assistance into a community's continuum of services.

To further foster community involvement, HUD also has 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. The Community Development Block Grant (CDBG), the HOME affordable housing program, as well as public housing programs are key resources that are available to communities.

Since he took office in 1993, President Clinton has built on this record by making AIDS a top national priority and increasing that national commitment by:

- o Signing the Ryan White CARE Act Amendments of 1996, and increasing Ryan White funding by 134 percent,

- o More than doubling funding for the AIDS Drug Assistance Program, which helps uninsured and underinsured individuals purchase prescription drugs,

- o Increasing funding for HOPWA by 96 percent,

- o Fighting to preserve the Medicaid guarantee of coverage for the over 50 percent of people with AIDS and 92 percent of children with AIDS who rely on this program for their health coverage, and

- o Revising eligibility rules for Social Security disability benefits to make it easier for people living with HIV to qualify for benefits.

2. Future Opportunities for Progress

The nation goal in this area is to ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs to have the opportunity to live productive lives. AIDS care and service programs must continue to provide access to care for those without insurance coverage, improve prioritization and accountability, and increase the cost-effectiveness of services they provide. As treatments improve and extend the productive lives of people with HIV, we must continually reexamine the range of services that are needed.

Two major challenges exist in meeting this goal:

- o Maintaining HIV-related care and services as an investment priority in budgeting in the context of a balanced federal budget: fighting to preserve Medicaid and continuing to seek increased funding for CARE Act and HOPWA programs

- o Assuring that available resources are used as effectively as possible.

a. Making investment in care and services a budget priority

Preserving Medicaid As the epidemic continues to spread in lower-income communities, Medicaid will be an even more essential lifeline of support for Americans living with HIV and AIDS. The need to maintain the historic Federal-State partnership on Medicaid has never been greater. Proposals in Congress to convert Medicaid into a block grant would endanger access to care for people living with HIV and AIDS, particularly proposals to eliminate the Federal guarantee of coverage for people living with disabilities. The President has vetoed one such proposal and has sustaining the entitlement to Medicaid is central to the national goal of ensuring appropriate and affordable care and services for persons living with HIV and AIDS.

Continuing Support for Ryan White CARE Act. The five-year reauthorization of the CARE Act signed by President Clinton on May 20, 1996 provides people living with HIV and AIDS

with peace of mind that support from the Federal government will be there through the year 2000. As the demand for care continues to grow, so must the resources for the CARE Act. President Clinton has proposed $827.5 million for this program in FY 1997.

Expanding Support for Housing Services Finally, maintaining consistent funding for the housing component of the services safety net will continue to be a national priority. Without stable housing, a person living with HIV has diminished access to care and services and a diminished opportunity to live a productive life. It is estimated that up to 50 percent of people living with HIV and AIDS are or will become homeless during the course of their illness.[2] The President's 1997 budget includes a request for $196 million for HOPWA.

b. Ensuring Effective Use of Limited Resources

There are three primary ways the federal government will be attempting to make the most of its limited resources: (1) Improving coordination among federal programs, (2) Improving the quality of care provided by those programs, and (3) evaluating program effectiveness to ensure that funds are well spent.

Improving Program Coordination

Integrating HIV and related services is another important step in assisting communities to build seamless systems of support for our most vulnerable citizens. Organizations receiving federal funding to provide AIDS-related care often require support from several federal agencies. For example, creating a comprehensive community-based program that integrates primary care, substance abuse treatment and prevention, and sexually transmitted disease screening, HIV prevention, access to clinical trials, and housing assistance requires separate applications to SAMHSA, HRSA, CDC, NIH, and HUD.

The agencies funding HIV-related services are committed to simplifying the application process for federal funding and to facilitating service integration. HRSA and SAMHSA have issued joint programs announcements, and HUD and HRSA have issued a joint program announcement for the Special Projects of National Significance (SPNS) program. These efforts to improve integration will be continued and expanded, with special attention to linking HIV and substance abuse prevention and services.

Improving Quality of Care

Federally-supported programs can and should consistently provide high-quality care. Ensuring consistency in care delivery requires increased training for health care professionals and greater accountability through the use of performance measures for quality care. It is also essential that practical information on research advances for practicing clinicians and their patients be provided in a timely manner. (See Section

Translation of Research Advances in Practice.) HRSA and HCFA will continue to offer guidance to grantees and the States regarding maintaining the quality and standard of care appropriate for people living with HIV. To this end, during FY 1997, the Office of HIV/AIDS Policy at DHHS is undertaking a program to develop clinical practice guidelines in conjunction with other government agencies and private sector clinicians.

Evaluating Program Effectiveness

Strong federal support for safety net programs must be accompanied by improved accountability and priority setting. Evaluating current activities provides valuable information for planners and those at the front lines of the epidemic and assist in providing better care to people living with HIV.

D. CIVIL RIGHTS

> *"Every person with HIV or AIDS is someone's son or daughter, brother or sister, parent or grandparent. We cannot allow discrimination of any kind to blind us to what we must do."*
>
> *President Clinton, May 20, 1996*
> *Signing of the Ryan White CARE Act Reauthorization*

Discrimination against people living with HIV or AIDS violates the human rights of individual Americans and undermines our efforts to prevent and treat HIV infection. The extraordinary stigma that has been attached to HIV disease hampers the ability of people living with HIV and AIDS to live full lives, free of fear.

Discrimination also undermines efforts to prevent and treat HIV infection and bring the epidemic under control. Fear of discrimination and stigma causes many people not to seek testing for HIV; thus many remain unaware of their HIV status and go without the care that could help them live longer, healthier lives. Opportunities to educate people are also lost as people at-risk avoid prevention programs because of the stigma associated with HIV.

The fourth goal of the national strategy is to eliminate discrimination and to provide national leadership in erasing the stigma associated with HIV and AIDS.

1. Record of Accomplishment

During the early years of the AIDS epidemic, protection of the civil rights of people living with HIV and AIDS was sporadic, at best. Individual lawsuits were the first line of action. By the late 1980s, however, the Federal government began to respond more aggressively with actions including:

- Enactment of the Harkin-Humphrey Amendment to the Civil Rights Restoration Act, clarifying that Section 504 of the Rehabilitation Act of 1973 applied to people with contagious diseases, including HIV; and

- Passage of the Americans with Disabilities Act of 1990 (ADA) which protects individuals living with HIV and AIDS, and people perceived to be at risk for HIV, from discrimination in housing, employment, and public accommodation.

Since he took office, President Clinton has directed relevant agencies to make enforcement of the civil rights of people living with HIV and AIDS a priority. Key actions include:

- Vigorously enforcing the ADA by the Justice Department, the Equal Employment Opportunities Commission, and the Department of Health and Human Services. The

Federal government has resolved nearly 800 charges alleging discrimination against people with HIV and AIDS obtaining monetary benefits of more than $6.1 million; [Are these figures correct? .. source(s)?]

- Vigorously enforcing Section 504 of the Rehabilitation Act of 1973 as it pertains to recipients of DHHS funds such as hospitals, nursing homes, and social service agencies;

- Forcefully opposing the so-called "Dornan Amendment," which would have required the discharge of all military personnel who are living with HIV. President Clinton declared the proposal unconstitutional and directed the Department of Justice not to defend it if challenged in court. The President led a successful effort to repeal the "Dornan Amendment" and continues to oppose its enactment;

- Establishing an AIDS education program for all Federal workers; and

- Using the Presidential "bully pulpit" to continually speak out against discrimination against people with HIV and AIDS. In December 1995, the President hosted the first ever White House Conference on HIV and AIDS, bringing to the White House over 300 people from around the country to discuss with the President the impact of the epidemic on their lives and communities.

2. Future Opportunities for Progress

There are four key ways that the Federal government is maintaining its commitment to meeting the goal of ensuring that people living with HIV are not subject to discrimination:

Enforcing Rights. Efforts to protect the civil rights of people with HIV and AIDS must be ever-vigilant. The Federal government will continue to exhibit strong leadership on this issue through its enforcement of the Americans with Disabilities Act and public condemnation of discriminatory acts or statements. Of particular concern is discrimination against people with HIV seeking access to health care facilities. A joint effort by the Department of Health and Human Services and the Department of Justice aimed at access to nursing homes is a significant step forward in protecting the rights of people living with HIV.

Protecting Workers. The Federal government is actively working to examine its own existing policies related to the exclusion of people living with HIV from employment. The Director of the Office of National AIDS Policy is working with Federal Agencies to examine individual policies to determine whether they comply with Federal public health guidelines.

Opposing Discriminatory Legislation. The Administration will continue to oppose, in the strongest terms possible, efforts by the Congress to discriminate against people living with HIV and AIDS.

Providing Leadership. Leaders of government have an obligation to use the power of their elected office to speak out against acts or words of discrimination against any group of people. President Clinton has used and will continue to use his position to oppose discrimination against people living with HIV and AIDS.

E. INTERNATIONAL ACTIVITIES

> *"The American people need to know that everybody in this country and, indeed, throughout the world, is now vulnerable to this disease."*
> President Clinton, December 5, 1996, to the White Conference on HIV and AIDS

AIDS is a global epidemic. The World Health Organization (WHO) estimates that 94 percent of new infections occur in developing countries. (footnote c) In the United States it is estimated that between 650,000 and 900,000 people are currently infected with HIV. The WHO and UNAIDS estimates that 27.9 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 by the year 2000. 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 epidemic jeopardizes decades of economic and social advances in many developing nations. In the nations of Africa and Asia, economic advances are threatened and in some cases may be reversed due to 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.[3] 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.

1. Record of Accomplishment

Since it began, HIV and AIDS has been a global concern. The U.S. has worked closely with developed and developing nations to design an international response that is both vigorous and coordinated. Sentinel achievements include:

- Provided initial funding and key leadership for the creation of the Global Programme on AIDS at the World Health Organization (WHO) in 1987; and
- Played an instrumental role in establishing the new streamlined Joint United Nations Programme on HIV/AIDS (UNAIDS) in 1996.

The United States is the largest contributor to international efforts to combat the pandemic of HIV and AIDS. Several Federal Agencies are working slow the AIDS epidemic internationally. (See Appendix E.) The Department of State works 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 of U.S. leadership in the global HIV arena are: preventing new infections; reducing the personal and social impact of the pandemic; and mobilizing and unifying national and international efforts.

The U.S. Agency for International Development (USAID) also plays leadership role in the global HIV effort through development assistance, research and policy formation. USAID focuses its efforts on developing prevention programs based on proven interventions; addressing social, cultural, regulatory and economic issues related to HIV and 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 Peace Corps trains a portion of its volunteers to directly address HIV-related concerns in their countries of placement. The U.S. Information Agency (USIA) supports programs that promote dissemination of U.S. policies and information related to HIV and AIDS.

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. The DOD is conducting clinical trials of candidate HIV vaccines in Thailand and NIH (working in collaboration with USAID), supports a range of scientific studies in developing countries. The results of the studies ultimately will be used to develop interventions to reduce behaviors that place individuals at risk for contracting HIV infection.

2. Future Opportunities for Progress

To accomplish the goal of providing strong continuing support for international efforts to address the HIV epidemic, the following steps will be taken:

International Leadership. The United States has established a global leadership role in combatting the epidemic. This leadership will continue. The U.S. strongly supports the newly established Joint United Nations Programme on AIDS (UNAIDS).[4] The U.S. is a member of the governing body of UNAIDS and signed the 1994 Paris Declaration and the Greater Involvement of People Living with HIV and AIDS Initiative (GIPA).

The U.S. also supports efforts to more effectively access available resources as well as encourage non-traditional donor countries to provide much-needed contributions. Supporting UNAIDS organizations such as UNICEF, WHO, UNDP (United Nations Development Program), the U.S.-Japan Common Agenda and its innovative programmatic efforts, and UNAIDS' 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.

Strengthening Partnerships. In addition to maintaining our multilateral partnerships, we must strengthen and expand our bilateral programs and funds for HIV activities. We must

reverse the current trend to reduce assistance to developing countries where more than 90 percent of the world's AIDS cases are found.

Sharing Technology and Bringing Lessons Home. Through USAID's "Lessons without Borders Project", the U.S. has gained valuable insights from experiences in participating countries and is applying them to communities here at home. The initiative brings lessons learned abroad back to inner city and rural areas with problems similar to those experienced overseas. These efforts should be continued and expanded for HIV and AIDS.

Improving 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. In order to ensure that efforts are productive, the Agencies supporting international activities must develop a mechanism for coordinating U.S. programs in a systematic and efficient manner.

F. TRANSLATION OF RESEARCH ADVANCES INTO PRACTICE

Insert Quote

An important element in our fight against AIDS is ensuring that research advances are translated into improved HIV prevention programs and better care for HIV positive persons. While directly related to earlier goals relating to research, prevention, and care and services, it is important to highlight this aspect of the nation's response to the epidemic to assure that we are taking what we are learning and translating it into benefit for people with or at risk for HIV.

An example of the importance of such efforts is the translation of the NIH-supported research study that found that the use of AZT by pregnant women during pregnancy and childbirth and its application to newborns for the first six weeks of life can reduce the risk of perinatal transmission of HIV by two-thirds. Translation of these results required actions by the Centers for Disease Control and Prevention, which prepared guidelines for physicians caring for pregnant women and for consumers; the Health Resources and Services Administration, which provided guidance to grantees on coverage of such services; the Health Care Financing Administration, which provided similar guidance to State Medicaid Directors.

1. Record of Accomplishment

Due in part to Federally-sponsored information dissemination activities, dramatic changes in the way HIV is treated have taken place. Ensuring dissemination of HIV-related information falls under the missions of several Agencies (See Appendix F). Key examples are:

- 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 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 tele-conferencing;

- NIH supports publicly available computerized databases such as AIDSDRUGS, AIDSTRIALS, and AIDSLINE;

- The toll-free 1-800 TRIALS-A AIDS Clinical Trials Information Service (ACTIS) is co-sponsored by NIH, CDC, and FDA;

- The Centers for Disease Control and Prevention disseminates information through the

National AIDS Hotline (1-800-342-AIDS); its toll-free 1-800-HIV-0440 HIV/AIDS Treatment Information Service (ATIS); and the AIDS Information Clearinghouse;

- The CDC also develops and issues guidelines for health professionals through its *Morbidity and Mortality Weekly Report*;

- 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; and,

- The Health Resources and Services Administration directs a nationwide system of AIDS Education and Training Centers that provide state of the art HIV clinical information to health care providers. HRSA also has developed guidances for its Ryan White CARE Act grantees and funds an AIDS warmline that responds to questions from clinicians across the country.

2. Future Opportunities for Progress

Ensuring that research advances are translated into improved HIV prevention programs and better care for HIV-positive persons, will require a number of steps, including:

Increasing Education and Training. As we continue to expand our base of knowledge about AIDS care, efforts to educate and train health care professionals in state-of-the-art care for people living with HIV and AIDS must be expanded. An AHCPR-supported study indicated that primary care physicians may miss significant HIV-related symptoms during patient examinations.[5] Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.[6] Reference Kittahare (sp?) article. To reverse this pattern, the Administration is fighting to restore funding for the AIDS Education and Training Centers, which play a vital role in training providers. Achieving this goal will also require a renewed emphasis on HIV on the part of medical schools, professional organizations, and individual clinicians.

Disseminating 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 for their patients. 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. To this end, during FY 1997, the Office of HIV/AIDS Policy at DHHS is undertaking a program to develop clinical practice guidelines in conjunction with other government agencies and private sector clinicians.

Improving Coordination of Federal Activities. Enhancing coordination of information

dissemination activities among Public Health Service Agencies is an important priority. Within DHHS, the Office of HIV/AIDS Policy (OHAP) 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 people and organizations, and that policies and standard-of-care practices for Federally-sponsored programs are modified to reflect the new standard, requires a continued high level of cooperation and coordination among Public Health Service Agencies.

Disseminating Prevention Models. Improved dissemination efforts also are needed in the area of primary prevention models. Models of effective prevention interventions have been developed, but often this valuable information is not reaching those people developing, implementing, and evaluating prevention programs. The Public Health Service will take the lead in ensuring that information that can be used to stem the tide of new infections reaches those who can make a difference.

Footnotes

a It is, however, ~~believed~~ hoped that with greater use of AZT ~~by HIV-positive pregnant~~ women, the number of new cases in newborns can be reduced.

b **(re-add footnote; check for Vancouver numbers).** Hellinger

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

d The Adolescent Medicine HIV/AIDS Research Network is cooperatively funded by the National Institute of Child Health and Human Development (NICHD), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute on Drug Abuse (NIDA), and the Health Resources and Services Administration (HRSA).

e 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.

1. *Morbidity and Mortality Weekly Report*. U.S. Department of Health and Human Services, Public Health Service. November 24, 1995, vol. 44, No. 46.

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

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

4. 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, multi-sectoral responses to the pandemic.

5. 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.

6. 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)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

EXECUTIVE SECRETARIAT

FACSIMILE

PLEASE NOTIFY OR HAND-CARRY THIS TRANSMISSION TO THE FOLLOWING PERSON AS SOON AS POSSIBLE:

NAME: Jane Donnell
OWAP

ADDRESS: _____

MESSAGE: _____

FAX NUMBER: _____

OFFICE NUMBER: _____

FROM: **GLEN HARELSON**
POLICY COORDINATOR

FAX NUMBER: **202 690-7203**

OFFICE NUMBER: **202 690-7699**

NUMBER OF PAGES (INCLUDING THIS ONE): ____

Office of AIDS Research
National Institutes of Health
Building 31, Room 4C02
9000 Rockville Pike
Bethesda, Maryland 20892
Phone: 301-496-0357
Fax: 301-496-4843

To: Glen Harelson
202-690-7203

From: William E. Paul

To Jane
from Patsy

As requested, we are providing information regarding technical inaccuracies in the document:

page 2, first bullet should read: "To provide...to find more effective treatments, a preventive..."

page 2, second bullet should read: "To provide...to reduce the number of new infections in adults and children in the U.S. and worldwide."

page 5 repeats this section, and therefore the same changes above should apply to page 5.

page 6, a grammatical error in para 3: "Today, this group...although they still represent the majority..."

page 6, para 4: "Adolescents... are increasingly at risk for HIV infection."

page 8, para 2: "The National Institutes of Health Revitalization Act of 1993 provided the Office of AIDS Research with enhanced authority to develop and implement an annual AIDS research plan and budget.

page 9, Record of Accomplishment: "Since the epidemic began...today, that total is estimated between 40,000 and 60,000..."

page 9, first bullet is incorrect, and should read "In 1981, the Centers for Disease Control reported the first cases of AIDS." CDC did not identify the original cases.

page 9, add two new bullets under Sentinel accomplishments:

"o Reductions in HIV-related risk behaviors among a number of populations, including gay men and injection drug users, as a result of NIH-sponsored prevention intervention research."

"o NIH-sponsored research demonstrated that administration of AZT can prevent transmission of HIV from an infected mother to her newborn."

page 10, para 2, last sentence should read: "Biomedical, behavioral, and social science prevention research, including epidemiological and natural history studies conducted and supported...will continue to expand our understanding of HIV transmission and of the determinants..."

page 10, para 3, sentence 2: "The National Institutes of Health (NIH), the Substance Abuse and Mental Health..."

page 11, Intervention Research, first sentence: "Intervention research focuses on...modified sexual and drug using behaviors and, as a consequence, reduced HIV transmission."

page 13, first bullet, fourth sentence: "Further, through outreach, research, and demonstration programs, SAMHSA, NIH, and CDC will work to enroll more people...

page 13, third bullet: "Preventing HIV transmission from the use of contaminated needles. Sharing of needles and syringes...In addition, CDC-supported research in the state of Connecticut showed that removal..." Add the following sentence at the end of the bullet: "NIH-supported research on existing needle exchange programs is identifying the characteristics that make them successful or not successful as an HIV prevention strategy."

page 13, last para, second sentence: "The NIH-supported research that showed AZT reduces perinatal transmission..."

page 14, Other STDs and TB: "Recent NIH-supported research has confirmed that treatment..." Second sentence of that para, delete Similarly.

page 15, Record of Accomplishment, first bullet: "Identification by the NIH of HIV as the etiologic agent

page 15, second bullet: "Development by NIH of a reliable test to determine HIV infection and demonstration that disease progression and therapeutic efficacy of antiretroviral drugs can be predicted by viral load tests." (There is no test to determine exposure to HIV).

page 15, third bullet should be rewritten: "NIH supported research determined the three-dimensional structure of the reverse transcriptase, providing the target for the use of AZT as the first antiretroviral drug proven effective against HIV in NIH-supported clinical trials."

Glen -- here is a good example of our deep concerns about the omission of research accomplishments. Three of the five bullets are FDA, not NIH. A long list of research successes was previously provided, but does not appear in the document.

Add a couple

page 15, under "Since he took office..." second bullet should read: "Signing the NIH Revitalization Act of 1993, granting the ...new authority to develop and implement an annual AIDS research plan and budget." In that section, add a new bullet: "Developing the first Federal Plan for Biomedical Research on AIDS to coordinate national and international HIV/AIDS research."

Oh, OK

page 16, title of first section should read "Contributions of AIDS research to research on other diseases

page 16, para 1, last sentence "AIDS research advances have also contributed to the prevention and treatment of other infectious diseases...

page 16, para 2 contains a grammatical error: "Progress in the treatment and prevention of HIV-related opportunistic infection has had an enormous..."

page 16, para 3, DELETE the following sentence: "Moreover, prior to the AIDS epidemic, little investment was made in research to treat viral diseases." This is not true.

page 16, para 4: third sentence, delete "Comparative". Sentence should read "Clinical trials of poxvirus vaccine vectors and adjuvants in HIV vaccine candidates..."

page 16, Future Opportunities for progress: "While tremendous progress has been made in biomedical and behavioral research, we cannot...d

page 17, first bullet: "Develop biomedical interventions that prevent HIV infection, including both vaccines and microbicides."

? page 17, second bullet: "Develop new and more effective therapies for HIV and related opportunistic infections and malignancies."

page 17, bullets under the Levine Report should be reordered and rewritten as follows:

- Increase NIH support for basic science through investigator-initiated research.
- Establish a restructured trans-NIH vaccine research effort

- Augment research efforts to better understand the human immune system
- Develop a comprehensive NIH HIV prevention science agenda, combining biomedical, behavioral, and social interventions
- Improve coordination among all NIH-supported clinical trials programs

page 17, Vaccine Development, should be rewritten as follows: "The scientific community continues to strive for an effective vaccine against HIV infection."

page 18, para 1: "This is our ultimate goal in the area of prevention, and in FY 1997, the President's budget request will allow the Federal government to increase its commitment to HIV vaccine research."

page 18, para 2, last sentence should read: "Both approaches are being pursued on a parallel and interrelated path. Small trials of more complex vaccine products and two types of vaccine candidates have been underway for several years, and larger trials are planned for the near future."

page 18, para 5: "To address these goals, the following steps..."

page 18, para 5, second bullet: "The Vice President will continue a high level dialogue...in the development of vaccines and microbicides."

page 18, para 5, third bullet: "Through U.S. participation in UNAIDS...international efforts to develop effective vaccines and microbicides."

... this ¶ refers only to microbs. Right?

Perhaps but ...

page 19, para 1, add to end of last sentence "There is no doubt that new drugs must be developed, and access to them by all persons in need must be ensured."

NO

page 19, para 2 "To accomplish this, NIH will spend an estimated $470 million in the area of therapeutic research in FY 1997." (Glen: The President's request includes a decrease in therapeutic research).

page 19, third bullet, increased focus in federal research on special populations, delete "who may not have received the full benefit of all research discoveries."

page 19, d. Continued Support for Research, second sentence: "Already, it has helped prolong and improve the quality of lives of HIV-infected individuals..."

page 20 "Recognizing the importance of biomedical and ...an increase of $485 million for the NIH overall, an increase of $24 million for NIH conducted and supported AIDS research and an increase of $??? million for AIDS research government-wide. (Glen: we do not have this last figure)

What = OMB $?

page 21, para 2 sentence 4, "Moreover, available case services were often directed toward meeting the acute care needs of persons diagnosed with AIDS, rather than intervening in the early stages of HIV disease."

page 29, last para, second sentence "Several Federal Agencies are working to slow the AIDS epidemic...

page 30, first para, "The major areas of U.S. leadership in the global HIV arena are: biomedical research, preventing new infections..."

page 32, para 2, second sentence: "Translation of these results required actions by the NIH and the Centers for Disease Control...

my copy does only to pp. 26

Glen, we apologize for the cumbersome list, but we felt compelled not only to correct the inaccuracies, but to address some important omissions.

Jack Whitescarver for

William E. Paul, M.D.
Director, Office of AIDS Research

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

August 27, 1996

MEMORANDUM FOR THE CHIEF OF STAFF

THROUGH: RICIA MC MAHON
JOHN CARNEVALE
DAN SCHECTER

FROM: BARBARA T. ROBERTS

SUBJECT: NATIONAL AIDS STRATEGY-8/20 DRAFT FOR REVIEW

July 22, 1996 ONDCP submitted text for inclusion in the National AIDS Strategy. August 20, 1996 ONDCP received a draft of the AIDS Strategy for review and sign-off. Copies were circulated to ONDCP staffers Mc Mahon, Gregrich and Carnevale for comment. Enclosed is feedback received. These comments should be forwarded to the AIDS Office for consideration of a revision of the draft.

In general, the draft reflects only partial inclusion of the ONDCP statement submitted (see Enclosure, 1). Although this may have been an editorial decision on the part of the AIDS Office, the resulting statement (see p.10) does not provide the full scope of demand and supply initiatives undertaken by this Office.

Another concern is the lack of inclusion in the document of marijuana, alcohol and tobacco as drugs whose effects also contribute to the risk of acquiring HIV. *All* illicit drugs (alcohol and tobacco by virtue of prohibition of use, by law, by underage youth) carry associated consequences. Each of these drugs alter mood and lower inhibitions which can lead to poor decision making, i.e., engaging in indiscriminant sex. In addition to the obvious inclusion of intravenous drug use, ONDCP urges the AIDS Office to revise the draft to include the use of the aforementioned drugs as having associated risk factors as well.

The needle exchange statement is circular and draws a conclusion not altogether borne of the current research. Needle exchange research, to date, is limited and cannot be termed "successful." ONDCP strongly urges rewording of this statement (see p. 13) to more accurately reflect the state of needle exchange studies, accompanied by the pros and cons of research results.

Finally, the AIDS Office has requested ONDCP to sign-off on the draft and, thus, clear it for publication. The Federal regulatory clearance process involves submission of a document to the Office of Management and Budget (OMB), first. OMB, in turn, fields the document to appropriate Federal agencies for comment and feedback, before it issues an official clearance statement. It does not appear OMB has cleared this document. The AIDS Office will need to clarify the issue of the clearance process followed before ONDCP can officially sanction a final draft.

Enclosures.: 1) July 22, 1996 ONDCP Memo.
2) ONDCP Staff Comments to AIDS Strategy Draft

cc: Dir., National AIDS Policy Office

ENCLOSURE 1

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

July 22, 1996

MEMORANDUM

TO: CHIEF OF STAFF 7/24

THRU: JOHN CARNEVALE
JOHN GREGRICH

FROM: BARBARA T. ROBERTS

SUBJECT: ONDCP STATEMENT FOR SUBMISSION IN THE OFFICE OF NATIONAL AIDS POLICY PLAN

The following statement has been drafted for inclusion in the Office of National AIDS Policy Plan. The finalized version of the Plan is due to go to press this evening. Ricia McMahon has read and given feedback on this statement:

STATEMENT

The White House Office of National Drug Control Policy is a partner with the Office of National Strategy for HIV and AIDS Policy. This partnership between offices results from efforts to develop strategies to effectively counter the problems of substance abuse and HIV/AIDS, and the devastating consequences caused by the interlink between two conditions that have contributed to the destruction of so many American lives. To this end, the theme of the 1996 ONDCP Strategy is "Reducing Drug Use and Its Consequences in America." The five goals of this Strategy are:

1. **Motivate America's youth to reject illegal drugs and substance abuse.**

2. **Increase the safety of America's citizens by substantially reducing drug-related crime and violence.**

3. **Reduce health, welfare, and crime costs resulting from illegal drug use.**

4. Shield America's air, land, and sea frontiers from the drug threat.

5. Break foreign and domestic drug sources of supply.

There are 2.6 million chronic drug users who are at high risk of contracting HIV/AIDS. Chronic drug users also engage in sexual behaviors that put them at high risk for contracting and spreading sexually transmitted diseases. Reducing the number of chronic addicts, and accompanying risks behaviors, has been determined as critical to the mission of ONDCP.

ONDCP has the regulatory responsibility to coordinate the policies, objectives, priorities and budgets of 52 Federal agencies including many agencies within the Department of Health and Human Services (DHHS). The ONDCP director can decertify an budget if it fails to comply in implementing the goals as specified by the President and ONDCP.

This Office will continue to work collaboratively with the AIDS Policy Office and other Federal, state and community agencies and services to reverse the devastation caused to Americans by these scourges.

---------End of Statement----------

ENCLOSURE 2

TABLE OF CONTENTS

"We must develop a clear, well-articulated national plan for confronting AIDS."
The Final Report of the National Commission on AIDS
June 1993

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 AIDS Strategy that would detail the Federal government's long-term approach in responding to this epidemic. The National AIDS Strategy has been developed by the Clinton Administration 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, businesses, schools, churches, families, and individuals.

The President has identified the following national goals to guide our efforts against HIV:

- **To provide strong continuing support for AIDS-related research in order to find additional treatments, a preventive vaccine to protect the uninfected, and a cure for those currently infected;**
- **To provide strong continuing support for effective AIDS prevention efforts to continue to reduce the number of new HIV infections in the U.S.;**
- **To ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs; and,**
- **To ensure that people living with HIV are not subject to discrimination.**
- **To provide strong continuing support for international efforts to address the HIV epidemic.**
- **To ensure that research advances are translated into improved HIV prevention programs and better care for HIV positive persons.**

This document is a snapshot of where we are as a Nation and where we need to go in achieving these national goals. It summarizes some of the key accomplishments of our Nation's scientific and public health professionals and identifies key areas for further effort. In addition, the appendices to this report lay out, for the first time, detailed descriptions of the objectives, goals, and budgets of all Agencies involved in the Federal response to HIV in

five major areas of HIV policy: prevention, research, care, civil rights, international activities, and translation of research into practice.

The National AIDS Strategy is intended to be a working document that requires regular updating and adjustment as goals are reached and new challenges emerge. This Strategy provides a reference point for continuing dialogues and collaborative efforts between the public and private sectors that are necessary to meet our national goals and objectives.

In that light, the Office of National AIDS Policy is seeking direct input from the Presidential Advisory Council on HIV/AIDS, national and community-based organizations, state and local government, clinicians and researchers, members of the infected and affected community, and other individuals and organizations who can contribute to this historic document. This Strategy is being released, first, in draft form to allow for maximum input to the first of an ongoing national effort to chart and plan Federal efforts in response to the epidemic of HIV/AIDS.

The development of a National AIDS Strategy 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 Federal government should focus its efforts.

The National AIDS Strategy was drafted in consultation with, and with guidance from, numerous groups and individuals. Within the Federal government, this effort began at the Agency level. Members of the Interdepartmental Task Force on HIV and AIDS (IDTF) representing all Federal Agencies involved in the national response to HIV and AIDS, identified their HIV-related goals, objectives, and highlighted areas requiring special attention.

Individuals living with HIV and AIDS, their families, friends, loved ones, and care givers made vital contributions to this Strategy. Numerous non-governmental groups and organizations have also been consulted including the Presidential Advisory Council on HIV/AIDS, participants in the historic White House Conference on HIV and AIDS, the ONAP-sponsored regional briefings, patient and consumer advocates, health care professionals, community-based organizations, educators, religious leaders, and business leaders. The earlier insights provided by the National Commission on AIDS, the Institute of Medicine and National Research Council, the General Accounting Office, and the Office of Technology Assessment have also been extraordinarily helpful in developing the National AIDS Strategy.

As a Nation, we face great challenges, but we are also facing equally great opportunities. After fifteen years, AIDS remains a terrible national tragedy that has affected -- and will

continue to affect -- far too many people in this Nation and around the world. But we have made tremendous progress in our understanding of HIV and HIV disease, ways we can treat those who are infected, and means by which we can prevent infection. Ultimately, HIV is a disease that we can defeat -- just as we have eradicated smallpox from our planet and polio from the western hemisphere. The National AIDS Strategy provides a foundation for the continuing public-private partnerships that are essential to our success. Together, with steadfast commitment, courage, and leadership, we will win the battle against HIV and AIDS.

Patricia S. Fleming
Director, Office of National AIDS Policy

"For nearly every American with eyes and ears open, the face of AIDS is no longer the face of a stranger. Millions and millions of us have now stood at the bedside of a dying friend and grieved. Millions and millions of us now know people who have had AIDS and who have died of it who are both gay and heterosexual. Millions and millions of us are now forced to admit that this is a problem which has diminished the life of every American."

President Clinton, December 1, 1993, Georgetown University

I. INTRODUCTION

Goals of the National Strategy

The President has identified the following national goals to guide our efforts against HIV:

- To provide strong continuing support for AIDS-related research in order to find additional treatments, a preventive vaccine to protect the uninfected, and a cure for those currently infected;
- To provide strong continuing support for effective AIDS prevention efforts to continue to reduce the number of new HIV infections in the U.S.;
- To ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs; and,
- To ensure that people living with HIV are not subject to discrimination.
- To provide strong continuing support for international efforts to address the HIV epidemic.
- To ensure that research advances are translated into improved HIV prevention programs and better care for HIV positive persons.

Scope of the HIV/AIDS Epidemic

The epidemic 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 around the world. While significant progress has been made in understanding the disease and developing treatments since the first case was reported in the U.S. in June 1981, 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 average of 100 Americans are diagnosed with AIDS every day and a similar number of men, women, and children become infected with HIV every 24 hours. **[Richard -- are you certain these numbers are correct?]** Globally, 7,50 people become infected each day.

An Expanding Public Health Threat

As of December 1995, the Centers for Disease Control and Prevention (CDC) had received reports of 513,486 cases of AIDS among persons in the U.S. and 319,849 of these persons have been reported to have died as a result of complications related to HIV. Since 1987, AIDS has risen from being the 15th cause of death among all Americans to the 8th. AIDS i now the leading cause of death among Americans aged 25 to 44 (See Figure 1). In 1995 alone, approximately 74,000 new cases of AIDS were reported in the U.S. and more than 46,000 AIDS related deaths were reported to the CDC in 1994. CDC estimates that betweer 40,000 and 60,000 Americans are becoming newly infected with HIV each year, and that between 650,000 and 900,000 Americans are currently living with HIV.

As the epidemic in the United States has expanded, the demographics of the epidemic have changed. The early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers (i.e., New York, San Francisco, and Los Angeles). Today, this group represents less than half of all new cases, although they still represent the majority of persons living with HIV and AIDS. Among the populations that are more heavily affected today are young gay men, women, and injecting drug users and their sexual partners as well as users of non-injecting drugs (i.e., crack cocaine and alcohol). In 1995, nearly 14,000 women were reported to CDC as having been diagnosed with AIDS. Women now comprise 14 percent of cumulatively reported AIDS cases. If this trend continues, it is estimated that 80,000 American children will have been orphaned as a result of AIDS by the end of this decade. In 1995, approximately 800 new cases of pediatric AIDS cases were reported. (Footnote a)

Adolescents (age 13-19) are at increased risk for HIV infection. CDC estimates that one-quarter of new HIV infections in the U.S. occur among people under age 21. A significant number of young people are engaging at earlier ages in sexual intercourse and drug and alcohol use. 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.

Racial and ethnic minorities have been disproportionately affected by the epidemic of HIV and AIDS. African-Americans, who represent approximately 12 percent of the U.S. population, accounted for 40 percent of newly reported AIDS cases in 1995. Hispanics, who account for about 9 percent of the general population, represented 19 percent of new cases reported in 1995. The number of African-Americans and Hispanics affected by HIV and

AIDS has risen dramatically. In 1982, Blacks and Hispanics represented 31 percent of all AIDS cases; however, as of December 1995, these groups comprised 52 percent of cumulative AIDS cases.

The HIV epidemic continues to spread into suburban and rural areas, with especially dramatic increases in certain regions of the South and Midwest. Between January 1993 and December 1995 the largest numbers of AIDS cases (86,462) were reported from the South. (Endnote 1)[1] While most cases are still reported from urban areas, the rate of reported cases in non-metropolitan areas is increasing more rapidly than in urban areas. AIDS cases have now been reported in all 50 States, the District of Columbia, Puerto Rico, Guam, and each of the U.S. territories (See Figure 2).

AIDS is an expensive disease. Average lifetime costs of medical care after diagnosis with HIV is $119,000 (Footnote 1). People living with HIV are disproportionately dependent on the public sector for their health care. Over 50 percent of people living with AIDS are enrolled in Medicaid, including more than 90 percent of children with AIDS. In FY 1996, the Federal government spent $1.8 billion on Medicaid benefits for people living with HIV and AIDS and another $690 million on Medicare benefits. Social Security benefits for people disabled by HIV/AIDS total $1.1 billion in FY 1996.

Globally, the toll of the epidemic is much greater and threatens to reverse decades of economic and public health progress in developing countries. The Joint United Programme on HIV and AIDS (UNAIDS) and the World Health Organization (WHO) estimate that 27.9 million people have been infected with HIV. Since the beginning of the pandemic, 6 million people, including 1.6 million children, have been diagnosed with AIDS. By the year 2000, WHO projects that between 30 million and 40 million people will have been infected with HIV and 10 million to 15 million children will be orphaned due to AIDS.

II. OVERVIEW OF FEDERAL EFFORTS

The scope and nature of the HIV/AIDS epidemic have drawn States, local governments, academic institutions, private foundations, health care institutions and community-based organizations and the Federal government 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 FY 1985 the Federal government spent $212 million for AIDS research, surveillance, and care. By FY 1995 that figure reached $6.8 billion. (See Appendix G).

In the past four years, under the leadership of President Clinton, spending for AIDS research, prevention, and care has increased by 47 percent. Funding for the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act alone has increased by 151 percent. Support for housing for people living with AIDS has increased by 91 percent. AIDS-related research funding has increased by 34 percent and AIDS prevention funding has increased by 24 percent. The National Institutes of Health Revitalization Act of 1993 provided the Office of AIDS Research with enhanced authority to prepare and carry out an annual AIDS research budget and plan. Approval of AIDS drugs by the Food and Drug Administration has been accelerated to record times. A community-based planning process has empowered local communities to develop innovative AIDS prevention programs. Eligibility for Social Security disability benefits for people with AIDS have been simplified and Federal laws prohibiting discrimination against people living with HIV and AIDS have been vigorously enforced.

As the epidemic continues, we must renew our vision for ending this epidemic. The sections that follow focus on six major policy areas: prevention, research, care and services, civil rights, international activities, and the translation of research advances into practice. They identify recent progress and future opportunities for further progress.

A. PREVENTION

"We have to set a goal. . . We have to reduce the number of new infections each and every year until there are no more new infections."

President Clinton, December 5, 1995, to the White House Conference on HIV and AIDS.

1. Record of Accomplishment

Since the epidemic began, there has been important progress in preventing HIV infection. Early in the epidemic, CDC estimated that more than 100,000 Americans were becoming infected with HIV each year; today, that total is between 40,000 and 60,000 people each year.

Sentinel accomplishments in prevention of HIV include:

- Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the first cases of AIDS;
- Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the risk factors associated with HIV infection; and
- Due in part to successful implementation of CDC-sponsored prevention strategies, a slowing in the growth of the epidemic.

Since President Clinton took office in 1993, efforts in HIV prevention have been accelerated. Actions include:

- Increasing funding for AIDS prevention by 24 percent;
- Launching the community planning partnership -- empowering local communities to make decisions about and develop innovative prevention efforts;
- Launching the Prevention Marketing Initiative, focusing on young adults (18 to 25) with frank public service announcements advocating sexual abstinence and, for the first time, the correct and consistent use of latex condoms; and,
- Reorganizing AIDS prevention efforts at the Centers for Disease Control and Prevention to foster greater coordination with efforts to reduce sexually transmitted diseases and tuberculosis.

Federal agencies have been instrumental in expanding our knowledge base about HIV prevention (see Appendix A). The CDC, the agency with primary Federal HIV surveillance and prevention responsibilities, has been pivotal in identifying risk factors associated with HIV transmission, seroprevalence of HIV in society, and trends in HIV infection.

Federal efforts have shown that HIV prevention programs can be effective. CDC's prevention projects, many in partnership with states, local governments, and community-based organizations, have demonstrated that prevention programs are most effective when designed and implemented at a local level. Biomedical, behavioral, and social science prevention research conducted and supported by the National Institutes of Health (NIH) and CDC has expanded and will continue to expand our understanding of the determinants of HIV-related risk behavior.

The nation has also combatted the dual epidemics of HIV and drug abuse. The National Institute on Drug Abuse (NIDA), the Substance Abuse and Mental Health Services Administration (SAMHSA), and CDC support efforts to prevent HIV infection among drug users. The Office of National Drug Control Policy has pursued efforts to counter the problem of substance abuse and its devastating consequences.

There have been advances in integrating primary prevention into health care service systems. The Health Resources and Services Administration (HRSA) and the Department of Veterans Affairs (VA) have encouraged broader access to prevention information through the integration of prevention interventions into primary health care services and through support of early intervention services. HRSA and HCFA also have undertaken special initiatives designed to reduce perinatal transmission of HIV and HRSA has promoted primary prevention through the training of health professionals in the AIDS Education and Training Centers program.

2. Future Opportunities for Progress

To achieve the national goal of no new infections requires efforts in the prevention area on five fronts:

- o Improving understanding of trends in HIV transmission and seroprevalence
- o Improving scientific knowledge about effective prevention models and strategies
- o Strengthening community based programs
- o Integrating HIV and other prevention efforts
- o Targeting special populations

a. Improving Understanding of Trends in the Epidemic

Understanding who is becoming infected and through what behaviors is critical to designing effective prevention interventions, as well as targeting service resources. As discussed in the introduction, the demographics of the epidemic have shifted, and effective prevention depends on rapidly understanding these shifts and responding to them.

CDC's AIDS case and case death reporting system provides important data for assessing AIDS prevalence and mortality by gender, race/ethnicity, age, and mode of exposure. However, this approach does not capture sufficient "front-end" information on the incidence and prevalence of HIV prior to an AIDS diagnosis. We, therefore, miss critical warning signs about new trends in affected populations and increasing risky behaviors.

To address this shortcoming, the CDC will work to improve its surveillance of HIV infection and related diseases and surveillance of HIV behavioral risk factors, both to better monitor the course of the epidemic and to provide guidance to community planners for targeting prevention and service dollars. This can and will be undertaken without compromising the confidentiality of those involved.

b. Research on Effective Prevention Strategies

Effective interventions must be based on sound research findings and evaluations. Funding for prevention and behavioral research did not receive the same priority in the early years of the epidemic as biomedical research. In response to the recommendations from the Report of the NIH AIDS Research Program Evaluation Task Force, NIH is developing a comprehensive HIV prevention science agenda. NIH and CDC are both committed to increasing future support for basic research on behavior, interventions, social marketing and program evaluation.

Behavioral Research Basic behavioral research answers key questions about the determinants of HIV-associated sexual and drug using behaviors. We still lack key knowledge in this area, which is critical to developing effective interventions.

(CDC studies?) OTC

Intervention Research Intervention research focuses on individual and community level interventions that result in modified sexual and drug using behaviors. There have been significant accomplishments in this area, but, as this portfolio expands, it will be critical to assess intervention in real world settings that are relevant to the growing number of populations that must be reached by prevention programs. This research should be designed by a broad range of scientists, public health, and community experts to assure its relevance.

drug prevention experts

Social Marketing Research The use of social marketing techniques is a relatively new approach to HIV prevention. This promising area requires use of basic and intervention

research

research, as well as careful design and evaluation of social marketing efforts.

Evaluation To ensure that prevention programs are actually working -- and so scarce resources are spent on the most effective intervention -- all federally funded prevention activities will routinely include evaluation components. The funding agencies will share widely the knowledge gained about what works and what does not to ensure promotion of best practices in the field. In addition, as part of the federal government's compliance with the Government Performance and Results Act, CDC and SAMHSA will continue to work with its constituents to develop appropriate performance measures for HIV prevention programs.

ONDCP MIE

c. Strengthening Community-based Programs

Community prevention planning is one of the key innovations in CDC's prevention programming over the last several years. This public/private partnership puts federal funds to work based on locally designed priorities. This three-year-old initiative is at a crucial stage of development, and ensuring its success is the third key element of this strategy's prevention agenda.

Community planning requires ongoing leadership from CDC and its partners as well as the resources to provide the technical assistance the community planning process needs to flourish. Successful HIV prevention often depends on small, new community based organizations, many serving minority populations. These organizations need assistance not just on how to plan and compete successfully for available resources, but also how to appropriately incorporate epidemiological and research information into community prevention programs.

d. Program Integration and Collaboration

The fourth of the prevention agenda is improving the integration of HIV prevention into other program areas that reach individuals at risk for HIV. HIV prevention programs cannot stand apart from other, related public health efforts.

Substance Abuse HIV transmission is directly related to ~~substance abuse~~ alcohol + drug use, both directly through needle sharing behaviors and indirectly as sex is traded for drugs or drug use impairs judgment and increases risk taking behaviors. Breaking that linkage will require: and alcohol

- o Integration of HIV prevention into substance abuse treatment and prevention programs. In August, 1996, at the request of President Clinton, the Public Health Service agencies jointly co-sponsored a national meeting of state and local officials, researchers, and community experts from the fields of HIV and substance abuse to develop an action plan to more effectively integrate HIV and substance abuse

prevention efforts. These agencies are committed to implementing this strategy in the year ahead.

- Enrolling more substance abusers into drug treatment. Substance abuse treatment is a major form of HIV prevention. This Administration will continue to press for increased funding for substance abuse treatment. Further, through outreach and demonstration programs, SAMHSA and CDC will work to enroll more people in treatment and to find more successful interventions to accomplish this end.

- Reducing the availability of illegal drugs. The Office of National Drug Control Policy (ONDCP) is leading the fight on two fronts: reducing demand for drugs through treatment and prevention programs, and reducing the availability of drugs through interdiction.

- Preventing HIV transmission through contaminated needles. Sharing of syringes among injecting drug users is the principal means of HIV transmission in this population. While abstinence from drug use is always the preferred means of prevention, the CDC has issued guidelines regarding the use of bleach to clean injection equipment. In addition, CDC-supported research showed that removal of restrictions on over-the-counter sale of needles results in decreased needle sharing. Current federal law prohibits the use of federal funds for needle exchange programs; however a number of communities ~~across the country have successfully undertaken these programs with~~ local resources.

Primary Care HIV prevention needs to be better integrated into primary care. New and promising medical interventions make it critical to improve our approach to HIV counseling and testing -- creating a critical bridge between prevention and primary care. CDC is committed to improving the return rate of those tested at publicly funded sites and the quality of referral to services for those who test positive.

The linkage must also go in the opposite direction: from primary care to prevention. Primary care providers must learn to incorporate a person's sexual and drug using history when a medical history is taken, offering HIV-related counseling and voluntary testing, and providing prevention education to HIV positive individuals as part of the provider- patient relationship. HRSA's AIDS Education and Training Centers (AETCs) have played a crucial role in giving providers the information and skills they need. The Administration is committed to restoring Congressionally-imposed cuts in the AETC program and giving it a renewed focus to support this goal.

Often primary care is a direct form of HIV prevention. The federally supported research that showed AZT could reduce perinatal transmission of HIV was a tremendous medical breakthrough. Realizing the promise of this advance requires a commitment to assuring that

all pregnant women are counseled and offered HIV testing -- and that AZT treatment is available for all who desire it. All federally funded programs reaching pregnant women -- from Medicaid to Ryan White CARE Act grantees to community and migrant health centers -- are required to take part in this effort. We are committed to expanding outreach and assuring appropriate care so that the Congressionally set goal of reducing perinatal transmission by 50 percent by the year 2000 is achieved.

Other STDs and TB Recent research has confirmed that treatment of sexually transmitted diseases (STDs) other than HIV can reduce the likelihood of HIV transmission -- making the need for collaboration between HIV and STD prevention efforts more compelling. Similarly, people living with HIV are at very high risk for developing active tuberculosis. Studies suggest that the risk of developing active TB is 7 to 10 percent per year for persons who are infected with both TB and HIV, as opposed to a 10 percent lifetime risk for persons not infected with HIV. [Footnote: Personal communication from CDC Division TB Elimination.]

To address the need to integrate work on these inter-related epidemics, CDC organized the new National Center for HIV, STD, and TB prevention. CDC has initiated -- and will aggressively pursue -- efforts to increase collaboration among these programs, including expanding the community planning experiment to cover STD programs.

e. Targeting Special Populations

As discussed above, the HIV epidemic continues to have a disproportionate impact on certain populations where infection rates are rising at a worrisome pace. A fifth and final challenge for prevention programming is to pay particular attention to groups which traditionally receive fewer services, but where the risk of infection is greatest. These include youth (especially young gay men), women, and minorities (especially young gay men of color), prisoners, and, as discussed above, substance abusers. Many federally funded HIV prevention activities already target these populations, but the President's increased funding request for CDC provides $35 million in new funds in FY 1997 specifically for programs and research targeting youth, women, and substance abusers.

B. RESEARCH

"Our common goal must ultimately be a cure, a cure for all those who are living with HIV, and a vaccine to protect us from the virus."
President Clinton, December 5, 1995, to the White House Conference on HIV and AIDS

1. Record of Accomplishment

Since 1981, the nation has made significant advances in HIV-related research including:

- Identification of HIV as the etiologic agent for AIDS,
- Development of a reliable test to determine exposure to HIV,
- Approval of zidovudine (AZT), the first treatment of HIV primary infection,
- Development by the Food and Drug Administration of a system of expedited review of treatments for life-threatening diseases, including HIV.
- Approval of by the FDA of 15 new drugs, 8 new indications, and three new diagnostics for HIV and related conditions, developed through public and private sector development efforts.

Since he took office in 1993, President Clinton has escalated our AIDS research efforts by:

- Increasing AIDS research funding by 34 percent,
- Signing the NIH Revitalization Act of 1993, granting the Office of AIDS Research at NIH new authority to plan and implement an annual AIDS research budget and plan,
- Accelerating AIDS drug approval to record times;
- Supporting research that led to finding that use of AZT during pregnancy, childbirth, and the first six weeks of life can reduce the transmission of HIV from mother to child by two-thirds,
- Launching a four-year, $100 million research effort to develop effective topical microbicides;
- Facilitating creation of the Forum for Collaborative HIV Research to identify opportunities for clinical effectiveness research to improve care for HIV-positive individuals.

Contributions of AIDS Research

AIDS research has provided significant benefits beyond the epidemic, in work on many other diseases. AIDS research has accelerated study of the human immune system, helping to better understand and treat diseases such as cancer; autoimmune diseases, including systemic lupus erythematosus; type I diabetes mellitus; rheumatoid arthritis; and multiple sclerosis. AIDS research advances have also contributed to the prevention of other infectious diseases and provided a new paradigm for treatment of viral diseases.

Progress in the treatment and prevention of HIV-related opportunistic infections have had an enormous impact on the care of patients with other immunodeficiency conditions who are susceptible to many of the same pathogens. This research effort has enhanced the care of cancer patients, patients who have received immunosuppressive therapy for transplants, and the treatment of diseases caused by elevated immune responses (i.e., allergies and lupus).

HIV research has assisted in identifying new infectious agents that may be responsible for malignancies, such as the recent discovery of the etiologic agent for Kaposi's sarcoma. These findings may help to identify other oncogenic agents. HIV research has led to a better understanding of the mechanisms by which infectious agents and inflammatory cells cross the blood/brain barrier, providing 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 additional viral diseases and led to development of treatments.

Efforts to develop drugs for the treatment of HIV have accelerated the development of methods of rational drug design using sophisticated techniques of structural biology and advanced computer imaging methods. These advances have implications for drug design for virtually all disorders. Comparative clinical trials of poxvirus vectors and vaccine adjuvants in HIV vaccine candidates have supported safety information for cancer vaccines. Research on HIV-related wasting has provided important information for research on nutritional disorders, metabolic abnormalities, and gastrointestinal dysfunctions.

2. Future Opportunities for Progress

While tremendous progress has been made in biomedical research, we cannot and will not diminish our effort until we have found a cure and a preventive vaccine. To accomplish this national goal, we must address four ongoing challenges:

o Provide leadership and coordination for the federal research effort

- o Develop biomedical interventions that prevent HIV infection, including both a vaccine and a microbicide
- o Develop new and more effective therapies for HIV and related conditions
- o Assure adequate funding for this research effort.

a. Leadership and coordination of research.

Developing and implementing the federal government's AIDS research agenda presents both scientific and logistical challenges that require leadership and coordination, first among the 24 institutes, centers, and divisions of the NIH, and second among the various Departments and Agencies throughout the government that support HIV research.

The strengthened authority and new leadership of the NIH Office of AIDS Research and the first Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS form the basis for better coordination of our research effort and provide the assurance that key questions are being answered systematically and without duplication. Over the next year, the Administration is committed to reauthorizing the OAR's authority and assuring that its budget powers are maintained throughout the appropriations process.

As part of the ongoing commitment to assess all aspects of our research effort, the OAR convened a panel of outside experts to evaluate the NIH AIDS programs. The Report of the NIH AIDS Research Program Evaluation Task Force included several key recommendations that will be implemented in the year ahead. These include:

[NIH: IS THIS THE RIGHT LIST OF KEY INITIATIVES RESULTING FROM LEVINE REPORT?]

- o increase the Nation's commitment to basic science advancement by expanding the resources available for investigator-initiated research;
- o improve coordination among all NIH-supported clinical trials groups;
- o give new and stronger leadership to the vaccine development programs; and
- o increase the commitment to behavioral research by developing a comprehensive NIH HIV prevention science agenda.

b. Biomedical Prevention of HIV infection

Vaccine Development The scientific community remains confident that, ultimately, an

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effective vaccine against HIV infection can be developed. This is our ultimate goal in the area of prevention and in FY 1997, the Federal government plans to increase its commitme to vaccine research by $xx million.

The federal government, through the NIH and the Department of Defense, will continue to support two approaches to vaccine development. The first approach is based on the belief that gathering additional basic science information offers the best hope in steering vaccine development and that many critical questions must be answered before human trials should begin. The second approach is guided by the belief that data gathered from clinical efficacy trials in humans can lead to the development of a successful candidate and that if a safe candidate is available, it is not necessary to resolve all of the scientific questions before proceeding with human trials. Both approaches will be pursued on a parallel and interrelate path.

Microbicides Many scientists believe that in the absence of a vaccine the development of safe and effective mechanical or chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections could dramatically reduce the sexual transmission of HIV. Worldwide, over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs. (Footnote: Alan B. Stone, and Penelope J. Hitchcock. Vaginal Microbicides for Preventing the Transmission of HIV. AIDS 1994, 8 (suppl 1):S285-S293.)

Condoms, the barrier methods that are currently available, have limitations. Most require the consent, if not the active participation of both partners and therefore cannot be independently used at the discretion of one partner. An easily available and inexpensive microbicide could provide a prevention option for millions of people worldwide.

To address this goal, the following steps will be taken:

o During FY 1997, the NIH and CDC will begin to implement the four-year, $100 million initiative on microbicides announced by Secretary of Health and Human Services Donna Shalala at the Eleventh International Conference on AIDS;

o The Vice President will continue a high-level dialogue designed to encourage private sector involvement in the development of microbicides;

o Through U.S. participation in UNAIDS, and in other forums, we will encourage international efforts to develop effective microbicides.

c. <u>Developing New and More Effective Therapies</u>.

Another challenge in the research arena is developing new and more effective therapies that allow us to transform HIV disease into a chronic, manageable condition. While the FDA is approving new treatments in record numbers and at record speed, the long-term clinical effectiveness of these new therapies remains unknown. There is no doubt that new drugs must be developed.

To accomplish this, federal support for drug development and clinical trials through NIH will increase by $xx million in FY 1997. In addition, several other initiatives will be undertaken or maintained:

- *Federal support for the Forum for Collaborative HIV Research will promote public-private collaboration in AIDS research.* This new group, formed at the behest of Vice President Gore, is designed to catalyze collaborations between the government research establishment, pharmaceutical companies, and third party payers for the purpose of capitalizing on recent scientific advances and learning how to optimally use available treatment regimens. The Federal government is committed to being an equal partner in this new effort as it begins its work later this year.

- *A federal commitment to continued access to sophisticated equipment and personnel that can be shared among researchers in both the private and public sectors.* The Department of Energy (DOE) has made available the use of sophisticated imaging equipment that would be prohibitively expensive for individual researchers or companies. This shared resource 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.

- *Increased focus in federal research on special populations.* Our research effort will increase its focus on the needs of special populations, including youth, women, minorities, and substance abusers who may not have received the full benefit of all research discoveries. The efforts of programs such as the Women's Interagency HIV Study (WIHS), the Terry Beirn Community Programs for Clinical Research on AIDS (CPCRA), and the Adolescent Medicine HIV/AIDS Research Network are important to improving our understanding of HIV disease in these populations and will continue.

d. Continued Support for Research

Research is an investment in our future. Already, it has helped prolong improve the quality of lives, and we must continue to make this investment. To unleash the talents of the best and the brightest in finding a cure, better therapies, and a vaccine will require a sustained commitment of funding to meet the research challenges. NIH currently receives many more outstanding research applications than it is able to fund -- representing a lost opportunity for scientific progress. Other departments and agencies, such as DOD and VA, also support

crucially important research that strengthens the overall U.S. research effort. Recognizing the importance of biomedical and AIDS research generally, the President has requested an increase of $xxx million for the NIH overall, an increase of $xx million for NIH-supported AIDS research, and an increase of $xx million for AIDS research government-wide.

C. CARE & SERVICES

"AIDS has taken too many friends and relatives and loved ones from everyone of us in this room. It has shaken the faith of many, but it has inspired a remarkable community spirit."
President Clinton, May 20, 1996
Signing of the Ryan White CARE Act Reauthorization

1. Record of Accomplishment

Since the epidemic of HIV and AIDS began in 1981, more than 500,000 Americans have been diagnosed with AIDS and required care. As the number of Americans living with AIDS increased, so did their needs. The demands on the U.S. health care system increased dramatically, but federal, state, and local governments along with community-based organizations and private clinicians have responded with compassionate, high-quality medical care. In 1985, Federal expenditures for HIV-related care and services were $xxx, by 1995 the Federal share reached $xxx.

In the early years of the epidemic, the health care infrastructure was particularly unprepared to accommodate the health care needs of persons with HIV. To meet their complex health care needs, HIV-positive persons were often forced to negotiate a fragmented system of care. There were few programs designed to meet the unique care needs of positive individuals. Moreover, available care services were often directed towards meeting the acute care needs of persons diagnosed with AIDS, rather than the early stages of HIV disease. While we still have far to go, the quality and availability of services for HIV-positive persons has improved significantly.

People living with HIV now access and finance necessary health care services in a variety of ways. Currently, over 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. JL cite.

In addition to Medicaid, the centerpiece of the national safety net for HIV positive people is the programs funded through the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, administered by the Health Resources and Services Administration (HRSA). The CARE Act programs were established to fill gaps in coverage and build systems of care to create access to health care for people living with HIV and AIDS. The first four titles of the CARE Act support direct services for people living with HIV:

• 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. Title II also provides drug reimbursement funding for persons living with HIV/AIDS under the AIDS Drug Assistance Program (ADAP).

• Title IIIb of the CARE Act provides early intervention services such as counseling and testing, medical care, and educational services for medically underserved persons with the goal of reducing HIV-related illness.

• Title IV seeks to increase the availability of research, 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 (IHS) which provides health care for HIV-positive Native Americans and Alaska Natives. Additionally, the Bureau of Prisons within the Department of Justice provides care for HIV-positive people in Federal prisons.

People living with HIV and their families face significant obstacles to locating affordable housing. Housing assistance for people living with HIV and AIDS is provided by the Department of Housing and Urban Development (HUD) through its Housing Opportunities for Persons with AIDS (HOPWA), enacted in 1990, and other programs, such as the Section 811 Supportive Housing Programs for Persons with Disabilities. These programs work in partnership with local initiatives incorporating housing assistance into a community's continuum of services.

To further foster community involvement, HUD also has 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. The Community Development Block Grant (CDBG), the HOME affordable housing program, as well as public housing programs are key resources that are available to communities.

Since he took office in 1993, President Clinton has built on this record by making AIDS a top national priority and increasing that national commitment by:

- o Signing the Ryan White CARE Act Amendments of 1996, and increasing Ryan White funding by 134 percent,
- o More than doubling funding for the AIDS Drug Assistance Program, which helps uninsured and underinsured individuals purchase prescription drugs,

- o Increasing funding for HOPWA by 96 percent,

- o Fighting to preserve the Medicaid guarantee of coverage for the over 50 percent of people with AIDS and 92 percent of children with AIDS who rely on this program for their health coverage, and

- o Revising eligibility rules for Social Security disability benefits to make it easier for people living with HIV to qualify for benefits.

2. Future Opportunities for Progress

The nation goal in this area is to ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs to have the opportunity to live productive lives. AIDS care and service programs must continue to provide access to care for those without insurance coverage, improve prioritization and accountability, and increase the cost-effectiveness of services they provide. As treatments improve and extend the productive lives of people with HIV, we must continually reexamine the range of services that are needed.

Two major challenges exist in meeting this goal:

- o Maintaining HIV-related care and services as an investment priority in budgeting in the context of a balanced federal budget: fighting to preserve Medicaid and continuing to seek increased funding for CARE Act and HOPWA programs

- o Assuring that available resources are used as effectively as possible.

a. Making investment in care and services a budget priority

Preserving Medicaid As the epidemic continues to spread in lower-income communities, Medicaid will be an even more essential lifeline of support for Americans living with HIV and AIDS. The need to maintain the historic Federal-State partnership on Medicaid has never been greater. Proposals in Congress to convert Medicaid into a block grant would endanger access to care for people living with HIV and AIDS, particularly proposals to eliminate the Federal guarantee of coverage for people living with disabilities. The President has vetoed one such proposal and has sustaining the entitlement to Medicaid is central to the national goal of ensuring appropriate and affordable care and services for persons living with HIV and AIDS.

Continuing Support for Ryan White CARE Act. The five-year reauthorization of the CARE Act signed by President Clinton on May 20, 1996 provides people living with HIV and AIDS

with peace of mind that support from the Federal government will be there through the year 2000. As the demand for care continues to grow, so must the resources for the CARE Act. President Clinton has proposed $827.5 million for this program in FY 1997.

Expanding Support for Housing Services Finally, maintaining consistent funding for the housing component of the services safety net will continue to be a national priority. Without stable housing, a person living with HIV has diminished access to care and services and a diminished opportunity to live a productive life. It is estimated that up to 50 percent of people living with HIV and AIDS are or will become homeless during the course of their illness.[2] The President's 1997 budget includes a request for $196 million for HOPWA.

b. Ensuring Effective Use of Limited Resources

There are three primary ways the federal government will be ~~attempting to~~ make the most of its limited resources: (1) Improving coordination among federal programs, (2) Improving the quality of care provided by those programs, and (3) evaluating program effectiveness to ensure that funds are well spent.

Improving Program Coordination

Integrating HIV and related services is another important step in assisting communities to build seamless systems of support for our most vulnerable citizens. Organizations receiving federal funding to provide AIDS-related care often require support from several federal agencies. For example, creating a comprehensive community-based program that integrates primary care, substance abuse treatment and prevention, and sexually transmitted disease screening, HIV prevention, access to clinical trials, and housing assistance requires separate applications to SAMHSA, HRSA, CDC, NIH, and HUD.

The agencies funding HIV-related services are committed to simplifying the application process for federal funding and to facilitating service integration. HRSA and SAMHSA have issued joint programs announcements, and HUD and HRSA have issued a joint program announcement for the Special Projects of National Significance (SPNS) program. These efforts to improve integration will be continued and expanded, with special attention to linking HIV and substance abuse prevention and services.

Improving Quality of Care

Federally-supported programs can and should consistently provide high-quality care. Ensuring consistency in care delivery requires increased training for health care professionals and greater accountability through the use of performance measures for quality care. It is also essential that practical information on research advances for practicing clinicians and their patients be provided in a timely manner. (See Section

Translation of Research Advances in Practice.) HRSA and HCFA will continue to offer guidance to grantees and the States regarding maintaining the quality and standard of care appropriate for people living with HIV. To this end, during FY 1997, the Office of HIV/AIDS Policy at DHHS is undertaking a program to develop clinical practice guidelines in conjunction with other government agencies and private sector clinicians.

Evaluating Program Effectiveness

- Strong federal support for safety net programs must be accompanied by improved accountability and priority setting. Evaluating current activities provides valuable information for planners and those at the front lines of the epidemic and assist in providing better care to people living with HIV.

D. CIVIL RIGHTS

"Every person with HIV or AIDS is someone's son or daughter, brother or sister, parent or grandparent. We cannot allow discrimination of any kind to blind us to what we must do."
President Clinton, May 20, 1996
Signing of the Ryan White CARE Act Reauthorization

Discrimination against people living with HIV or AIDS violates the human rights of individual Americans and undermines our efforts to prevent and treat HIV infection. The extraordinary stigma that has been attached to HIV disease hampers the ability of people living with HIV and AIDS to live full lives, free of fear.

Discrimination also undermines efforts to prevent and treat HIV infection and bring the epidemic under control. Fear of discrimination and stigma causes many people not to seek testing for HIV; thus many remain unaware of their HIV status and go without the care that could help them live longer, healthier lives. Opportunities to educate people are also lost as people at-risk avoid prevention programs because of the stigma associated with HIV.

The fourth goal of the national strategy is to eliminate discrimination and to provide national leadership in erasing the stigma associated with HIV and AIDS.

1. Record of Accomplishment

During the early years of the AIDS epidemic, protection of the civil rights of people living with HIV and AIDS was sporadic, at best. Individual lawsuits were the first line of action. By the late 1980s, however, the Federal government began to respond more aggressively with actions including:

- Enactment of the Harkin-Humphrey Amendment to the Civil Rights Restoration Act, clarifying that Section 504 of the Rehabilitation Act of 1973 applied to people with contagious diseases, including HIV; and

- Passage of the Americans with Disabilities Act of 1990 (ADA) which protects individuals living with HIV and AIDS, and people perceived to be at risk for HIV, from discrimination in housing, employment, and public accommodation.

Since he took office, President Clinton has directed relevant agencies to make enforcement of the civil rights of people living with HIV and AIDS a priority. Key actions include:

- Vigorously enforcing the ADA by the Justice Department, the Equal Employment Opportunities Commission, and the Department of Health and Human Services. The

Federal government has resolved nearly 800 charges alleging discrimination against people with HIV and AIDS obtaining monetary benefits of more than $6.1 million; [Are these figures correct? ; Source(s)?]

- Vigorously enforcing Section 504 of the Rehabilitation Act of 1973 as it pertains to recipients of DHHS funds such as hospitals, nursing homes, and social service agencies;

- Forcefully opposing the so-called "Dornan Amendment," which would have required the discharge of all military personnel who are living with HIV. President Clinton declared the proposal unconstitutional and directed the Department of Justice not to defend it if challenged in court. The President led a successful effort to repeal the "Dornan Amendment" and continues to oppose its enactment;

- Establishing an AIDS education program for all Federal workers; and

- Using the Presidential "bully pulpit" to continually speak out against discrimination against people with HIV and AIDS. In December 1995, the President hosted the first ever White House Conference on HIV and AIDS, bringing to the White House over 300 people from around the country to discuss with the President the impact of the epidemic on their lives and communities.

2. Future Opportunities for Progress

There are four key ways that the Federal government is maintaining its commitment to meeting the goal of ensuring that people living with HIV are not subject to discrimination:

Enforcing Rights. Efforts to protect the civil rights of people with HIV and AIDS must be ever-vigilant. The Federal government will continue to exhibit strong leadership on this issue through its enforcement of the Americans with Disabilities Act and public condemnation of discriminatory acts or statements. Of particular concern is discrimination against people with HIV seeking access to health care facilities. A joint effort by the Department of Health and Human Services and the Department of Justice aimed at access to nursing homes is a significant step forward in protecting the rights of people living with HIV.

Protecting Workers. The Federal government is actively working to examine its own existing policies related to the exclusion of people living with HIV from employment. The Director of the Office of National AIDS Policy is working with Federal Agencies to examine individual policies to determine whether they comply with Federal public health guidelines.

Opposing Discriminatory Legislation. The Administration will continue to oppose, in the strongest terms possible, efforts by the Congress to discriminate against people living with HIV and AIDS.

Providing Leadership. Leaders of government have an obligation to use the power of their elected office to speak out against acts or words of discrimination against any group of people. President Clinton has used and will continue to use his position to oppose discrimination against people living with HIV and AIDS.

E. INTERNATIONAL ACTIVITIES

> *"The American people need to know that everybody in this country and, indeed, throughout the world, is now vulnerable to this disease."*
> President Clinton, December 5, 1996, to the White Conference on HIV and AIDS

AIDS is a global epidemic. The World Health Organization (WHO) estimates that 94 percent of new infections occur in developing countries. (footnote c) In the United States it is estimated that between 650,000 and 900,000 people are currently infected with HIV. The WHO and UNAIDS estimates that 27.9 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 by the year 2000. 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 epidemic jeopardizes decades of economic and social advances in many developing nations. In the nations of Africa and Asia, economic advances are threatened and in some cases may be reversed due to 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.[3] 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.

1. Record of Accomplishment

Since it began, HIV and AIDS has been a global concern. The U.S. has worked closely with developed and developing nations to design an international response that is both vigorous and coordinated. Sentinel achievements include:

- Provided initial funding and key leadership for the creation of the Global Programme on AIDS at the World Health Organization (WHO) in 1987; and
- Played an instrumental role in establishing the new streamlined Joint United Nations Programme on HIV/AIDS (UNAIDS) in 1996.

The United States is the largest contributor to international efforts to combat the pandemic of HIV and AIDS. Several Federal Agencies are working slow the AIDS epidemic internationally. (See Appendix E.) The Department of State works 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 of U.S. leadership in the global HIV arena are: preventing new infections; reducing the personal and social impact of the pandemic; and mobilizing and unifying national and international efforts.

The U.S. Agency for International Development (USAID) also plays leadership role in the global HIV effort through development assistance, research and policy formation. USAID focuses its efforts on developing prevention programs based on proven interventions; addressing social, cultural, regulatory and economic issues related to HIV and 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 Peace Corps trains a portion of its volunteers to directly address HIV-related concerns in their countries of placement. The U.S. Information Agency (USIA) supports programs that promote dissemination of U.S. policies and information related to HIV and AIDS.

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. The DOD is conducting clinical trials of candidate HIV vaccines in Thailand and NIH (working in collaboration with USAID), supports a range of scientific studies in developing countries. The results of the studies ultimately will be used to develop interventions to reduce behaviors that place individuals at risk for contracting HIV infection.

2. Future Opportunities for Progress

To accomplish the goal of providing strong continuing support for international efforts to address the HIV epidemic, the following steps will be taken:

International Leadership. The United States has established a global leadership role in combatting the epidemic. This leadership will continue. The U.S. strongly supports the newly established Joint United Nations Programme on AIDS (UNAIDS).[4] The U.S. is a member of the governing body of UNAIDS and signed the 1994 Paris Declaration and the Greater Involvement of People Living with HIV and AIDS Initiative (GIPA).

The U.S. also supports efforts to more effectively access available resources as well as encourage non-traditional donor countries to provide much-needed contributions. Supporting UNAIDS organizations such as UNICEF, WHO, UNDP (United Nations Development Program), the U.S.-Japan Common Agenda and its innovative programmatic efforts, and UNAIDS' 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.

Strengthening Partnerships. In addition to maintaining our multilateral partnerships, we must strengthen and expand our bilateral programs and funds for HIV activities. We must

reverse the current trend to reduce assistance to developing countries where more than 90 percent of the world's AIDS cases are found.

Sharing Technology and Bringing Lessons Home. Through USAID's "Lessons without Borders Project", the U.S. has gained valuable insights from experiences in participating countries and is applying them to communities here at home. The initiative brings lessons learned abroad back to inner city and rural areas with problems similar to those experienced overseas. These efforts should be continued and expanded for HIV and AIDS.

Improving 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. In order to ensure that efforts are productive, the Agencies supporting international activities must develop a mechanism for coordinating U.S. programs in a systematic and efficient manner.

F. TRANSLATION OF RESEARCH ADVANCES INTO PRACTICE

Insert Quote

An important element in our fight against AIDS is ensuring that research advances are translated into improved HIV prevention programs and better care for HIV positive persons. While directly related to earlier goals relating to research, prevention, and care and services, it is important to highlight this aspect of the nation's response to the epidemic to assure that we are taking what we are learning and translating it into benefit for people with or at risk for HIV.

An example of the importance of such efforts is the translation of the NIH-supported research study that found that the use of AZT by pregnant women during pregnancy and childbirth and its application to newborns for the first six weeks of life can reduce the risk of perinatal transmission of HIV by two-thirds. Translation of these results required actions by the Centers for Disease Control and Prevention, which prepared guidelines for physicians caring for pregnant women and for consumers; the Health Resources and Services Administration, which provided guidance to grantees on coverage of such services; the Health Care Financing Administration, which provided similar guidance to State Medicaid Directors.

1. Record of Accomplishment

Due in part to Federally-sponsored information dissemination activities, dramatic changes in the way HIV is treated have taken place. Ensuring dissemination of HIV-related information falls under the missions of several Agencies (See Appendix F). Key examples are:

- 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 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 tele-conferencing;

- NIH supports publicly available computerized databases such as AIDSDRUGS, AIDSTRIALS, and AIDSLINE;

- The toll-free 1-800 TRIALS-A AIDS Clinical Trials Information Service (ACTIS) is co-sponsored by NIH, CDC, and FDA;

- The Centers for Disease Control and Prevention disseminates information through the

National AIDS Hotline (1-800-342-AIDS); its toll-free 1-800-HIV-0440 HIV/AIDS Treatment Information Service (ATIS); and the AIDS Information Clearinghouse;

- The CDC also develops and issues guidelines for health professionals through its *Morbidity and Mortality Weekly Report*;

- 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; and,

- The Health Resources and Services Administration directs a nationwide system of AIDS Education and Training Centers that provide state of the art HIV clinical information to health care providers. HRSA also has developed guidances for its Ryan White CARE Act grantees and funds an AIDS warmline that responds to questions from clinicians across the country.

2. Future Opportunities for Progress

Ensuring that research advances are translated into improved HIV prevention programs and better care for HIV positive persons, will require a number of steps, including:

Increasing Education and Training. As we continue to expand our base of knowledge about AIDS care, efforts to educate and train health care professionals in state-of-the-art care for people living with HIV and AIDS must be expanded. An AHCPR-supported study indicated that primary care physicians may miss significant HIV-related symptoms during patient examinations.[5] Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.[6] Reference Kitahara (sp?) article. To reverse this pattern, the Administration is fighting to restore funding for the AIDS Education and Training Centers, which play a vital role in training providers. Achieving this goal will also require a renewed emphasis on HIV on the part of medical schools, professional organizations, and individual clinicians.

Disseminating 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 for their patients. 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. To this end, during FY 1997, the Office of HIV/AIDS Policy at DHHS is undertaking a program to develop clinical practice guidelines in conjunction with other government agencies and private sector clinicians.

Improving Coordination of Federal Activities. Enhancing coordination of information

dissemination activities among Public Health Service Agencies is an important priority. Within DHHS, the Office of HIV/AIDS Policy (OHAP) 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 people and organizations, and that policies and standard-of-care practices for Federally-sponsored programs are modified to reflect the new standard, requires a continued high level of cooperation and coordination among Public Health Service Agencies.

Disseminating Prevention Models. Improved dissemination efforts also are needed in the area of primary prevention models. Models of effective prevention interventions have been developed, but often this valuable information is not reaching those people developing, implementing, and evaluating prevention programs. The Public Health Service will take the lead in ensuring that information that can be used to stem the tide of new infections reaches those who can make a difference.

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The Final Report of the National Commission on AIDS
June 1993

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 AIDS Strategy that would detail the Federal government's long-term approach in responding to this epidemic. The National AIDS Strategy has been developed by the Clinton Administration 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, businesses, schools, churches, families, and individuals.

The President has identified the following national goals to guide our efforts against HIV:

- **To provide strong continuing support for AIDS-related research in order to find additional treatments, a preventive vaccine to protect the uninfected, and a cure for those currently infected;**

- **To provide strong continuing support for effective AIDS prevention efforts to continue to reduce the number of new HIV infections in the U.S.;**

- **To ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs; and,**

- **To ensure that people living with HIV are not subject to discrimination.**

- **To provide strong continuing support for international efforts to address the HIV epidemic.**

- **To ensure that research advances are translated into improved HIV prevention programs and better care for HIV positive persons.**

This document is a snapshot of where we are as a Nation and where we need to go in achieving these national goals. It summarizes some of the key accomplishments of our Nation's scientific and public health professionals and identifies key areas for further effort. In addition, the appendices to this report lay out, for the first time, detailed descriptions of the objectives, goals, and budgets of all Agencies involved in the Federal response to HIV in

five major areas of HIV policy: prevention, research, care, civil rights, international activities, and translation of research into practice.

The National AIDS Strategy is intended to be a working document that requires regular updating and adjustment as goals are reached and new challenges emerge. This Strategy provides a reference point for continuing dialogues and collaborative efforts between the public and private sectors that are necessary to meet our national goals and objectives.

In that light, the Office of National AIDS Policy is seeking direct input from the Presidential Advisory Council on HIV/AIDS, national and community-based organizations, state and local government, clinicians and researchers, members of the infected and affected community, and other individuals and organizations who can contribute to this historic document. This Strategy is being released, first, in draft form to allow for maximum input to the first of an ongoing national effort to chart and plan Federal efforts in response to the epidemic of HIV/AIDS.

The development of a National AIDS Strategy 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 Federal government should focus its efforts.

The National AIDS Strategy was drafted in consultation with, and with guidance from, numerous groups and individuals. Within the Federal government, this effort began at the Agency level. Members of the Interdepartmental Task Force on HIV and AIDS (IDTF) representing all Federal Agencies involved in the national response to HIV and AIDS, identified their HIV-related goals, objectives, and highlighted areas requiring special attention.

Individuals living with HIV and AIDS, their families, friends, loved ones, and care givers made vital contributions to this Strategy. Numerous non-governmental groups and organizations have also been consulted including the Presidential Advisory Council on HIV/AIDS, participants in the historic White House Conference on HIV and AIDS, the ONAP-sponsored regional briefings, patient and consumer advocates, health care professionals, community-based organizations, educators, religious leaders, and business leaders. The earlier insights provided by the National Commission on AIDS, the Institute of Medicine and National Research Council, the General Accounting Office, and the Office of Technology Assessment have also been extraordinarily helpful in developing the National AIDS Strategy.

As a Nation, we face great challenges, but we are also facing equally great opportunities. After fifteen years, AIDS remains a terrible national tragedy that has affected -- and will

continue to affect -- far too many people in this Nation and around the world. But we have made tremendous progress in our understanding of HIV and HIV disease, ways we can treat those who are infected, and means by which we can prevent infection. Ultimately, HIV is a disease that we can defeat -- just as we have eradicated smallpox from our planet and polio from the western hemisphere. The National AIDS Strategy provides a foundation for the continuing public-private partnerships that are essential to our success. Together, with steadfast commitment, courage, and leadership, we will win the battle against HIV and AIDS.

Patricia S. Fleming
Director, Office of National AIDS Policy

"For nearly every American with eyes and ears open, the face of AIDS is no longer the face of a stranger. Millions and millions of us have now stood at the bedside of a dying friend and grieved. Millions and millions of us now know people who have had AIDS and who have died of it who are both gay and heterosexual. Millions and millions of us are now forced to admit that this is a problem which has diminished the life of every American."

President Clinton, December 1, 1993, Georgetown University

I. INTRODUCTION

Goals of the National Strategy

The President has identified the following national goals to guide our efforts against HIV:

- To provide strong continuing support for AIDS-related research in order to find additional treatments, a preventive vaccine to protect the uninfected, and a cure for those currently infected;
- To provide strong continuing support for effective AIDS prevention efforts to continue to reduce the number of new HIV infections in the U.S.;
- To ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs; and,
- To ensure that people living with HIV are not subject to discrimination.
- To provide strong continuing support for international efforts to address the HIV epidemic.
- To ensure that research advances are translated into improved HIV prevention programs and better care for HIV positive persons.

Scope of the HIV/AIDS Epidemic

The epidemic 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 around the world. While significant progress has been made in understanding the disease and developing treatments since the first case was reported in the U.S. in June 1981, 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 average of 100 Americans are diagnosed with AIDS every day and a similar number of men, women, and children become infected with HIV every 24 hours. **[Richard -- are you certain these numbers are correct?]** Globally, 7,500 people become infected each day.

Oh, this is to reassure

An Expanding Public Health Threat

As of December 1995, the Centers for Disease Control and Prevention (CDC) had received reports of 513,486 cases of AIDS among persons in the U.S. and 319,849 of these persons have been reported to have died as a result of complications related to HIV. Since 1987, AIDS has risen from being the 15th cause of death among all Americans to the 8th. AIDS is now the leading cause of death among Americans aged 25 to 44 (See Figure 1). In 1995 alone, approximately 74,000 new cases of AIDS were reported in the U.S. and more than 46,000 AIDS related deaths were reported to the CDC in 1994. CDC estimates that between 40,000 and 60,000 Americans are becoming newly infected with HIV each year, and that between 650,000 and 900,000 Americans are currently living with HIV.

As the epidemic in the United States has expanded, the demographics of the epidemic have changed. The early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers (i.e., New York, San Francisco, and Los Angeles). Today, this group represents less than half of all new cases, although they still represent the majority of persons living with HIV and AIDS. Among the populations that are more heavily affected today are young gay men, women, and injecting drug users and their sexual partners as well as users of non-injecting drugs (i.e., crack cocaine and alcohol). In 1995, nearly 14,000 women were reported to CDC as having been diagnosed with AIDS. Women now comprise 14 percent of cumulatively reported AIDS cases. If this trend continues, it is estimated that 80,000 American children will have been orphaned as a result of AIDS by the end of this decade. In 1995, approximately 800 new cases of pediatric AIDS cases were reported. (Footnote a)

Adolescents (age 13-19) are at increased risk for HIV infection. CDC estimates that one-quarter of new HIV infections in the U.S. occur among people under age 21. A significant number of young people are engaging at earlier ages in sexual intercourse and drug and alcohol use. 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.

Racial and ethnic minorities have been disproportionately affected by the epidemic of HIV and AIDS. African-Americans, who represent approximately 12 percent of the U.S. population, accounted for 40 percent of newly reported AIDS cases in 1995. Hispanics, who account for about 9 percent of the general population, represented 19 percent of new cases reported in 1995. The number of African-Americans and Hispanics affected by HIV and

AIDS has risen dramatically. In 1982, Blacks and Hispanics represented 31 percent of all AIDS cases; however, as of December 1995, these groups comprised 52 percent of cumulative AIDS cases.
The HIV epidemic continues to spread into suburban and rural areas, with especially dramatic increases in certain regions of the South and Midwest. Between January 1993 and December 1995 the largest numbers of AIDS cases (86,462) were reported from the South. (Endnote 1)[1] While most cases are still reported from urban areas, the rate of reported cases in non-metropolitan areas is increasing more rapidly than in urban areas. AIDS cases have now been reported in all 50 States, the District of Columbia, Puerto Rico, Guam, and each of the U.S. territories (See Figure 2).

AIDS is an expensive disease. Average lifetime costs of medical care after diagnosis with HIV is $119,000 (Footnote b). People living with HIV are disproportionately dependent on the public sector for their health care. Over 50 percent of people living with AIDS are enrolled in Medicaid, including more than 90 percent of children with AIDS. In FY 1996, the Federal government spent $1.8 billion on Medicaid benefits for people living with HIV and AIDS and another $690 million on Medicare benefits. Social Security benefits for people disabled by HIV/AIDS total $1.1 billion in FY 1996.

Globally, the toll of the epidemic is much greater and threatens to reverse decades of economic and public health progress in developing countries. The Joint United Programme on HIV and AIDS (UNAIDS) and the World Health Organization (WHO) estimate that 27.9 million people have been infected with HIV. Since the beginning of the pandemic, 6 million people, including 1.6 million children, have been diagnosed with AIDS. By the year 2000, WHO projects that between 30 million and 40 million people will have been infected with HIV and 10 million to 15 million children will be orphaned due to AIDS.

II. OVERVIEW OF FEDERAL EFFORTS

The scope and nature of the HIV/AIDS epidemic have drawn States, local governments, academic institutions, private foundations, health care institutions and community-based organizations and the Federal government 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 FY 1985 the Federal government spent $212 million for AIDS research, surveillance, and care. By FY 1995 that figure reached $6.8 billion. (See Appendix G).

In the past four years, under the leadership of President Clinton, spending for AIDS research, prevention, and care has increased by 47 percent. Funding for the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act alone has increased by 151 percent. Support for housing for people living with AIDS has increased by 91 percent. AIDS-related research funding has increased by 34 percent and AIDS prevention funding has increased by 24 percent. The National Institutes of Health Revitalization Act of 1993 provided the Office of AIDS Research with enhanced authority to prepare and carry out an annual AIDS research budget and plan. Approval of AIDS drugs by the Food and Drug Administration has been accelerated to record times. A community-based planning process has empowered local communities to develop innovative AIDS prevention programs. Eligibility for Social Security disability benefits for people with AIDS have been simplified and Federal laws prohibiting discrimination against people living with HIV and AIDS have been vigorously enforced.

As the epidemic continues, we must renew our vision for ending this epidemic. The sections that follow focus on six major policy areas: prevention, research, care and services, civil rights, international activities, and the translation of research advances into practice. They identify recent progress and future opportunities for further progress.

A. PREVENTION

"We have to set a goal. . . We have to reduce the number of new infections each and every year until there are no more new infections."

President Clinton, December 5, 1995, to the White House Conference on HIV and AIDS.

1. Record of Accomplishment

Since the epidemic began, there has been important progress in preventing HIV infection. Early in the epidemic, CDC estimated that more than 100,000 Americans were becoming infected with HIV each year; today, that total is between 40,000 and 60,000 people each year.

Sentinel accomplishments in prevention of HIV include:

- Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the first cases of AIDS;
- Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the risk factors associated with HIV infection; and
- Due in part to successful implementation of CDC-sponsored prevention strategies, a slowing in the growth of the epidemic.

Since President Clinton took office in 1993, efforts in HIV prevention have been accelerated. Actions include:

- Increasing funding for AIDS prevention by 24 percent;
- Launching the community planning partnership -- empowering local communities to make decisions about and develop innovative prevention efforts;
- Launching the Prevention Marketing Initiative, focusing on young adults (18 to 25) with frank public service announcements advocating sexual abstinence and, for the first time, the correct and consistent use of latex condoms; and,
- Reorganizing AIDS prevention efforts at the Centers for Disease Control and Prevention to foster greater coordination with efforts to reduce sexually transmitted diseases and tuberculosis.

Federal agencies have been instrumental in expanding our knowledge base about HIV prevention (see Appendix A). The CDC, the agency with primary Federal HIV surveillance and prevention responsibilities, has been pivotal in identifying risk factors associated with HIV transmission, seroprevalence of HIV in society, and trends in HIV infection.

Federal efforts have shown that HIV prevention programs can be effective. CDC's prevention projects, many in partnership with states, local governments, and community-based organizations, have demonstrated that prevention programs are most effective when designed and implemented at a local level. Biomedical, behavioral, and social science prevention research conducted and supported by the National Institutes of Health (NIH) and CDC has expanded and will continue to expand our understanding of the determinants of HIV-related risk behavior.

The nation has also combatted the dual epidemics of HIV and drug abuse. The National Institute on Drug Abuse (NIDA), the Substance Abuse and Mental Health Services Administration (SAMHSA), and CDC support efforts to prevent HIV infection among drug users. The Office of National Drug Control Policy has pursued efforts to counter the problem of substance abuse and its devastating consequences.

There have been advances in integrating primary prevention into health care service systems. The Health Resources and Services Administration (HRSA) and the Department of Veterans Affairs (VA) have encouraged broader access to prevention information through the integration of prevention interventions into primary health care services and through support of early intervention services. HRSA and HCFA also have undertaken special initiatives designed to reduce perinatal transmission of HIV and HRSA has promoted primary prevention through the training of health professionals in the AIDS Education and Training Centers program.

2. Future Opportunities for Progress

To achieve the national goal of no new infections requires efforts in the prevention area on five fronts:

- o Improving understanding of trends in HIV transmission and seroprevalence
- o Improving scientific knowledge about effective prevention models and strategies
- o Strengthening community based programs
- o Integrating HIV and other prevention efforts
- o Targeting special populations

a. Improving Understanding of Trends in the Epidemic

Understanding who is becoming infected and through what behaviors is critical to designing effective prevention interventions, as well as targeting service resources. As discussed in the introduction, the demographics of the epidemic have shifted, and effective prevention depends on rapidly understanding these shifts and responding to them.

CDC's AIDS case and case death reporting system provides important data for assessing AIDS prevalence and mortality by gender, race/ethnicity, age, and mode of exposure. However, this approach does not capture sufficient "front-end" information on the incidence and prevalence of HIV prior to an AIDS diagnosis. We, therefore, miss critical warning signs about new trends in affected populations and increasing risky behaviors.

To address this shortcoming, the CDC will work to improve its surveillance of HIV infection and related diseases and surveillance of HIV behavioral risk factors, both to better monitor the course of the epidemic and to provide guidance to community planners for targeting prevention and service dollars. This can and will be undertaken without compromising the confidentiality of those involved.

b. Research on Effective Prevention Strategies

Effective interventions must be based on sound research findings and evaluations. Funding for prevention and behavioral research did not receive the same priority in the early years of the epidemic as biomedical research. In response to the recommendations from the Report of the NIH AIDS Research Program Evaluation Task Force, NIH is developing a comprehensive HIV prevention science agenda. NIH and CDC are both committed to increasing future support for basic research on behavior, interventions, social marketing and program evaluation.

Behavioral Research Basic behavioral research answers key questions about the determinants of HIV-associated sexual and drug using behaviors. We still lack key knowledge in this area, which is critical to developing effective interventions.

Intervention Research Intervention research focuses on individual and community level interventions that result in modified sexual and drug using behaviors. There have been significant accomplishments in this area, but, as this portfolio expands, it will be critical to assess intervention in real world settings that are relevant to the growing number of populations that must be reached by prevention programs. This research should be designed by a broad range of scientists, public health, and community experts to assure its relevance.

Social Marketing Research The use of social marketing techniques is a relatively new approach to HIV prevention. This promising area requires use of basic and intervention

research, as well as careful design and evaluation of social marketing efforts.

Evaluation To ensure that prevention programs are actually working -- and so scarce resources are spent on the most effective intervention -- all federally funded prevention activities will routinely include evaluation components. The funding agencies will share widely the knowledge gained about what works and what does not to ensure promotion of best practices in the field. In addition, as part of the federal government's compliance with the Government Performance and Results Act, CDC and SAMHSA will continue to work with its constituents to develop appropriate performance measures for HIV prevention programs.

c. Strengthening Community-based Programs

Community prevention planning is one of the key innovations in CDC's prevention programming over the last several years. This public/private partnership puts federal funds to work based on locally designed priorities. This three-year-old initiative is at a crucial stage of development, and ensuring its success is the third key element of this strategy's prevention agenda.

Community planning requires ongoing leadership from CDC and its partners as well as the resources to provide the technical assistance the community planning process needs to flourish. Successful HIV prevention often depends on small, new community based organizations, many serving minority populations. These organizations need assistance not just on how to plan and compete successfully for available resources, but also how to appropriately incorporate epidemiological and research information into community prevention programs.

d. Program Integration and Collaboration

The fourth of the prevention agenda is improving the integration of HIV prevention into other program areas that reach individuals at risk for HIV. HIV prevention programs cannot stand apart from other, related public health efforts.

Substance Abuse HIV transmission is directly related to substance abuse, both directly through needle sharing behaviors and indirectly as sex is traded for drugs or drug use impairs judgment and increases risk taking behaviors. Breaking that linkage will require:

- Integration of HIV prevention into substance abuse treatment and prevention programs. In August, 1996, at the request of President Clinton, the Public Health Service agencies jointly co-sponsored a national meeting of state and local officials, researchers, and community experts from the fields of HIV and substance abuse to develop an action plan to more effectively integrate HIV and substance abuse

prevention efforts. These agencies are committed to implementing this strategy in the year ahead.

- Enrolling more substance abusers into drug treatment. Substance abuse treatment is a major form of HIV prevention. This Administration will continue to press for increased funding for substance abuse treatment. Further, through outreach and demonstration programs, SAMHSA and CDC will work to enroll more people in treatment and to find more successful interventions to accomplish this end.

- Reducing the availability of illegal drugs. The Office of National Drug Control Policy (ONDCP) is leading the fight on two fronts: reducing demand for drugs through treatment and prevention programs, and reducing the availability of drugs through ~~interdiction~~. supply reduction programs

- Preventing HIV transmission through contaminated needles. Sharing of syringes among injecting drug users is the principal means of HIV transmission in this population. While abstinence from drug use is always the preferred means of prevention, the CDC has issued guidelines regarding the use of bleach to clean injection equipment. In addition, CDC-supported research showed that removal of restrictions on over-the-counter sale of needles results in decreased needle sharing. Current federal law prohibits the use of federal funds for needle exchange programs; however a number of communities across the country have successfully undertaken these programs with local resources.

Primary Care HIV prevention needs to be better integrated into primary care. New and promising medical interventions make it critical to improve our approach to HIV counseling and testing -- creating a critical bridge between prevention and primary care. CDC is committed to improving the return rate of those tested at publicly funded sites and the quality of referral to services for those who test positive.

The linkage must also go in the opposite direction: from primary care to prevention. Primary care providers must learn to incorporate a person's sexual and drug using history when a medical history is taken, offering HIV-related counseling and voluntary testing, and providing prevention education to HIV positive individuals as part of the provider- patient relationship. HRSA's AIDS Education and Training Centers (AETCs) have played a crucial role in giving providers the information and skills they need. The Administration is committed to restoring Congressionally-imposed cuts in the AETC program and giving it a renewed focus to support this goal.

Often primary care is a direct form of HIV prevention. The federally supported research that showed AZT could reduce perinatal transmission of HIV was a tremendous medical breakthrough. Realizing the promise of this advance requires a commitment to assuring that

all pregnant women are counseled and offered HIV testing -- and that AZT treatment is available for all who desire it. All federally funded programs reaching pregnant women -- from Medicaid to Ryan White CARE Act grantees to community and migrant health centers -- are required to take part in this effort. We are committed to expanding outreach and assuring appropriate care so that the Congressionally set goal of reducing perinatal transmission by 50 percent by the year 2000 is achieved.

Other STDs and TB Recent research has confirmed that treatment of sexually transmitted diseases (STDs) other than HIV can reduce the likelihood of HIV transmission -- making the need for collaboration between HIV and STD prevention efforts more compelling. Similarly, people living with HIV are at very high risk for developing active tuberculosis. Studies suggest that the risk of developing active TB is 7 to 10 percent per year for persons who are infected with both TB and HIV, as opposed to a 10 percent lifetime risk for persons not infected with HIV. [Footnote: Personal communication from CDC Division TB Elimination.]

To address the need to integrate work on these inter-related epidemics, CDC organized the new National Center for HIV, STD, and TB prevention. CDC has initiated -- and will aggressively pursue -- efforts to increase collaboration among these programs, including expanding the community planning experiment to cover STD programs.

e. Targeting Special Populations

As discussed above, the HIV epidemic continues to have a disproportionate impact on certain populations where infection rates are rising at a worrisome pace. A fifth and final challenge for prevention programming is to pay particular attention to groups which traditionally receive fewer services, but where the risk of infection is greatest. These include youth (especially young gay men), women, and minorities (especially young gay men of color), prisoners, and, as discussed above, substance abusers. Many federally funded HIV prevention activities already target these populations, but the President's increased funding request for CDC provides $35 million in new funds in FY 1997 specifically for programs and research targeting youth, women, and substance abusers.

B. RESEARCH

"Our common goal must ultimately be a cure, a cure for all those who are living with HIV, and a vaccine to protect us from the virus."
President Clinton, December 5, 1995, to the White House Conference on HIV and AIDS

1. Record of Accomplishment

Since 1981, the nation has made significant advances in HIV-related research including:

- Identification of HIV as the etiologic agent for AIDS,
- Development of a reliable test to determine exposure to HIV,
- Approval of zidovudine (AZT), the first treatment of HIV primary infection,
- Development by the Food and Drug Administration of a system of expedited review of treatments for life-threatening diseases, including HIV.
- Approval of by the FDA of 15 new drugs, 8 new indications, and three new diagnostics for HIV and related conditions, developed through public and private sector development efforts.

Since he took office in 1993, President Clinton has escalated our AIDS research efforts by:

- Increasing AIDS research funding by 34 percent,
- Signing the NIH Revitalization Act of 1993, granting the Office of AIDS Research at NIH new authority to plan and implement an annual AIDS research budget and plan,
- Accelerating AIDS drug approval to record times;
- Supporting research that led to finding that use of AZT during pregnancy, childbirth, and the first six weeks of life can reduce the transmission of HIV from mother to child by two-thirds,
- Launching a four-year, $100 million research effort to develop effective topical microbicides;
- Facilitating creation of the Forum for Collaborative HIV Research to identify opportunities for clinical effectiveness research to improve care for HIV-positive individuals.

Contributions of AIDS Research

AIDS research has provided significant benefits beyond the epidemic, in work on many other diseases. AIDS research has accelerated study of the human immune system, helping to better understand and treat diseases such as cancer; autoimmune diseases, including systemic lupus erythematosus; type I diabetes mellitus; rheumatoid arthritis; and multiple sclerosis. AIDS research advances have also contributed to the prevention of other infectious diseases and provided a new paradigm for treatment of viral diseases.

Progress in the treatment and prevention of HIV-related opportunistic infections have had an enormous impact on the care of patients with other immunodeficiency conditions who are susceptible to many of the same pathogens. This research effort has enhanced the care of cancer patients, patients who have received immunosuppressive therapy for transplants, and the treatment of diseases caused by elevated immune responses (i.e., allergies and lupus).

HIV research has assisted in identifying new infectious agents that may be responsible for malignancies, such as the recent discovery of the etiologic agent for Kaposi's sarcoma. These findings may help to identify other oncogenic agents. HIV research has led to a better understanding of the mechanisms by which infectious agents and inflammatory cells cross the blood/brain barrier, providing 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 additional viral diseases and led to development of treatments.

Efforts to develop drugs for the treatment of HIV have accelerated the development of methods of rational drug design using sophisticated techniques of structural biology and advanced computer imaging methods. These advances have implications for drug design for virtually all disorders. Comparative clinical trials of poxvirus vectors and vaccine adjuvants in HIV vaccine candidates have supported safety information for cancer vaccines. Research on HIV-related wasting has provided important information for research on nutritional disorders, metabolic abnormalities, and gastrointestinal dysfunctions.

2. Future Opportunities for Progress

While tremendous progress has been made in biomedical research, we cannot and will not diminish our effort until we have found a cure and a preventive vaccine. To accomplish this national goal, we must address four ongoing challenges:

o Provide leadership and coordination for the federal research effort

- o Develop biomedical interventions that prevent HIV infection, including both a vaccine and a microbicide
- o Develop new and more effective therapies for HIV and related conditions
- o Assure adequate funding for this research effort.

a. Leadership and coordination of research.

Developing and implementing the federal government's AIDS research agenda presents both scientific and logistical challenges that require leadership and coordination, first among the 24 institutes, centers, and divisions of the NIH, and second among the various Departments and Agencies throughout the government that support HIV research.

The strengthened authority and new leadership of the NIH Office of AIDS Research and the first Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS form the basis for better coordination of our research effort and provide the assurance that key questions are being answered systematically and without duplication. Over the next year, the Administration is committed to reauthorizing the OAR's authority and assuring that its budget powers are maintained throughout the appropriations process.

As part of the ongoing commitment to assess all aspects of our research effort, the OAR convened a panel of outside experts to evaluate the NIH AIDS programs. The Report of the NIH AIDS Research Program Evaluation Task Force included several key recommendations that will be implemented in the year ahead. These include:

[NIH: IS THIS THE RIGHT LIST OF KEY INITIATIVES RESULTING FROM LEVINE REPORT?

- o increase the Nation's commitment to basic science advancement by expanding the resources available for investigator-initiated research;
- o improve coordination among all NIH-supported clinical trials groups;
- o give new and stronger leadership to the vaccine development programs; and
- o increase the commitment to behavioral research by developing a comprehensive NIH HIV prevention science agenda.

b. Biomedical Prevention of HIV infection

Vaccine Development The scientific community remains confident that, ultimately, an

effective vaccine against HIV infection can be developed. This is our ultimate goal in the area of prevention and in FY 1997, the Federal government plans to increase its commitment to vaccine research by $xx million.

The federal government, through the NIH and the Department of Defense, will continue to support two approaches to vaccine development. The first approach is based on the belief that gathering additional basic science information offers the best hope in steering vaccine development and that many critical questions must be answered before human trials should begin. The second approach is guided by the belief that data gathered from clinical efficacy trials in humans can lead to the development of a successful candidate and that if a safe candidate is available, it is not necessary to resolve all of the scientific questions before proceeding with human trials. Both approaches will be pursued on a parallel and interrelated path.

Microbicides Many scientists believe that in the absence of a vaccine the development of safe and effective mechanical or chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections could dramatically reduce the sexual transmission of HIV. Worldwide, over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs. (Footnote: Alan B. Stone, and Penelope J. Hitchcock. Vaginal Microbicides for Preventing the Transmission of HIV. AIDS 1994, 8 (suppl 1):S285-S293.)

Condoms, the barrier methods that are currently available, have limitations. Most require the consent, if not the active participation of both partners and therefore cannot be independently used at the discretion of one partner. An easily available and inexpensive microbicide could provide a prevention option for millions of people worldwide.

To address this goal, the following steps will be taken:

o During FY 1997, the NIH and CDC will begin to implement the four-year, $100 million initiative on microbicides announced by Secretary of Health and Human Services Donna Shalala at the Eleventh International Conference on AIDS;

o The Vice President will continue a high-level dialogue designed to encourage private sector involvement in the development of microbicides;

o Through U.S. participation in UNAIDS, and in other forums, we will encourage international efforts to develop effective microbicides.

c. Developing New and More Effective Therapies.

Another challenge in the research arena is developing new and more effective therapies that allow us to transform HIV disease into a chronic, manageable condition. While the FDA is approving new treatments in record numbers and at record speed, the long-term clinical effectiveness of these new therapies remains unknown. There is no doubt that new drugs must be developed.

To accomplish this, federal support for drug development and clinical trials through NIH will increase by $xx million in FY 1997. In addition, several other initiatives will be undertaken or maintained:

- *Federal support for the Forum for Collaborative HIV Research will promote public-private collaboration in AIDS research.* This new group, formed at the behest of Vice President Gore, is designed to catalyze collaborations between the government research establishment, pharmaceutical companies, and third party payers for the purpose of capitalizing on recent scientific advances and learning how to optimally use available treatment regimens. The Federal government is committed to being an equal partner in this new effort as it begins its work later this year.

- *A federal commitment to continued access to sophisticated equipment and personnel that can be shared among researchers in both the private and public sectors.* The Department of Energy (DOE) has made available the use of sophisticated imaging equipment that would be prohibitively expensive for individual researchers or companies. This shared resource 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.

- *Increased focus in federal research on special populations.* Our research effort will increase its focus on the needs of special populations, including youth, women, minorities, and substance abusers who may not have received the full benefit of all research discoveries. The efforts of programs such as the Women's Interagency HIV Study (WIHS), the Terry Beirn Community Programs for Clinical Research on AIDS (CPCRA), and the Adolescent Medicine HIV/AIDS Research Network are important to improving our understanding of HIV disease in these populations and will continue.

d. Continued Support for Research

Research is an investment in our future. Already, it has helped prolong improve the quality of lives, and we must continue to make this investment. To unleash the talents of the best and the brightest in finding a cure, better therapies, and a vaccine will require a sustained commitment of funding to meet the research challenges. NIH currently receives many more outstanding research applications than it is able to fund -- representing a lost opportunity for scientific progress. Other departments and agencies, such as DOD and VA, also support

crucially important research that strengthens the overall U.S. research effort. Recognizing the importance of biomedical and AIDS research generally, the President has requested an increase of $xxx million for the NIH overall, an increase of $xx million for NIH-supported AIDS research, and an increase of $xx million for AIDS research government-wide.

C. CARE & SERVICES

"AIDS has taken too many friends and relatives and loved ones from everyone of us in this room. It has shaken the faith of many, but it has inspired a remarkable community spirit."
President Clinton, May 20, 1996
Signing of the Ryan White CARE Act Reauthorization

1. Record of Accomplishment

Since the epidemic of HIV and AIDS began in 1981, more than 500,000 Americans have been diagnosed with AIDS and required care. As the number of Americans living with AIDS increased, so did their needs. The demands on the U.S. health care system increased dramatically, but federal, state, and local governments along with community-based organizations and private clinicians have responded with compassionate, high-quality medical care. In 1985, Federal expenditures for HIV-related care and services were $xxx, by 1995 the Federal share reached $xxx.

In the early years of the epidemic, the health care infrastructure was particularly unprepared to accommodate the health care needs of persons with HIV. To meet their complex health care needs, HIV-positive persons were often forced to negotiate a fragmented system of care. There were few programs designed to meet the unique care needs of positive individuals. Moreover, available care services were often directed towards meeting the acute care needs of persons diagnosed with AIDS, rather than the early stages of HIV disease. While we still have far to go, the quality and availability of services for HIV-positive persons has improved significantly.

People living with HIV now access and finance necessary health care services in a variety of ways. Currently, over 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. JL cite.

In addition to Medicaid, the centerpiece of the national safety net for HIV positive people is the programs funded through the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, administered by the Health Resources and Services Administration (HRSA). The CARE Act programs were established to fill gaps in coverage and build systems of care to create access to health care for people living with HIV and AIDS. The first four titles of the CARE Act support direct services for people living with HIV:

- 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. Title II also provides drug reimbursement funding for persons living with HIV/AIDS under the AIDS Drug Assistance Program (ADAP).

- Title IIIb of the CARE Act provides early intervention services such as counseling and testing, medical care, and educational services for medically underserved persons with the goal of reducing HIV-related illness.

- Title IV seeks to increase the availability of research, 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 (IHS) which provides health care for HIV-positive Native Americans and Alaska Natives. Additionally, the Bureau of Prisons within the Department of Justice provides care for HIV-positive people in Federal prisons.

People living with HIV and their families face significant obstacles to locating affordable housing. Housing assistance for people living with HIV and AIDS is provided by the Department of Housing and Urban Development (HUD) through its Housing Opportunities for Persons with AIDS (HOPWA), enacted in 1990, and other programs, such as the Section 811 Supportive Housing Programs for Persons with Disabilities. These programs work in partnership with local initiatives incorporating housing assistance into a community's continuum of services.

To further foster community involvement, HUD also has 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. The Community Development Block Grant (CDBG), the HOME affordable housing program, as well as public housing programs are key resources that are available to communities.

Since he took office in 1993, President Clinton has built on this record by making AIDS a top national priority and increasing that national commitment by:

- o Signing the Ryan White CARE Act Amendments of 1996, and increasing Ryan White funding by 134 percent,

- o More than doubling funding for the AIDS Drug Assistance Program, which helps uninsured and underinsured individuals purchase prescription drugs,

- o Increasing funding for HOPWA by 96 percent,

- o Fighting to preserve the Medicaid guarantee of coverage for the over 50 percent of people with AIDS and 92 percent of children with AIDS who rely on this program for their health coverage, and

- o Revising eligibility rules for Social Security disability benefits to make it easier for people living with HIV to qualify for benefits.

2. Future Opportunities for Progress

The nation goal in this area is to ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs to have the opportunity to live productive lives. AIDS care and service programs must continue to provide access to care for those without insurance coverage, improve prioritization and accountability, and increase the cost-effectiveness of services they provide. As treatments improve and extend the productive lives of people with HIV, we must continually reexamine the range of services that are needed.

Two major challenges exist in meeting this goal:

- o Maintaining HIV-related care and services as an investment priority in budgeting in the context of a balanced federal budget: fighting to preserve Medicaid and continuing to seek increased funding for CARE Act and HOPWA programs

- o Assuring that available resources are used as effectively as possible.

a. Making investment in care and services a budget priority

Preserving Medicaid As the epidemic continues to spread in lower-income communities, Medicaid will be an even more essential lifeline of support for Americans living with HIV and AIDS. The need to maintain the historic Federal-State partnership on Medicaid has never been greater. Proposals in Congress to convert Medicaid into a block grant would endanger access to care for people living with HIV and AIDS, particularly proposals to eliminate the Federal guarantee of coverage for people living with disabilities. The President has vetoed one such proposal and has sustaining the entitlement to Medicaid is central to the national goal of ensuring appropriate and affordable care and services for persons living with HIV and AIDS.

Continuing Support for Ryan White CARE Act. The five-year reauthorization of the CARE Act signed by President Clinton on May 20, 1996 provides people living with HIV and AIDS

with peace of mind that support from the Federal government will be there through the year 2000. As the demand for care continues to grow, so must the resources for the CARE Act. President Clinton has proposed $827.5 million for this program in FY 1997.

Expanding Support for Housing Services Finally, maintaining consistent funding for the housing component of the services safety net will continue to be a national priority. Without stable housing, a person living with HIV has diminished access to care and services and a diminished opportunity to live a productive life. It is estimated that up to 50 percent of people living with HIV and AIDS are or will become homeless during the course of their illness.[2] The President's 1997 budget includes a request for $196 million for HOPWA.

b. Ensuring Effective Use of Limited Resources

There are three primary ways the federal government will be attempting to make the most of its limited resources: (1) Improving coordination among federal programs, (2) Improving the quality of care provided by those programs, and (3) evaluating program effectiveness to ensure that funds are well spent.

Improving Program Coordination

Integrating HIV and related services is another important step in assisting communities to build seamless systems of support for our most vulnerable citizens. Organizations receiving federal funding to provide AIDS-related care often require support from several federal agencies. For example, creating a comprehensive community-based program that integrates primary care, substance abuse treatment and prevention, and sexually transmitted disease screening, HIV prevention, access to clinical trials, and housing assistance requires separate applications to SAMHSA, HRSA, CDC, NIH, and HUD.

The agencies funding HIV-related services are committed to simplifying the application process for federal funding and to facilitating service integration. HRSA and SAMHSA have issued joint programs announcements, and HUD and HRSA have issued a joint program announcement for the Special Projects of National Significance (SPNS) program. These efforts to improve integration will be continued and expanded, with special attention to linking HIV and substance abuse prevention and services.

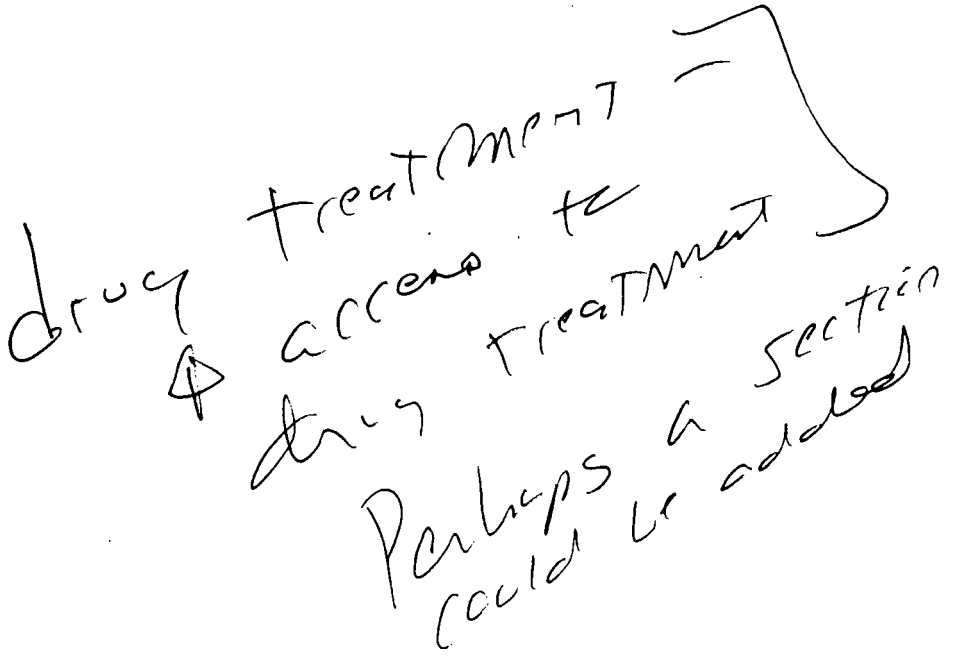
Improving Quality of Care

Federally-supported programs can and should consistently provide high-quality care. Ensuring consistency in care delivery requires increased training for health care professionals and greater accountability through the use of performance measures for quality care. It is also essential that practical information on research advances for practicing clinicians and their patients be provided in a timely manner. (See Section

Translation of Research Advances in Practice.) HRSA and HCFA will continue to offer guidance to grantees and the States regarding maintaining the quality and standard of care appropriate for people living with HIV. To this end, during FY 1997, the Office of HIV/AIDS Policy at DHHS is undertaking a program to develop clinical practice guidelines in conjunction with other government agencies and private sector clinicians.

Evaluating Program Effectiveness

Strong federal support for safety net programs must be accompanied by improved accountability and priority setting. Evaluating current activities provides valuable information for planners and those at the front lines of the epidemic and assist in providing better care to people living with HIV.



D. CIVIL RIGHTS

> *"Every person with HIV or AIDS is someone's son or daughter, brother or sister, parent or grandparent. We cannot allow discrimination of any kind to blind us to what we must do."*
>
> *President Clinton, May 20, 1996*
> *Signing of the Ryan White CARE Act Reauthorization*

Discrimination against people living with HIV or AIDS violates the human rights of individual Americans and undermines our efforts to prevent and treat HIV infection. The extraordinary stigma that has been attached to HIV disease hampers the ability of people living with HIV and AIDS to live full lives, free of fear.

Discrimination also undermines efforts to prevent and treat HIV infection and bring the epidemic under control. Fear of discrimination and stigma causes many people not to seek testing for HIV; thus many remain unaware of their HIV status and go without the care that could help them live longer, healthier lives. Opportunities to educate people are also lost as people at-risk avoid prevention programs because of the stigma associated with HIV.

The fourth goal of the national strategy is to eliminate discrimination and to provide national leadership in erasing the stigma associated with HIV and AIDS.

1. Record of Accomplishment

During the early years of the AIDS epidemic, protection of the civil rights of people living with HIV and AIDS was sporadic, at best. Individual lawsuits were the first line of action. By the late 1980s, however, the Federal government began to respond more aggressively with actions including:

- Enactment of the Harkin-Humphrey Amendment to the Civil Rights Restoration Act, clarifying that Section 504 of the Rehabilitation Act of 1973 applied to people with contagious diseases, including HIV; and

- Passage of the Americans with Disabilities Act of 1990 (ADA) which protects individuals living with HIV and AIDS, and people perceived to be at risk for HIV, from discrimination in housing, employment, and public accommodation.

Since he took office, President Clinton has directed relevant agencies to make enforcement of the civil rights of people living with HIV and AIDS a priority. Key actions include:

- Vigorously enforcing the ADA by the Justice Department, the Equal Employment Opportunities Commission, and the Department of Health and Human Services. The

Federal government has resolved nearly 800 charges alleging discrimination against people with HIV and AIDS obtaining monetary benefits of more than $6.1 million; [Are these figures correct? .. source(s)?]

- Vigorously enforcing Section 504 of the Rehabilitation Act of 1973 as it pertains to recipients of DHHS funds such as hospitals, nursing homes, and social service agencies;

- Forcefully opposing the so-called "Dornan Amendment," which would have required the discharge of all military personnel who are living with HIV. President Clinton declared the proposal unconstitutional and directed the Department of Justice not to defend it if challenged in court. The President led a successful effort to repeal the "Dornan Amendment" and continues to oppose its enactment;

- Establishing an AIDS education program for all Federal workers; and

- Using the Presidential "bully pulpit" to continually speak out against discrimination against people with HIV and AIDS. In December 1995, the President hosted the first ever White House Conference on HIV and AIDS, bringing to the White House over 300 people from around the country to discuss with the President the impact of the epidemic on their lives and communities.

2. Future Opportunities for Progress

There are four key ways that the Federal government is maintaining its commitment to meeting the goal of ensuring that people living with HIV are not subject to discrimination:

Enforcing Rights. Efforts to protect the civil rights of people with HIV and AIDS must be ever-vigilant. The Federal government will continue to exhibit strong leadership on this issue through its enforcement of the Americans with Disabilities Act and public condemnation of discriminatory acts or statements. Of particular concern is discrimination against people with HIV seeking access to health care facilities. A joint effort by the Department of Health and Human Services and the Department of Justice aimed at access to nursing homes is a significant step forward in protecting the rights of people living with HIV.

Protecting Workers. The Federal government is actively working to examine its own existing policies related to the exclusion of people living with HIV from employment. The Director of the Office of National AIDS Policy is working with Federal Agencies to examine individual policies to determine whether they comply with Federal public health guidelines.

Opposing Discriminatory Legislation. The Administration will continue to oppose, in the strongest terms possible, efforts by the Congress to discriminate against people living with HIV and AIDS.

Providing Leadership. Leaders of government have an obligation to use the power of their elected office to speak out against acts or words of discrimination against any group of people. President Clinton has used and will continue to use his position to oppose discrimination against people living with HIV and AIDS.

E. INTERNATIONAL ACTIVITIES

> *"The American people need to know that everybody in this country and, indeed, throughout the world, is now vulnerable to this disease."*
> President Clinton, December 5, 1996, to the White Conference on HIV and AIDS

AIDS is a global epidemic. The World Health Organization (WHO) estimates that 94 percent of new infections occur in developing countries. (footnote c) In the United States it is estimated that between 650,000 and 900,000 people are currently infected with HIV. The WHO and UNAIDS estimates that 27.9 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 by the year 2000. 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 epidemic jeopardizes decades of economic and social advances in many developing nations. In the nations of Africa and Asia, economic advances are threatened and in some cases may be reversed due to 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.[3] 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.

1. Record of Accomplishment

Since it began, HIV and AIDS has been a global concern. The U.S. has worked closely with developed and developing nations to design an international response that is both vigorous and coordinated. Sentinel achievements include:

- Provided initial funding and key leadership for the creation of the Global Programme on AIDS at the World Health Organization (WHO) in 1987; and
- Played an instrumental role in establishing the new streamlined Joint United Nations Programme on HIV/AIDS (UNAIDS) in 1996.

The United States is the largest contributor to international efforts to combat the pandemic of HIV and AIDS. Several Federal Agencies are working slow the AIDS epidemic internationally. (See Appendix E.) The Department of State works 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 of U.S. leadership in the global HIV arena are: preventing new infections; reducing the personal and social impact of the pandemic; and mobilizing and unifying national and international efforts.

The U.S. Agency for International Development (USAID) also plays leadership role in the global HIV effort through development assistance, research and policy formation. USAID focuses its efforts on developing prevention programs based on proven interventions; addressing social, cultural, regulatory and economic issues related to HIV and 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 Peace Corps trains a portion of its volunteers to directly address HIV-related concerns in their countries of placement. The U.S. Information Agency (USIA) supports programs that promote dissemination of U.S. policies and information related to HIV and AIDS.

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. The DOD is conducting clinical trials of candidate HIV vaccines in Thailand and NIH (working in collaboration with USAID), supports a range of scientific studies in developing countries. The results of the studies ultimately will be used to develop interventions to reduce behaviors that place individuals at risk for contracting HIV infection.

2. Future Opportunities for Progress

To accomplish the goal of providing strong continuing support for international efforts to address the HIV epidemic, the following steps will be taken:

International Leadership. The United States has established a global leadership role in combatting the epidemic. This leadership will continue. The U.S. strongly supports the newly established Joint United Nations Programme on AIDS (UNAIDS).[4] The U.S. is a member of the governing body of UNAIDS and signed the 1994 Paris Declaration and the Greater Involvement of People Living with HIV and AIDS Initiative (GIPA).

The U.S. also supports efforts to more effectively access available resources as well as encourage non-traditional donor countries to provide much-needed contributions. Supporting UNAIDS organizations such as UNICEF, WHO, UNDP (United Nations Development Program), the U.S.-Japan Common Agenda and its innovative programmatic efforts, and UNAIDS' 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.

Strengthening Partnerships. In addition to maintaining our multilateral partnerships, we must strengthen and expand our bilateral programs and funds for HIV activities. We must

reverse the current trend to reduce assistance to developing countries where more than 90 percent of the world's AIDS cases are found.

Sharing Technology and Bringing Lessons Home. Through USAID's "Lessons without Borders Project", the U.S. has gained valuable insights from experiences in participating countries and is applying them to communities here at home. The initiative brings lessons learned abroad back to inner city and rural areas with problems similar to those experienced overseas. These efforts should be continued and expanded for HIV and AIDS.

Improving 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. In order to ensure that efforts are productive, the Agencies supporting international activities must develop a mechanism for coordinating U.S. programs in a systematic and efficient manner.

F. TRANSLATION OF RESEARCH ADVANCES INTO PRACTICE

Insert Quote

An important element in our fight against AIDS is ensuring that research advances are translated into improved HIV prevention programs and better care for HIV positive persons. While directly related to earlier goals relating to research, prevention, and care and services, it is important to highlight this aspect of the nation's response to the epidemic to assure that we are taking what we are learning and translating it into benefit for people with or at risk for HIV.

An example of the importance of such efforts is the translation of the NIH-supported research study that found that the use of AZT by pregnant women during pregnancy and childbirth and its application to newborns for the first six weeks of life can reduce the risk of perinatal transmission of HIV by two-thirds. Translation of these results required actions by the Centers for Disease Control and Prevention, which prepared guidelines for physicians caring for pregnant women and for consumers; the Health Resources and Services Administration, which provided guidance to grantees on coverage of such services; the Health Care Financing Administration, which provided similar guidance to State Medicaid Directors.

1. Record of Accomplishment

Due in part to Federally-sponsored information dissemination activities, dramatic changes in the way HIV is treated have taken place. Ensuring dissemination of HIV-related information falls under the missions of several Agencies (See Appendix F). Key examples are:

- 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 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 tele-conferencing;

- NIH supports publicly available computerized databases such as AIDSDRUGS, AIDSTRIALS, and AIDSLINE;

- The toll-free 1-800 TRIALS-A AIDS Clinical Trials Information Service (ACTIS) is co-sponsored by NIH, CDC, and FDA;

- The Centers for Disease Control and Prevention disseminates information through the

National AIDS Hotline (1-800-342-AIDS); its toll-free 1-800-HIV-0440 HIV/AIDS Treatment Information Service (ATIS); and the AIDS Information Clearinghouse;

- The CDC also develops and issues guidelines for health professionals through its *Morbidity and Mortality Weekly Report*;

- 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; and,

- The Health Resources and Services Administration directs a nationwide system of AIDS Education and Training Centers that provide state of the art HIV clinical information to health care providers. HRSA also has developed guidances for its Ryan White CARE Act grantees and funds an AIDS warmline that responds to questions from clinicians across the country.

2. Future Opportunities for Progress

Ensuring that research advances are translated into improved HIV prevention programs and better care for HIV positive persons, will require a number of steps, including:

Increasing Education and Training. As we continue to expand our base of knowledge about AIDS care, efforts to educate and train health care professionals in state-of-the-art care for people living with HIV and AIDS must be expanded. An AHCPR-supported study indicated that primary care physicians may miss significant HIV-related symptoms during patient examinations.[5] Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.[6] Reference Kittahare (sp?) article. To reverse this pattern, the Administration is fighting to restore funding for the AIDS Education and Training Centers, which play a vital role in training providers. Achieving this goal will also require a renewed emphasis on HIV on the part of medical schools, professional organizations, and individual clinicians.

Disseminating 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 for their patients. 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. To this end, during FY 1997, the Office of HIV/AIDS Policy at DHHS is undertaking a program to develop clinical practice guidelines in conjunction with other government agencies and private sector clinicians.

Improving Coordination of Federal Activities. Enhancing coordination of information

dissemination activities among Public Health Service Agencies is an important priority. Within DHHS, the Office of HIV/AIDS Policy (OHAP) 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 people and organizations, and that policies and standard-of-care practices for Federally-sponsored programs are modified to reflect the new standard, requires a continued high level of cooperation and coordination among Public Health Service Agencies.

Disseminating Prevention Models. Improved dissemination efforts also are needed in the area of primary prevention models. Models of effective prevention interventions have been developed, but often this valuable information is not reaching those people developing, implementing, and evaluating prevention programs. The Public Health Service will take the lead in ensuring that information that can be used to stem the tide of new infections reaches those who can make a difference.

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"We must develop a clear, well-articulated national plan for confronting AIDS."
The Final Report of the National Commission on AIDS
June 1993

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 AIDS Strategy that would detail the Federal government's long-term approach in responding to this epidemic. The National AIDS Strategy has been developed by the Clinton Administration 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, businesses, schools, churches, families, and individuals.

The President has identified the following national goals to guide our efforts against HIV:

- **To provide strong continuing support for AIDS-related research in order to find additional treatments, a preventive vaccine to protect the uninfected, and a cure for those currently infected;**

- **To provide strong continuing support for effective AIDS prevention efforts to continue to reduce the number of new HIV infections in the U.S.;**

- **To ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs; and,**

- **To ensure that people living with HIV are not subject to discrimination.**

- **To provide strong continuing support for international efforts to address the HIV epidemic.**

- **To ensure that research advances are translated into improved HIV prevention programs and better care for HIV positive persons.**

This document is a snapshot of where we are as a Nation and where we need to go in achieving these national goals. It summarizes some of the key accomplishments of our Nation's scientific and public health professionals and identifies key areas for further effort. In addition, the appendices to this report lay out, for the first time, detailed descriptions of the objectives, goals, and budgets of all Agencies involved in the Federal response to HIV in

five major areas of HIV policy: prevention, research, care, civil rights, international activities, and translation of research into practice.

The National AIDS Strategy is intended to be a working document that requires regular updating and adjustment as goals are reached and new challenges emerge. This Strategy provides a reference point for continuing dialogues and collaborative efforts between the public and private sectors that are necessary to meet our national goals and objectives.

In that light, the Office of National AIDS Policy is seeking direct input from the Presidential Advisory Council on HIV/AIDS, national and community-based organizations, state and local government, clinicians and researchers, members of the infected and affected community, and other individuals and organizations who can contribute to this historic document. This Strategy is being released, first, in draft form to allow for maximum input to the first of an ongoing national effort to chart and plan Federal efforts in response to the epidemic of HIV/AIDS.

The development of a National AIDS Strategy 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 Federal government should focus its efforts.

The National AIDS Strategy was drafted in consultation with, and with guidance from, numerous groups and individuals. Within the Federal government, this effort began at the Agency level. Members of the Interdepartmental Task Force on HIV and AIDS (IDTF) representing all Federal Agencies involved in the national response to HIV and AIDS, identified their HIV-related goals, objectives, and highlighted areas requiring special attention.

Individuals living with HIV and AIDS, their families, friends, loved ones, and care givers made vital contributions to this Strategy. Numerous non-governmental groups and organizations have also been consulted including the Presidential Advisory Council on HIV/AIDS, participants in the historic White House Conference on HIV and AIDS, the ONAP-sponsored regional briefings, patient and consumer advocates, health care professionals, community-based organizations, educators, religious leaders, and business leaders. The earlier insights provided by the National Commission on AIDS, the Institute of Medicine and National Research Council, the General Accounting Office, and the Office of Technology Assessment have also been extraordinarily helpful in developing the National AIDS Strategy.

As a Nation, we face great challenges, but we are also facing equally great opportunities. After fifteen years, AIDS remains a terrible national tragedy that has affected -- and will

continue to affect -- far too many people in this Nation and around the world. But we have made tremendous progress in our understanding of HIV and HIV disease, ways we can treat those who are infected, and means by which we can prevent infection. Ultimately, HIV is a disease that we can defeat -- just as we have eradicated smallpox from our planet and polio from the western hemisphere. The National AIDS Strategy provides a foundation for the continuing public-private partnerships that are essential to our success. Together, with steadfast commitment, courage, and leadership, we will win the battle against HIV and AIDS.

Patricia S. Fleming
Director, Office of National AIDS Policy

"For nearly every American with eyes and ears open, the face of AIDS is no longer the face of a stranger. Millions and millions of us have now stood at the bedside of a dying friend and grieved. Millions and millions of us now know people who have had AIDS and who have died of it who are both gay and heterosexual. Millions and millions of us are now forced to admit that this is a problem which has diminished the life of every American."

President Clinton, December 1, 1993, Georgetown University

I. INTRODUCTION

Goals of the National Strategy

The President has identified the following national goals to guide our efforts against HIV:

- To provide strong continuing support for AIDS-related research in order to find additional treatments, a preventive vaccine to protect the uninfected, and a cure for those currently infected;
- To provide strong continuing support for effective AIDS prevention efforts to continue to reduce the number of new HIV infections in the U.S.;
- To ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs; and,
- To ensure that people living with HIV are not subject to discrimination.
- To provide strong continuing support for international efforts to address the HIV epidemic.
- To ensure that research advances are translated into improved HIV prevention programs and better care for HIV positive persons.

Scope of the HIV/AIDS Epidemic

The epidemic 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 around the world. While significant progress has been made in understanding the disease and developing treatments since the first case was reported in the U.S. in June 1981, 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 average of 100 Americans are diagnosed with AIDS every day and a similar number of men, women, and children become infected with HIV every 24 hours. **[Richard -- are you certain these numbers are correct?]** Globally, 7,500 people become infected each day.

An Expanding Public Health Threat

As of December 1995, the Centers for Disease Control and Prevention (CDC) had received reports of 513,486 cases of AIDS among persons in the U.S. and 319,849 of these persons have been reported to have died as a result of complications related to HIV. Since 1987, AIDS has risen from being the 15th cause of death among all Americans to the 8th. AIDS is now the leading cause of death among Americans aged 25 to 44 (See Figure 1). In 1995 alone, approximately 74,000 new cases of AIDS were reported in the U.S. and more than 46,000 AIDS related deaths were reported to the CDC in 1994. CDC estimates that between 40,000 and 60,000 Americans are becoming newly infected with HIV each year, and that between 650,000 and 900,000 Americans are currently living with HIV.

As the epidemic in the United States has expanded, the demographics of the epidemic have changed. The early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers (i.e., New York, San Francisco, and Los Angeles). Today, this group represents less than half of all new cases, although they still represents the majority of persons living with HIV and AIDS. Among the populations that are more heavily affected today are young gay men, women, and injecting drug users and their sexual partners as well as users of non-injecting drugs (i.e., crack cocaine and alcohol). In 1995, nearly 14,000 women were reported to CDC as having been diagnosed with AIDS. Women now comprise 14 percent of cumulatively reported AIDS cases. If this trend continues, it is estimated that 80,000 American children will have been orphaned as a result of AIDS by the end of this decade. In 1995, approximately 800 new cases of pediatric AIDS cases were reported. (Footnote a)

Adolescents (age 13-19) are at increased risk for HIV infection. CDC estimates that one-quarter of new HIV infections in the U.S. occur among people under age 21. A significant number of young people are engaging at earlier ages in sexual intercourse and drug and alcohol use. 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.

Racial and ethnic minorities have been disproportionately affected by the epidemic of HIV and AIDS. African-Americans, who represent approximately 12 percent of the U.S. population, accounted for 40 percent of newly reported AIDS cases in 1995. Hispanics, who account for about 9 percent of the general population, represented 19 percent of new cases reported in 1995. The number of African-Americans and Hispanics affected by HIV and

AIDS has risen dramatically. In 1982, Blacks and Hispanics represented 31 percent of all AIDS cases; however, as of December 1995, these groups comprised 52 percent of cumulative AIDS cases.

The HIV epidemic continues to spread into suburban and rural areas, with especially dramatic increases in certain regions of the South and Midwest. Between January 1993 and December 1995 the largest numbers of AIDS cases (86,462) were reported from the South. (Endnote 1)[1] While most cases are still reported from urban areas, the rate of reported cases in non-metropolitan areas is increasing more rapidly than in urban areas. AIDS cases have now been reported in all 50 States, the District of Columbia, Puerto Rico, Guam, and each of the U.S. territories (See Figure 2).

AIDS is an expensive disease. Average lifetime costs of medical care after diagnosis with HIV is $119,000 (Footnote b). People living with HIV are disproportionately dependent on the public sector for their health care. Over 50 percent of people living with AIDS are enrolled in Medicaid, including more than 90 percent of children with AIDS. In FY 1996, the Federal government spent $1.8 billion on Medicaid benefits for people living with HIV and AIDS and another $690 million on Medicare benefits. Social Security benefits for people disabled by HIV/AIDS total $1.1 billion in FY 1996.

Globally, the toll of the epidemic is much greater and threatens to reverse decades of economic and public health progress in developing countries. The Joint United Programme on HIV and AIDS (UNAIDS) and the World Health Organization (WHO) estimate that 27.9 million people have been infected with HIV. Since the beginning of the pandemic, 6 million people, including 1.6 million children, have been diagnosed with AIDS. By the year 2000, WHO projects that between 30 million and 40 million people will have been infected with HIV and 10 million to 15 million children will be orphaned due to AIDS.

II. OVERVIEW OF FEDERAL EFFORTS

The scope and nature of the HIV/AIDS epidemic have drawn States, local governments, academic institutions, private foundations, health care institutions and community-based organizations and the Federal government 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 FY 1985 the Federal government spent $212 million for AIDS research, surveillance, and care. By FY 1995 that figure reached $6.8 billion. (See Appendix G).

In the past four years, under the leadership of President Clinton, spending for AIDS research, prevention, and care has increased by 47 percent. Funding for the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act alone has increased by 151 percent. Support for housing for people living with AIDS has increased by 91 percent. AIDS-related research funding has increased by 34 percent and AIDS prevention funding has increased by 24 percent. The National Institutes of Health Revitalization Act of 1993 provided the Office of AIDS Research with enhanced authority to prepare and carry out an annual AIDS research budget and plan. Approval of AIDS drugs by the Food and Drug Administration has been accelerated to record times. A community-based planning process has empowered local communities to develop innovative AIDS prevention programs. Eligibility for Social Security disability benefits for people with AIDS have been simplified and Federal laws prohibiting discrimination against people living with HIV and AIDS have been vigorously enforced.

As the epidemic continues, we must renew our vision for ending this epidemic. The sections that follow focus on six major policy areas: prevention, research, care and services, civil rights, international activities, and the translation of research advances into practice. They identify recent progress and future opportunities for further progress.

A. PREVENTION

"We have to set a goal. . .We have to reduce the number of new infections each and every year until there are no more new infections."

President Clinton, December 5, 1995, to the White House Conference on HIV and AIDS.

1. Record of Accomplishment

Since the epidemic began, there has been important progress in preventing HIV infection. Early in the epidemic, CDC estimated that more than 100,000 Americans were becoming infected with HIV each year; today, that total is between 40,000 and 60,000 people each year.

Sentinel accomplishments in prevention of HIV include:

- Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the first cases of AIDS;
- Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the risk factors associated with HIV infection; and
- Due in part to successful implementation of CDC-sponsored prevention strategies, a slowing in the growth of the epidemic.

Since President Clinton took office in 1993, efforts in HIV prevention have been accelerated. Actions include:

- Increasing funding for AIDS prevention by 24 percent;
- Launching the community planning partnership -- empowering local communities to make decisions about and develop innovative prevention efforts;
- Launching the Prevention Marketing Initiative, focusing on young adults (18 to 25) with frank public service announcements advocating sexual abstinence and, for the first time, the correct and consistent use of latex condoms; and,
- Reorganizing AIDS prevention efforts at the Centers for Disease Control and Prevention to foster greater coordination with efforts to reduce sexually transmitted diseases and tuberculosis.

Federal agencies have been instrumental in expanding our knowledge base about HIV prevention (see Appendix A). The CDC, the agency with primary Federal HIV surveillance and prevention responsibilities, has been pivotal in identifying risk factors associated with HIV transmission, seroprevalence of HIV in society, and trends in HIV infection.

Federal efforts have shown that HIV prevention programs can be effective. CDC's prevention projects, many in partnership with states, local governments, and community-based organizations, have demonstrated that prevention programs are most effective when designed and implemented at a local level. Biomedical, behavioral, and social science prevention research conducted and supported by the National Institutes of Health (NIH) and CDC has expanded and will continue to expand our understanding of the determinants of HIV-related risk behavior.

The nation has also combatted the dual epidemics of HIV and drug abuse. The National Institute on Drug Abuse (NIDA), the Substance Abuse and Mental Health Services Administration (SAMHSA), and CDC support efforts to prevent HIV infection among drug users. The Office of National Drug Control Policy has pursued efforts to counter the problem of substance abuse and its devastating consequences.

There have been advances in integrating primary prevention into health care service systems. The Health Resources and Services Administration (HRSA) and the Department of Veterans Affairs (VA) have encouraged broader access to prevention information through the integration of prevention interventions into primary health care services and through support of early intervention services. HRSA and HCFA also have undertaken special initiatives designed to reduce perinatal transmission of HIV and HRSA has promoted primary prevention through the training of health professionals in the AIDS Education and Training Centers program.

2. Future Opportunities for Progress

To achieve the national goal of no new infections requires efforts in the prevention area on five fronts:

- Improving understanding of trends in HIV transmission and seroprevalence
- Improving scientific knowledge about effective prevention models and strategies
- Strengthening community based programs
- Integrating HIV and other prevention efforts
- Targeting special populations

a. Improving Understanding of Trends in the Epidemic

Understanding who is becoming infected and through what behaviors is critical to designing effective prevention interventions, as well as targeting service resources. As discussed in the introduction, the demographics of the epidemic have shifted, and effective prevention depends on rapidly understanding these shifts and responding to them.

CDC's AIDS case and case death reporting system provides important data for assessing AIDS prevalence and mortality by gender, race/ethnicity, age, and mode of exposure. However, this approach does not capture sufficient "front-end" information on the incidence and prevalence of HIV prior to an AIDS diagnosis. We, therefore, miss critical warning signs about new trends in affected populations and increasing risky behaviors.

To address this shortcoming, the CDC will work to improve its surveillance of HIV infection and related diseases and surveillance of HIV behavioral risk factors, both to better monitor the course of the epidemic and to provide guidance to community planners for targeting prevention and service dollars. This can and will be undertaken without compromising the confidentiality of those involved.

b. Research on Effective Prevention Strategies

Effective interventions must be based on sound research findings and evaluations. Funding for prevention and behavioral research did not receive the same priority in the early years of the epidemic as biomedical research. In response to the recommendations from the Report of the NIH AIDS Research Program Evaluation Task Force, NIH is developing a comprehensive HIV prevention science agenda. NIH and CDC are both committed to increasing future support for basic research on behavior, interventions, social marketing and program evaluation.

Behavioral Research Basic behavioral research answers key questions about the determinants of HIV-associated sexual and drug using behaviors. We still lack key knowledge in this area, which is critical to developing effective interventions.

Intervention Research Intervention research focuses on individual and community level interventions that result in modified sexual and drug using behaviors. There have been significant accomplishments in this area, but, as this portfolio expands, it will be critical to assess intervention in real world settings that are relevant to the growing number of populations that must be reached by prevention programs. This research should be designed by a broad range of scientists, public health, and community experts to assure its relevance.

Social Marketing Research The use of social marketing techniques is a relatively new approach to HIV prevention. This promising area requires use of basic and intervention

research, as well as careful design and evaluation of social marketing efforts.

Evaluation To ensure that prevention programs are actually working -- and so scarce resources are spent on the most effective intervention -- all federally funded prevention activities will routinely include evaluation components. The funding agencies will share widely the knowledge gained about what works and what does not to ensure promotion of best practices in the field. In addition, as part of the federal government's compliance with the Government Performance and Results Act, CDC and SAMHSA will continue to work with its constituents to develop appropriate performance measures for HIV prevention programs.

c. Strengthening Community-based Programs

Community prevention planning is one of the key innovations in CDC's prevention programming over the last several years. This public/private partnership puts federal funds to work based on locally designed priorities. This three-year-old initiative is at a crucial stage of development, and ensuring its success is the third key element of this strategy's prevention agenda.

Community planning requires ongoing leadership from CDC and its partners as well as the resources to provide the technical assistance the community planning process needs to flourish. Successful HIV prevention often depends on small, new community based organizations, many serving minority populations. These organizations need assistance not just on how to plan and compete successfully for available resources, but also how to appropriately incorporate epidemiological and research information into community prevention programs.

d. Program Integration and Collaboration

The fourth of the prevention agenda is improving the integration of HIV prevention into other program areas that reach individuals at risk for HIV. HIV prevention programs cannot stand apart from other, related public health efforts.

Substance Abuse HIV transmission is directly related to substance abuse, both directly through needle sharing behaviors and indirectly as sex is traded for drugs or drug use impairs judgment and increases risk taking behaviors. Breaking that linkage will require:

- Integration of HIV prevention into substance abuse treatment and prevention programs. In August, 1996, at the request of President Clinton, the Public Health Service agencies jointly co-sponsored a national meeting of state and local officials, researchers, and community experts from the fields of HIV and substance abuse to develop an action plan to more effectively integrate HIV and substance abuse

prevention efforts. These agencies are committed to implementing this strategy in the year ahead.

- Enrolling more substance abusers into drug treatment. Substance abuse treatment is a major form of HIV prevention. This Administration will continue to press for increased funding for substance abuse treatment. Further, through outreach and demonstration programs, SAMHSA and CDC will work to enroll more people in treatment and to find more successful interventions to accomplish this end.

- Reducing the availability of illegal drugs. The Office of National Drug Control Policy (ONDCP) is leading the fight on two fronts: reducing demand for drugs through treatment and prevention programs, and reducing the availability of drugs through interdiction.

- Preventing HIV transmission through contaminated needles. Sharing of syringes among injecting drug users is the principal means of HIV transmission in this population. While abstinence from drug use is always the preferred means of prevention, the CDC has issued guidelines regarding the use of bleach to clean injection equipment. In addition, CDC-supported research ~~showed~~ that removal of restrictions on over-the-counter sale of needles ~~results~~ in decreased needle sharing. Current federal law prohibits the use of federal funds for needle exchange programs; however a number of communities across the country have ~~successfully~~ undertaken these programs with local resources.

Primary Care HIV prevention needs to be better integrated into primary care. New and promising medical interventions make it critical to improve our approach to HIV counseling and testing -- creating a critical bridge between prevention and primary care. CDC is committed to improving the return rate of those tested at publicly funded sites and the quality of referral to services for those who test positive.

The linkage must also go in the opposite direction: from primary care to prevention. Primary care providers must learn to incorporate a person's sexual and drug using history when a medical history is taken, offering HIV-related counseling and voluntary testing, and providing prevention education to HIV positive individuals as part of the provider- patient relationship. HRSA's AIDS Education and Training Centers (AETCs) have played a crucial role in giving providers the information and skills they need. The Administration is committed to restoring Congressionally-imposed cuts in the AETC program and giving it a renewed focus to support this goal.

Often primary care is a direct form of HIV prevention. The federally supported research that showed AZT could reduce perinatal transmission of HIV was a tremendous medical breakthrough. Realizing the promise of this advance requires a commitment to assuring that

all pregnant women are counseled and offered HIV testing -- and that AZT treatment is available for all who desire it. All federally funded programs reaching pregnant women -- from Medicaid to Ryan White CARE Act grantees to community and migrant health centers -- are required to take part in this effort. We are committed to expanding outreach and assuring appropriate care so that the Congressionally set goal of reducing perinatal transmission by 50 percent by the year 2000 is achieved.

Other STDs and TB Recent research has confirmed that treatment of sexually transmitted diseases (STDs) other than HIV can reduce the likelihood of HIV transmission -- making the need for collaboration between HIV and STD prevention efforts more compelling. Similarly, people living with HIV are at very high risk for developing active tuberculosis. Studies suggest that the risk of developing active TB is 7 to 10 percent per year for persons who are infected with both TB and HIV, as opposed to a 10 percent lifetime risk for persons not infected with HIV. [Footnote: Personal communication from CDC Division TB Elimination.]

To address the need to integrate work on these inter-related epidemics, CDC organized the new National Center for HIV, STD, and TB prevention. CDC has initiated -- and will aggressively pursue -- efforts to increase collaboration among these programs, including expanding the community planning experiment to cover STD programs.

e. Targeting Special Populations

As discussed above, the HIV epidemic continues to have a disproportionate impact on certain populations where infection rates are rising at a worrisome pace. A fifth and final challenge for prevention programming is to pay particular attention to groups which traditionally receive fewer services, but where the risk of infection is greatest. These include youth (especially young gay men), women, and minorities (especially young gay men of color), prisoners, and, as discussed above, substance abusers. Many federally funded HIV prevention activities already target these populations, but the President's increased funding request for CDC provides $35 million in new funds in FY 1997 specifically for programs and research targeting youth, women, and substance abusers.

B. RESEARCH

"Our common goal must ultimately be a cure, a cure for all those who are living with HIV, and a vaccine to protect us from the virus."
President Clinton, December 5, 1995, to the White House Conference on HIV and AIDS

1. Record of Accomplishment

Since 1981, the nation has made significant advances in HIV-related research including:

- Identification of HIV as the etiologic agent for AIDS,
- Development of a reliable test to determine exposure to HIV,
- Approval of zidovudine (AZT), the first treatment of HIV primary infection,
- Development by the Food and Drug Administration of a system of expedited review of treatments for life-threatening diseases, including HIV.
- Approval of by the FDA of 15 new drugs, 8 new indications, and three new diagnostics for HIV and related conditions, developed through public and private sector development efforts.

Since he took office in 1993, President Clinton has escalated our AIDS research efforts by:

- Increasing AIDS research funding by 34 percent,
- Signing the NIH Revitalization Act of 1993, granting the Office of AIDS Research at NIH new authority to plan and implement an annual AIDS research budget and plan,
- Accelerating AIDS drug approval to record times;
- Supporting research that led to finding that use of AZT during pregnancy, childbirth, and the first six weeks of life can reduce the transmission of HIV from mother to child by two-thirds,
- Launching a four-year, $100 million research effort to develop effective topical microbicides;
- Facilitating creation of the Forum for Collaborative HIV Research to identify opportunities for clinical effectiveness research to improve care for HIV-positive individuals.

Contributions of AIDS Research

AIDS research has provided significant benefits beyond the epidemic, in work on many other diseases. AIDS research has accelerated study of the human immune system, helping to better understand and treat diseases such as cancer; autoimmune diseases, including systemic lupus erythematosus; type I diabetes mellitus; rheumatoid arthritis; and multiple sclerosis. AIDS research advances have also contributed to the prevention of other infectious diseases and provided a new paradigm for treatment of viral diseases.

Progress in the treatment and prevention of HIV-related opportunistic infections have had an enormous impact on the care of patients with other immunodeficiency conditions who are susceptible to many of the same pathogens. This research effort has enhanced the care of cancer patients, patients who have received immunosuppressive therapy for transplants, and the treatment of diseases caused by elevated immune responses (i.e., allergies and lupus).

HIV research has assisted in identifying new infectious agents that may be responsible for malignancies, such as the recent discovery of the etiologic agent for Kaposi's sarcoma. These findings may help to identify other oncogenic agents. HIV research has led to a better understanding of the mechanisms by which infectious agents and inflammatory cells cross the blood/brain barrier, providing 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 additional viral diseases and led to development of treatments.

Efforts to develop drugs for the treatment of HIV have accelerated the development of methods of rational drug design using sophisticated techniques of structural biology and advanced computer imaging methods. These advances have implications for drug design for virtually all disorders. Comparative clinical trials of poxvirus vectors and vaccine adjuvants in HIV vaccine candidates have supported safety information for cancer vaccines. Research on HIV-related wasting has provided important information for research on nutritional disorders, metabolic abnormalities, and gastrointestinal dysfunctions.

2. Future Opportunities for Progress

While tremendous progress has been made in biomedical research, we cannot and will not diminish our effort until we have found a cure and a preventive vaccine. To accomplish this national goal, we must address four ongoing challenges:

o Provide leadership and coordination for the federal research effort

- o Develop biomedical interventions that prevent HIV infection, including both a vaccine and a microbicide
- o Develop new and more effective therapies for HIV and related conditions
- o Assure adequate funding for this research effort.

a. Leadership and coordination of research.

Developing and implementing the federal government's AIDS research agenda presents both scientific and logistical challenges that require leadership and coordination, first among the 24 institutes, centers, and divisions of the NIH, and second among the various Departments and Agencies throughout the government that support HIV research.

The strengthened authority and new leadership of the NIH Office of AIDS Research and the first Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS form the basis for better coordination of our research effort and provide the assurance that key questions are being answered systematically and without duplication. Over the next year, the Administration is committed to reauthorizing the OAR's authority and assuring that its budget powers are maintained throughout the appropriations process.

As part of the ongoing commitment to assess all aspects of our research effort, the OAR convened a panel of outside experts to evaluate the NIH AIDS programs. The Report of the NIH AIDS Research Program Evaluation Task Force included several key recommendations that will be implemented in the year ahead. These include:

[NIH: IS THIS THE RIGHT LIST OF KEY INITIATIVES RESULTING FROM LEVINE REPORT?]

- o increase the Nation's commitment to basic science advancement by expanding the resources available for investigator-initiated research;
- o improve coordination among all NIH-supported clinical trials groups;
- o give new and stronger leadership to the vaccine development programs; and
- o increase the commitment to behavioral research by developing a comprehensive NIH HIV prevention science agenda.

b. Biomedical Prevention of HIV infection

Vaccine Development The scientific community remains confident that, ultimately, an

effective vaccine against HIV infection can be developed. This is our ultimate goal in the area of prevention and in FY 1997, the Federal government plans to increase its commitment to vaccine research by $xx million.

The federal government, through the NIH and the Department of Defense, will continue to support two approaches to vaccine development. The first approach is based on the belief that gathering additional basic science information offers the best hope in steering vaccine development and that many critical questions must be answered before human trials should begin. The second approach is guided by the belief that data gathered from clinical efficacy trials in humans can lead to the development of a successful candidate and that if a safe candidate is available, it is not necessary to resolve all of the scientific questions before proceeding with human trials. Both approaches will be pursued on a parallel and interrelated path.

Microbicides Many scientists believe that in the absence of a vaccine the development of safe and effective mechanical or chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections could dramatically reduce the sexual transmission of HIV. Worldwide, over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs. (Footnote: Alan B. Stone, and Penelope J. Hitchcock. Vaginal Microbicides for Preventing the Transmission of HIV. AIDS 1994, 8 (suppl 1):S285-S293.)

Condoms, the barrier methods that are currently available, have limitations. Most require the consent, if not the active participation of both partners and therefore cannot be independently used at the discretion of one partner. An easily available and inexpensive microbicide could provide a prevention option for millions of people worldwide.

To address this goal, the following steps will be taken:

- o During FY 1997, the NIH and CDC will begin to implement the four-year, $100 million initiative on microbicides announced by Secretary of Health and Human Services Donna Shalala at the Eleventh International Conference on AIDS;

- o The Vice President will continue a high-level dialogue designed to encourage private sector involvement in the development of microbicides;

- o Through U.S. participation in UNAIDS, and in other forums, we will encourage international efforts to develop effective microbicides.

c. Developing New and More Effective Therapies.

Another challenge in the research arena is developing new and more effective therapies that allow us to transform HIV disease into a chronic, manageable condition. While the FDA is approving new treatments in record numbers and at record speed, the long-term clinical effectiveness of these new therapies remains unknown. There is no doubt that new drugs must be developed.

To accomplish this, federal support for drug development and clinical trials through NIH will increase by $xx million in FY 1997. In addition, several other initiatives will be undertaken or maintained:

- *Federal support for the Forum for Collaborative HIV Research will promote public-private collaboration in AIDS research.* This new group, formed at the behest of Vice President Gore, is designed to catalyze collaborations between the government research establishment, pharmaceutical companies, and third party payers for the purpose of capitalizing on recent scientific advances and learning how to optimally use available treatment regimens. The Federal government is committed to being an equal partner in this new effort as it begins its work later this year.

- *A federal commitment to continued access to sophisticated equipment and personnel that can be shared among researchers in both the private and public sectors.* The Department of Energy (DOE) has made available the use of sophisticated imaging equipment that would be prohibitively expensive for individual researchers or companies. This shared resource 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.

- *Increased focus in federal research on special populations.* Our research effort will increase its focus on the needs of special populations, including youth, women, minorities, and substance abusers who may not have received the full benefit of all research discoveries. The efforts of programs such as the Women's Interagency HIV Study (WIHS), the Terry Beirn Community Programs for Clinical Research on AIDS (CPCRA), and the Adolescent Medicine HIV/AIDS Research Network are important to improving our understanding of HIV disease in these populations and will continue.

d. Continued Support for Research

Research is an investment in our future. Already, it has helped prolong improve the quality of lives, and we must continue to make this investment. To unleash the talents of the best and the brightest in finding a cure, better therapies, and a vaccine will require a sustained commitment of funding to meet the research challenges. NIH currently receives many more outstanding research applications than it is able to fund -- representing a lost opportunity for scientific progress. Other departments and agencies, such as DOD and VA, also support

crucially important research that strengthens the overall U.S. research effort. Recognizing the importance of biomedical and AIDS research generally, the President has requested an increase of $xxx million for the NIH overall, an increase of $xx million for NIH-supported AIDS research, and an increase of $xx million for AIDS research government-wide.

C. CARE & SERVICES

"AIDS has taken too many friends and relatives and loved ones from everyone of us in this room. It has shaken the faith of many, but it has inspired a remarkable community spirit."
President Clinton, May 20, 1996
Signing of the Ryan White CARE Act Reauthorization

1. Record of Accomplishment

Since the epidemic of HIV and AIDS began in 1981, more than 500,000 Americans have been diagnosed with AIDS and required care. As the number of Americans living with AIDS increased, so did their needs. The demands on the U.S. health care system increased dramatically, but federal, state, and local governments along with community-based organizations and private clinicians have responded with compassionate, high-quality medical care. In 1985, Federal expenditures for HIV-related care and services were $xxx, by 1995 the Federal share reached $xxx.

In the early years of the epidemic, the health care infrastructure was particularly unprepared to accommodate the health care needs of persons with HIV. To meet their complex health care needs, HIV-positive persons were often forced to negotiate a fragmented system of care. There were few programs designed to meet the unique care needs of positive individuals. Moreover, available care services were often directed towards meeting the acute care needs of persons diagnosed with AIDS, rather than the early stages of HIV disease. While we still have far to go, the quality and availability of services for HIV-positive persons has improved significantly.

People living with HIV now access and finance necessary health care services in a variety of ways. Currently, over 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. JL cite.

In addition to Medicaid, the centerpiece of the national safety net for HIV positive people is the programs funded through the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, administered by the Health Resources and Services Administration (HRSA). The CARE Act programs were established to fill gaps in coverage and build systems of care to create access to health care for people living with HIV and AIDS. The first four titles of the CARE Act support direct services for people living with HIV:

- 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. Title II also provides drug reimbursement funding for persons living with HIV/AIDS under the AIDS Drug Assistance Program (ADAP).

- Title IIIb of the CARE Act provides early intervention services such as counseling and testing, medical care, and educational services for medically underserved persons with the goal of reducing HIV-related illness.

- Title IV seeks to increase the availability of research, 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 (IHS) which provides health care for HIV-positive Native Americans and Alaska Natives. Additionally, the Bureau of Prisons within the Department of Justice provides care for HIV-positive people in Federal prisons.

People living with HIV and their families face significant obstacles to locating affordable housing. Housing assistance for people living with HIV and AIDS is provided by the Department of Housing and Urban Development (HUD) through its Housing Opportunities for Persons with AIDS (HOPWA), enacted in 1990, and other programs, such as the Section 811 Supportive Housing Programs for Persons with Disabilities. These programs work in partnership with local initiatives incorporating housing assistance into a community's continuum of services.

To further foster community involvement, HUD also has 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. The Community Development Block Grant (CDBG), the HOME affordable housing program, as well as public housing programs are key resources that are available to communities.

Since he took office in 1993, President Clinton has built on this record by making AIDS a top national priority and increasing that national commitment by:

- o Signing the Ryan White CARE Act Amendments of 1996, and increasing Ryan White funding by 134 percent,

- o More than doubling funding for the AIDS Drug Assistance Program, which helps uninsured and underinsured individuals purchase prescription drugs,

- o Increasing funding for HOPWA by 96 percent,

- o Fighting to preserve the Medicaid guarantee of coverage for the over 50 percent of people with AIDS and 92 percent of children with AIDS who rely on this program for their health coverage, and

- o Revising eligibility rules for Social Security disability benefits to make it easier for people living with HIV to qualify for benefits.

2. Future Opportunities for Progress

The nation goal in this area is to ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs to have the opportunity to live productive lives. AIDS care and service programs must continue to provide access to care for those without insurance coverage, improve prioritization and accountability, and increase the cost-effectiveness of services they provide. As treatments improve and extend the productive lives of people with HIV, we must continually reexamine the range of services that are needed.

Two major challenges exist in meeting this goal:

- o Maintaining HIV-related care and services as an investment priority in budgeting in the context of a balanced federal budget: fighting to preserve Medicaid and continuing to seek increased funding for CARE Act and HOPWA programs

- o Assuring that available resources are used as effectively as possible.

a. Making investment in care and services a budget priority

Preserving Medicaid As the epidemic continues to spread in lower-income communities, Medicaid will be an even more essential lifeline of support for Americans living with HIV and AIDS. The need to maintain the historic Federal-State partnership on Medicaid has never been greater. Proposals in Congress to convert Medicaid into a block grant would endanger access to care for people living with HIV and AIDS, particularly proposals to eliminate the Federal guarantee of coverage for people living with disabilities. The President has vetoed one such proposal and has sustaining the entitlement to Medicaid is central to the national goal of ensuring appropriate and affordable care and services for persons living with HIV and AIDS.

Continuing Support for Ryan White CARE Act. The five-year reauthorization of the CARE Act signed by President Clinton on May 20, 1996 provides people living with HIV and AIDS

with peace of mind that support from the Federal government will be there through the year 2000. As the demand for care continues to grow, so must the resources for the CARE Act. President Clinton has proposed $827.5 million for this program in FY 1997.

Expanding Support for Housing Services Finally, maintaining consistent funding for the housing component of the services safety net will continue to be a national priority. Without stable housing, a person living with HIV has diminished access to care and services and a diminished opportunity to live a productive life. It is estimated that up to 50 percent of people living with HIV and AIDS are or will become homeless during the course of their illness.[2] The President's 1997 budget includes a request for $196 million for HOPWA.

b. Ensuring Effective Use of Limited Resources

There are three primary ways the federal government will be attempting to make the most of its limited resources: (1) Improving coordination among federal programs, (2) Improving the quality of care provided by those programs, and (3) evaluating program effectiveness to ensure that funds are well spent.

Improving Program Coordination

Integrating HIV and related services is another important step in assisting communities to build seamless systems of support for our most vulnerable citizens. Organizations receiving federal funding to provide AIDS-related care often require support from several federal agencies. For example, creating a comprehensive community-based program that integrates primary care, substance abuse treatment and prevention, and sexually transmitted disease screening, HIV prevention, access to clinical trials, and housing assistance requires separate applications to SAMHSA, HRSA, CDC, NIH, and HUD.

The agencies funding HIV-related services are committed to simplifying the application process for federal funding and to facilitating service integration. HRSA and SAMHSA have issued joint programs announcements, and HUD and HRSA have issued a joint program announcement for the Special Projects of National Significance (SPNS) program. These efforts to improve integration will be continued and expanded, with special attention to linking HIV and substance abuse prevention and services.

Improving Quality of Care

Federally-supported programs can and should consistently provide high-quality care. Ensuring consistency in care delivery requires increased training for health care professionals and greater accountability through the use of performance measures for quality care. It is also essential that practical information on research advances for practicing clinicians and their patients be provided in a timely manner. (See Section

Translation of Research Advances in Practice.) HRSA and HCFA will continue to offer guidance to grantees and the States regarding maintaining the quality and standard of care appropriate for people living with HIV. To this end, during FY 1997, the Office of HIV/AIDS Policy at DHHS is undertaking a program to develop clinical practice guidelines in conjunction with other government agencies and private sector clinicians.

Evaluating Program Effectiveness

Strong federal support for safety net programs must be accompanied by improved accountability and priority setting. Evaluating current activities provides valuable information for planners and those at the front lines of the epidemic and assist in providing better care to people living with HIV.

D. CIVIL RIGHTS

> *"Every person with HIV or AIDS is someone's son or daughter, brother or sister, parent or grandparent. We cannot allow discrimination of any kind to blind us to what we must do."*
>
> *President Clinton, May 20, 1996*
> *Signing of the Ryan White CARE Act Reauthorization*

Discrimination against people living with HIV or AIDS violates the human rights of individual Americans and undermines our efforts to prevent and treat HIV infection. The extraordinary stigma that has been attached to HIV disease hampers the ability of people living with HIV and AIDS to live full lives, free of fear.

Discrimination also undermines efforts to prevent and treat HIV infection and bring the epidemic under control. Fear of discrimination and stigma causes many people not to seek testing for HIV; thus many remain unaware of their HIV status and go without the care that could help them live longer, healthier lives. Opportunities to educate people are also lost as people at-risk avoid prevention programs because of the stigma associated with HIV.

The fourth goal of the national strategy is to eliminate discrimination and to provide national leadership in erasing the stigma associated with HIV and AIDS.

1. Record of Accomplishment

During the early years of the AIDS epidemic, protection of the civil rights of people living with HIV and AIDS was sporadic, at best. Individual lawsuits were the first line of action. By the late 1980s, however, the Federal government began to respond more aggressively with actions including:

- Enactment of the Harkin-Humphrey Amendment to the Civil Rights Restoration Act, clarifying that Section 504 of the Rehabilitation Act of 1973 applied to people with contagious diseases, including HIV; and

- Passage of the Americans with Disabilities Act of 1990 (ADA) which protects individuals living with HIV and AIDS, and people perceived to be at risk for HIV, from discrimination in housing, employment, and public accommodation.

Since he took office, President Clinton has directed relevant agencies to make enforcement of the civil rights of people living with HIV and AIDS a priority. Key actions include:

- Vigorously enforcing the ADA by the Justice Department, the Equal Employment Opportunities Commission, and the Department of Health and Human Services. The

Federal government has resolved nearly 800 charges alleging discrimination against people with HIV and AIDS obtaining monetary benefits of more than $6.1 million; [Are these figures correct? .. source(s)?]

- Vigorously enforcing Section 504 of the Rehabilitation Act of 1973 as it pertains to recipients of DHHS funds such as hospitals, nursing homes, and social service agencies;

- Forcefully opposing the so-called "Dornan Amendment," which would have required the discharge of all military personnel who are living with HIV. President Clinton declared the proposal unconstitutional and directed the Department of Justice not to defend it if challenged in court. The President led a successful effort to repeal the "Dornan Amendment" and continues to oppose its enactment;

- Establishing an AIDS education program for all Federal workers; and

- Using the Presidential "bully pulpit" to continually speak out against discrimination against people with HIV and AIDS. In December 1995, the President hosted the first ever White House Conference on HIV and AIDS, bringing to the White House over 300 people from around the country to discuss with the President the impact of the epidemic on their lives and communities.

2. Future Opportunities for Progress

There are four key ways that the Federal government is maintaining its commitment to meeting the goal of ensuring that people living with HIV are not subject to discrimination:

Enforcing Rights. Efforts to protect the civil rights of people with HIV and AIDS must be ever-vigilant. The Federal government will continue to exhibit strong leadership on this issue through its enforcement of the Americans with Disabilities Act and public condemnation of discriminatory acts or statements. Of particular concern is discrimination against people with HIV seeking access to health care facilities. A joint effort by the Department of Health and Human Services and the Department of Justice aimed at access to nursing homes is a significant step forward in protecting the rights of people living with HIV.

Protecting Workers. The Federal government is actively working to examine its own existing policies related to the exclusion of people living with HIV from employment. The Director of the Office of National AIDS Policy is working with Federal Agencies to examine individual policies to determine whether they comply with Federal public health guidelines.

Opposing Discriminatory Legislation. The Administration will continue to oppose, in the strongest terms possible, efforts by the Congress to discriminate against people living with HIV and AIDS.

Providing Leadership. Leaders of government have an obligation to use the power of their elected office to speak out against acts or words of discrimination against any group of people. President Clinton has used and will continue to use his position to oppose discrimination against people living with HIV and AIDS.

E. INTERNATIONAL ACTIVITIES

> *"The American people need to know that everybody in this country and, indeed, throughout the world, is now vulnerable to this disease."*
> President Clinton, December 5, 1996, to the White Conference on HIV and AIDS

AIDS is a global epidemic. The World Health Organization (WHO) estimates that 94 percent of new infections occur in developing countries. (footnote c) In the United States it is estimated that between 650,000 and 900,000 people are currently infected with HIV. The WHO and UNAIDS estimates that 27.9 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 by the year 2000. 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 epidemic jeopardizes decades of economic and social advances in many developing nations. In the nations of Africa and Asia, economic advances are threatened and in some cases may be reversed due to 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.[3] 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.

1. Record of Accomplishment

Since it began, HIV and AIDS has been a global concern. The U.S. has worked closely with developed and developing nations to design an international response that is both vigorous and coordinated. Sentinel achievements include:

- Provided initial funding and key leadership for the creation of the Global Programme on AIDS at the World Health Organization (WHO) in 1987; and
- Played an instrumental role in establishing the new streamlined Joint United Nations Programme on HIV/AIDS (UNAIDS) in 1996.

The United States is the largest contributor to international efforts to combat the pandemic of HIV and AIDS. Several Federal Agencies are working slow the AIDS epidemic internationally. (See Appendix E.) The Department of State works 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 of U.S. leadership in the global HIV arena are: preventing new infections; reducing the personal and social impact of the pandemic; and mobilizing and unifying national and international efforts.

The U.S. Agency for International Development (USAID) also plays leadership role in the global HIV effort through development assistance, research and policy formation. USAID focuses its efforts on developing prevention programs based on proven interventions; addressing social, cultural, regulatory and economic issues related to HIV and 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 Peace Corps trains a portion of its volunteers to directly address HIV-related concerns in their countries of placement. The U.S. Information Agency (USIA) supports programs that promote dissemination of U.S. policies and information related to HIV and AIDS.

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. The DOD is conducting clinical trials of candidate HIV vaccines in Thailand and NIH (working in collaboration with USAID), supports a range of scientific studies in developing countries. The results of the studies ultimately will be used to develop interventions to reduce behaviors that place individuals at risk for contracting HIV infection.

2. Future Opportunities for Progress

To accomplish the goal of providing strong continuing support for international efforts to address the HIV epidemic, the following steps will be taken:

International Leadership. The United States has established a global leadership role in combatting the epidemic. This leadership will continue. The U.S. strongly supports the newly established Joint United Nations Programme on AIDS (UNAIDS).[4] The U.S. is a member of the governing body of UNAIDS and signed the 1994 Paris Declaration and the Greater Involvement of People Living with HIV and AIDS Initiative (GIPA).

The U.S. also supports efforts to more effectively access available resources as well as encourage non-traditional donor countries to provide much-needed contributions. Supporting UNAIDS organizations such as UNICEF, WHO, UNDP (United Nations Development Program), the U.S.-Japan Common Agenda and its innovative programmatic efforts, and UNAIDS' 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.

Strengthening Partnerships. In addition to maintaining our multilateral partnerships, we must strengthen and expand our bilateral programs and funds for HIV activities. We must

reverse the current trend to reduce assistance to developing countries where more than 90 percent of the world's AIDS cases are found.

Sharing Technology and Bringing Lessons Home. Through USAID's "Lessons without Borders Project", the U.S. has gained valuable insights from experiences in participating countries and is applying them to communities here at home. The initiative brings lessons learned abroad back to inner city and rural areas with problems similar to those experienced overseas. These efforts should be continued and expanded for HIV and AIDS.

Improving 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. In order to ensure that efforts are productive, the Agencies supporting international activities must develop a mechanism for coordinating U.S. programs in a systematic and efficient manner.

F. TRANSLATION OF RESEARCH ADVANCES INTO PRACTICE

Insert Quote

An important element in our fight against AIDS is ensuring that research advances are translated into improved HIV prevention programs and better care for HIV positive persons. While directly related to earlier goals relating to research, prevention, and care and services, it is important to highlight this aspect of the nation's response to the epidemic to assure that we are taking what we are learning and translating it into benefit for people with or at risk for HIV.

An example of the importance of such efforts is the translation of the NIH-supported research study that found that the use of AZT by pregnant women during pregnancy and childbirth and its application to newborns for the first six weeks of life can reduce the risk of perinatal transmission of HIV by two-thirds. Translation of these results required actions by the Centers for Disease Control and Prevention, which prepared guidelines for physicians caring for pregnant women and for consumers; the Health Resources and Services Administration, which provided guidance to grantees on coverage of such services; the Health Care Financing Administration, which provided similar guidance to State Medicaid Directors.

1. Record of Accomplishment

Due in part to Federally-sponsored information dissemination activities, dramatic changes in the way HIV is treated have taken place. Ensuring dissemination of HIV-related information falls under the missions of several Agencies (See Appendix F). Key examples are:

- 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 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 tele-conferencing;

- NIH supports publicly available computerized databases such as AIDSDRUGS, AIDSTRIALS, and AIDSLINE;

- The toll-free 1-800 TRIALS-À AIDS Clinical Trials Information Service (ACTIS) is co-sponsored by NIH, CDC, and FDA;

- The Centers for Disease Control and Prevention disseminates information through the

National AIDS Hotline (1-800-342-AIDS); its toll-free 1-800-HIV-0440 HIV/AIDS Treatment Information Service (ATIS); and the AIDS Information Clearinghouse;

- The CDC also develops and issues guidelines for health professionals through its *Morbidity and Mortality Weekly Report*;

- 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; and,

- The Health Resources and Services Administration directs a nationwide system of AIDS Education and Training Centers that provide state of the art HIV clinical information to health care providers. HRSA also has developed guidances for its Ryan White CARE Act grantees and funds an AIDS warmline that responds to questions from clinicians across the country.

2. Future Opportunities for Progress

Ensuring that research advances are translated into improved HIV prevention programs and better care for HIV positive persons, will require a number of steps, including:

Increasing Education and Training. As we continue to expand our base of knowledge about AIDS care, efforts to educate and train health care professionals in state-of-the-art care for people living with HIV and AIDS must be expanded. An AHCPR-supported study indicated that primary care physicians may miss significant HIV-related symptoms during patient examinations.[5] Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.[6] Reference Kittahare (sp?) article. To reverse this pattern, the Administration is fighting to restore funding for the AIDS Education and Training Centers, which play a vital role in training providers. Achieving this goal will also require a renewed emphasis on HIV on the part of medical schools, professional organizations, and individual clinicians.

Disseminating 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 for their patients. 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. To this end, during FY 1997, the Office of HIV/AIDS Policy at DHHS is undertaking a program to develop clinical practice guidelines in conjunction with other government agencies and private sector clinicians.

Improving Coordination of Federal Activities. Enhancing coordination of information

dissemination activities among Public Health Service Agencies is an important priority. Within DHHS, the Office of HIV/AIDS Policy (OHAP) 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 people and organizations, and that policies and standard-of-care practices for Federally-sponsored programs are modified to reflect the new standard, requires a continued high level of cooperation and coordination among Public Health Service Agencies.

Disseminating Prevention Models. Improved dissemination efforts also are needed in the area of primary prevention models. Models of effective prevention interventions have been developed, but often this valuable information is not reaching those people developing, implementing, and evaluating prevention programs. The Public Health Service will take the lead in ensuring that information that can be used to stem the tide of new infections reaches those who can make a difference.