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Global Network of People
living w/ HIV/AIDS - GNP⁺

GAAN - Global AIDS
Action Network

National Council for
International Health
(NCIH)

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***The National AIDS Strategy
November 1996 Draft***

The National AIDS Strategy Draft

November 1996

"We'll keep going until normal life is returned to people who have HIV."

**President Clinton, August 29, 1996
Acceptance Speech before the Democratic National Convention**

**The National AIDS Strategy
November 1996 Draft**

*Faxed
to Melissa
Sheppard.*

The National AIDS Strategy Draft

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"We'll keep going until normal life is returned to people who have HIV."

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National
AIDS
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Draft**

November 1996

"We'll keep going until normal life is returned to people who have HIV."

**President Clinton, August 29, 1996
Acceptance Speech before the Democratic National Convention**

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

The epidemic of HIV and AIDS constitutes a public health crisis of unprecedented proportions. After 15 years, this terrible national tragedy has affected -- and will continue to affect -- far too many people in the U.S. and around the world. HIV is a disease that we can defeat -- just as we have eradicated smallpox from our planet and polio from the western hemisphere. We have made tremendous progress in our understanding of HIV and HIV disease, ways in which we can treat those who are infected, and the means by which we can prevent infection. We also have more work to do. The National AIDS Strategy provides a foundation for the continuing public-private partnerships that are essential to our success in ending this epidemic.

In 1993, the Office of National AIDS Policy (ONAP) was created by President Clinton to provide a national focus and direction for the U.S. 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 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 Agencies, communities, State and local governments, businesses, schools, churches, families, and individuals.

This document is a snapshot of where we

are as a Nation and where we need to go in achieving these national goals and in ultimately ending the epidemic. 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 major areas of HIV policy: prevention, research, care and services, civil rights, international activities, and translation of research advances into practice.

The National AIDS Strategy sets forth a framework and identifies opportunities for progress that will serve as the foundation for the Administration's response to the epidemic in the years ahead. An implementation process for defining specifically how to reach these goals will be a joint effort of the Interdepartmental Task Force on HIV and AIDS, the Presidential Advisory Council on HIV and AIDS, the private sector, and the community. These formal and systematic consultations will be integral to identifying and implementing solutions. Moreover, the National AIDS Strategy is intended to be a living document that requires regular updating and adjustment as goals are reached and new challenges emerge.

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

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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 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. 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 also have been extraordinarily helpful in developing the National AIDS Strategy.

We face great challenges as a Nation. We are also facing great opportunities.

Together, with steadfast commitment, courage, and leadership, we will win the battle against HIV and AIDS.

Patricia S. Fleming
National AIDS Policy Director

"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 to end the epidemic of HIV and AIDS:

- To develop more effective treatments, a preventive vaccine to protect the uninfected, and a cure for those currently infected through strong continuing support for HIV-related research;
- To reduce the number of new HIV infections in adults and children in the U.S. and worldwide until the rate of new infections reaches zero by providing strong continuing support for effective AIDS prevention efforts;
- To ensure that all people living

with HIV have access to services that are affordable, of high quality, and responsive to their needs;

- To ensure that all people living with HIV are not subject to 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 enhanced 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.

Globally, 8,500 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 (e.g., New York, San Francisco, and Los Angeles). Today, this group represents less than half of all new cases, although it still represents a majority of persons living with HIV and AIDS. Among the populations that are heavily affected today are young gay and bisexual men, women, and injecting drug users and their sexual partners as well as users of non-

injecting drugs (e.g., 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.¹

Adolescents (age 13-19) are increasingly at 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, makes young Americans 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 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.² 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 now have been reported in all 50 States, the District of Columbia, Puerto Rico, Guam, and each of the U.S. territories (See Figure 2).

Average lifetime cost of medical care after an HIV diagnosis is \$119,000.³ For heart disease and cancer the comparable figures are \$61,211⁴ and \$25,000 to \$84,000⁵, respectively. With the development of protease inhibitors, treatment for HIV and AIDS is \$10,000 to \$18,000 per life-year gained. For coronary artery bypass surgery the cost per life-year saved is \$113,000.⁶ People living with HIV are disproportionately dependent on the public sector for their health care. More than 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 an estimated \$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 totaled nearly \$1.1 billion in

FY 1996. Many Federal programs such as HOPWA and CDC's prevention efforts contribute to reducing the short- and long-term economic costs of the epidemic.

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, schools, academic institutions, private foundations, health care institutions, business leaders, community-based organizations, and the Federal government into many HIV-related activities. The Federal government, through its public health responsibilities in areas such as research, prevention, health care, and housing has seen a dramatic increase in its activities since the beginning of the epidemic. In FY 1986 the Federal government expenditures for AIDS research, surveillance, income maintenance, and care were \$508 million. By FY 1995 that figure reached \$6.8 billion.

In the past four years, under the leadership of President Clinton, the Administration has increased spending for AIDS research, prevention, income maintenance, and care by approximately 50 percent. Funding for the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act has increased by 158 percent since FY 1993. Support for housing for people living with AIDS has increased by 96 percent in the same time period. AIDS-related research funding budget has increased by 40 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 develop and implement an annual AIDS research plan and budget.

Approval of AIDS drugs by the Food and Drug Administration has been further accelerated. A community-based AIDS prevention planning process has empowered local communities to develop innovative AIDS prevention programs. Eligibility for Social Security disability benefits for people with AIDS has 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
The White House Conference
on HIV and AIDS**

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 estimated to be

approximately 40,000 people each year.

Sentinel accomplishments in prevention of HIV include:

- Publication in *Morbidity and Mortality Weekly Report* by the Centers for Disease Control and Prevention (CDC) in 1981 of the first AIDS cases;
- Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the risk factors associated with HIV infection;
- Due to NIH-sponsored research, demonstration that administration of AZT can prevent transmission of HIV from an infected mother to her newborn; 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 at CDC by 24 percent (since FY 1993);
- Launching the AIDS prevention community planning partnership -- empowering local communities to 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 of efforts to reduce sexually transmitted diseases and tuberculosis.

Federal agencies have been instrumental in expanding our knowledge base about HIV prevention (see Appendix A). 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 and AIDS.

Federal efforts have shown that HIV prevention programs can be effective. CDC's prevention projects, many in partnership with states, local governments, schools, 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, including epidemiological and natural history studies, conducted and supported by the National Institutes of Health (NIH) and CDC has expanded and will continue to expand our understanding of HIV transmission and the

determinants of HIV-related risk behavior.

The Nation also has 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 and their sexual partners. The White House Office of National Drug Control Policy (ONDCP) has pursued and coordinated efforts to combat 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 AIDS prevention information through the integration of prevention interventions into primary health care services and through support of early intervention services. HRSA and HCFA have also 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.

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, seroprevalence, and risk behaviors;
- Improving scientific knowledge about effective prevention models and strategies;
- Strengthening community-based programs;
- Integrating HIV and other prevention efforts;
- Targeting vulnerable populations; and,
- Improving integration of prevention into primary care and improving linkages between counseling and testing and primary care.

■ *Improving Understanding of Trends in the Epidemic*

Understanding who is becoming infected and through what behaviors is critical to designing effective HIV prevention interventions, as well as for targeting appropriate service resources. As discussed in the introduction, the demographics of the epidemic are evolving, 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. Therefore, we miss critical warning signs about new trends in affected populations and increasing risky behaviors.

To address this concern, 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.

■ ***Research on Effective Prevention Strategies***

Effective interventions must be based on sound research findings and evaluations. 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 critical knowledge in this area, which is central to developing effective interventions.

Intervention Research. Intervention research focuses on individual and community level interventions that result in modified sexual and drug-using behaviors and, as a consequence, reduced HIV transmission. There have been significant accomplishments in this area, but, as this portfolio expands, it will be critical to assess interventions in the context of community cultures and social networks that are relevant to the growing number of populations that must be reached by HIV 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 actually are working -- and to ensure that scarce resources are spent on the most effective interventions -- all Federally-funded prevention activities routinely will include evaluation components. Funding Agencies will share widely the knowledge gained about what works and what does not work to ensure promotion of innovation and 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 their grantees to develop appropriate performance measures for HIV prevention programs, including those developed under the community planning process.

■ ***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 only on how to plan and compete successfully for available resources but also how to appropriately incorporate epidemiological and research information into community prevention programs.

■ ***Program Integration and Collaboration***

The fourth component 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.

Prevention Education. Collaboration with communities and schools is a critical factor in communicating HIV prevention messages to our youth. The Centers for Disease Control and Prevention's *Guidelines for Effective School Health Programs to Prevent the Spread of AIDS* helps assure that young people understand the nature of the HIV epidemic and the specific actions they can take to prevent HIV infection. Strong support for these programs should and will continue.

Substance Abuse. HIV transmission is closely related to substance abuse, through needle-sharing behaviors, as sex is traded for drugs, and as drug and alcohol use impairs judgment and increases risk-taking behaviors. Breaking these linkages 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, research, and demonstration programs, SAMHSA, NIH, 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 White House Office of National Drug Control Policy (ONDCP) is leading this fight on two fronts: reducing demand for drugs through treatment and prevention programs and reducing the availability of drugs through supply reduction programs.
- *Preventing HIV transmission from the use of contaminated injection equipment.* The sharing of needles and syringes among injecting drug users is a major means of HIV transmission in the drug-injecting 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 has indicated that removal of restrictions on over-the-counter sale of syringes resulted in decreased reported needle sharing.

Current Federal law prohibits the use of Federal funds for needle exchange programs; however, a number of communities across the country have undertaken these programs with local resources. NIH-supported research on existing needle exchange programs is identifying the characteristics that influence program success as an HIV prevention strategy.

Primary Care. HIV prevention needs to be better integrated into primary health 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 health care professionals the information and skills they need. The Administration strongly supports the AETC program and will give it a renewed focus to support this goal.

Often primary care is a direct form of HIV prevention. The NIH-supported research that showed AZT reduces 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. In addition, 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.⁷

To address the need to integrate work on these interrelated 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 program to cover STD programs.

■ *Targeting Vulnerable Populations*

The HIV epidemic continues to have a disproportionate impact on certain populations where infection rates are rising at a rapid pace. A fifth and final challenge for prevention programming is to pay particular attention to groups that traditionally receive fewer services, but where the risk of infection is greatest. These include adolescents (especially young gay men), women, minorities, gay men of color, substance abusers, and prisoners. Many Federally-funded HIV prevention activities already target these populations, but the President's increased funding request for CDC would provide \$35 million in new funds in FY 1997, specifically for programs and research targeting adolescents, women, and substance abusers. To ensure that prevention programs, including community planning efforts, are as effective as possible all Federally-funded prevention activities routinely will include monitoring and evaluation components.

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, 1996
The White House Conference on
HIV and AIDS**

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;
- Determination by NIH of the three-dimensional structure of reverse transcriptase, providing the target for the use of AZT as the first antiretroviral drug proven effective against HIV in NIH-supported clinical trials;
- Approval of AZT, the first treatment of HIV primary infection;
- Development by the Food and Drug Administration (FDA) of a system of expedited review,⁸ initiated in 1992, of treatments for life-threatening diseases, including HIV; and

Since he took office in 1993, President

Clinton has escalated AIDS research efforts by:

- Increasing AIDS research funding at NIH by 40 percent (since FY 1993);
- Signing the NIH Revitalization Act of 1993, granting the Office of AIDS Research at NIH new authority to develop and implement an annual AIDS research plan and budget;
- Accelerating AIDS drug approval to record times;
- Approval by the FDA since January 1993 of 16 new HIV-related drugs, 8 new indications, and three new diagnostics for HIV and related conditions, developed through public and private sector development efforts;
- 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;
- Approving in record time a promising new class of AIDS drugs known as protease inhibitors;
- Launching a four-year, \$100 million research effort to develop effective topical microbicides;
- Developing the first Federal Plan for Biomedical Research on HIV and

AIDS to improve coordination of HIV-related research; and

- 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 to Research on Other Diseases

AIDS research has provided significant benefits in the fight against many other diseases. AIDS research has accelerated study of the human immune system, helping to better understand and treat such diseases as cancer; autoimmune diseases, including systemic lupus erythematosus; type I diabetes mellitus; rheumatoid arthritis; and multiple sclerosis. AIDS research advances also have contributed to the prevention and treatment 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 has 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 (e.g., 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. 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 targeted drug design using sophisticated techniques of structural biology and advanced computer imaging methods. These advances have implications for drug design for virtually all disorders. Clinical trials of poxvirus vaccine vectors and 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.

Future Opportunities for Progress

While tremendous progress has been made in HIV 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:

- Provide leadership and coordination for the Federal research effort;
- Develop biomedical interventions that prevent HIV infection, including both vaccines and microbicides;
- Develop new and more effective therapies for HIV and related conditions; and
- Assure adequate funding for this research effort.

■ ***Leadership and Coordination of Research***

Developing and implementing the Federal government's AIDS research agenda presents both scientific and logistical challenges that require leadership, coordination, and strategic planning, 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 Clinton

Administration is committed to the reauthorization of 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 NIH's AIDS research 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:

- 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; and,
- Improve coordination among all NIH-supported AIDS clinical trials programs.

■ ***Biomedical Prevention of HIV Infection***

Vaccine Development. The scientific community continues to strive for an effective vaccine against HIV infection. 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 of vaccine candidates 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 continue to be 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.

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, more than 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.⁹

Latex condoms, the most effective barrier methods currently available, still 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 these goals, the following steps will be taken:

- During FY 1997, NIH and CDC will begin to implement a four-year, \$100 million initiative on microbicides announced by HHS Secretary Shalala at the Eleventh International Conference on AIDS;
- The Vice President will continue a high-level dialogue designed to encourage private sector involvement in the development of both microbicides and vaccines; and,
- Through U.S. participation in UNAIDS, and in other forums, we will encourage international efforts to develop effective microbicides.

■ ***Developing New and More Effective Therapies***

Another challenge in the research arena is developing new and more effective therapies

that may 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, NIH will spend an estimated \$470 million in the area of therapeutic research 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 among the government research establishment, pharmaceutical companies, and third-party payers to capitalize on recent scientific advances and learn how to optimally use available treatment regimens. The Federal government is committed to being an equal partner in this new effort.
- *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 otherwise be prohibitively expensive for individual researchers

or companies. This shared resource has accelerated the understanding of molecular structures in a number of research fields, including HIV. Information gained from this research can form the basis for targeted drug design and development.

- *Increased focus in Federal research on vulnerable populations.* Our research effort will increase its focus on the needs of vulnerable populations, including youth, women, minorities, and substance abusers. The efforts of programs such as the Women's Interagency HIV Study (WIHS), the Terry Bein 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.

■ *Continued Support for Research*

HIV research is an investment in our future. Already, it has helped prolong and improve the quality of lives of HIV-infected individuals, 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 funding commitment 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 Agencies, such as DOD, CDC, and VA, also support crucially important HIV research that strengthens the overall U.S. research effort. Recognizing the importance of biomedical and AIDS research generally, for FY 1997, the President has requested an increase of \$449 million for the NIH overall, an increase of \$24 million for NIH-conducted and -supported AIDS research, and an increase of \$4 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**

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, 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 1986, Federal expenditures for HIV-related care and services were \$193 million, by 1995 the Federal share reached \$3.5 billion.

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 HIV-positive individuals. Moreover, available care services were often directed towards meeting the acute care

needs of persons diagnosed with AIDS, rather than intervening in 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 health care services in a variety of ways. Currently, approximately 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.¹⁰

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.
- Title V provides reimbursement for dental care for low income persons living with HIV and AIDS and supports AIDS Education and Training Centers which provide up-to-date HIV-related training for health care professionals.

HRSA also provides primary care to persons living with HIV through its Community Health Centers and Maternal and Child Health Block Grant 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:

- Increasing funding for the Ryan White CARE Act by 158 percent since FY 1993 and signing the Ryan White CARE Act Amendments of

1996, extending this program until 2001;

- Tripling Federal funding for State AIDS Drug Assistance Programs, which help uninsured and underinsured individuals purchase prescription drugs;
- Increasing funding for HOPWA by 96 percent since FY 1993;
- Winning the fight to preserve the Medicaid guarantee of coverage for the more than 50 percent of people with AIDS and 90 percent of children with AIDS who rely on this program for their health coverage; and,
- Revising eligibility rules for Social Security disability benefits to make it easier for people living with HIV to qualify for benefits.

Future Opportunities for Progress

The national goal in this area is to ensure that people living with HIV have the opportunity to live productive lives by having access to services that are affordable, of high quality, and responsive to their needs. 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:

- 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 funding for CARE Act and HOPWA programs.
- Assuring that available resources are used as effectively as possible.

■ *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 or weaken the Federal guarantee of coverage for people living with disabilities. The President has vetoed one such proposal and has made sustaining the entitlement to Medicaid central to the national goal of ensuring appropriate and affordable care and services for persons living with HIV and AIDS.

Assessing Social Security Administration Programs. With the improved quality of life realized by many people due to the advent of protease inhibitors and combination therapy, it is important to assess programs such as Supplemental Security Income and Social Security Disability Insurance regarding their flexibility in meeting the needs of individuals as they seek to move off and on to disability. The current system of disability programs, which assures continued access to health insurance, often places obstacles in the way of individuals who want to return to work. The Administration is exploring mechanisms to ensure that Federal programs support people with disabilities who want to work or return to work.

Continuing Support for the 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 continue. President Clinton has proposed \$896 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 be at risk of becoming homeless during the course of their illness.¹¹ The President's FY 1997

amended budget request for HOPWA is \$196 million.

■ ***Ensuring Effective Use of Limited Resources***

There are three primary ways the Federal government will work to make the most of its limited resources by: (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 an 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, 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 and improving the application process for Federal funding and to facilitating service integration. HRSA and SAMHSA have issued joint program announcements, and HUD and HRSA have issued a joint program announcement for the Special Projects of

National Significance (SPNS) program. These concerted efforts to improve integration will be continued and expanded, with special attention to linking HIV and substance abuse prevention and services.

in providing better care to people living with HIV.

Improving Quality of Care. Federally-supported efforts such as Medicaid, Medicare, and the health care delivery systems at the Department of Veterans Affairs (VA) and the Department of Defense (DOD) 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 HHS is undertaking a program to develop clinical practice guidelines in conjunction with other government Agencies such as the VA and DOD 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 assists

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 avoid prevention programs because of the stigma associated with HIV.

The fourth goal of the National AIDS Strategy is to fight discrimination on all fronts, including employment, access to health care, education, housing, service establishments, and other areas covered by Federal law, and to provide national

leadership in erasing the stigma associated with HIV and AIDS.

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
- Enactment 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;

- Vigorously enforcing Section 504 of the Rehabilitation Act of 1973 as it pertains to recipients of Federal funds such as hospitals, nursing homes, and social service agencies;
- Leading the effort to repeal the "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;
- Establishing an HIV/AIDS education program available to all Federal workers; and
- Using the Presidential "bully pulpit" to speak out repeatedly 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 more than 300 people from around the country to discuss with the President the impact of the epidemic on their lives and communities.

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 and 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 examining existing policies related to the exclusion of people living with HIV from Federal 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 and members of his Administration have used and will continue to use their positions 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
The White House 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. 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, 30 to 40 million people will have been infected around the globe.

The epidemic jeopardizes decades of economic and social advances in many developing nations. In some of 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.¹² 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.

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:

- Providing initial funding and key leadership for the creation of the Global Programme on AIDS at the World Health Organization (WHO) in 1987; and
- Playing 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 to slow the AIDS epidemic internationally. (See Appendix E). The Department of State works with other Agencies and non-governmental organizations to implement 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: mobilizing and unifying national and international efforts; preventing new infections; biomedical

research; and reducing the personal and social impact of the epidemic.

The U.S. Agency for International Development (USAID) plays a leadership role in the global HIV response through development assistance, research, and policy formulation. 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.

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 HIV/AIDS (UNAIDS).¹³ The U.S. is a member of the governing body of UNAIDS, signed the 1994 Paris Declaration, and also supports the Greater Involvement of People Living with HIV and AIDS Initiative (GIPA).

The U.S. also supports efforts to access available resources more effectively 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 multilateral partnerships, the U.S. must strengthen its bilateral programs for HIV activities and continue to support 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 will 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 U.S. Agencies supporting international activities must develop a mechanism for coordinating programs in a systematic and efficient manner.

F. TRANSLATION OF RESEARCH ADVANCES INTO PRACTICE

"I want all our fellow Americans to know that this investment in science has paid tremendous dividends."

**President Clinton, December 5, 1996
The White House Conference on
HIV and AIDS**

An important element in the fight against HIV and 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 National Institutes of Health and 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.

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, patients, the media, and the public;
- DHHS supports and directs the International HIV/AIDS Clinical Conference Call series, which disseminates 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 to clinicians, patients, and the public through the National AIDS Hotline (1-800-342-AIDS); its toll-free 1-800-HIV-0440 HIV/AIDS Treatment Information Service (ATIS); and the National AIDS Information Clearinghouse;
- The CDC also develops and issues guidelines for health professionals and the public through its *Morbidity and Mortality Weekly Report*;
- The Agency for Health Care Policy and Research (AHCPR) publishes 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.

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 maintained. An AHCPR-supported study indicated that primary care physicians may miss significant HIV-related symptoms during patient examinations.¹⁴ Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.¹⁵ 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.

Consumer education efforts are also important. In light of the potential public health benefits that could result from the proper use of a wide range of therapies, it is vital to support programs that provide consumers with the information they need to make treatment decisions and comply with therapeutic regimens.

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 as quickly as possible. To this end, during FY 1997, the Office of HIV/AIDS Policy at HHS is undertaking a program to develop clinical practice guidelines in conjunction with other government Agencies and private sector clinicians.

make a difference.

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 latest treatment developments, 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

Endnotes

1. It is, however, hoped that with greater use of AZT by HIV-positive pregnant women, the number of new cases in newborns can be reduced.
2. *Morbidity and Mortality Weekly Report*. U.S. Department of Health and Human Services, Public Health Service. November 24, 1995, vol. 44, No. 46.
3. Hellinger, F. The Lifetime Cost of Treating a Person with HIV. AHCPR Publication Number 93-0080.
4. For 5 years of care after initial heart attack. Source: *American Journal of Cardiology*, 1990.
5. Depending on stage diagnosed -- early or late. Source: Swartz & Rollins, *Business and Health*, 1985, 85, 24-6.
6. Richard D. Moore and John G. Bartlett. Combination Anti- retroviral Therapy in HIV Infection, An Economic Perspective. *PharmacoEconomics* August 1996; 10(2):109-113.
7. Personal communication from the Centers for Disease Control and Prevention, Division of TB Elimination, 1995.
8. 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.
9. Alan B. Stone, and Penelope J. Hitchcock. Vaginal Microbicides for Preventing the Transmission of HIV. *AIDS* 1994, 8 (suppl 1):S285-S293.
10. Agency for Health Care Policy and Research: Data from the Screener Questionnaire, AIDS Cost and Services Utilization Survey. 1991.
11. Housing and the HIV/AIDS Epidemic: Recommendations for Action. National Commission on AIDS. Washington, D.C. July 1992.

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

13. 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.

14. 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.

15. 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)

FIGURE 1

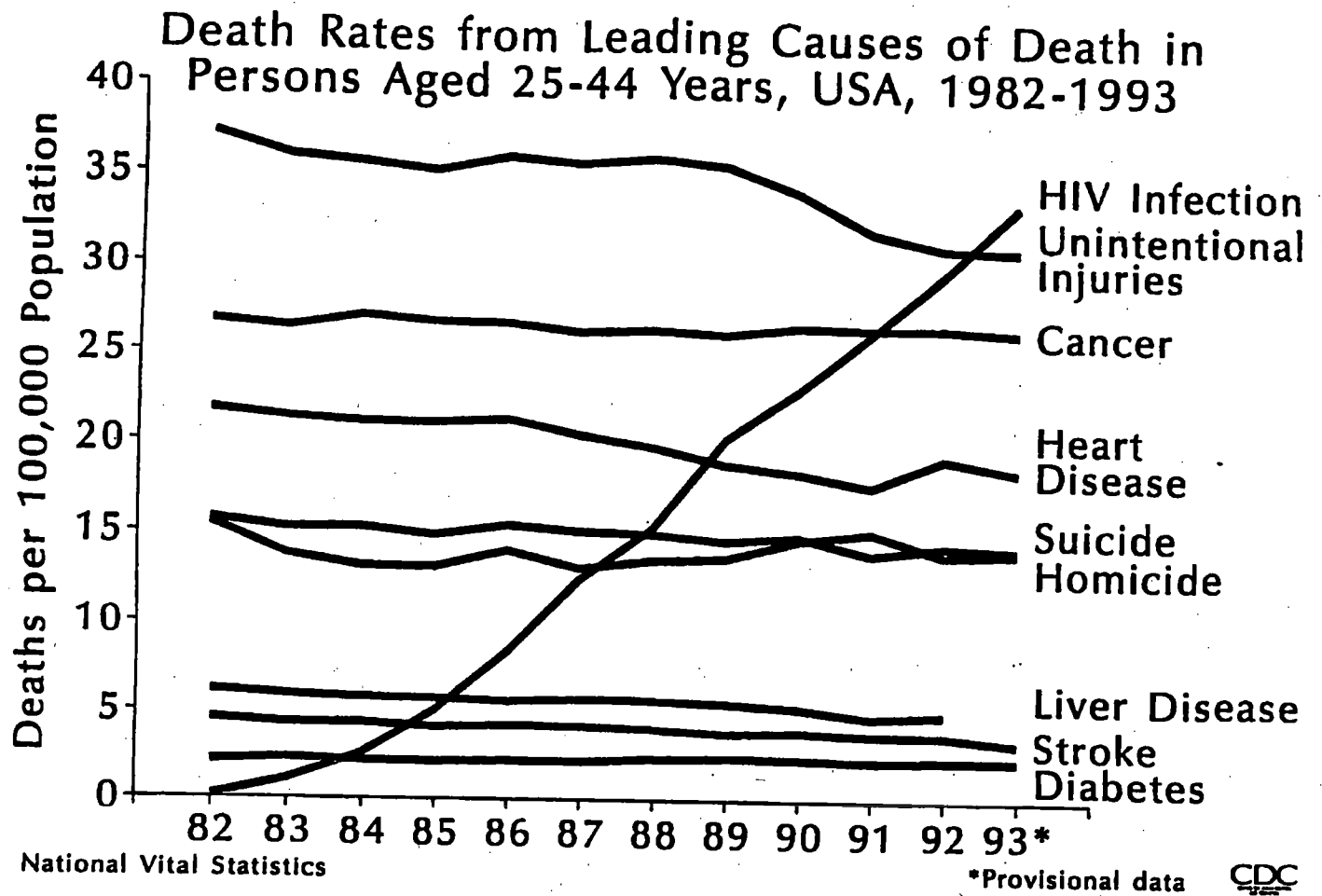
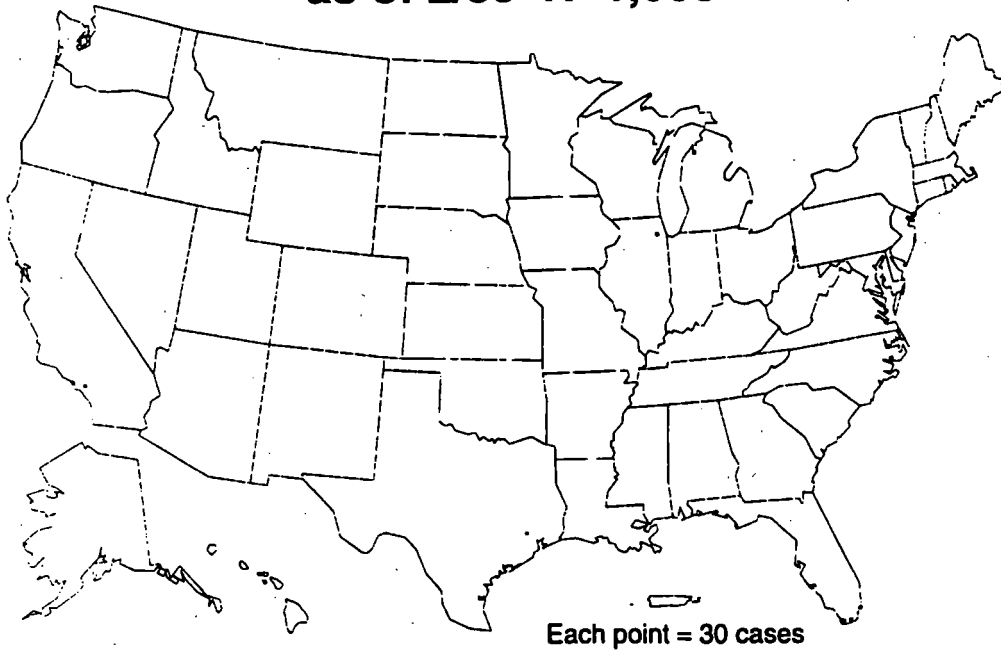
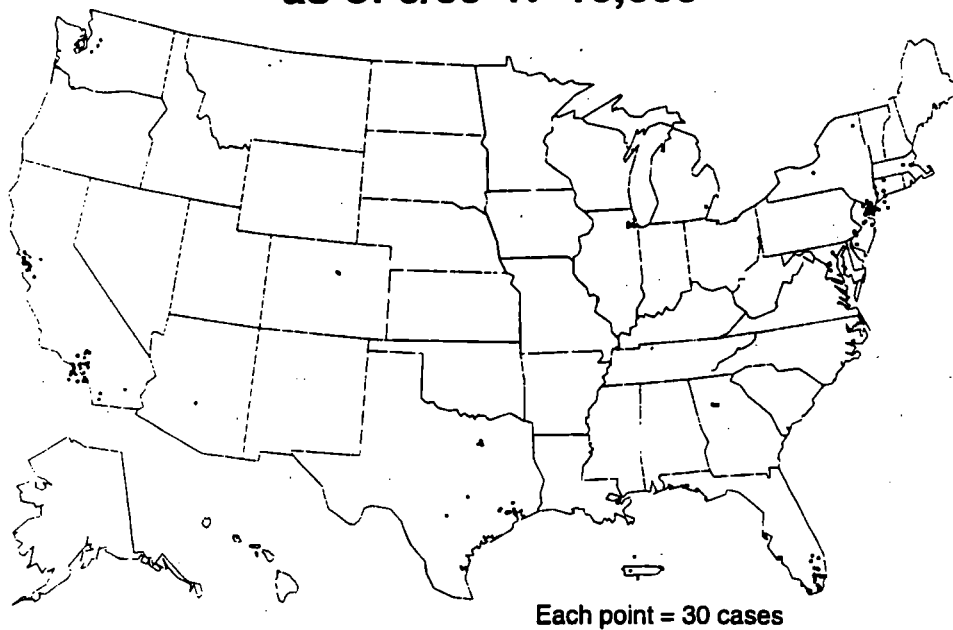


FIGURE 2

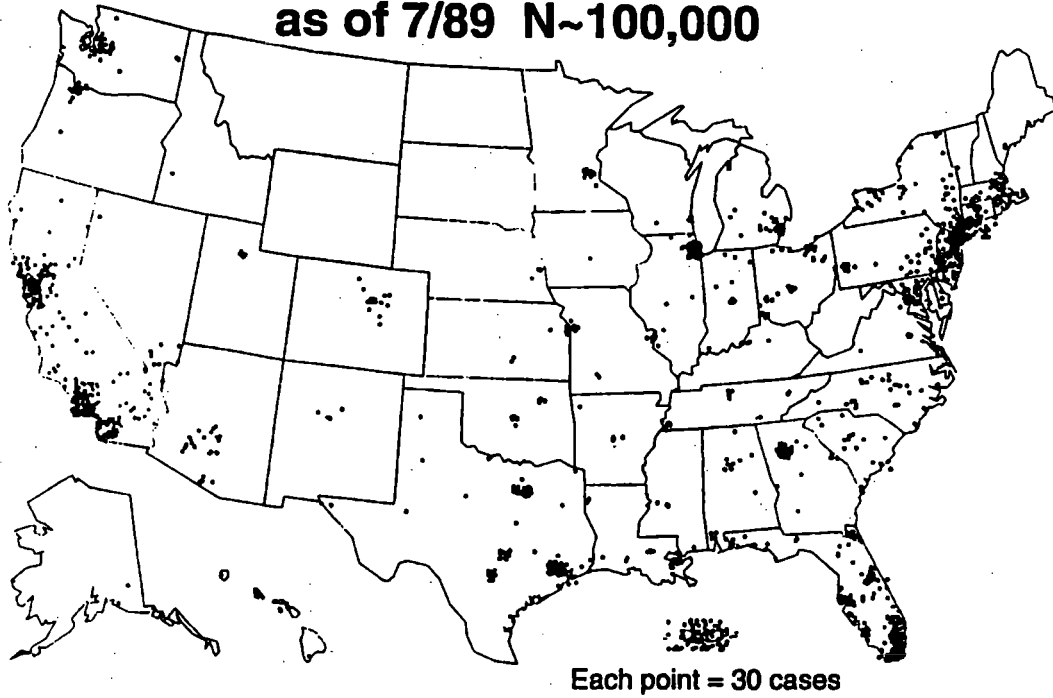
**Cumulative U.S. AIDS Cases
as of 2/83 N~1,000**



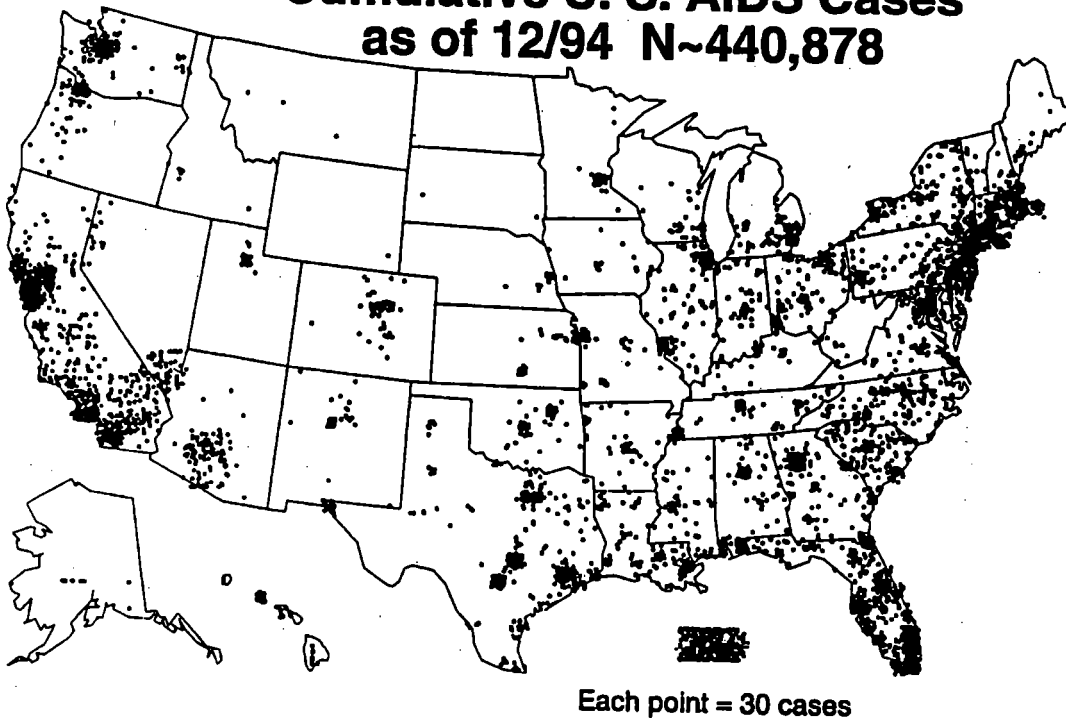
**Cumulative U. S. AIDS Cases
as of 5/85 N~10,000**



**Cumulative U.S. AIDS Cases
as of 7/89 N~100,000**



**Cumulative U. S. AIDS Cases
as of 12/94 N~440,878**



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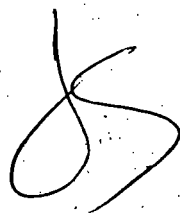


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**OFFICE OF NATIONAL AIDS POLICY
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DATE: 11/15/96

PAGES INCLUDING COVER SHEET: 40

COMMENTS:

Draft AIDS Strategy.

**The
National
AIDS
Strategy
Draft**

November 1996

"We'll keep going until normal life is returned to people who have HIV."

**President Clinton, August 29, 1996
Acceptance Speech before the Democratic National Convention**

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

The epidemic of HIV and AIDS constitutes a public health crisis of unprecedented proportions. After 15 years, this terrible national tragedy has affected -- and will continue to affect -- far too many people in the U.S. and around the world. HIV is a disease that we can defeat -- just as we have eradicated smallpox from our planet and polio from the western hemisphere. We have made tremendous progress in our understanding of HIV and HIV disease, ways in which we can treat those who are infected, and the means by which we can prevent infection. We also have more work to do. The National AIDS Strategy provides a foundation for the continuing public-private partnerships that are essential to our success in ending this epidemic.

In 1993, the Office of National AIDS Policy (ONAP) was created by President Clinton to provide a national focus and direction for the U.S. 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 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 Agencies, communities, State and local governments, businesses, schools, churches, families, and individuals.

This document is a snapshot of where we

are as a Nation and where we need to go in achieving these national goals and in ultimately ending the epidemic. 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 major areas of HIV policy: prevention, research, care and services, civil rights, international activities, and translation of research advances into practice.

The National AIDS Strategy sets forth a framework and identifies opportunities for progress that will serve as the foundation for the Administration's response to the epidemic in the years ahead. An implementation process for defining specifically how to reach these goals will be a joint effort of the Interdepartmental Task Force on HIV and AIDS, the Presidential Advisory Council on HIV and AIDS, the private sector, and the community. These formal and systematic consultations will be integral to identifying and implementing solutions. Moreover, the National AIDS Strategy is intended to be a living document that requires regular updating and adjustment as goals are reached and new challenges emerge.

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

The National AIDS Strategy
November 1996 Draft

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 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. 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 also have been extraordinarily helpful in developing the National AIDS Strategy.

We face great challenges as a Nation. We are also facing great opportunities.

Together, with steadfast commitment, courage, and leadership, we will win the battle against HIV and AIDS.

Patricia S. Fleming
National AIDS Policy Director

"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 to end the epidemic of HIV and AIDS:

- To develop more effective treatments, a preventive vaccine to protect the uninfected, and a cure for those currently infected through strong continuing support for HIV-related research;
- To reduce the number of new HIV infections in adults and children in the U.S. and worldwide until the rate of new infections reaches zero by providing strong continuing support for effective AIDS prevention efforts;
- To ensure that all people living

with HIV have access to services that are affordable, of high quality, and responsive to their needs;

- To ensure that all people living with HIV are not subject to 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 enhanced 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.

Globally, 8,500 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 (e.g., New York, San Francisco, and Los Angeles). Today, this group represents less than half of all new cases, although it still represents a majority of persons living with HIV and AIDS. Among the populations that are heavily affected today are young gay and bisexual men, women, and injecting drug users and their sexual partners as well as users of non-

injecting drugs (e.g., 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.¹

Adolescents (age 13-19) are increasingly at 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, makes young Americans 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 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.² 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 now have been reported in all 50 States, the District of Columbia, Puerto Rico, Guam, and each of the U.S. territories (See Figure 2).

Average lifetime cost of medical care after an HIV diagnosis is \$119,000.³ For heart disease and cancer the comparable figures are \$61,211⁴ and \$25,000 to \$84,000⁵, respectively. With the development of protease inhibitors, treatment for HIV and AIDS is \$10,000 to \$18,000 per life-year gained. For coronary artery bypass surgery the cost per life-year saved is \$113,000.⁶ People living with HIV are disproportionately dependent on the public sector for their health care. More than 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 an estimated \$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 totaled nearly \$1.1 billion in

FY 1996. Many Federal programs such as HOPWA and CDC's prevention efforts contribute to reducing the short- and long-term economic costs of the epidemic.

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, schools, academic institutions, private foundations, health care institutions, business leaders, community-based organizations, and the Federal government into many HIV-related activities. The Federal government, through its public health responsibilities in areas such as research, prevention, health care, and housing has seen a dramatic increase in its activities since the beginning of the epidemic. In FY 1986 the Federal government expenditures for AIDS research, surveillance, income maintenance, and care were \$508 million. By FY 1995 that figure reached \$6.8 billion.

In the past four years, under the leadership of President Clinton, the Administration has increased spending for AIDS research, prevention, income maintenance, and care by approximately 50 percent. Funding for the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act has increased by 158 percent since FY 1993. Support for housing for people living with AIDS has increased by 96 percent in the same time period. AIDS-related research funding budget has increased by 40 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 develop and implement an annual AIDS research plan and budget.

Approval of AIDS drugs by the Food and Drug Administration has been further accelerated. A community-based AIDS prevention planning process has empowered local communities to develop innovative AIDS prevention programs. Eligibility for Social Security disability benefits for people with AIDS has 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
The White House Conference
on HIV and AIDS**

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 estimated to be

approximately 40,000 people each year.

Sentinel accomplishments in prevention of HIV include:

- Publication in *Morbidity and Mortality Weekly Report* by the Centers for Disease Control and Prevention (CDC) in 1981 of the first AIDS cases;
 - Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the risk factors associated with HIV infection;
 - Due to NIH-sponsored research, demonstration that administration of AZT can prevent transmission of HIV from an infected mother to her newborn; and,
 - Due in part to successful implementation of CDC-sponsored prevention strategies, a slowing in the growth of the epidemic.
- 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 of efforts to reduce sexually transmitted diseases and tuberculosis.

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

- Increasing funding for AIDS prevention at CDC by 24 percent (since FY 1993);
- Launching the AIDS prevention community planning partnership -- empowering local communities to develop innovative prevention efforts;

Federal agencies have been instrumental in expanding our knowledge base about HIV prevention (see Appendix A). 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 and AIDS.

Federal efforts have shown that HIV prevention programs can be effective. CDC's prevention projects, many in partnership with states, local governments, schools, 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, including epidemiological and natural history studies, conducted and supported by the National Institutes of Health (NIH) and CDC has expanded and will continue to expand our understanding of HIV transmission and the

determinants of HIV-related risk behavior.

The Nation also has 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 and their sexual partners. The White House Office of National Drug Control Policy (ONDCP) has pursued and coordinated efforts to combat 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 AIDS prevention information through the integration of prevention interventions into primary health care services and through support of early intervention services. HRSA and HCFA have also 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.

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, seroprevalence, and risk behaviors;
- Improving scientific knowledge about effective prevention models and strategies;
- Strengthening community-based programs;
- Integrating HIV and other prevention efforts;
- Targeting vulnerable populations; and,
- Improving integration of prevention into primary care and improving linkages between counseling and testing and primary care.

■ *Improving Understanding of Trends in the Epidemic*

Understanding who is becoming infected and through what behaviors is critical to designing effective HIV prevention interventions, as well as for targeting appropriate service resources. As discussed in the introduction, the demographics of the epidemic are evolving, 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. Therefore, we miss critical warning signs about new trends in affected populations and increasing risky behaviors.

To address this concern, 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.

■ ***Research on Effective Prevention Strategies***

Effective interventions must be based on sound research findings and evaluations. 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 critical knowledge in this area, which is central to developing effective interventions.

Intervention Research. Intervention research focuses on individual and community level interventions that result in modified sexual and drug-using behaviors and, as a consequence, reduced HIV transmission. There have been significant accomplishments in this area, but, as this portfolio expands, it will be critical to assess interventions in the context of community cultures and social networks that are relevant to the growing number of populations that must be reached by HIV 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 actually are working -- and to ensure that scarce resources are spent on the most effective interventions -- all Federally-funded prevention activities routinely will include evaluation components. Funding Agencies will share widely the knowledge gained about what works and what does not work to ensure promotion of innovation and 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 their grantees to develop appropriate performance measures for HIV prevention programs, including those developed under the community planning process.

■ ***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 only on how to plan and compete successfully for available resources but also how to appropriately incorporate epidemiological and research information into community prevention programs.

■ ***Program Integration and Collaboration***

The fourth component 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.

Prevention Education. Collaboration with communities and schools is a critical factor in communicating HIV prevention messages to our youth. The Centers for Disease Control and Prevention's *Guidelines for Effective School Health Programs to Prevent the Spread of AIDS* helps assure that young people understand the nature of the HIV epidemic and the specific actions they can take to prevent HIV infection. Strong support for these programs should and will continue.

Substance Abuse. HIV transmission is closely related to substance abuse, through needle-sharing behaviors, as sex is traded for drugs, and as drug and alcohol use impairs judgment and increases risk-taking behaviors. Breaking these linkages 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, research, and demonstration programs, SAMHSA, NIH, 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 White House Office of National Drug Control Policy (ONDCP) is leading this fight on two fronts: reducing demand for drugs through treatment and prevention programs and reducing the availability of drugs through supply reduction programs.
- *Preventing HIV transmission from the use of contaminated injection equipment.* The sharing of needles and syringes among injecting drug users is a major means of HIV transmission in the drug-injecting 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 has indicated that removal of restrictions on over-the-counter sale of syringes resulted in decreased reported needle sharing.

Current Federal law prohibits the use of Federal funds for needle exchange programs; however, a number of communities across the country have undertaken these programs with local resources. NIH-supported research on existing needle exchange programs is identifying the characteristics that influence program success as an HIV prevention strategy.

Primary Care. HIV prevention needs to be better integrated into primary health 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 health care professionals the information and skills they need. The Administration strongly supports the AETC program and will give it a renewed focus to support this goal.

Often primary care is a direct form of HIV prevention. The NIH-supported research that showed AZT reduces 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. In addition, 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.⁷

To address the need to integrate work on these interrelated 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 program to cover STD programs.

■ *Targeting Vulnerable Populations*

The HIV epidemic continues to have a disproportionate impact on certain populations where infection rates are rising at a rapid pace. A fifth and final challenge for prevention programming is to pay particular attention to groups that traditionally receive fewer services, but where the risk of infection is greatest. These include adolescents (especially young gay men), women, minorities, gay men of color, substance abusers, and prisoners. Many Federally-funded HIV prevention activities already target these populations, but the President's increased funding request for CDC would provide \$35 million in new funds in FY 1997, specifically for programs and research targeting adolescents, women, and substance abusers. To ensure that prevention programs, including community planning efforts, are as effective as possible all Federally-funded prevention activities routinely will include monitoring and evaluation components.

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, 1996
The White House Conference on
HIV and AIDS**

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;
- Determination by NIH of the three-dimensional structure of reverse transcriptase, providing the target for the use of AZT as the first antiretroviral drug proven effective against HIV in NIH-supported clinical trials;
- Approval of AZT, the first treatment of HIV primary infection;
- Development by the Food and Drug Administration (FDA) of a system of expedited review,⁸ initiated in 1992, of treatments for life-threatening diseases, including HIV; and

Since he took office in 1993, President

Clinton has escalated AIDS research efforts by:

- Increasing AIDS research funding at NIH by 40 percent (since FY 1993);
- Signing the NIH Revitalization Act of 1993, granting the Office of AIDS Research at NIH new authority to develop and implement an annual AIDS research plan and budget;
- Accelerating AIDS drug approval to record times;
- Approval by the FDA since January 1993 of 16 new HIV-related drugs, 8 new indications, and three new diagnostics for HIV and related conditions, developed through public and private sector development efforts;
- 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;
- Approving in record time a promising new class of AIDS drugs known as protease inhibitors;
- Launching a four-year, \$100 million research effort to develop effective topical microbicides;
- Developing the first Federal Plan for Biomedical Research on HIV and

AIDS to improve coordination of HIV-related research; and

- 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 to Research on Other Diseases

AIDS research has provided significant benefits in the fight against many other diseases. AIDS research has accelerated study of the human immune system, helping to better understand and treat such diseases as cancer; autoimmune diseases, including systemic lupus erythematosus; type I diabetes mellitus; rheumatoid arthritis; and multiple sclerosis. AIDS research advances also have contributed to the prevention and treatment 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 has 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 (e.g., 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. 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 targeted drug design using sophisticated techniques of structural biology and advanced computer imaging methods. These advances have implications for drug design for virtually all disorders. Clinical trials of poxvirus vaccine vectors and 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.

Future Opportunities for Progress

While tremendous progress has been made in HIV 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:

- Provide leadership and coordination for the Federal research effort;
- Develop biomedical interventions that prevent HIV infection, including both vaccines and microbicides;
- Develop new and more effective therapies for HIV and related conditions; and
- Assure adequate funding for this research effort.

■ *Leadership and Coordination of Research*

Developing and implementing the Federal government's AIDS research agenda presents both scientific and logistical challenges that require leadership, coordination, and strategic planning, 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 Clinton

Administration is committed to the reauthorization of 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 NIH's AIDS research 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:

- 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; and,
- Improve coordination among all NIH-supported AIDS clinical trials programs.

■ ***Biomedical Prevention of HIV Infection***

Vaccine Development. The scientific community continues to strive for an effective vaccine against HIV infection. 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 of vaccine candidates 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 continue to be 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.

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, more than 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.⁹

Latex condoms, the most effective barrier methods currently available, still 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 these goals, the following steps will be taken:

- During FY 1997, NIH and CDC will begin to implement a four-year, \$100 million initiative on microbicides announced by HHS Secretary Shalala at the Eleventh International Conference on AIDS;
- The Vice President will continue a high-level dialogue designed to encourage private sector involvement in the development of both microbicides and vaccines; and,
- Through U.S. participation in UNAIDS, and in other forums, we will encourage international efforts to develop effective microbicides.

■ ***Developing New and More Effective Therapies***

Another challenge in the research arena is developing new and more effective therapies

that may 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, NIH will spend an estimated \$470 million in the area of therapeutic research 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 among the government research establishment, pharmaceutical companies, and third-party payers to capitalize on recent scientific advances and learn how to optimally use available treatment regimens. The Federal government is committed to being an equal partner in this new effort.
- *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 otherwise be prohibitively expensive for individual researchers

or companies. This shared resource has accelerated the understanding of molecular structures in a number of research fields, including HIV. Information gained from this research can form the basis for targeted drug design and development.

- *Increased focus in Federal research on vulnerable populations.* Our research effort will increase its focus on the needs of vulnerable populations, including youth, women, minorities, and substance abusers. The efforts of programs such as the Women's Interagency HIV Study (WIHS), the Terry Bein 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.

■ *Continued Support for Research*

HIV research is an investment in our future. Already, it has helped prolong and improve the quality of lives of HIV-infected individuals, 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 funding commitment 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 Agencies, such as DOD, CDC, and VA, also support crucially important HIV research that strengthens the overall U.S. research effort. Recognizing the importance of biomedical and AIDS research generally, for FY 1997, the President has requested an increase of \$449 million for the NIH overall, an increase of \$24 million for NIH-conducted and -supported AIDS research, and an increase of \$4 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**

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, 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 1986, Federal expenditures for HIV-related care and services were \$193 million, by 1995 the Federal share reached \$3.5 billion.

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 HIV-positive individuals. Moreover, available care services were often directed towards meeting the acute care

needs of persons diagnosed with AIDS, rather than intervening in 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 health care services in a variety of ways. Currently, approximately 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.¹⁰

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.
- Title V provides reimbursement for dental care for low income persons living with HIV and AIDS and supports AIDS Education and Training Centers which provide up-to-date HIV-related training for health care professionals.

HRSA also provides primary care to persons living with HIV through its Community Health Centers and Maternal and Child Health Block Grant 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:

- Increasing funding for the Ryan White CARE Act by 158 percent since FY 1993 and signing the Ryan White CARE Act Amendments of

1996, extending this program until 2001;

- Tripling Federal funding for State AIDS Drug Assistance Programs, which help uninsured and underinsured individuals purchase prescription drugs;
- Increasing funding for HOPWA by 96 percent since FY 1993;
- Winning the fight to preserve the Medicaid guarantee of coverage for the more than 50 percent of people with AIDS and 90 percent of children with AIDS who rely on this program for their health coverage; and,
- Revising eligibility rules for Social Security disability benefits to make it easier for people living with HIV to qualify for benefits.

Future Opportunities for Progress

The national goal in this area is to ensure that people living with HIV have the opportunity to live productive lives by having access to services that are affordable, of high quality, and responsive to their needs. 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:

- 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 funding for CARE Act and HOPWA programs.
 - Assuring that available resources are used as effectively as possible.
- ***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 or weaken the Federal guarantee of coverage for people living with disabilities. The President has vetoed one such proposal and has made sustaining the entitlement to Medicaid central to the national goal of ensuring appropriate and affordable care and services for persons living with HIV and AIDS.

Assessing Social Security Administration Programs. With the improved quality of life realized by many people due to the advent of protease inhibitors and combination therapy, it is important to assess programs such as Supplemental Security Income and Social Security Disability Insurance regarding their flexibility in meeting the needs of individuals as they seek to move off and on to disability. The current system of disability programs, which assures continued access to health insurance, often places obstacles in the way of individuals who want to return to work. The Administration is exploring mechanisms to ensure that Federal programs support people with disabilities who want to work or return to work.

Continuing Support for the 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 continue. President Clinton has proposed \$896 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 be at risk of becoming homeless during the course of their illness.¹¹ The President's FY 1997

amended budget request for HOPWA is \$196 million.

■ ***Ensuring Effective Use of Limited Resources***

There are three primary ways the Federal government will work to make the most of its limited resources by: (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 an 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, 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 and improving the application process for Federal funding and to facilitating service integration. HRSA and SAMHSA have issued joint program announcements, and HUD and HRSA have issued a joint program announcement for the Special Projects of

National Significance (SPNS) program. These concerted efforts to improve integration will be continued and expanded, with special attention to linking HIV and substance abuse prevention and services.

in providing better care to people living with HIV.

Improving Quality of Care. Federally-supported efforts such as Medicaid, Medicare, and the health care delivery systems at the Department of Veterans Affairs (VA) and the Department of Defense (DOD) 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 HHS is undertaking a program to develop clinical practice guidelines in conjunction with other government Agencies such as the VA and DOD 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 assists

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 avoid prevention programs because of the stigma associated with HIV.

The fourth goal of the National AIDS Strategy is to fight discrimination on all fronts, including employment, access to health care, education, housing, service establishments, and other areas covered by Federal law, and to provide national

leadership in erasing the stigma associated with HIV and AIDS.

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
- Enactment 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;

- Vigorously enforcing Section 504 of the Rehabilitation Act of 1973 as it pertains to recipients of Federal funds such as hospitals, nursing homes, and social service agencies;
- Leading the effort to repeal the "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;
- Establishing an HIV/AIDS education program available to all Federal workers; and
- Using the Presidential "bully pulpit" to speak out repeatedly 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 more than 300 people from around the country to discuss with the President the impact of the epidemic on their lives and communities.

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 and 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 examining existing policies related to the exclusion of people living with HIV from Federal 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 and members of his Administration have used and will continue to use their positions 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
The White House 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. 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, 30 to 40 million people will have been infected around the globe.

The epidemic jeopardizes decades of economic and social advances in many developing nations. In some of 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.¹² 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.

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:

- Providing initial funding and key leadership for the creation of the Global Programme on AIDS at the World Health Organization (WHO) in 1987; and
- Playing 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 to slow the AIDS epidemic internationally. (See Appendix E). The Department of State works with other Agencies and non-governmental organizations to implement 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: mobilizing and unifying national and international efforts; preventing new infections; biomedical

research; and reducing the personal and social impact of the epidemic.

The U.S. Agency for International Development (USAID) plays a leadership role in the global HIV response through development assistance, research, and policy formulation. 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.

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 HIV/AIDS (UNAIDS).¹³ The U.S. is a member of the governing body of UNAIDS, signed the 1994 Paris Declaration, and also supports the Greater Involvement of People Living with HIV and AIDS Initiative (GIPA).

The U.S. also supports efforts to access available resources more effectively 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 multilateral partnerships, the U.S. must strengthen its bilateral programs for HIV activities and continue to support 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 will 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 U.S. Agencies supporting international activities must develop a mechanism for coordinating programs in a systematic and efficient manner.

F. TRANSLATION OF RESEARCH ADVANCES INTO PRACTICE

"I want all our fellow Americans to know that this investment in science has paid tremendous dividends."

**President Clinton, December 5, 1996
The White House Conference on
HIV and AIDS**

An important element in the fight against HIV and 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 National Institutes of Health and 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.

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, patients, the media, and the public;
- DHHS supports and directs the International HIV/AIDS Clinical Conference Call series, which disseminates 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 to clinicians, patients, and the public through the National AIDS Hotline (1-800-342-AIDS); its toll-free 1-800-HIV-0440 HIV/AIDS Treatment Information Service (ATIS); and the National AIDS Information Clearinghouse;
- The CDC also develops and issues guidelines for health professionals and the public through its *Morbidity and Mortality Weekly Report*;
- The Agency for Health Care Policy and Research (AHCPR) publishes 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.

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 maintained. An AHCPR-supported study indicated that primary care physicians may miss significant HIV-related symptoms during patient examinations.¹⁴ Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.¹⁵ 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.

Consumer education efforts are also important. In light of the potential public health benefits that could result from the proper use of a wide range of therapies, it is vital to support programs that provide consumers with the information they need to make treatment decisions and comply with therapeutic regimens.

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 as quickly as possible. To this end, during FY 1997, the Office of HIV/AIDS Policy at HHS is undertaking a program to develop clinical practice guidelines in conjunction with other government Agencies and private sector clinicians.

make a difference.

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 latest treatment developments, 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

Endnotes

1. It is, however, hoped that with greater use of AZT by HIV-positive pregnant women, the number of new cases in newborns can be reduced.
2. *Morbidity and Mortality Weekly Report*. U.S. Department of Health and Human Services, Public Health Service. November 24, 1995, vol. 44, No. 46.
3. Hellinger, F. The Lifetime Cost of Treating a Person with HIV. AHCPR Publication Number 93-0080.
4. For 5 years of care after initial heart attack. Source: *American Journal of Cardiology*, 1990.
5. Depending on stage diagnosed -- early or late. Source: Swartz & Rollins, *Business and Health*, 1985, 85, 24-6.
6. Richard D. Moore and John G. Bartlett. Combination Anti- retroviral Therapy in HIV Infection, An Economic Perspective. *PharmacoEconomics* August 1996; 10(2):109-113.
7. Personal communication from the Centers for Disease Control and Prevention, Division of TB Elimination, 1995.
8. 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.
9. Alan B. Stone, and Penelope J. Hitchcock. Vaginal Microbicides for Preventing the Transmission of HIV. *AIDS* 1994, 8 (suppl 1):S285-S293.
10. Agency for Health Care Policy and Research: Data from the Screener Questionnaire, AIDS Cost and Services Utilization Survey. 1991.
11. Housing and the HIV/AIDS Epidemic: Recommendations for Action. National Commission on AIDS. Washington, D.C. July 1992.

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

13. 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.

14. 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.

15. 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)

FIGURE 1

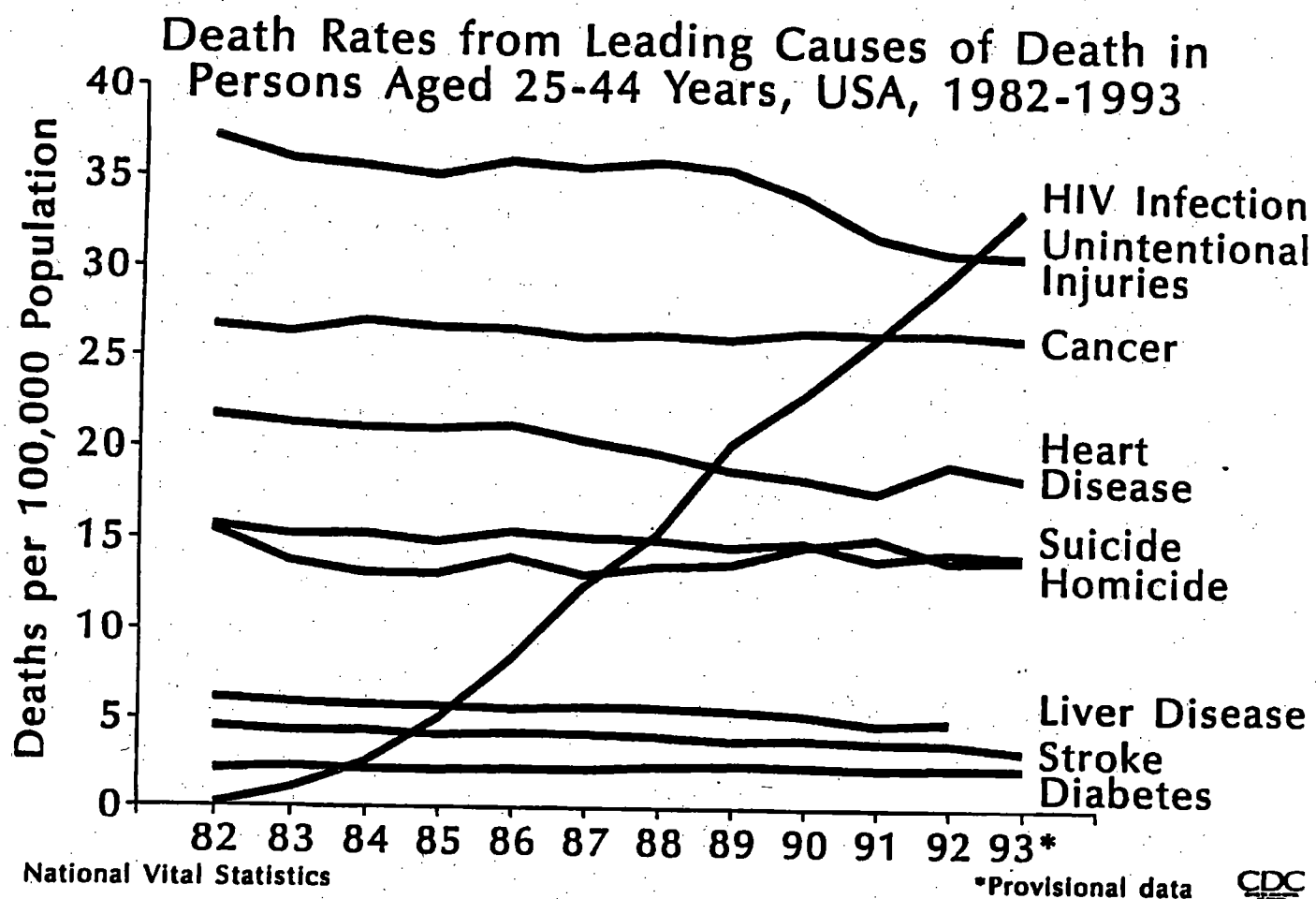
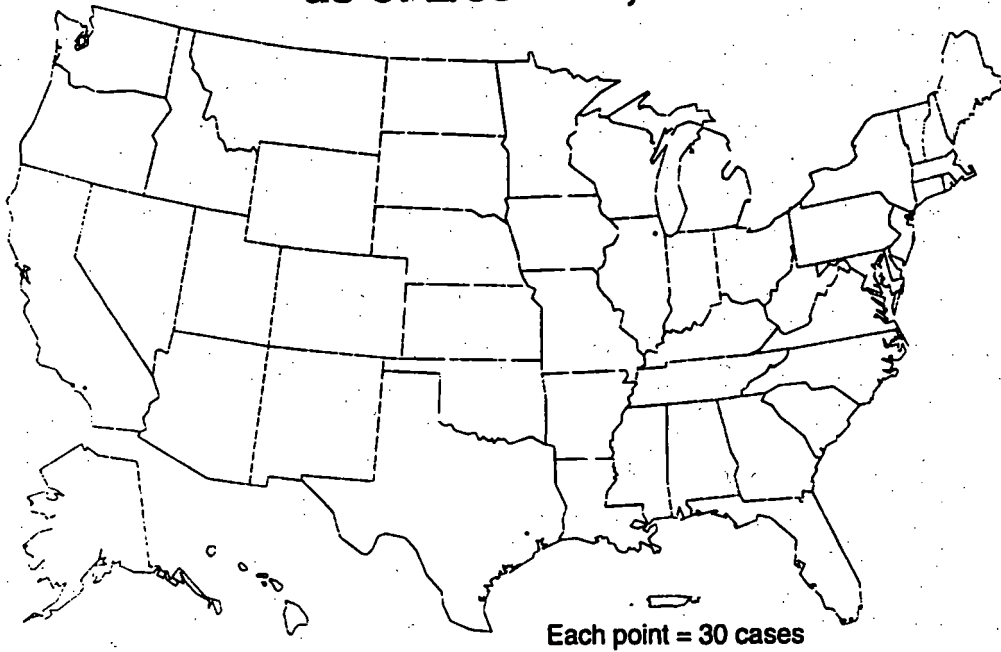
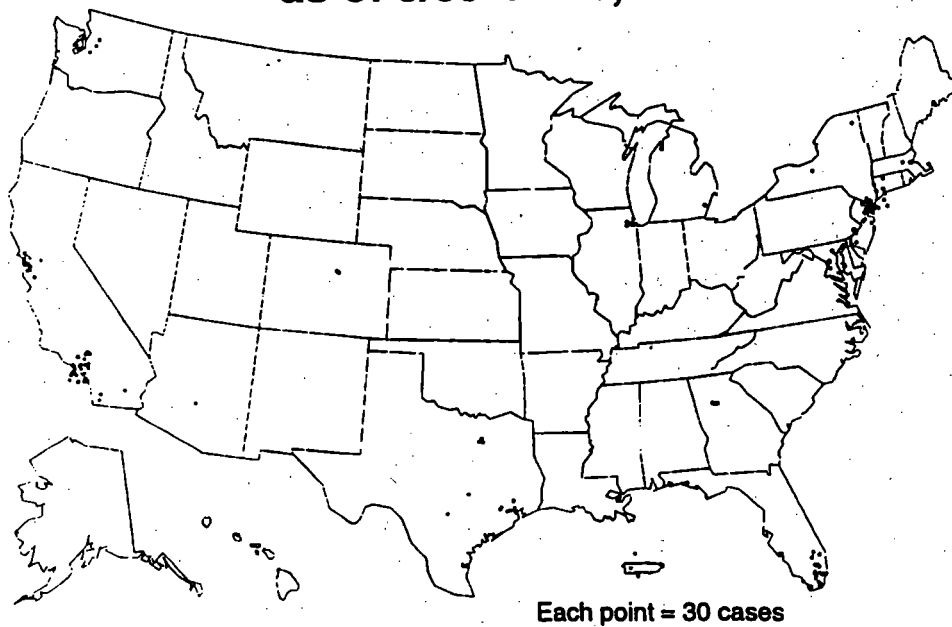


FIGURE 2

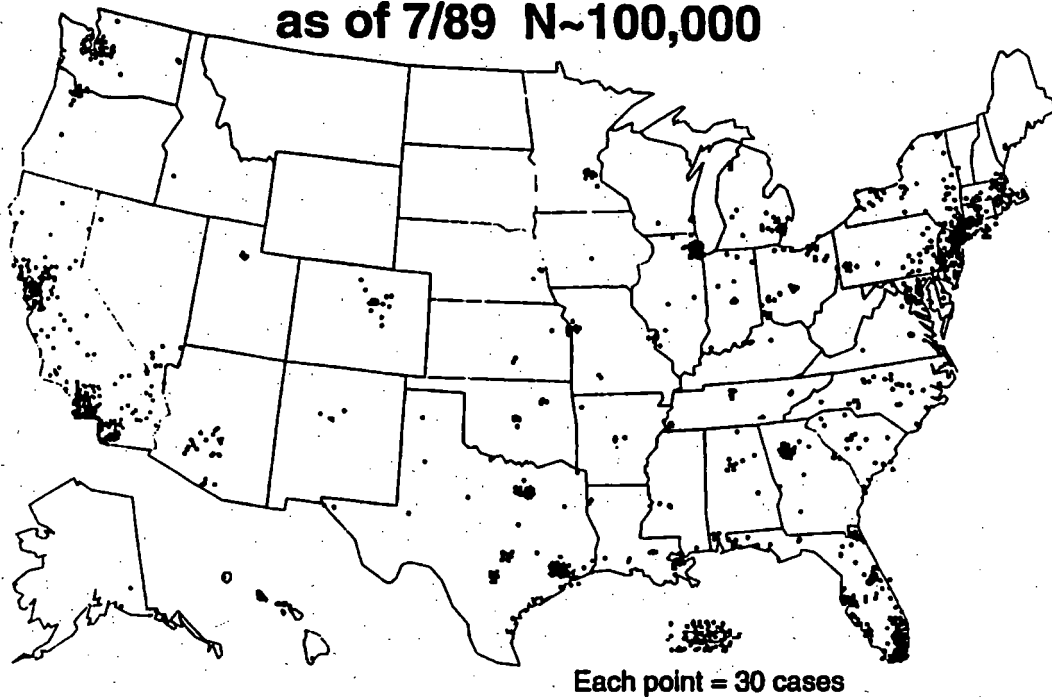
**Cumulative U.S. AIDS Cases
as of 2/83 N~1,000**



**Cumulative U. S. AIDS Cases
as of 5/85 N~10,000**



**Cumulative U.S. AIDS Cases
as of 7/89 N~100,000**



**Cumulative U. S. AIDS Cases
as of 12/94 N~440,878**

