

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

Collection/Record Group: Clinton Presidential Records
Subgroup/Office of Origin: National AIDS Policy Office
Series/Staff Member: Patsy Fleming
Subseries: National AIDS Strategy

OA/ID Number: 9006
FolderID:

Folder Title:
Printer's Copy 9/6/96

Stack:	Row:	Section:	Shelf:	Position:
S	66	5	9	1

Date: 9/4/96
Phone: 632-1090

96

Delivery Requested
9/6/96 6:00
Date/Time pm

Executive Order 12873 (October 20, 1993) sets a goal that "all government documents printed internally be printed double-sided."

LANE SNOWVILLE

FIGURE 1

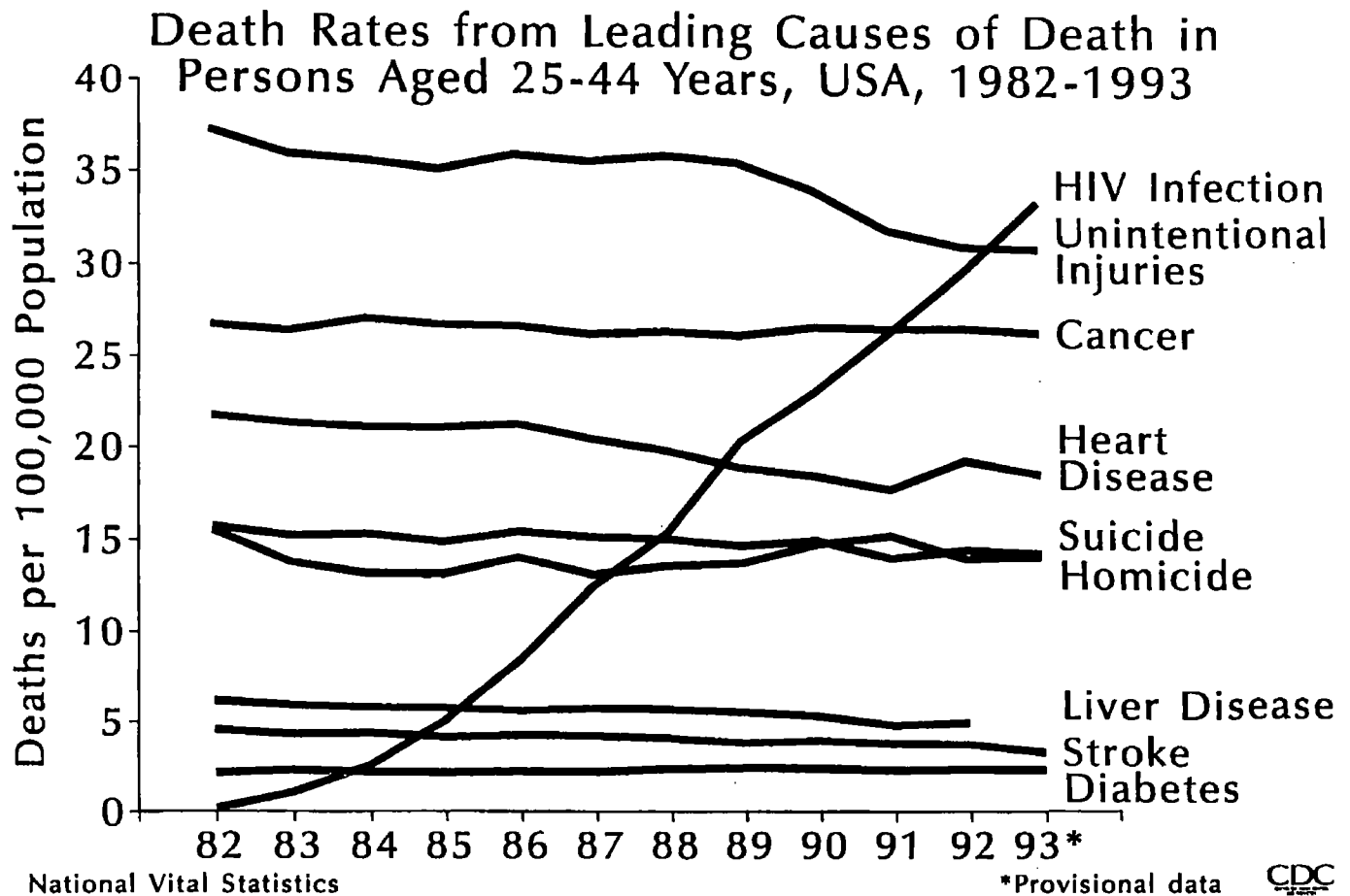
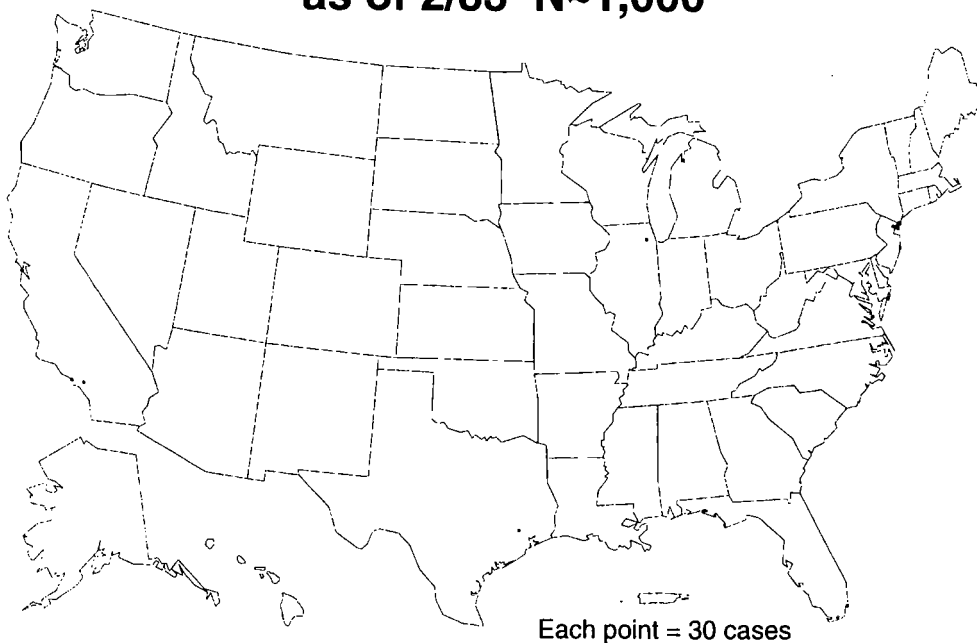
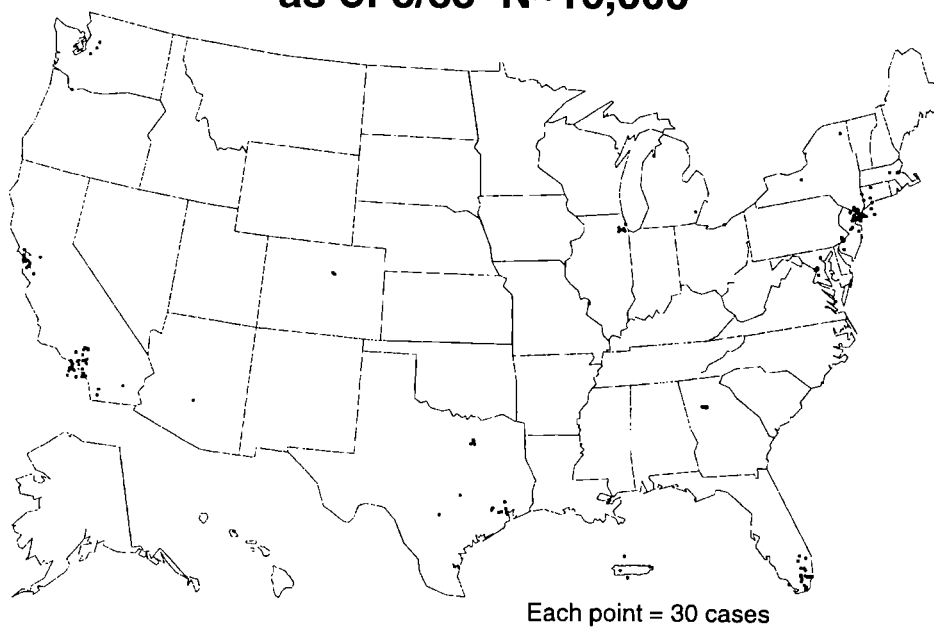


FIGURE 2

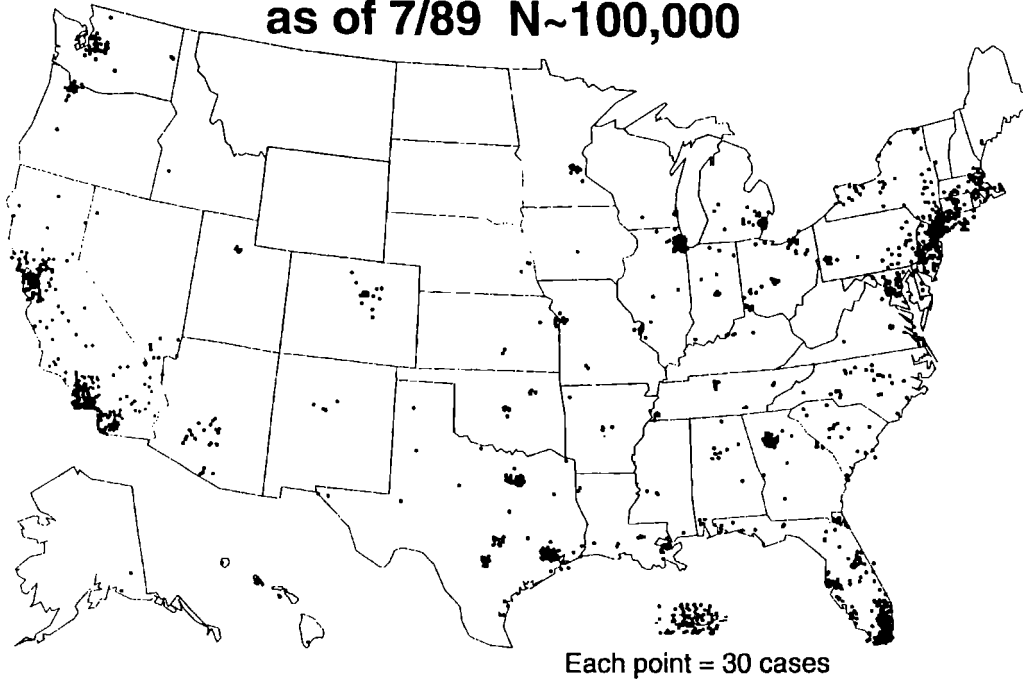
**Cumulative U.S. AIDS Cases
as of 2/83 N~1,000**



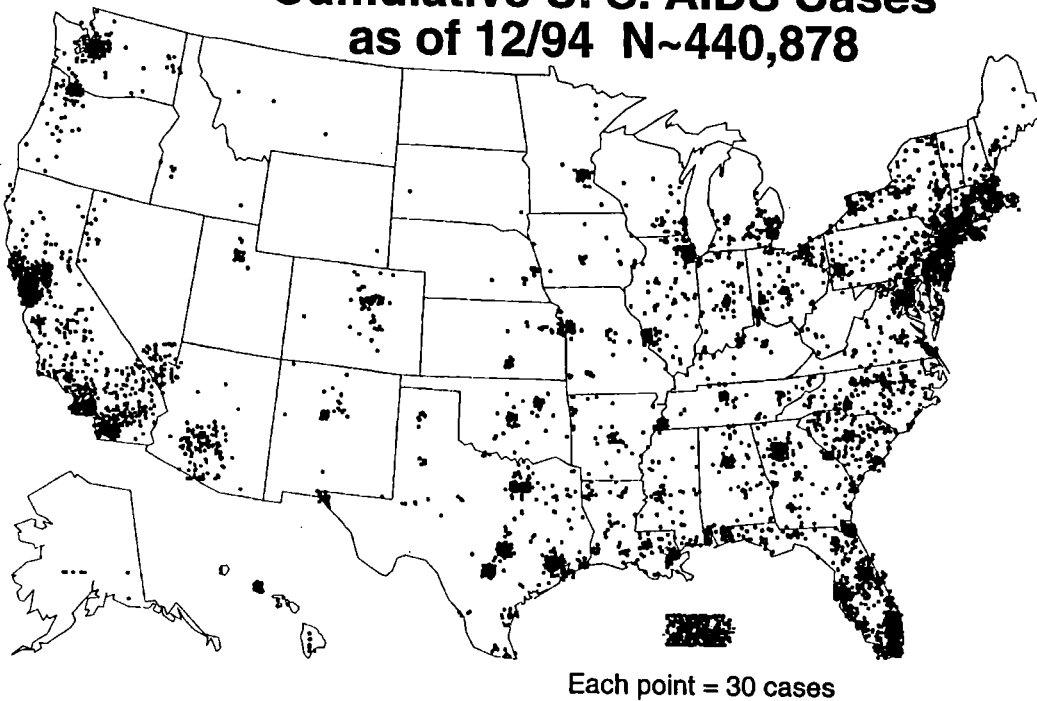
**Cumulative U. S. AIDS Cases
as of 5/85 N~10,000**



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



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



The National AIDS Strategy

Confidential Draft for Review by the Presidential Advisory Council on HIV/AIDS

DETERMINED TO BE AN ADMINISTRATIVE

MARKING INITIALS: Nr DATE: 3/17/19
2018-0755-F

The National AIDS Strategy Draft

September 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**

TABLE OF CONTENTS

MESSAGE FROM THE NATIONAL AIDS POLICY DIRECTOR	3
I. INTRODUCTION	6
II. OVERVIEW OF FEDERAL EFFORTS	9
<i>Prevention</i>	<i>9</i>
<i>Research</i>	<i>16</i>
<i>Care and Services</i>	<i>22</i>
<i>Civil Rights</i>	<i>27</i>
<i>International Activities</i>	<i>30</i>
<i>Translation of Research Advances into Practice</i>	<i>33</i>
<i>Endnotes</i>	<i>36</i>
<i>Figures</i>	<i>38</i>
III. APPENDICES	
<i>Appendix A: Prevention</i>	<i>A-1</i>
<i>Appendix B: Research</i>	<i>B-1</i>
<i>Appendix C: Care and Services</i>	<i>C-1</i>
<i>Appendix D: Civil Rights</i>	<i>D-1</i>
<i>Appendix E: International Activities</i>	<i>E-1</i>
<i>Appendix F: Translation of Research Advances into Practice</i>	<i>F-1</i>
<i>Appendix G: Acronyms List</i>	<i>G-1</i>
<i>Appendix H: Members of the Interdepartmental Task Force on HIV and AIDS</i>	<i>H-1</i>
<i>Appendix I: Summary Budget Table</i>	<i>I-1</i>

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

The epidemic of HIV and AIDS constitutes a public health crisis of unprecedented proportions. In 1993, the Office of National AIDS Policy (ONAP) was created by President Clinton to provide a national focus and direction for the 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.

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

- **To provide strong continuing support for HIV-related research in order to find more effective treatments, a preventive vaccine to protect the uninfected, and a cure for those currently infected;**
- **To provide strong continuing support for effective AIDS prevention efforts to continue to reduce the number of new HIV infections in adults and children in**

the U.S. and worldwide;

- **To ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs;**
- **To ensure that people living with HIV are not subject to discrimination;**
- **To provide strong continuing support for international efforts to address the HIV epidemic; and,**
- **To ensure that research advances are translated into improved HIV prevention programs and better care for HIV- positive persons.**

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

reached and new challenges emerge. This Strategy provides a reference point for continuing dialogues and collaborative efforts between the public and private sectors that are necessary to meet our national goals and objectives.

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

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

The National AIDS Strategy was drafted in consultation with, and with guidance from, numerous groups and individuals. Within the Federal government, this effort began at the Agency level. Members of the Interdepartmental Task Force on HIV and AIDS (IDTF), representing all Federal Agencies involved in the national response

to HIV and AIDS, identified their HIV-related goals, objectives, and highlighted areas requiring special attention. Individuals living with HIV and AIDS, their families, friends, loved ones, and care givers made vital contributions to this Strategy. Numerous non-governmental groups and organizations have also been consulted, including the Presidential Advisory Council on HIV/AIDS, participants in the 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. 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. We have, nonetheless, 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. Ultimately, HIV is a disease that we can defeat -- just as we have eradicated smallpox from our planet and polio from the western hemisphere. The National AIDS Strategy provides a foundation for the continuing public-private partnerships that are essential

~~*The National AIDS Strategy*~~
Confidential Draft for Review by the Presidential Advisory Council on HIV/AIDS

to our success. 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 against HIV:

- **To provide strong continuing support for HIV-related research in order to find more effective treatments, a preventive vaccine to protect the uninfected, and a cure for those currently infected;**
- **To provide strong continuing support for effective AIDS prevention efforts to continue to reduce the number of new HIV infections in adults and children in the U.S. and worldwide;**
- **To ensure that people living with HIV have access to services that**

are affordable, of high quality, and responsive to their needs;

- **To ensure that people living with HIV are not subject to discrimination;**
- **To provide strong continuing support for international efforts to address the HIV epidemic; and,**
- **To ensure that research advances are translated into improved HIV prevention programs and better care for HIV-positive persons.**

Scope of the HIV/AIDS Epidemic

The epidemic of Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) presents unique social, economic, and public health challenges to governments and individuals here in the United States and around the world. While significant progress has been made in understanding the disease and developing treatments since the first case was reported in the U.S. in June 1981, HIV remains a deadly infection for which there is no vaccine, no cure, and for which there is an expanding, but still limited, inventory of available treatments. An average of 100 Americans are diagnosed with AIDS every day and a similar number of men, women, and children become infected with HIV every 24 hours. 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).

AIDS is a costly disease. Average lifetime costs of medical care after diagnosis with HIV are \$119,000.³ 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.

Globally, the toll of the epidemic is much greater and threatens to reverse decades of economic and public health progress in developing countries. The Joint United Programme on HIV and AIDS (UNAIDS) and the World Health Organization (WHO) estimate that 27.9 million people have been infected with HIV. Since the beginning of the pandemic, 6 million people, including

1.6 million children, have been diagnosed with AIDS. By the year 2000, WHO projects that between 30 million and 40 million people will have been infected with HIV and 10 million to 15 million children will be orphaned due to AIDS.

II. OVERVIEW OF FEDERAL EFFORTS

The scope and nature of the HIV/AIDS epidemic have drawn States, local governments, academic institutions, private foundations, health care institutions, 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 proposed to increase spending for AIDS research, prevention, income maintenance, and care by 49 percent. Funding proposed for the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act in the FY 1997 Budget has increased by 157 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 in the FY 1997 budget has increased by 21 percent and AIDS prevention funding has increased by 12 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 accelerated. A community-based planning process has empowered local communities to develop innovative AIDS prevention programs. Eligibility for Social Security disability benefits for people with AIDS 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 between

40,000 and 60,000 people each year.

Sentinel accomplishments in prevention of HIV include:

- o Publication in *Morbidity and Mortality Weekly Report* by the Centers for Disease Control and Prevention (CDC) in 1981 of the first AIDS cases;
- o Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the risk factors associated with HIV infection;
- o Due to NIH-sponsored research, demonstration that administration of AZT can prevent transmission of HIV from an infected mother to her newborn; and,
- o 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:

- o Proposing to increase funding in the FY 1997 Budget for AIDS prevention at HHS by 27 percent (since FY 1993);
- o Launching the community planning partnership -- empowering local communities to develop innovative prevention efforts;

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

There have been advances in integrating primary prevention into health care service systems. The Health Resources and Services Administration (HRSA) and the Department of Veterans Affairs (VA) have encouraged broader access to 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:

- o Improving understanding of trends in

HIV transmission and seroprevalence;

- o Improving scientific knowledge about effective prevention models and strategies;
- o Strengthening community-based programs;
- o Integrating HIV and other prevention efforts; and,
- o Targeting vulnerable populations

■ *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 shortcoming, 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

intervention in real-world settings 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 intervention -- 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 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.

■ ***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.

Substance Abuse. HIV transmission is intimately 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:

- o *Integration of HIV prevention into*

substance abuse treatment and prevention programs. In August 1996, at the request of President Clinton, the Public Health Service agencies jointly co-sponsored a national meeting of state and local officials, researchers, and community experts from the fields of HIV and substance abuse to develop an action plan to more effectively integrate HIV and substance abuse prevention efforts. These agencies are committed to implementing this strategy in the year ahead.

- o *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.
- o *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.
- o *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.⁴ abusers.

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, prisoners, and substance abusers. 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

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:

- o Identification of HIV as the etiologic agent for AIDS;
- o Development of a reliable test to determine exposure to HIV;
- o 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;
- o Approval of AZT, the first treatment of HIV primary infection;
- o Development by the Food and Drug Administration (FDA) of a system of expedited review,⁵ initiated in 1992, of treatments for life-threatening diseases, including HIV; and
- o 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.

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

- o Proposing in the FY 1997 Budget to increase AIDS research funding at DHHS by 27 percent (since FY 1993);
- o 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;
- o Accelerating AIDS drug approval to record times;
- o 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;
- o Approving in record time a promising new class of AIDS drugs known as protease inhibitors;
- o Launching a four-year, \$100 million research effort to develop effective topical microbicides;

- o Developing the first Federal Plan for Biomedical Research on HIV and AIDS to improve coordination of HIV-related research; and
- o 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

The National AIDS Strategy

Confidential Draft for Review by the Presidential Advisory Council on HIV/AIDS

cure and a preventive vaccine. To accomplish this national goal, we must address four ongoing challenges:

- o Provide leadership and coordination for the Federal research effort;
- o Develop biomedical interventions that prevent HIV infection, including both vaccines and microbicides;
- o Develop new and more effective therapies for HIV and related conditions; and
- o 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 and coordination, first among the 24 institutes, centers, and divisions of the NIH, and second among the various Departments and Agencies throughout the government that support HIV research.

The strengthened authority and new leadership of the NIH Office of AIDS Research and the first Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS form the basis for better coordination of our research effort and provide the assurance that key questions are

being answered systematically and without duplication. Over the next year, the 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:

- o Increase NIH support for basic science through investigator-initiated research;
- o Establish a restructured trans-NIH vaccine research effort;
- o Augment research efforts to better understand the human immune system;
- o Develop a comprehensive NIH HIV prevention science agenda, combining biomedical, behavioral, and social interventions; and,
- o 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.⁶

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:

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

- o *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.
- o *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.

- o *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.⁷

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:

- o 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).

- o 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.
- o Title IV seeks to increase the availability of research, care and services for women, infants, children, and youth in a community-based family-centered system of care.

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

- o Signing the Ryan White CARE Act Amendments of 1996, and proposing to increase Ryan White CARE Act funding by 157 percent since FY 1993;
- o More than doubling Federal funding for State AIDS Drug Assistance Programs, which assist uninsured and underinsured individuals purchase prescription drugs;
- o Proposing to increase funding for

HOPWA in the FY 1997 Budget by 96 percent since FY 1993;

- o Fighting 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,
- o 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:

- o Maintaining HIV-related care and services as an investment priority in budgeting in the context of a balanced Federal budget: fighting to

preserve Medicaid and continuing to seek funding for CARE Act and HOPWA programs.

- o 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.

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.⁸ 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 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 efforts to improve integration will be continued and expanded, with special attention to linking HIV and substance abuse prevention and services.

Improving Quality of Care. Federally-supported programs can and should consistently provide high-quality care. Ensuring consistency in care delivery requires increased training for health care professionals and greater accountability through the use of performance measures for quality care. It is also essential that practical information on research advances for practicing clinicians and their patients be provided in a timely manner. (See Section Translation of Research Advances in Practice.) HRSA and HCFA will continue to offer guidance to grantees and the States regarding maintaining the quality and standard of care appropriate for people living with HIV. To this end, during FY 1997, the Office of HIV/AIDS Policy at HHS is undertaking a program to develop clinical practice guidelines in conjunction with other government Agencies and private-sector clinicians.

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

D. CIVIL RIGHTS

"Every person with HIV or AIDS is someone's son or daughter, brother or sister, parent or grandparent. We cannot allow discrimination of any kind to blind us to what we must do."

**President Clinton, May 20, 1996
Signing of the Ryan White
CARE Act Reauthorization**

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

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

- o 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
- o 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:

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

- o Vigorously enforcing Section 504 of the Rehabilitation Act of 1973 as it pertains to recipients of DHHS funds such as hospitals, nursing homes, and social service agencies;
- o Forcefully opposing the "Dornan Amendment," which would have required the discharge of all military personnel who are living with HIV. President Clinton declared his belief that the proposal is unconstitutional and directed the Department of Justice not to defend it if challenged in court. The President led a successful effort to repeal the "Dornan Amendment" and continues to oppose its enactment;
- o Establishing an HIV/AIDS education program available to all Federal workers; and
- o 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 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

The National AIDS Strategy

Confidential Draft for Review by the Presidential Advisory Council on HIV/AIDS

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

E. INTERNATIONAL ACTIVITIES

"The American people need to know that everybody in this country and, indeed, throughout the world, is now vulnerable to this disease."

**President Clinton, December 5, 1996
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.⁹ 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:

- o Providing initial funding and key leadership for the creation of the Global Programme on AIDS at the World Health Organization (WHO) in 1987; and
- o 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).¹⁰ 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:

- o The National Institutes of Health (NIH) supports a broad range of efforts including a "Clinical Alerts" mechanism for the dissemination of clinical trials results to health professionals, the media, and the public;
- o 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;
- o NIH supports publicly available computerized databases such as AIDSDRUGS, AIDSTRIALS, and AIDSLINE;
- o The toll-free 1-800 TRIALS-A AIDS Clinical Trials Information Service (ACTIS) is co-sponsored by NIH, CDC, and FDA;

- o The Centers for Disease Control and Prevention disseminates information through the National AIDS Hotline (1-800-342-AIDS); its toll-free 1-800-HIV-0440 HIV/AIDS Treatment Information Service (ATIS); and the National AIDS Information Clearinghouse;
- o The CDC also develops and issues guidelines for health professionals through its *Morbidity and Mortality Weekly Report*;
- o 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,
- o 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.¹¹ Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.¹² To reverse this pattern, the Administration is fighting to restore funding for the AIDS Education and Training Centers, which play a vital role in training providers. Achieving this goal will also require a renewed emphasis on HIV on the part of medical schools, professional organizations, and individual clinicians.

Disseminating Guidelines. One of the most difficult tasks for clinicians and patients is interpreting the patchwork of data and articles regarding treatments and converting it into a therapeutic strategy for their patients. With every research breakthrough, this task becomes more difficult. It is essential that practical information for practicing clinicians and their patients be provided in a timely manner. To this end, during FY 1997, the Office of HIV/AIDS Policy at HHS is undertaking a program to develop clinical practice guidelines in conjunction with other government Agencies and private sector clinicians.

Improving Coordination of Federal Activities. Enhancing coordination of information dissemination activities among Public Health Service Agencies is an important priority. Within DHHS, the Office of HIV/AIDS Policy (OHAP) has the lead responsibility for coordinating the HIV-related activities of the Public Health Service Agencies. Ensuring that information about a research breakthrough is easily available, reaches the appropriate people and organizations, and that policies and standard-of-care practices for Federally-sponsored programs are modified to reflect the 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 make a difference.

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. Personal communication from the Centers for Disease Control and Prevention, Division of TB Elimination, 1995.
5. 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.
6. Alan B. Stone, and Penelope J. Hitchcock. Vaginal Microbicides for Preventing the Transmission of HIV. *AIDS* 1994, 8 (suppl 1):S285-S293.
7. Agency for Health Care Policy and Research: Data from the Screener Questionnaire, AIDS Cost and Services Utilization Survey. 1991.
8. Housing and the HIV/AIDS Epidemic: Recommendations for Action. National Commission on AIDS. Washington, D.C. July 1992.
9. *HIV/AIDS Policy Guidance*. U.S. Agency for International Development. September 1995.
10. 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.

11. 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.

12. 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)

```
*****
* User name:   SANVILLE_U (3)                Queue:  ONAPC/HP4-1060      *
* File name:   Server: HP4-1060                *
* Directory:   *
* Description: Reflection 2                      *
*             September 6, 1996                  9:17pm      *
*****
*
*      SSS      A      N      N V      V      III      L      L      EEEEE      U      U      *
*      S      S      A A      N      N V      V      I      L      L      E      U      U      *
*      S      A      A NN      N V      V      I      L      L      E      U      U      *
*      SSS      A      A N N N V      V      I      L      L      EEEE      U      U      *
*      S      S AAAA      N      NN V      V      I      L      L      E      U      U      *
*      S      S A      A N      N      V V      I      L      L      E      U      U      *
*      SSS      A      A N      N      V      III      LLLLL LLLLL EEEEE      UUU      *
*
*
*
*****
*
*      L      SSS      TTTTT      *
*      L      S      S      T      *
*      L      S      T      ::      *
*      L      SSS      T      ::      *
*      L      S      T      *
*      L      S      S      T      ::      *
*      LLLLL      SSS      T      ::      *
*
*
*****
```

LAST LAUGHS:

Jay Leno: "During a campaign speech yesterday to US veterans, Ross Perot said if he's commander-in-chief he'll have two signs on his desk, two signs. One reading first, 'Commit the nation.' The second one reading, 'Then commit the troops.' If Ross Perot is elected, we need a third sign, 'Commit the President.'"

Jay Leno: "Surprisingly, Ross Perot is doing well in several states. I believe they are denial, paranoia and delusion."

Jay Leno: "Looks like poor old Bob Dole has lost all the Republican convention momentum he had going there. He's down 21 points in the polls. But he said today, 'Those 21 points could swing overnight.' Oh, yeah. Then he'd be down 42 points."

Jay Leno: "Last week, Clinton campaign strategist Dick Morris was on the cover of Time magazine. You know that huge story, the cover of Time. Then he was caught on that hooker. This week he's on Time and Newsweek. It's strange country we live in, isn't it? You're barking out orders to the President; that gets you on one cover. But barking like a dog with a hooker in a hotel room gets you on two covers."

Jay Leno: "Sherry Rowlands, this is the prostitute Dick Morris was with. She said on 'Hard copy' last night, she said, 'He liked to be dominated. That's why he was barking.' He liked being treated like a dog. That's what he said. The guy liked being treated like a dog. Isn't that amazing? You realize, Dick Morris might be the first guy in history ever to get hit on the nose with a rolled up copy of the same magazine he's on the cover of. What are the odds?"

Conan O'Brien: "President Clinton's former strategist Dick Morris -- you know, this is the guy involved in the sex scandal. Well, he announced that he's writing a book. Yeah, and it's called 'Washington, D.C., On \$200 An Hour.'"

FIGURE 1

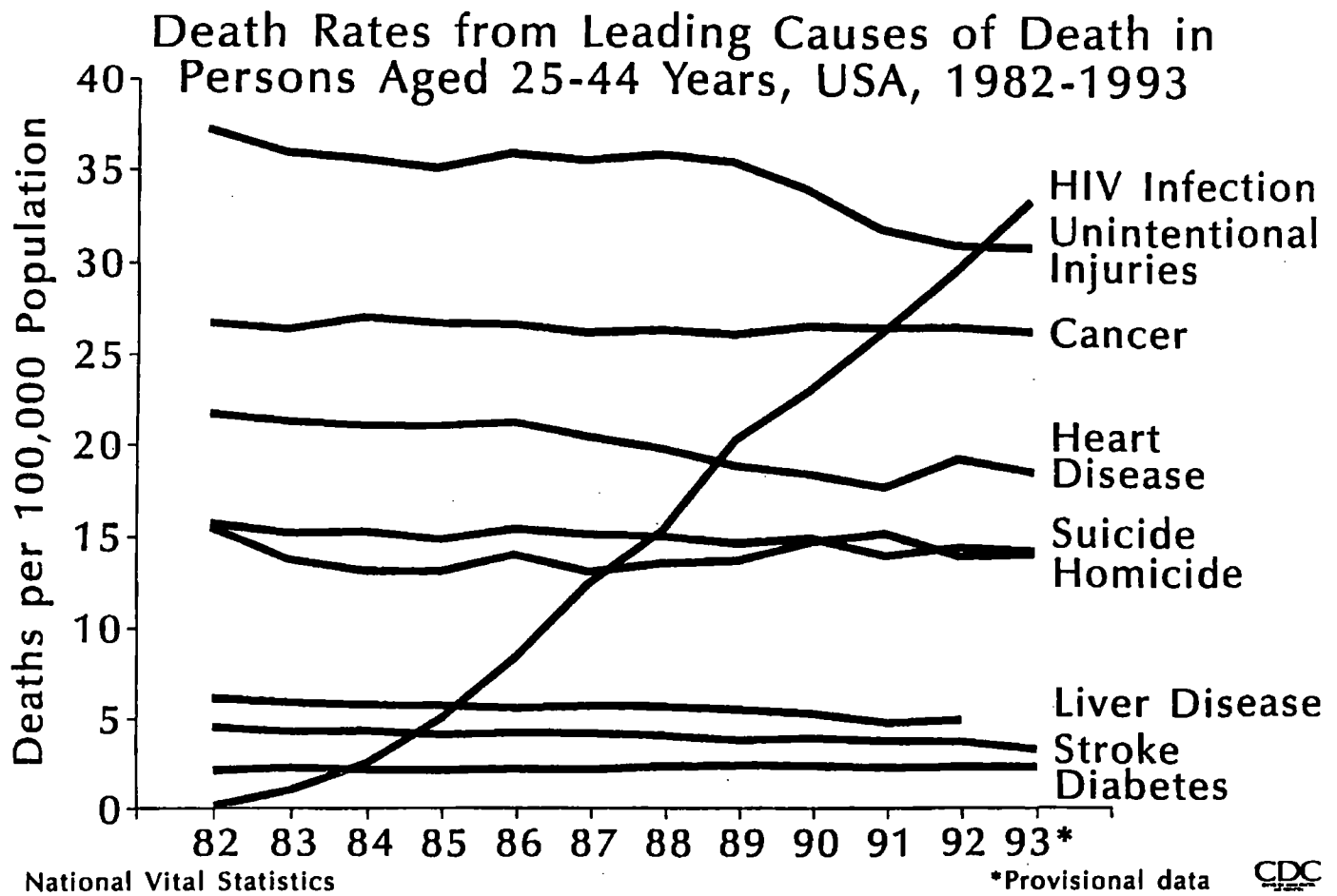
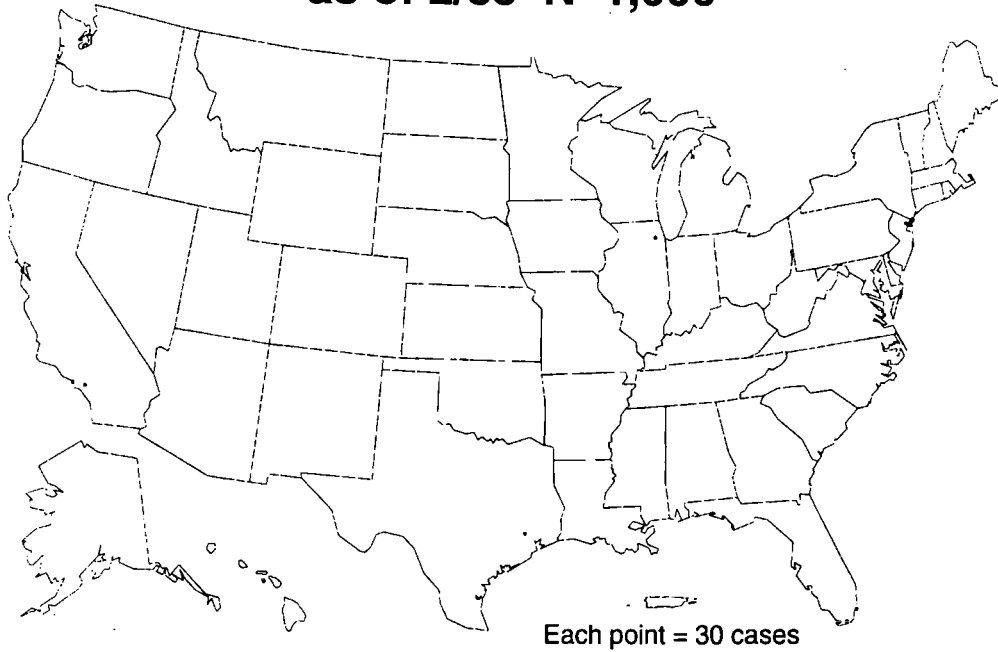
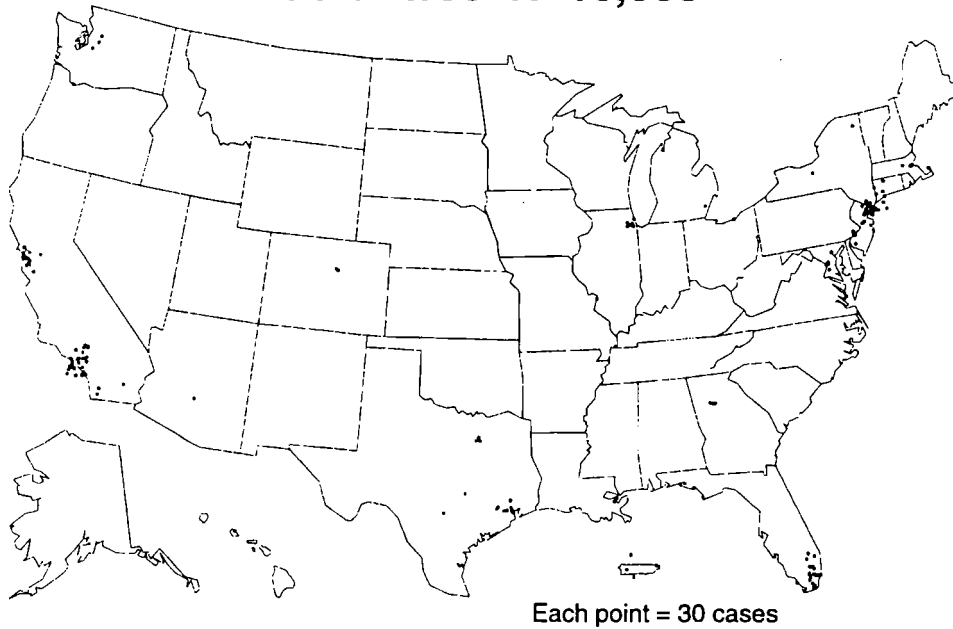


FIGURE 2

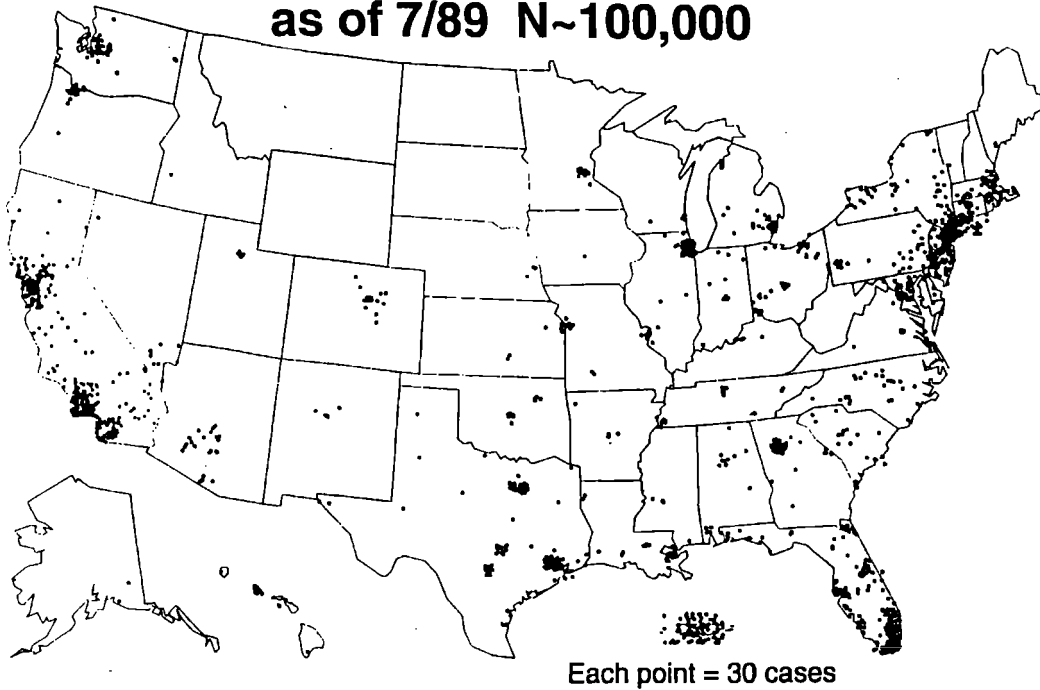
**Cumulative U.S. AIDS Cases
as of 2/83 N~1,000**



**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**

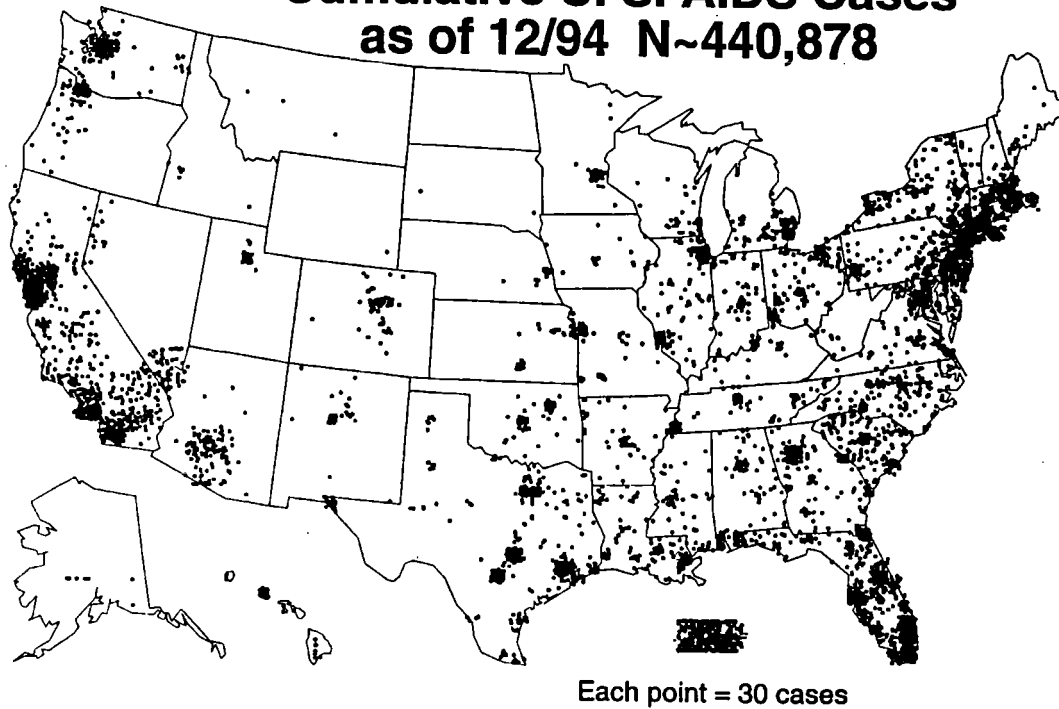


TABLE OF CONTENTS

MESSAGE FROM THE DIRECTOR OF THE OFFICE OF NATIONAL AIDS POLICY

I. INTRODUCTION

II. OVERVIEW OF FEDERAL EFFORTS

Introduction

Prevention

Research

Care and Services

Civil Rights

International Activities

Translation of Research into Practice

III. APPENDICES

Appendices A - F (Prevention, Research, Care and Services, Civil Rights, International Activities, and Translation of Research into Practice,)

Appendix G Budget Tables

IV. FIGURES, ACRONYMS, AND MEMBERS OF THE INTERDEPARTMENTAL TASK FORCE ON HIV AND AIDS

Figure 1 Death Rates from Leading Causes of Death in Persons Aged 25-44 Years, USA, 1982 -1993

Figure 2 Cumulative U.S. AIDS Cases: 2/83 through 12/94

Acronym List

Members of the Interdepartmental Task Force on HIV and AIDS

→ National Commission → quote on plan

→ HHS / Jeremy

→

Friday am → full new draft
→ PF + Jeremy

C.O.B Monday to HHS →

12th →

19th

~~only 50% of PM~~

An → Δ → ↓

Aug 23rd Ph

RS on
leave
Sept 1st

Press Release
Exec. Summary

RS will write kept.

Media

- August 6th - 3:00 late for the group?

CP: 10/6/66

Kennedy / Kassebaum → C+S

Final
Media
Plan

Message from the Director of the Office of National AIDS Policy

The epidemic of HIV and AIDS constitutes a public health crisis of unprecedented proportions. In 1993, the Office of National AIDS Policy (ONAP) was created by President Clinton to provide a national focus and direction for the government's response to HIV and AIDS. More recently, President Clinton asked ONAP to develop a comprehensive National AIDS Strategy that would chart the Administration's long-term direction in responding to the national and international epidemic. The National AIDS Strategy has been developed to capitalize upon progress already made in fighting the epidemic and to catalyze collaborative efforts among Federal Departments and Agencies, communities, State and local governments, and the private sector.

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

- To provide strong continuing support for research in order to find additional treatments, a cure for those currently infected, and a preventive vaccine to protect the uninfected;
- To provide strong continuing support for effective prevention strategies to reduce the number of new infections each year until there are no new infections;
- To ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs; and,
- To ensure that people living with HIV are not subject to unlawful discrimination.

This document is a snapshot of where we are as a Nation and where we think we need to go in achieving these national goals. It summarizes some of the key achievements of this Administration's scientific and public health professionals and it identifies key areas for further work. In addition, the appendices provide detailed descriptions of programmatic objectives, linking goals to budgets of all Federal government efforts in the five key areas of HIV policy: prevention, research, care and services, civil rights, international activities, and translation of research into practice.

This is intended to be a living document that will require regular updating and adjustment as goals are reached and as new challenges emerge. The Strategy serves as a reference point for lengthier

dialogues and collaborative efforts between the public and private sectors that will be necessary to implement this strategy.

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

The Strategy was developed through consultation with, and guidance from, many groups and individuals. The Executive Branch Agencies represented on the Interdepartmental Task Force on HIV and AIDS (IDTF) identified their HIV-related goals, objectives, and highlighted areas requiring special attention.

In developing the document, we have relied heavily on groups outside of government as well -- they, too, have been, and will continue to be, essential partners in developing solutions that capitalize on the opportunities for progress that are now before us. The Presidential Advisory Council on HIV/AIDS (PAC) recommendations have been invaluable. In addition, the advocacy community, participants in the White House Conference on HIV and AIDS and the regional briefings around the Nation co-sponsored by ONAP and the National AIDS Fund, Funders Concerned About AIDS, health care and service providers on the front lines of the epidemic, and many HIV-positive persons, their families, friends and care givers have been instrumental in identifying areas that require special attention. The insights provided by the National Commission on AIDS, the Institute of Medicine and National Research Council, the General Accounting Office, and the reports of the Office of Technology Assessment have also been extraordinarily helpful in developing the National AIDS Strategy.

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

I. INTRODUCTION

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 worldwide. While significant progress in understanding the disease and developing treatments has been made since the first case was identified by the Centers for Disease Control and Prevention (CDC) in June 1981, with this progress comes the challenge of preventing new infections, ensuring access to new treatments, and assuring that health care professionals know how to care for their patients. Still, HIV remains a deadly infection for which there is no vaccine, no cure, and for which there is an expanding, but still limited, inventory of available treatments.

An Expanding Public Health Threat

As of December 1995, the Centers for Disease Control and Prevention (CDC) reported 513,486 cases of AIDS among persons in the U.S.; 319,849 of these persons have been reported to have died as a result of complications related to HIV. Since 1987, AIDS has gone from being the 15th ranked cause of death among all Americans to the 8th. AIDS strikes those in the prime of life during their most economically productive years. It 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 to the CDC. More than 46,000 AIDS related deaths were reported to the CDC in 1994. CDC estimates that between 40,000 and 60,000 Americans are becoming newly infected with HIV each year, and that between 650,000 and 900,000 Americans are currently living with HIV.

As the epidemic in the United States has expanded, the demographics of the epidemic have changed. The early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers (i.e., New York, San Francisco, and Los Angeles). Today, this group represents less than half of all new cases. Among the populations that are more heavily affected today are young gay men, women, and heterosexual injecting drug users and their partners as well as users of non-injecting drugs (i.e., crack cocaine and alcohol). Although gay men no longer represent the majority of new cases, this group still represents the majority of persons living with HIV and AIDS. 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 pediatric AIDS cases were reported.¹

Adolescents are at increased risk. CDC estimates that one in four new HIV infections in the U.S. occur among people under age 21. A significant number of young people are engaging in sexual intercourse as well as drug and alcohol use at earlier ages. This fact, coupled with the disturbing number of adolescents who are prone to high-risk behavior due to homelessness, sexual abuse, and other circumstances, places young Americans in a situation that leaves them extremely vulnerable to HIV infection.

Communities of color have been disproportionately affected by the epidemic. African-Americans, while representing approximately 12 percent of the general 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. 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. AIDS is not just an urban problem. The HIV epidemic has and continues to spread into suburban and rural areas, with especially dramatic increases in certain regions of the South and Midwest. Between January 1993 and December 1995 the largest numbers of AIDS cases (86,462) were reported from the South.¹ While most cases are still reported from urban areas, the rate of reported cases in non-metropolitan areas is increasing more rapidly than in urban areas. AIDS cases have now been reported in all 50 States, the District of Columbia, Puerto Rico, Guam, and each of the U.S. territories. (See Figure 2.)

AIDS is a costly disease. Average lifetime costs of medical care after diagnosis with HIV is \$119,000 (re-add footnote; check for Vancouver numbers). This compares with cancer (\$25-\$42,000) and heart disease (\$61,211). In addition, people living with HIV are disproportionately dependent on the public sector for their health care. Nearly 50 percent of people with AIDS are on Medicaid; over 90 percent of children with AIDS are on this program. The Federal government alone spends \$1.7 billion (check) on Medicaid and \$xxx billion on Social Security benefits for people disabled by AIDS.

Globally, the toll of the epidemic is greater still and threatens to reverse decades of economic and public health progress in

¹ It is, however, believed that with greater use of AZT by HIV-positive pregnant women, the number of new cases in newborns can be reduced.

Re-write for RS review

August 7, 1996, 1:00 pm (n:\text4.g96)

developing countries. The Joint United Programme on HIV and AIDS (UNAIDS) and the World Health Organization (WHO) estimate that since the beginning of the epidemic, 6 million cases of AIDS have occurred worldwide. They also estimated that since the beginning of the epidemic 27.9 million people have been infected and more than 1.6 million children have been developed AIDS. WHO projects that by the year 2000 between 30-40 million people will have been infected with HIV. In addition, WHO estimates that 10 to 15 million children will be orphaned due to AIDS by the year 2000.

II. OVERVIEW OF FEDERAL EFFORTS

"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*

The scope and nature of the HIV/AIDS epidemic have drawn States, local governments, academic institutions, private foundations, health care institutions and community-based organizations and the Federal government into many HIV-related activities. The Federal government, through its public health responsibilities in such areas as research, prevention, health care, and housing has seen a dramatic increase in its activities since the beginning of the epidemic. In 1985 the Federal government spent \$212 million for AIDS research, surveillance, and care. With the dramatic increase in cases, by 1995 that figure had reached \$6.8 billion. (See Appendix G).

We must renew our vision for ending this epidemic. The sections that follow focus on the six major policy areas (i.e., prevention, research, care and services, civil rights, international activities, and the translation of research into practice), accounting our accomplishments and charting our future opportunities for future progress.

A. PREVENTION

"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

Insert 'vision language'.

1. Record of Accomplishment

The Nation has made advances in preventing new HIV infections. Since January 1993 the Federal government has:

- Increased funding for AIDS prevention by 24 percent in four years;
- Launched the community planning partnership, which empowers local communities to make decisions about the distribution of AIDS prevention funding;
- Launched the Prevention Marketing Initiative, focusing on the risk to young adults (18 to 25) with frank public service announcements recommending sexual abstinence and the correct and consistent use of latex condoms; and
- Reorganized AIDS prevention efforts at the Centers for Disease Control and Prevention to foster greater coordination with efforts to reduce sexually transmitted diseases and tuberculosis.

The efforts of Federal Agencies (see Appendix A) have been instrumental in expanding our knowledge base about HIV prevention. The Centers for Disease Control and Prevention (CDC), the Agency with primary Federal HIV surveillance and prevention responsibilities, has been pivotal in identifying trends in the epidemic. It was CDC that identified the risk factors associated with HIV transmission in 1981. Research conducted at the National Institutes of Health (NIH) identified the etiologic agent. As a result of this work, we now know the risk factors, have a test to ascertain HIV serostatus and can, therefore, protect the blood supply with a high degree of certainty.

Federal efforts have shown that HIV prevention programs can be effective. CDC's prevention projects, many in partnership with States, local governments, and community-based organizations, have demonstrated that prevention programs are most effective when

designed and implemented at a local level. Biomedical, behavioral, and social science prevention research conducted and supported by the National Institutes of Health (NIH) has expanded and will continue to expand our understanding of the determinants of HIV-related risk behavior.

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

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

2. Future Opportunities for Progress

Despite these advances, significant challenges remain if we are to reach the nation's prevention goal. Prevention priorities must be guided toward gaining knowledge that improves efforts to develop effective prevention programs. Inclusive in this process, we need to:

- improve our understanding about the major modes of transmission;
- close gaps in scientific knowledge, which includes identifying effective prevention models and strategies; and
- eliminate gaps in program areas.

a. Improving Understanding of Modes of Transmission

An important aspect of strengthening prevention activities is to

Re-write for RS review

August 7, 1996, 1:00 pm (n:\text4.g96)

have a clearer understanding of those who are becoming infected and what behaviors are placing people at risk for infection. Recent epidemiologic data show that the HIV epidemic continues to spread most rapidly among people who engage in injection drug use, their sexual partners, women, young and minority men who have sex with men, through heterosexuals and infants through perinatal transmission. These trends in the epidemic must continue to be considered when prioritizing prevention research and service programs.

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

There are, however, opportunities for refinement. Effective prevention intervention programs begin with sound information about who is at risk. Current CDC surveillance systems do not capture sufficient "front-end" information on the incidence and prevalence of HIV, prior to an AIDS diagnosis, in the population, and trends in modes of transmission, and new infections. (These data must be collected with the appropriate confidentiality protections. CDC is exploring innovative approaches for collecting HIV incidence information without mandatory testing; these effort must continue.) Collection of these data are needed as part of an enhanced effort to link surveillance and epidemiological data to priority setting, in addition to the design and evaluation of prevention programs.

The CDC recognizes the value of this combined approach and has incorporated data collection design into its community planning process. Still, shifts in data needs may also require that CDC reevaluate and reconfigure certain of its data collection efforts. As part of the Agency's implementation of the recommendations set forth in the external review of CDC's HIV prevention strategies², CDC has initiated efforts to evaluate current data collection efforts and implement necessary changes. This work should continue.

b. Prevention Research: Closing Gaps in Scientific Knowledge²

²Information on NIH-supported behavioral and epidemiological research relevant to primary prevention can be found in Appendix B: Research.

Factors that place individuals at risk for acquiring HIV infection entail a complex combination of behavioral, social, cognitive, and biological influences. Given this complexity, we must not *assume* to intuitively know which interventions will work, but instead must base our efforts on sound research findings and evaluation. The three main areas where gaps in knowledge have been identified are: basic behavioral research, intervention research, and social marketing research.

Basic Behavioral Research. Information provided by basic behavioral research should serve as the foundation for prevention programs. To capitalize on what is known and to improve HIV prevention programs that are targeted to reach diverse populations of Americans, more information on the determinants of HIV-associated sexual and drug-using behaviors is needed. Such data enable scientists to establish theories of behavioral change, which then provide researchers with tools for identifying approaches that may be most effective for an individual or a community.³

Intervention Research. A second major gap in prevention research is research to improve prevention interventions, i.e., studies that concentrate on modifying behaviors, such as those related to drug use and sexual practices. In HIV and AIDS, this intervention research can focus on both individuals and communities, each of which often adhere to norms that influence personal behavior. Since the beginning of the epidemic we have made advances in our understanding of factors that are relevant to the design of intervention programs intended to reduce rates of HIV infection.

However, despite these indications of success, there is more that we need to know if we are to develop effective prevention programs. We must incorporate findings from basic behavioral research into effective prevention interventions. Agencies supporting intervention and behavioral research must include scientists from a broad range of disciplines in their planning activities and improve their data-sharing and collaborative efforts with Agencies responsible for implementing prevention programs. Intensifying the dialogue between researchers in these two related fields will improve the development of effective prevention interventions.

Social Marketing Research. It is important that the findings from basic behavioral and intervention research serve as a foundation for prevention programs. Agencies supporting social marketing activities need to build on current knowledge in addition to strengthening efforts to understand barriers to the implementation and replication of promising prevention programs. Given the highly innovative nature of these endeavors, CDC must consider providing broader technical assistance and training to community

organizations. Moreover, a community-based effort that would test prevention models in a real-world setting should be carefully considered.

c. Strengthening Prevention Programs

In order to stop new infections, the results of basic behavioral, intervention, and social marketing research must serve as a foundation for prevention intervention programs that reach people at risk for acquiring or transmitting HIV. It is therefore important that prevention planners carefully prioritize local efforts based on who is and who is becoming infected.

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

One of the most important innovations in the prevention area is community planning. The community planning process is an outstanding model of a public-private partnership. Through this effort, it has been possible to establish joint goals for the prevention of HIV that are responsive to local needs. However, this process is early in its development and requires continuing significant leadership and technical assistance from CDC.

It is crucial that prevention research advances are widely disseminated and incorporated into prevention programs. Models of effective prevention interventions have been developed, but often this valuable information is not reaching those people developing, implementing, and evaluating prevention programs. (See Section on Translation of Research into Practice.)

Insert RS language on minority CEOs and technical assistance.

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

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

Handwritten:
* insert
into CP
stubs.

Re-write for RS review

August 7, 1996, 1:00 pm (n:\text4.g96)

integrate HIV prevention into current substance abuse programs and integrate substance abuse prevention into HIV prevention.

A key to controlling the spread of HIV among substance abusers is enrollment into drug treatment programs. Substance abuse treatment is a major form of HIV prevention. Moreover, substance abuse problems that contribute to the spread of HIV are not limited to injecting drug use; use of non-injectable drugs such as alcohol and crack cocaine can adversely influence risk-taking behavior.

Work on these issues has begun and will continue. CDC has initiated State-by-State discussion, including meetings with State Legislators and the National Conference of State Legislatures regarding HIV prevention issues. SAMHSA's new "Knowledge Development Application (KDA) Program" will address emerging issues in the fields of substance abuse and mental health, including a focus on HIV and AIDS. In addition, CDC, HRSA, NIDA, and SAMHSA are co-sponsoring a national meeting of State and local officials from the fields of public health and drug abuse prevention to develop an action plan that more effectively integrates HIV and substance abuse prevention efforts.

Treatment for Sexually Transmitted Diseases and Tuberculosis. Studies have shown that the presence of sexually transmitted diseases (STDs) can significantly increase the efficiency of HIV transmission, by as much as twenty-fold. Studies have also shown that widespread treatment of STDs in certain communities has led to a 40 percent reduction in new HIV infections in these groups.^{4,5} These data suggest treating STDs can be a very effective HIV prevention strategy and points to a need for all clinicians to be vigilant in efforts to prevent and treat STDs. NIH-supported research to further understanding of the effect of STD treatment on HIV transmission is underway and should continue.

It is important that Federal and State efforts to reduce the incidence of sexually transmitted diseases (STDs) include an HIV prevention element and that HIV prevention programs incorporate STD prevention and treatment efforts. The traditional model of targeting most STD prevention efforts towards individuals who have already contracted one STD is not necessarily effective for HIV prevention. Linkages between STD and HIV prevention efforts need to be established and where they do exist, enhanced.

HIV positive people are at very high for developing active tuberculosis (TB) disease. Studies suggest that the risk of developing active TB disease is 7 to 10 percent each year for persons who are infected with both TB and HIV, whereas the risk is

10 percent over a lifetime for persons not infected with HIV.⁶ In addition to the health implications for infected persons, there is an increased risk of transmission of TB to household members, health care workers, and other persons having regular contact with the person with active TB.

The newly organized National Center for HIV, STD, and TB Prevention at CDC demonstrates the importance of integrating the interdependent aspects of the epidemic and illustrates our determination to integrate and coordinate HIV, STD, and TB programs.

Integration Into Primary Care. To reach our prevention goal, we must also improve the integration of prevention activities and messages into primary health care services. HIV counseling and voluntary testing often provide an important bridge between HIV prevention and care for many at-risk persons, including youth, women, and ethnic minorities. To assure that all persons seeking HIV testing can have access to such services, CDC's counseling and testing guidelines should acknowledge and address the needs of persons seeking such services, and provide training for personnel at CDC-funded sites.

Incorporating a patient's sexual and drug use history when a medical history is taken, offering HIV-related counseling and voluntary testing, and providing prevention education to HIV positive individuals so they do not infect others is also important. In addition, to reduce perinatal transmission, all pregnant women should be offered HIV counseling and voluntary testing, and information about and access to AZT. Training should be made available to improve primary care providers' skill, comfort level and sensitivity in these areas.

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

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

Given that prisoners are often at increased risk for HIV infection, offering educational programs during incarceration provides a unique opportunity to reach these persons. Research has shown that individuals who are well informed about HIV and substance abuse issues do modify their risk-taking behaviors. It is important that

Re-write for RS review

August 7, 1996, 1:00 pm (n:\text4.g96)

the Federal government build upon the knowledge and opportunity that currently exists to further improve HIV prevention efforts for incarcerated persons.

Evaluation. It is important to assess the effectiveness of the prevention interventions that have or will be implemented. Prospectively set performance measures can be used as a basis for evaluation and program improvement and must become a routine part of all Federally-funded programs. It is only through sound evaluations that we will be able to determine whether our efforts have been effective in slowing the epidemic.

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 all the rest of us from the virus. A cure and a vaccine, that must be our first and top priority."

President Clinton, December 5, 1995

The White House Conference on HIV and AIDS

Concerns: this section is about more than biomedical research, it includes health services research, clinical effectiveness research, ...

The above quote -- "... to protect all the rest of us from the virus ..". Sets up them v. us situation. Would change to "... to protect us from the virus ..".

Insert 'vision language'.

1. Record of Accomplishment

The Nation has made significant HIV-related research advances the Administration has strived to provide solid ongoing support for the research effort.³ Since January 1993 the Federal government has:

- Increased AIDS research funding by 34 percent in four years;
- Signed the NIH Revitalization Act of 1993, creating a permanent Office of AIDS Research at NIH and vesting it with new authority to plan and carry out the AIDS research agenda;
- Accelerated AIDS drug approval to record times. (Since 1993, the Food and Drug Administration has approved 12 new AIDS drugs and two new diagnostic tests.)
- Worked aggressively to reduce transmission of HIV from mother to child;
- Launched a four-year \$100 million effort to develop microbicides to allow women to protect themselves from HIV.
- Charged Vice President Gore to work with drug companies and

³This section focuses primarily on biomedical and health services research. Discussion of behavioral and social science research is presented in the Prevention section.

AIDS researchers and advocates to accelerate AIDS drug development.

The Contributions of Research

The Nation has already realized benefits of supporting research in general and HIV-related research specifically. Several Federal Agencies play a significant role in U.S. AIDS research efforts. (See Appendix B.) The effort to understand HIV and AIDS has led to, and will continue to result in, scientific advances that benefit research on many other diseases. AIDS research has accelerated study of the human immune system. This basic immunologic information is being applied to research to better understand and treat many other diseases, such as cancer; autoimmune diseases, including systemic lupus erythematosus; type I diabetes mellitus; rheumatoid arthritis; and multiple sclerosis. AIDS research contributes to the prevention of other infectious diseases and provides a new paradigm for treatment of viral diseases.

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

HIV research has assisted in identifying new infectious agents that may be responsible for malignancies, such as the recent discovery of the etiologic agent for Kaposi's sarcoma. These findings may help to identify other oncogenic agents. HIV research has led to a better understanding of the mechanisms by which infectious agents and inflammatory cells cross the blood/brain barrier, providing valuable clues for research on Alzheimer's disease, dementia, multiple sclerosis, neuropsychological disorders, encephalitis, and meningitis. Moreover, prior to the AIDS epidemic, little investment was made in research to treat viral diseases. Studies to develop anti-HIV therapies have improved our understanding of additional viral diseases and led to development of treatments.

Efforts to develop drugs for the treatment of HIV have accelerated the development of methods of rational drug design using sophisticated techniques of structural biology and advanced computer imaging methods. These advances have implications for drug design for virtually all disorders. Comparative clinical trials of poxvirus vectors and vaccine adjuvants in HIV vaccine

candidates have supported safety information for cancer vaccines. Research on HIV-related wasting has provided important information for research on nutritional disorders, metabolic abnormalities, and gastrointestinal dysfunctions.

Due in great part to Federally-sponsored research, a number of new and exciting research advances have brought optimism and opened new areas for investigation. One of the recent research advances has been the development of a new class of drugs, known as protease inhibitors. When used in combination with other types of anti-retroviral drugs, there is the potential to dramatically reduce the amount of HIV in the bloodstream and possibly improve a person's clinical status and reduce transmission. A landmark advance in HIV prevention was the demonstration that AZT can dramatically reduce the risk of transmission of HIV infection from a pregnant woman to her child. Advances in effective treatments for HIV-related conditions can prolong and improve the quality of life of persons living with HIV. Breakthroughs in our understanding of the genes and proteins of the human immunodeficiency virus have allowed the development of increasingly effective anti-retroviral drugs.

In addition, the Food and Drug Administration, through its expedited review and accelerated approval programs, is now approving drugs faster than ever before. And recent planning efforts on the part of various Federal Agencies, such as the annual NIH plan for HIV-related research and the Federal Biomedical and Behavioral Research Plan for HIV and AIDS have improved the coordination of HIV research.

2. Future Opportunities for Progress

Despite these advances, many complex biomedical and behavioral challenges remain. However, we must ensure that the Nation capitalizes on the most promising scientific opportunities.

Coordinating Federal Research. Developing and implementing the Federal government's AIDS research agenda presents both scientific and logistical challenges. Planning and overseeing a Federal effort of this magnitude requires coordinating efforts at two levels: one within NIH and the second among the Departments and Agencies supporting HIV research.

Within NIH, research is supported throughout 24 institutes, centers, and divisions (ICDs). In order to better plan, coordinate, evaluate, and fund the AIDS research activities of these ICDs the Congress, through the NIH Revitalization Act Amendments of 1993, provided the Office of AIDS Research (OAR) with

new oversight and budget authorities. It is crucial that the authority granted OAR in the revitalization legislation, including the consolidated appropriation, be supported and maintained.

Add RS language about the Levine Report

For the government to effectively support a diversity of promising approaches, these research efforts must also be well-planned and coordinated. To achieve this the Director of the Office of National AIDS Policy created an inter-departmental working group, chaired by the Director of the Office of AIDS Research, charged with developing a coordinated plan and budget for HIV and AIDS research across all Agencies.

The first Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS was completed in April 1996. The development of this plan brought together representatives from the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Department of Defense, the Department of Energy, and the Department of Veterans Affairs. This plan provides an initial blueprint to focus and coordinate existing Federal HIV/AIDS research initiatives and thereby utilize available resources more efficiently and effectively. It also serves as a foundation for continued planning and evaluation.

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

On the scientific level, researchers are pursuing two approaches to vaccine development. Some scientists believe our best hope is gather more basic science information to guide us in vaccine development. Other researchers are conducting clinical efficacy trials in humans to find answers that will lead to the development of a successful candidate. This group believes that if a safe candidate is available, it is not necessary to resolve all of the scientific questions before proceeding, and, that in the face of a global emergency testing in people should begin immediately. Both groups have valid arguments.

Developing a vaccine cannot be accomplished by the government or the private sector working apart: a public-private partnership will be needed. In order to identify areas for fruitful collaboration and to accelerate the pace of development for vaccines, the Vice President convened a meeting of government scientists and leaders

of the pharmaceutical and biotechnology industries to identify barriers to the development of these agents. Further dialogue involving key players regarding critical problems, and opportunities for development, and viable solutions has begun and will continue.

Microbicides. Many scientists believe that in the absence of a vaccine the development of safe, effective, female-controlled mechanical or chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections could dramatically reduce the sexual transmission of HIV. Worldwide over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs⁷.

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

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

Examining the Impact of HIV on Youth. HIV-related research has made great strides on many fronts, however, adolescents have not received the full benefit of research discoveries. There is however information indicating that HIV may behave differently in infected adolescents. We need more information on impact of puberty on the course of HIV infection and behavioral trends that play a key factor in HIV treatment and prevention.

Adolescents must factor more significantly into the research process. NIH and the Food and Drug Administration (FDA) should examine options for lowering barriers to participation and continue to encourage sponsors to enroll adolescents, when feasible and appropriate, in HIV/AIDS clinical trials. The efforts of the collaboratively-funded the Adolescent Medicine HIV/AIDS Research

Network⁴, are important in improving our understanding of HIV disease in adolescents and should continue.

New and More Effective Therapies. Strong and continuing research to develop new and more effective therapies for HIV infection and its associated conditions must be a priority if we hope to transform HIV disease into a chronic, manageable condition. ***

Due in part to the FDA's accelerated approval program⁵, the Federal government is now approving new treatments in record numbers and at record speed, but it is not always known whether a treatment confers a clinical benefit for the person. While some treatments have shown promise based on surrogate markers and/or laboratory tests, data regarding long-term clinical effectiveness are unavailable. Patients may be receiving less effective treatments or combinations of treatments, and Federal programs such as Medicaid and Medicare and private insurers may be paying for treatment strategies that are not optimally effective.

It is incumbent upon the government and the private sector to ensure that post-marketing effectiveness studies, currently mandated through regulation, are carried out. In order for the results to be relevant to as many persons as possible, it will be necessary that these studies include people representing a diversity of race, ethnicity, gender, age, and drug using behaviors.

Through the efforts of the Vice President, the Forum for

⁴ The Adolescent Medicine HIV/AIDS Research Network is cooperatively funded by the National Institute of Child Health and Human Development (NICHD), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute on Drug Abuse (NIDA), and the Health Resources and Services Administration (HRSA).

⁵The 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.

Collaborative HIV Research has been established. This group will assess approaches for accelerating this research in this area. Participants in the Forum include pharmaceutical firms, public and private payors and insurers, researchers, FDA, NIH, and the advocacy community.

Public-Private Partnerships. A key role for the Federal government is to act in partnership with the private sector and support areas where there is a market failure, or more specifically, areas where industry is unlikely to pursue research that would be beneficial to the public health. Vaccine development is one such area, but there are others.

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

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

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

At present, NIH receives many more outstanding research applications than it is able to fund; these unfunded proposals represent a lost opportunity for scientific progress. Other

Re-write for RS review
August 7, 1996, 1:00 pm (n:\text4.g96)

Departments and Agencies, such as DOD and VA, also support crucially important research that strengthens the overall U.S. research effort. Research has been key to prolonging and improving the quality of lives and the Nation must continue to make this investment.

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

Another quote for C&S?

Insert 'vision language'.

1. Record of Accomplishment

The Nation has made significant efforts to ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs. As the number of people with HIV has increased, so did their need for care. In 1985, Federal expenditures for HIV-related care and services were \$xxx, by 1995 the Federal share reached \$xxx. The Federal government has continued to respond this expanding need by:

- Increasing funding for the Ryan White CARE Act 134 percent in four years;
- Doubling funding for the AIDS Drug Assistance Program in the last two years;
- Increasing funding for Housing Opportunities for People with AIDS 96 percent in four years;
- Preserving the Medicaid guarantee of coverage for the nearly 50 percent of people with AIDS and 92 percent of children with AIDS rely on this health coverage; and
- Revising eligibility rules for Social Security Disability Insurance to make it easier for people living with HIV to qualify for benefits.

Background

In the early years of the epidemic, the health care infrastructure was particularly unprepared to accomodate the health care needs of persons with HIV. To meet their complex health care needs, HIV-

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

People living with HIV now access the necessary health care services in a variety of ways. Currently, nearly 50 percent of adult Americans and 90 percent of children living with AIDS receive their medical coverage through the Medicaid program and another 5 percent receive Medicare benefits. An estimated 15 percent of people living with AIDS have private health insurance and the remaining 30 percent are uninsured and must rely on personal payment or charity care.⁶ However, for a disproportionate number of people living with HIV and AIDS, their lives often depend on the Federal health care safety net.

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

After Medicaid, the centerpiece of the national safety net consists of 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/AIDS. Titles I and II of the CARE Act provide funds for outpatient care, support services, and case management that are given to cities and States primarily on a formula basis so the areas most affected by the epidemic receive a proportional share of available dollars. Title II also provides drug reimbursement funding for persons living with AIDS. Title IIIb of the Act provides early intervention services such as counseling and testing, medical care, and educational services for medically underserved persons with the goal of reducing HIV-related illness. Title IV seeks to increase the availability of care and services for women, infants, children, and youth in a community-based family-centered system of care. HRSA also provides primary care to persons living with HIV through its Community Health Centers and

⁶ JL cite. Add Vancouver numbers.

Maternal and Child Health Programs.

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

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

2. Future Opportunities for Progress

The challenge before us today is to ensure that persons living with HIV receive the care they need so they may have the opportunity to live productive lives. AIDS care and service programs must build upon past successes, continue to improve prioritization efforts, improve accountability, and increase the cost-effectiveness of services they provide. As treatments improve and extend the productive lives of people with HIV, we must continually re-examine the range of service that are needed.

The Health Care Safety Net. The cornerstone of care for people living with AIDS in the U.S. is Medicaid. In fiscal year 1996, Federal Medicaid spending for people living with AIDS is estimated at \$1.9 billion, nearly six times the amount expended on the Ryan White CARE Act.

Maintenance of the Federal guarantee of Medicaid coverage for eligible individuals is essential to the continued ability of the Nation to respond to the health care needs of people living with HIV and AIDS. The 30-year State partnership in Medicaid also must be maintained while the program is made more flexible for State innovations. It is also vital that the Ryan White CARE Act be maintained and expanded to fill the gaps in coverage.

Integrated Continuum of Care. Many health care providers believe that one of the most potentially effective approaches to treating HIV-positive people rests in providing people access to an integrated continuum of health care services. One of the more powerful methods of recruiting people into primary care is knowledge of HIV serostatus since people who know they are HIV-positive are more likely to seek health care. Counseling and

Re-write for RS review

August 7, 1996, 1:00 pm (n:\text4.g96)

testing services can serve as a gateway to accessing this care. Linking HIV-positive people with care also provides an opportunity for education about behaviors which may reduce their chances of infecting others.

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

Housing Services. Housing is an important element in the effort to provide comprehensive care for people living with HIV. Without stable housing, a person living with HIV has diminished access to programs and services and a diminished opportunity to live a productive life. It is estimated that up to 50 percent of people living with HIV and AIDS will become homeless or are at risk for becoming homeless during the course of their illness.⁸

People living with HIV and their families face significant obstacles locating affordable housing. The HOPWA program was created in 1992 to assist communities meet the increased need for resources, effective planning, and coordination with existing public and private efforts. The program is representative of HUD's "Continuum of Care" approach to building local systems that address homelessness.

To further foster community involvement, HUD has also established the Consolidated Planning process for communities that receive funds under the Department's economic and community development programs, including recipients of HOPWA formula allocations. 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.

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

Prisoners. Another group of people frequently underserved are prisoners. Most prisoners living with HIV are incarcerated in State and local prisons. Medical care for Federal prisoners is provided under the direction of the Department of Justice's Bureau

of Prisons.

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

Program Coordination. For HIV care and services to have the most beneficial impact, they should be part of a continuum of care. For organizations at the front lines of the epidemic, building a comprehensive integrated program requires support from numerous Federal Agencies. For example, creating a community-based program that integrates primary care, substance abuse treatment and prevention, and sexually transmitted disease screening, HIV prevention, access to clinical trials, and housing assistance would require separate applications to SAMHSA, HRSA, CDC, NIH, and HUD.

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

Quality of Care. Federally supported programs can and should consistently provide quality care. Quality care for HIV-positive people is possible, but quality care is not consistently available throughout the health care system. Ensuring consistency in care delivery will require increased training for health care professionals and more accountability through the use of performance measures for quality care. Again, goal attainment will require the cooperation of Federal Agencies, States, professional organizations, professional and medical schools, and individual clinicians.

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

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.

One of the national goals is to ensure that people living with HIV are not subject to unlawful discrimination. Discrimination based on HIV status is illegal and morally wrong.

Discrimination undermines the Nation's efforts to prevent and treat HIV infection and bring the epidemic under control. Because of fear of discrimination and stigma, many people do not voluntarily seek testing for HIV, remain unaware of their HIV status, consequently do not take advantage of care that could help them live longer, healthier lives. This fear can also cause HIV-positive people to delay treatment. Opportunities to educate people are lost as people at-risk avoid prevention programs because of the stigma associated with HIV. Discrimination can also wrongfully deny people access to housing, insurance, employment, and health care.

1. Record of Accomplishment

The Federal government has vigorously enforced the Americans with Disabilities Act of 1990 (ADA), the primary source of Federal statutory protection for people living with HIV. It has resolved nearly 800 charges alleging employment discrimination against people with HIV and AIDS obtaining monetary benefits of more than \$6.1 million.

The Federal government has strongly enforced protections provided under Section 504 the Rehabilitation Act of 1973, which prohibit Federal Agencies and recipients of Federal funds from discriminating against people with disabilities. The DHHS Office of Civil Rights enforces Section 504 as it pertains to recipients of DHHS funds such as hospitals, nursing homes, and social service agencies. And the Health Care Financing Administration (HCFA) enforces regulations regarding the treatment of HIV-infected people.

The Administration has also spoken out frequently against discrimination. We led the fight to repeal the discriminatory "Dornan Amendment," which would have discharged all HIV-positive

military personnel. And we other public statements/acts?

2. Future Opportunities for Progress

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

Federal Policies. The Federal government must also actively work to remedy any of its own existing discriminatory policies. The Director of the Office of National AIDS Policy is working with Federal Agencies to ensure that HIV testing programs follow the recommendations of public health professionals. The Administration will also continue to oppose Congressional attempts to force discharge of infected military personnel who are still able to serve their country.

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

E. INTERNATIONAL ACTIVITIES

Insert quote:

Insert 'visionary language'

AIDS is a global pandemic. In the United States it is estimated that between 650,000 and 900,000 people are currently infected with HIV. The World Health Organization (WHO) 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/AIDS by the year 2000. WHO also estimates that two to three million new HIV infections can be expected annually, and by the year 2000, thirty to forty million people will have been infected around the globe.

The pandemic jeopardizes decades of economic and social advances in many developing nations. In Africa and Asia, economic advances are threatened and in some cases may be reversed due to the pandemic of HIV and AIDS. Socio-economic studies have shown a decrease in overall domestic savings and investment levels, negative effects on foreign investments, reductions in the volumes of imports and exports, and a reduction in receipts from tourism.⁹ In many countries governments will be forced to cope with increasing numbers of cases, weakened health care systems, a deleterious economic impact on the most productive segments of society, and the reduction in the number of healthy men and women able to serve in the government and the military.

1. Record of Achievement

At present several Federal Agencies are working at slowing the AIDS epidemic internationally. (See Appendix D.) The Department of State works with other Departments, Agencies, and non-governmental organizations to develop a framework to guide U.S. foreign policy in the global efforts against HIV and AIDS. The major areas of U.S. leadership in the HIV arena are: preventing new infections; reducing the personal and social impact of the pandemic; and mobilizing and unifying national and international efforts.

The U.S. Agency for International Development (USAID) also has a leadership role in the global HIV effort through development assistance, research and policy formation. USAID focuses its strategy on developing prevention programs based on proven interventions, addressing social, cultural, regulatory and economic issues related to HIV/AIDS and other sexually transmitted infections, and developing and testing new interventions and methods to prevent transmission and mitigate the impact of the

epidemic. The U.S. Information Agency (USIA) supports programs that promote dissemination of U.S. policies and information related to HIV and AIDS. The Peace Corps trains a portion of its volunteers to directly address HIV-related concerns in their countries of placement.

In addition, several Agencies support research overseas, including the National Institutes of Health, the Centers for Disease Control and Prevention, and the Department of Defense (DOD). The DOD is conducting clinical trials of candidate HIV vaccines in Thailand and NIH (working in collaboration with USAID), supports basic scientific studies on social and behavioral aspects of AIDS in developing countries. The results of the studies ultimately will be used to develop interventions to reduce behaviors that place individuals at risk for contracting HIV infection.

2. Future Opportunities for Progress

International Leadership. The United States has established a global leadership role in combatting the epidemic. This leadership must continue. The U.S. strongly supports the newly established Joint and Co-sponsored United Nations Programme on AIDS (UNAIDS).¹⁰ Moreover, the U.S. is a member of the governing body of UNAIDS and signed the 1994 Paris Declaration and the Greater Involvement of People Living with HIV/AIDS Initiative (GIPA).

The U.S. also supports efforts to more effectively make use of available resources as well as to encourage non-traditional donor countries to provide much-needed contributions. Supporting UNAIDS organizations such as UNICEF, WHO, UNDP, 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.

In addition to maintaining our multilateral partnerships, we must strengthen and expand our bilateral programs and funds for HIV activities. We must reverse the current trend to reduce assistance to developing countries where more than 90 percent of the world's AIDS cases are found. The impact of strong USAID HIV/AIDS program on the global stage can not be undermined. **OK??? LR added**

Sharing Technology and Bringing Lessons Home. In addition to financing the development of large scale, comprehensive AIDS prevention programs in many countries, USAID has gained valuable insights and lessons from experiences from these countries and is applying them to U.S. populations. The "Lessons without Borders

Re-write for RS review
August 7, 1996, 1:00 pm (n:\text4.g96)

Project" initiative brings lessons learned abroad home to inner city and rural areas with problems similar to those experienced overseas.

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

Effectively planning, coordinating, and evaluating the overall U.S. international effort requires organizational efforts. In order to improve this endeavor, the Agencies supporting international activities must develop a mechanism for identifying and coordinating this effort in a systematic and timely way.

F. TRANSLATION OF RESEARCH INTO PRACTICE

Insert Quote

Insert 'vision language'

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

1. Record of Achievement

Due in part to Federally-sponsored information dissemination activities, dramatic changes in the way HIV is treated have taken place over the last 15 years. Ensuring dissemination of HIV-related information falls under the missions of several Agencies. (See Appendix E.) The National Institutes of Health (NIH) supports a broad range of efforts including a "Clinical Alerts" mechanism for the dissemination of clinical trials results to health professionals, the media, and the general public. DHHS supports and directs the International HIV/AIDS Clinical Conference Call series, which disseminates critical, state-of-the-art clinical care information to primary care providers via live worldwide audio tele-conferencing.

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

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

of AIDS Education and Training Centers that provide state of the art HIV clinical information to health care providers.

2. Future Opportunities for Progress

Despite these advances, there are opportunities for improvement. An AHCPR-supported study indicated that primary care physicians may miss significant HIV-related symptoms during patient examinations.¹¹ Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.¹² Reference Kittahare (sp?) article.

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

The Federal government currently supports a number mechanisms for periodically assessing advances in clinical care. It is essential that these assessment efforts continue and that crucial information be widely disseminated. This will require collaboration with industry, government, and professional groups.

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

Within the DHHS, the Office of HIV/AIDS Policy (OHAP) has the lead responsibility for coordinating the HIV-related activities of the Public Health Service Agencies. Ensuring that information about a research breakthrough is easily available, reaches the appropriate people and organizations, and that policies and standard-of-care practices for Federally-sponsored programs are modified to reflect the new standard, requires a continued high level of cooperation

Re-write for RS review
August 7, 1996, 1:00 pm (n:\text4.g96)

and coordination among Public Health Service Agencies.

Improved information dissemination efforts are also 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. Here again, the Public Health Service must take the lead in ensuring that information that can be used to stem the tide of new infections reaches those who can make a difference.

Footnotes

1. *Morbidity and Mortality Weekly Report*. U.S. Department of Health and Human Services, Public Health Service. November 24, 1995, vol. 44, No. 46.
2. External Review of HIV Prevention Strategies by the CDC Advisory Committee on the Prevention of HIV Infection. U.S. Department of Health and Human Services, Public Health Service. June 1994.
3. *AIDS and Behavior: An Integrated Approach*. Judith D. Auerbach, Christian Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine. National Academy Press. Washington, DC. 1994.
4. Heiner Grosskurth, Frankc Mosha, James Todd, Extra Mwijarubi, Arnould Clokke, Kesheni Senkoro, Philippe Mayaud, John Changalucha, Angus Nicoll, Gina ka-Gina, James Newell, Kokuugonza Mugeye, David Mabey, Richard Hayes. Impact of Improved Treatment of Sexually Transmitted Diseases on HIV Infection in Rural Tanzania: Randomized Controlled Trial. *The Lancet*, Vol. 346, August 26, 1995.
5. Maria Wawer, *Science*. 9.08.95, vol. 269, No. 5229
6. Personal communication from CDC Division TB Elimination.
7. Alan B. Stone, and Penelope J. Hitchcock. Vaginal Microbicides for Preventing the Transmission of HIV. *AIDS* 1994, 8 (suppl 1):S285-S293.
8. Housing and the HIV/AIDS Epidemic: Recommendations for Action. National Commission on AIDS. Washington, D.C. July 1992.
9. *HIV/AIDS Policy Guidance*. U.S. Agency for International Development. September 1995.
10. Until recently, the United Nations' response to HIV/AIDS was carried out primarily by the World Health Organization's Global Programme on AIDS. On January 1, 1996 the U.N. launched UNAIDS, co-sponsored by six U.N. agencies to strengthen coordination and focus support for HIV/AIDS activities at the global and country levels. UNAIDS has established three mutually reinforcing roles: to be a major source of policy development and research; provide technical support; and be an advocate for comprehensive, multisectoral responses to the pandemic.
11. 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

Re-write for RS review
August 7, 1996, 1:00 pm (n:\text4.g96)

HIV Infection. *JAMA*. 1995; 274:1380-1382.

12. 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)

DRAFT:

National AIDS Strategy Re-write
August 9, 1996 (n:\text5.g96)

TABLE OF CONTENTS

MESSAGE FROM THE DIRECTOR OF THE OFFICE OF NATIONAL AIDS POLICY

I. INTRODUCTION

II. OVERVIEW OF FEDERAL EFFORTS

Introduction

Prevention

Research

Care and Services

Civil Rights

International Activities

Translation of Research into Practice

Advances

III. APPENDICES

Appendices A - F

(Prevention, Research, Care and Services, Civil Rights, International Activities, and Translation of Research into Practice,)

Appendix G

Budget Tables

IV. FIGURES, ACRONYMS, AND MEMBERS OF THE INTERDEPARTMENTAL TASK FORCE ON HIV AND AIDS

Figure 1

Death Rates from Leading Causes of Death in Persons Aged 25-44 Years, USA, 1982 -1993

Figure 2

Cumulative U.S. AIDS Cases: 2/83 through 12/94

Acronym List

Members of the Interdepartmental Task Force on HIV and AIDS

Search
must/don't
Translation of
Research Advances
→

[Note: This could be reworked as a message from the President to the world or as a letter from Patsy to the President presenting the draft Strategy to him.]

"We must develop a clear, well-articulated national plan for confronting AIDS."

*The Final Report of the National Commission on AIDS
June 1993*

Message from the Director of the Office of National AIDS Policy

The epidemic of HIV and AIDS constitutes a public health crisis of unprecedented proportions. In 1993, the Office of National AIDS Policy (ONAP) was created by President Clinton to provide a national focus and direction for the government's response to HIV and AIDS. More recently, President Clinton asked ONAP to develop a comprehensive National AIDS Strategy that would detail the Federal government's long-term approach in responding to this epidemic. The National AIDS Strategy has been developed by the Clinton Administration to capitalize upon progress already made in fighting the epidemic and to catalyze collaborative efforts among Federal Departments and Agencies, communities, State and local governments, businesses, schools, churches, families, and individuals.

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

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

This document is a snapshot of where we are as a Nation and where we need to go in achieving these national goals. It summarizes

some of the key accomplishments of our Nation's scientific and public health professionals and identifies key areas for further effort. In addition, the appendices to this report lay out, for the first time, detailed descriptions of the objectives, goals, and budgets of all Agencies involved in the Federal response to HIV in the five key areas of HIV policy: prevention, research, care, civil rights, international activities, and translation of research into practice. *major*

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

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

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

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

Individuals living with HIV and AIDS, their families, friends, loved ones, and care givers made vital contributions to this Strategy. Numerous non-governmental groups and organizations have also been consulted including the Presidential Advisory Council on HIV/AIDS, participants in the historic White House Conference on HIV and AIDS, the ONAP-sponsored regional briefings, patient and consumer advocates, health care professionals, community-based

National AIDS Strategy Re-write
August 9, 1996, (n:\text5.g96)

organizations, educators, religious leaders, and business leaders. The earlier insights provided by the National Commission on AIDS, the Institute of Medicine and National Research Council, the General Accounting Office, and the Office of Technology Assessment have also been extraordinarily helpful in developing the National AIDS Strategy.

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

Patricia S. Fleming
Director, Office of National AIDS Policy

or

William J. Clinton

"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

Scope of the HIV/AIDS Epidemic

The epidemic of Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) presents unique social, economic, and public health challenges to governments and individuals here in the United States and around the world. While significant progress has been made in understanding the disease and developing treatments since the first case was reported in the U.S. in June 1981, HIV remains a deadly infection for which there is no vaccine, no cure, and for which there is an expanding but still limited inventory of available treatments. An average of 100 Americans are diagnosed with AIDS every day and a similar number of men, women, and children become infected with HIV every 24 hours. **[Richard -- are you certain these numbers are correct?]** Globally, 7,500 people become infected each day.

An Expanding Public Health Threat

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

As the epidemic in the United States has expanded, the demographics of the epidemic have changed. The early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers (i.e., New York, San Francisco, and Los Angeles).

Today, this group represents less than half of all new cases, ^{although they} Among the populations that are more heavily affected today are young gay men, women, and injecting drug users and their sexual partners as well as users of non-injecting drugs (i.e., crack cocaine and alcohol). ~~Although gay and bisexual men no longer represent the majority of new cases, this group~~ (still represents the majority of persons living with HIV and AIDS). In 1995, nearly 14,000 women were reported to CDC as having been diagnosed with AIDS. Women now comprise 14 percent of cumulatively reported AIDS cases. If this trend continues, it is estimated that 80,000 American children will have been orphaned as a result of AIDS by the end of this decade. In 1995, approximately 800 new cases of pediatric AIDS cases were reported. (Footnote a)

Adolescents (age 13-19) are at increased risk for HIV infection. CDC estimates that one-quarter of new HIV infections in the U.S. occur among people under age 21. A significant number of young people are engaging at earlier ages in sexual intercourse and drug and alcohol use. This fact, coupled with the disturbing number of adolescents who are prone to high-risk behavior due to homelessness, sexual abuse, and other circumstances, places young Americans in a situation that leaves them extremely vulnerable to HIV infection.

Communities of color OR racial and ethnic minorities have been disproportionately affected by the epidemic of HIV and AIDS. African-Americans, who represent approximately 12 percent of the U.S. population, accounted for 40 percent of newly reported AIDS cases in 1995. Hispanics, who account for about 9 percent of the general population, represented 19 percent of new cases reported in 1995. The number of African-Americans and Hispanics affected by HIV and AIDS has risen dramatically. In 1982, Blacks and Hispanics represented 31 percent of all AIDS cases; however, as of December 1995, these groups comprised 52 percent of cumulative AIDS cases.

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

AIDS is an expensive disease. Average lifetime costs of medical care after diagnosis with HIV is \$119,000 (Footnote b). People living with HIV are disproportionately dependent on the public

1.6
sector for their health care. Over 50 percent of people living with AIDS are enrolled in Medicaid, including more than 90 percent of children with AIDS. In FY 1996, the Federal government spent \$1.9 billion on Medicaid benefits for people living with HIV and AIDS and another \$690 million on Medicare benefits. Social Security benefits for people disabled by HIV/AIDS total \$1.1 billion in FY 1996.

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

II. OVERVIEW OF FEDERAL EFFORTS

The scope and nature of the HIV/AIDS epidemic have drawn States, local governments, academic institutions, private foundations, health care institutions and community-based organizations and the Federal government into many HIV-related activities. The Federal government, through its public health responsibilities in such areas as research, prevention, health care, and housing has seen a dramatic increase in its activities since the beginning of the epidemic. In FY 1985 the Federal government spent \$212 million for AIDS research, surveillance, and care. By FY 1995 that figure reached \$6.8 billion. (See Appendix G).

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

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

advances

A. PREVENTION

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

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

1. Record of Accomplishment

Since the epidemic began, the Nation has made important progress in prevention of HIV infection. In the early years of the epidemic, it was estimated that more than 100,000 Americans were becoming infected with HIV each year. Today, that total is between 40,000 and 60,000 people each year.

Sentinel accomplishments in prevention of HIV include:

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

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

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

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

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

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

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

2. Future Opportunities for Progress

Significant challenges remain if we are to reach the Nation's prevention goal -- no new infections. Primary to this progress are efforts to:

- Improve our understanding about the major trends in transmission and seroprevalence of HIV transmission;
- Close gaps in scientific knowledge, which includes identifying additional effective prevention models and

strategies; and

Eliminate gaps in HIV prevention program areas.

a. Improving Understanding of Trends in the Epidemic

An important aspect of strengthening prevention activities is to have a clearer understanding of those who are becoming infected and what behaviors are placing people at risk. Recent epidemiologic data show that the HIV epidemic continues to spread most rapidly among people who engage in injection drug use and their sexual partners, women, young and minority men who have sex with men, heterosexuals and infants who are infected through perinatal transmission. These trends must be considered when prioritizing prevention research and service programs.

A crucial element of effective prevention strategies is support for adequate surveillance of HIV infection and related diseases in order to gauge future directions of the epidemic and assess the effectiveness of prevention interventions. 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.

Effective prevention interventions begin with sound information about who is at risk. However, current CDC surveillance systems do not capture sufficient "front-end" information on the incidence and prevalence of HIV prior to an AIDS diagnosis in the population and trends in modes of transmission and new infections. These data must be collected with appropriate confidentiality protections for the identity of those who are living with HIV. CDC is exploring additional innovative approaches for collecting HIV incidence information. These effort must continue. Collection of these data are needed as part of an enhanced effort to link surveillance and epidemiological data to priority setting as well as in the design and evaluation of HIV prevention programs.

The CDC has incorporated data collection design into its community planning process. Shifts in data needs may also require that CDC reevaluate and reconfigure certain of its data collection efforts. As part of the Agency's implementation of the recommendations set forth in the external review of CDC's HIV prevention strategies², CDC has initiated efforts to evaluate current data collection efforts and implement necessary changes.

b. Prevention Research: Closing Gaps in Scientific Knowledge
(Footnote c)

Factors that place individuals at risk for acquiring HIV infection entail a complex combination of behavioral, social, cognitive, and biological influences. Given this complexity, we must not *assume* to intuitively know which interventions will work, but instead base our efforts on research findings. Development of effective interventions are based on sound research findings and evaluation. The three main gaps in current knowledge are: basic behavioral research, intervention research, ~~and~~ social marketing research.

Basic Behavioral Research. Information provided by basic behavioral research serves as the foundation for prevention programs. To capitalize on what is known and to improve HIV prevention programs that are targeted to reach diverse populations of Americans, more information on the determinants of HIV-associated sexual and drug-using behaviors is needed. Such data enable scientists to establish theories of behavioral change, which then provide researchers with tools for identifying approaches that may be most effective for an individual or a community.³

Intervention Research. Research to improve prevention interventions concentrate~~d~~ on modifying behaviors, such as those related to drug use and sex. Intervention research can focus on both individuals and communities, each of which often adhere to norms that influence personal behavior. Since the beginning of the epidemic we have made advances in our understanding of factors that are relevant to the design of intervention programs intended to reduce rates of HIV infection. There is more that we need to know if we are to develop more effective prevention programs. We must incorporate findings from basic behavioral research into effective prevention interventions. Agencies supporting intervention and behavioral research must include scientists from a broad range of disciplines in their planning activities and improve their data-sharing and collaborative efforts with Agencies responsible for implementing prevention programs. Intensifying the dialogue between researchers in these ~~two~~ ^{prevention} related fields will improve the development of effective prevention interventions. ✓

Social Marketing Research. It is important that the findings from basic behavioral and intervention research serve as a foundation for prevention programs. Agencies supporting social marketing activities need to build on current knowledge in addition to strengthening efforts to understand barriers to the implementation and replication of promising prevention programs. As these models are developed, community-based organizations will require additional technical assistance and training in order to test those models in a "real-world" setting. ✓

c. Strengthening Prevention Programs

For prevention interventions to be effective they must reach people at risk and be responsive to their needs. For individuals to take control of their own lives in fighting the spread of this virus, they must first have the information and skills to protect themselves. It is important that prevention planners carefully prioritize local efforts based on who is and who is becoming infected.

One of the most important innovations in HIV/AIDS prevention is the creation of community planning. Through this public-private partnership it has been possible to establish joint goals for the prevention of HIV that are responsive to local needs. However, this process is early in its development and requires continuing significant leadership and technical assistance.

It is crucial that prevention research results be disseminated and incorporated into prevention programs. Models of effective prevention interventions have been developed but often this valuable information is not reaching those people developing, implementing, and evaluating prevention programs. (See Section on Translation of Research into Practice.)

Advances
Small, new, community-based organizations -- especially those serving minority populations -- often require additional technical assistance in order to compete for available resources. The CDC and other Agencies provide such assistance and will continue to do so.

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

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

A key to controlling the spread of HIV among substance abusers is enrollment into drug treatment programs. Substance abuse treatment is a major form of HIV prevention. [add some stuff about what we've done to increase treatment slots, etc. ... Richard -- there' no specific reference in the text because we haven't done

much to increase treatment slots, if anything they have decreased. Also, "treatment slot" is an OMB forbidden word.] Moreover, substance abuse problems that contribute to the spread of HIV are not limited to injecting drug use; use of non-injectable drugs such as alcohol and crack cocaine can adversely influence risk-taking behavior. The efforts of the Office of National Drug Control Strategy to motivate Americans to reject illegal drugs and substance abuse are an important element in controlling the epidemic.

Work on these issues has begun and will continue. CDC has initiated State-by-State discussion, including meetings with State Legislators and the National Conference of State Legislatures regarding HIV prevention issues. SAMHSA's new "Knowledge Development Application (KDA) Program" will address emerging issues in the fields of substance abuse and mental health, including a focus on HIV and AIDS. CDC, HRSA, NIDA, and SAMHSA are co-sponsoring a national meeting of State and local officials from the fields of public health and drug abuse prevention to develop an action plan that more effectively integrates HIV and substance abuse prevention efforts.

CDC has initiated discussions on this topic, including meetings with State officials regarding HIV and substance abuse prevention issues. SAMHSA's new "Knowledge Development Application (KDA) Program" will address emerging issues in the fields of substance abuse and mental health, including a focus on HIV and AIDS. CDC, HRSA, NIDA, and SAMHSA are co-sponsoring a national meeting of State and local officials from the fields of public health and drug abuse prevention to develop an action plan that more effectively integrates HIV and substance abuse prevention efforts.

Res to
Treatment for Sexually Transmitted Diseases and Tuberculosis.
~~Studies have~~ shown that the presence of other sexually transmitted diseases (STDs) can significantly increase the efficiency of HIV transmission, by as much as twenty-fold. *Research has* ~~Studies have~~ also shown that widespread treatment of STDs in certain communities has led to a 40 percent reduction in new HIV infections in these groups.^{4,5} These data suggest, *that* ~~treating~~ STDs can be a very effective HIV prevention strategy and points to a need for all clinicians to be vigilant in efforts to prevent and treat STDs. NIH-supported research to further understanding of the effect of STD treatment on HIV transmission is underway and will continue.

It is important that Federal and State efforts to reduce the incidence of sexually transmitted diseases (STDs) include an HIV prevention element and that HIV prevention programs incorporate STD

prevention and treatment efforts. The traditional model of targeting most STD prevention efforts towards individuals who have already contracted an STD is not necessarily effective for HIV prevention. Linkages between STD and HIV prevention efforts need to be established and, where they do exist, enhanced.

People living with HIV are at very high risk for developing active tuberculosis (TB) disease. Studies suggest that the risk of developing active TB disease is 7-to-10 percent per year for persons who are infected with both TB and HIV, whereas the risk is 10 percent per lifetime for persons not infected with HIV.⁶ In addition to the health implications for infected persons, there is an increased risk of transmission of TB to household members, health care workers, and other persons having regular contact with a person with active TB.

The newly organized National Center for HIV, STD, and TB Prevention at CDC demonstrates the importance of integrating the interdependent aspects of the epidemic and illustrates the determination to integrate and coordinate HIV, STD, and TB prevention efforts.

Integration of Prevention Into Primary Care. To reach our prevention goal, we must also improve the integration of prevention activities and messages into primary health care services. HIV counseling and voluntary testing often provide an important bridge between HIV prevention and care for many at-risk persons. To assure that all persons seeking HIV testing can have access to such services, CDC's counseling and testing guidelines must acknowledge and address the needs of persons seeking such services, and provide training for personnel at CDC-funded sites.

Incorporating a person's sexual and drug use history when a medical history is taken, offering HIV-related counseling and voluntary testing, and providing prevention education to HIV positive individuals so they do not infect others is also important. In addition, to reduce perinatal transmission, all pregnant women should be offered HIV counseling and voluntary testing as well as information about and access to AZT. Training should be made available to improve primary care providers' skill, comfort level, and sensitivity in these areas.

Achieving this level of integration requires active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to State, local, and Federal governments. Presently HRSA's primary care, RWCA, and professional training programs emphasize the value of integrating prevention into primary

care. These are important efforts and that will continue.

Prisoners. Those in prison are at high risk for both substance abuse and HIV infection. ^{especially} There is often a high prevalence of ~~both~~ ^{bad} behaviors that lead to substance abuse and HIV infection in people entering prison. Given that prisoners often are at increased risk for HIV infection, offering educational programs during incarceration provides a unique opportunity to reach these persons. ^{people} Research has shown that individuals who are well informed about HIV and substance abuse issues modify their risk-taking behaviors. It is important that the Federal government build upon the knowledge and opportunity that currently exists to further improve HIV prevention efforts for incarcerated persons. ✓

Evaluation. It is important to assess the effectiveness of the HIV/AIDS prevention interventions. Prospectively-set performance measures can be used as a basis for evaluation and program improvement and must become a routine part of all Federally-funded programs. It is only through sound evaluations that we will be able to determine whether our efforts have been effective in slowing the epidemic. ✓

B. RESEARCH

"Our common goal must ultimately be a cure, a cure for all those who are living with HIV, and a vaccine to protect us from the virus."

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

1. Record of Accomplishment

Since the epidemic began in 1981, the Nation has made significant advances in HIV-related research advances. Sentinel points of that progress include:

- Identification in ~~April 1984~~^{me} of HIV as the etiologic agent for AIDS. (April 1984)
- Development in ~~March 1985~~^{me} of a reliable test to determine exposure to HIV; (March 1985)
- Approval in ~~September 1986~~ of zidovudine (AZT), the first treatment of HIV primary infection; and
- Development by the Food and Drug Administration of a system of expedited review of treatments for life-threatening diseases, including HIV.

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

- Increasing AIDS research funding by 34 percent;
- Signing the NIH Revitalization Act of 1993, creating a permanent Office of AIDS Research at NIH and vesting it with new authority to plan and implement an annual AIDS research plan;
- Accelerating AIDS drug approval to record times. (Since 1993, the Food and Drug Administration has approved 12 new AIDS drugs and three new diagnostic tests.)
- Supporting research that led to finding that use of AZT during pregnancy, childbirth, and the first six weeks of life can reduce the transmission of HIV from mother to child by two-thirds;
- Launching a four-year, \$100 million research effort to develop effective topical microbicides;

- Facilitating creation of the Forum for Collaborative HIV Research to identify opportunities for clinical effectiveness research to improve care for HIV-positive individuals.

Contributions of AIDS Research

Beyond the impact that AIDS research has had on the epidemic, the Nation has realized additional benefits of supporting such research. Several Federal Agencies play a significant role in AIDS research (See Appendix B). The effort to understand HIV and AIDS has produced scientific advances that benefit research on many other diseases. For example, AIDS research has accelerated study of the human immune system, which helps us to better understand and treat many other diseases, such as cancer; autoimmune diseases, including systemic lupus erythematosus; type I diabetes mellitus; rheumatoid arthritis; and multiple sclerosis. AIDS research also contributes to the prevention of other infectious diseases and provides a new paradigm for treatment of viral diseases.

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

HIV research has assisted in identifying new infectious agents that may be responsible for malignancies, such as the recent discovery of the etiologic agent for Kaposi's sarcoma. These findings may help to identify other oncogenic agents. HIV research has led to a better understanding of the mechanisms by which infectious agents and inflammatory cells cross the blood/brain barrier, providing valuable clues for research on Alzheimer's disease, dementia, multiple sclerosis, neuropsychological disorders, encephalitis, and meningitis. Moreover, prior to the AIDS epidemic, little investment was made in research to treat viral diseases. Studies to develop anti-HIV therapies have improved our understanding of additional viral diseases and led to development of treatments.

Efforts to develop drugs for the treatment of HIV have accelerated the development of methods of rational drug design using sophisticated techniques of structural biology and advanced computer imaging methods. These advances have implications for drug design for virtually all disorders. Comparative clinical trials of poxvirus vectors and vaccine adjuvants in HIV vaccine candidates have supported safety information for cancer vaccines.

Research on HIV-related wasting has provided important information for research on nutritional disorders, metabolic abnormalities, and gastrointestinal dysfunctions.

Due in great part to Federally-sponsored AIDS research, a number of new and exciting research advances have brought optimism and opened new areas for investigation. One of the recent research advances has been the development of a new class of drugs, known as protease inhibitors. When used in combination with other types of anti-retroviral drugs, there is the potential to dramatically reduce the amount of HIV in the bloodstream and possibly improve a person's clinical status and reduce the risk of HIV transmission. A landmark advance in HIV prevention was the demonstration that AZT can dramatically reduce the risk of transmission of HIV infection from a pregnant woman to her child. Advances in effective treatments for HIV-related conditions can prolong and improve the quality of life of persons living with HIV. Breakthroughs in our understanding of the genes and proteins of the human immunodeficiency virus have allowed the development of increasingly effective anti-retroviral drugs.

In addition, the Food and Drug Administration through its expedited review and accelerated approval programs is now approving drugs more rapidly than ever before. Recent planning efforts on the part of various Federal Agencies, such as the annual NIH plan for HIV-related research and the Federal Biomedical and Behavioral Research Plan for HIV and AIDS have greatly improved the coordination of HIV research.

II Future Opportunities for Progress

Despite these advances, many complex biomedical and behavioral challenges remain. We must ensure that the Nation capitalizes on the most promising scientific opportunities.

Coordinating Federal Research. Developing and implementing the Federal government's AIDS research agenda presents both scientific and logistical challenges. Planning and overseeing a Federal effort of this magnitude requires coordinating efforts at two levels: First, within NIH and second among the Departments and Agencies supporting HIV research.

Within NIH, research is supported throughout 24 institutes, centers, and divisions (ICDs). In order to better plan, coordinate, evaluate, and fund the AIDS research activities of these ICDs the NIH Revitalization Act Amendments of 1993, provided the Office of AIDS Research (OAR) with new oversight and budget

authorities. It is crucial that the authority granted OAR in the revitalization legislation, including the consolidated appropriation, be maintained.

Add RS language about the Levine Report

For the government to effectively support a diversity of promising approaches, these research efforts must also be well-planned and coordinated. To achieve this the Director of the Office of National AIDS Policy created an inter-departmental working group, chaired by the Director of the Office of AIDS Research, charged with developing a coordinated plan and budget for HIV and AIDS research across all Agencies.

On December 6, 1996, at the White House Conference on HIV and AIDS, President Clinton directed OAR Director Dr. William Paul to develop the first Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS. This plan was completed in April, 1996. The development of this plan brought together representatives from the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Department of Defense, the Department of Energy, and the Department of Veterans Affairs. This plan provides an blueprint to focus and coordinate all Federal HIV/AIDS research initiatives and serves as a foundation for continued planning and evaluation.

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

On the scientific level, researchers are pursuing two approaches to vaccine development. One approach is based on the belief that gathering additional basic science information offers the best hope in steering vaccine development. The second approach is guided by the belief that data gathered from clinical efficacy trials in humans can lead to the development of a successful candidate. This group maintains that if a safe candidate is available, it is not necessary to resolve all of the scientific questions before proceeding with human trials, and, that in the face of a global emergency, testing in people should be begin immediately. Both approaches have valid arguments.

Developing a vaccine cannot be accomplished by the government or the private sector working apart: a continuing public-private partnership is needed. In order to identify areas for fruitful collaboration and to accelerate the pace of development for

vaccines, in February 1996, Vice President Gore convened a meeting of government scientists and leaders of the pharmaceutical and biotechnology industries to identify barriers to the development of these agents. Further dialogue involving key players regarding critical problems, and opportunities for development, and viable solutions has begun and will continue.

Microbicides. Many scientists believe that in the absence of a vaccine the development of safe and effective mechanical or chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections could dramatically reduce the sexual transmission of HIV. Worldwide over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs⁷.

Condoms, the barrier methods that are currently available, have limitations. Most require consent, if not 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.

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

Examining the Impact of HIV on Youth. HIV-related research has made great strides on many fronts, however, adolescents have not received the full benefit of research discoveries. There is evidence indicating that HIV may behave differently in infected adolescents. We need more information on impact of puberty on the course of HIV infection and behavioral trends that play a key factor in HIV treatment and prevention. Adolescents also must factor more significantly into the research process. NIH and the Food and Drug Administration (FDA) are examining options for lowering barriers to participation of adolescent in clinical trials and research protocols and will continue to encourage sponsors to enroll adolescents when feasible and appropriate, in such trials. The efforts of the collaboratively-funded Adolescent Medicine HIV/AIDS Research Network (Footnote D) are important in improving our understanding of HIV disease in adolescents and will continue.

New and More Effective Therapies. Strong and continuing research to develop new and more effective therapies for HIV infection and its associated conditions must be a priority if we hope to transform HIV disease into a chronic, manageable condition. Due to the FDA's accelerated approval program (Footnote E), the Federal government is now approving new treatments in record numbers and at record speed, but it is not always known whether a treatment confers a clinical benefit for patients. While some treatments have shown promise based on surrogate markers and/or laboratory tests data regarding long-term clinical effectiveness are unavailable. Patients may be receiving less effective treatments or combinations of treatments, and private insurers and Federal programs such as Medicaid and Medicare may be paying for treatment strategies that are not optimally effective.

It is incumbent upon the government and the private sector to ensure that post-marketing effectiveness studies, currently mandated through regulation, are carried out. In order for the results to be relevant to as many persons as possible, it is necessary that these studies include people representing a diversity of race, ethnicity, gender, age, and drug using behaviors. Through the efforts of Vice President Gore, the Forum for Collaborative HIV Research has been established to assess approaches for accelerating clinical effectiveness research.

Public-Private Partnerships. A key role for the Federal government is to act in partnership with the private sector and support research that would be beneficial to the public health in areas where there is a market failure. For example, it is unlikely that the free market system will push the implementation of head-to-head clinical trials of therapies that have been approved or are in development. However, information about these therapies is critical to improving patient care. The National Institutes of Health (NIH) and the Department of Veterans Affairs (VA) have been successful in carrying out this type of valuable research in collaboration with the pharmaceutical industry. It is unlikely that the private sector would support research for therapies that are on the market but have not been tested in controlled clinical trials, such as alternative therapies. However, through collaborative partnerships that include the NIH, studies of alternative therapies have been and will continue to be conducted.

It also is cost-effective for the government to provide access to sophisticated equipment and personnel that can be shared among many researchers in both the private and public sectors. The Department of Energy (DOE) has made available the use of sophisticated imaging equipment that would be prohibitively expensive for individual researchers or companies to purchase. This shared resource has

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

Continued Support for Research. Research is an investment in our future. It must receive consistent and adequate funding if we hope to bring the best and the brightest to meet the research challenges that will lead to a cure, better therapies, and a vaccine. At present, NIH receives many more outstanding research applications than it is able to fund; these unfunded proposals represent a lost opportunity for scientific progress. Other Departments and Agencies, such as DOD and VA, also support crucially important research that strengthens the overall U.S. research effort. Research has been key to prolonging and improving the quality of lives and the Nation must continue to make this investment.

C. CARE & SERVICES

"AIDS has taken too many friends and relatives and loved ones from everyone of us in this room. It has shaken the faith of many, but it has inspired a remarkable community spirit."

President Clinton, May 20, 1996

Signing of the Ryan White CARE Act Reauthorization

1. Record of Accomplishment

Since the epidemic of HIV and AIDS began in 1981, more than 500,000 Americans have been diagnosed with AIDS and required care. As the number of Americans living with AIDS increased, the demands on the U.S. health care system increased dramatically. Federal, State, and local governments along with community-based organizations and private clinicians have responded with compassionate, high-quality medical care. Among the sentinel achievements of these efforts are:

- Enactment in 1989 of the Housing Opportunities for People with AIDS (HOPWA) program; and
- Enactment in 1990 of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act.

The Nation has made significant efforts to ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs. As the number of people with HIV has increased, so did their need for care. In 1985, Federal expenditures for HIV-related care and services were \$xxx, by 1995 the Federal share reached \$xxx.

Since he took office in 1993, President Clinton has, as one of his highest priorities, sought to increase the national commitment to care for people living with HIV or AIDS. Among those actions are:

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

with AIDS by 96 percent;

- Fighting to preserve the Medicaid guarantee of coverage for the nearly 50 percent of people with AIDS and 92 percent of children with AIDS who rely on this program for their health coverage; and
- Revising eligibility rules for Social Security Disability Insurance to make it easier for people living with HIV to qualify for benefits.

Background

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

People living with HIV now access finance necessary health care services in a variety of ways. Currently, over 50 percent of adult Americans and 90 percent of children living with AIDS receive their medical coverage through the Medicaid program and another 5 percent receive Medicare benefits. An estimated 15 percent of people living with AIDS have private health insurance and the remaining 30 percent are uninsured and must rely on personal payment or charity care.¹ However, for a disproportionate number of people living with HIV and AIDS, their lives often depend on the Federal health care safety net.

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

Medicaid, a jointly financed Federal-State program of health care for the poor and the disabled, is the primary source of care for

¹ JL cite. Add Vancouver numbers.

people living with AIDS and a major source of care for those who are living with HIV. In FY 1996, Federal Medicaid expenditures for people living with AIDS totaled \$1.6 billion. The Medicaid statute authorizes Federal matching payments to the states to provide services to eligible individuals.

In addition to Medicaid, the centerpiece of the national safety net consists of 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 CARE Act is comprised of four separate titles:

- 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 care and services for women, infants, children, and youth in a community-based family-centered system of care.

HRSA also provides primary care to persons living with HIV through its Community Health Centers and Maternal and Child Health Programs. Other sources of primary care supported by the Federal government include the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service (IHS) which provides health care for HIV-positive Native Americans and Alaska Natives. Additionally, the Bureau of Prisons within the Department of Justice provides care for HIV-positive people in Federal prisons.

People living with HIV and their families face significant obstacles to locating affordable housing. Housing assistance for people living with HIV/AIDS is provided by the Department of Housing and Urban Development (HUD) through its Housing Opportunities for Persons with AIDS (HOPWA) 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.

2. Future Opportunities for Progress

The challenge before us today is to ensure that persons living with HIV receive the care they need so they may have the opportunity to live productive lives. AIDS care and service programs must continue to expand 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.

Preserving Medicaid. Medicaid is a lifeline of support for Americans living with HIV and AIDS. As the epidemic continues to spread in lower-income communities, the need for Medicaid coverage of people living with HIV/AIDS will increase. 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/AIDS. In particular, proposals to eliminate the Federal guarantee of coverage for people living with disabilities would have a dramatic impact on people living with HIV/AIDS. President Clinton has vetoed one such proposal and has promised to veto any future proposals that reach his desk.

Continuing Support for Ryan White CARE Act. The five-year reauthorization of the CARE Act signed by President Clinton on May 20, 1996 provides people living with HIV/AIDS with peace of mind that support from the Federal government will be there through FY 2000. As the demand for care continues to grow so must the resources for the CARE Act. President Clinton has proposed \$827.5 million for this program in FY 1997; enactment of that request is essential.

Expanding Support for Housing Services. Without stable housing a person living with HIV has diminished access to care and services and a diminished opportunity to live a productive life. It is estimated that up to 50 percent of people living with HIV and AIDS are or will become homeless during the course of their illness.⁸

President Clinton has requested \$196 million in FY 1997 for HOPWA; it is imperative that Congress approve that request.

Providing consistent funding for the housing component of the safety net will continue to be a Federal priority. Integrating AIDS housing services into other programs and ensuring a shared responsibility among Federal, State, local governments and community organizations is another important step in assisting communities to build seamless systems of support for our most vulnerable citizens.

Integrating the Continuum of Care. One of the most effective approaches to treating people living with HIV is providing access to an integrated continuum of health care services. A powerful method of recruiting people into primary care is knowledge of HIV serostatus. People who know their HIV status are more likely to seek health care and act to prevent HIV transmission. Counseling and confidential voluntary testing services serve as a gateway to care. Linking HIV-positive people with care also provides an opportunity for education about behaviors which may reduce their chances of infecting others.

**** *****

Achieving this level of integration requires active collaborative efforts by physicians, nurses, other clinicians, insurance plans, medical schools, and professional organizations in addition to State, local and Federal governments.

Improving Program Coordination. Organizations receiving funding from the Federal government in providing AIDS-related care often require support from several Federal Agencies. For example, creating a community-based program that integrates primary care, substance abuse treatment and prevention, and sexually transmitted disease screening, HIV prevention, access to clinical trials, and housing assistance requires separate applications to SAMHSA, HRSA, CDC, NIH, and HUD.

As part of its effort to "reinvent government," [Do we know if this effort is part REGO?] the Clinton Administration has been working to simplify Federal funding applications to facilitate improved integration of service programs. HRSA and SAMHSA have issued joint programs announcements and HUD and HRSA have also issued a joint program announcement for the Special Projects of National Significance (SPNS) program. These efforts to improve integration will be continued and expanded.

Improving Quality of Care. Federally-supported programs can and should consistently provide high-quality care. Ensuring consistency in care delivery requires increased training for health

care professionals and greater accountability through the use of performance measures for quality care. It is also essential that practical information on research advances for practicing clinicians and their patients be provided in a timely manner. (See Section Translation of Research Advances in Practice.) Achieving these goals requires the cooperation of Federal Agencies, States, professional organizations, professional and medical schools, and individual clinicians.

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

D. CIVIL RIGHTS

"Every person with HIV or AIDS is someone's son or daughter, brother or sister, parent or grandparent. We cannot allow discrimination of any kind to blind us to what we must do."

President Clinton, May 20, 1996

Signing of the Ryan White CARE Act Reauthorization

Discrimination against people living with HIV or AIDS violates the human rights of individual Americans and undermines our Nation's 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/AIDS to live full lives, free of fear.

Discrimination also undermines the Nation's efforts to prevent and treat HIV infection and bring the epidemic under control. Because of fear of discrimination and stigma, many people do not voluntarily seek testing for HIV, remain unaware of their HIV status, and consequently do not seek the care that could help them live longer, healthier lives. Opportunities to educate people are also lost as people at-risk avoid prevention programs because of the stigma associated with HIV.

1. Record of Accomplishment

During the early years of the AIDS epidemic, protection of the civil rights of people living with HIV/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. Sentinel achievements include:

- Enactment of the Harkin-Humphrey Amendment to the Civil Rights Restoration Act, clarifying that Section 504 of the Rehabilitation Act of 1973 applied to people with contagious diseases, including HIV; and
- Passage of the Americans with Disabilities Act of 1990 (ADA) which protects individuals living with HIV and AIDS, and people perceived to be at risk for HIV [Are we sure this is true?], 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/AIDS a priority. Key actions include:

- Vigorously enforcing the ADA by the Justice Department, the Equal Employment Opportunities Commission, and the Department of Health and Human Services. The Federal government has resolved nearly 800 charges alleging discrimination against people with HIV and AIDS obtaining monetary benefits of more than \$6.1 million; [Are these figures correct? ... source(s)?]
- Vigorously enforcing Section 504 of the Rehabilitation Act of 1973 as it pertains to recipients of DHHS funds such as hospitals, nursing homes, and social service agencies;
- Forcefully opposing the so-called "Dornan Amendment," which would require the discharge of all military personnel who are living with HIV. President Clinton declared the proposal unconstitutional and directed the Department of Justice not to defend it if challenged in court. The President led a successful effort to repeal the "Dornan Amendment" and continues to oppose its enactment;
- Establishing an AIDS education program for all Federal workers; [Do we want reference to this?]
- Using the Presidential "bully pulpit" to continually speak out against discrimination against people with HIV and AIDS.

2. Future Opportunities for Progress

Enforcing Rights. Efforts to protect the civil rights of people with HIV/AIDS must be ever-vigilant. The Federal government must 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 in health care facilities. A joint effort by the Department of Health and Human Services and the Department of Justice aimed at nursing homes is a significant step forward.

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

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

E. INTERNATIONAL ACTIVITIES

Insert quote:

AIDS is a global epidemic. Eighty 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 World Health Organization (WHO) 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/AIDS by the year 2000. WHO also estimates that two to three million new HIV infections can be expected annually, and by the year 2000, thirty to forty million people will have been infected around the globe.

The epidemic jeopardizes decades of economic and social advances in many developing nations. In the nations of Africa and Asia, economic advances are threatened and in some cases may be reversed due to HIV and AIDS. Socio-economic studies have shown a decrease in overall domestic savings and investment levels, negative effects on foreign investments, reductions in the volumes of imports and exports, and a reduction in receipts from tourism.⁹ In many countries governments will be forced to cope with increasing numbers of cases, weakened health care systems, a deleterious economic impact on the most productive segments of society, and the reduction in the number of healthy men and women able to serve in the government and the military.

1. Record of Accomplishment

Since it began, HIV/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:

- Founding of the Global Programme on AIDS in 1987, and
- Founding of the United Nations Programme on AIDS (UNAIDS) in 1995 (correct date?).

The United States is the largest contributor to international efforts to combat the pandemic of HIV/AIDS. Several Federal Agencies are working slow the AIDS epidemic internationally. (See Appendix D.) The Department of State works with other Departments, Agencies, and non-governmental organizations to develop a framework to guide U.S. foreign policy in the global efforts against HIV and AIDS. The major areas of U.S. leadership in the HIV arena are: preventing new infections; reducing the personal and social impact

of the pandemic; and mobilizing and unifying national and international efforts.

The U.S. Agency for International Development (USAID) also plays leadership role in the global HIV effort through development assistance, research and policy formation. USAID focuses its efforts on developing prevention programs based on proven interventions; addressing social, cultural, regulatory and economic issues related to HIV/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 basic scientific studies on social and behavioral aspects of AIDS in developing countries. The results of the studies ultimately will be used to develop interventions to reduce behaviors that place individuals at risk for contracting HIV infection.

2. Future Opportunities for Progress

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 and Co-sponsored United Nations Programme on AIDS (UNAIDS).¹⁰ The U.S. is a member of the governing body of UNAIDS and signed the 1994 Paris Declaration and the Greater Involvement of People Living with HIV/AIDS Initiative (GIPA).

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

Strengthening Partnerships. In addition to maintaining our

multilateral partnerships, we must strengthen and expand our bilateral programs and funds for HIV activities. We must reverse the current trend to reduce assistance to developing countries where more than 90 percent of the world's AIDS cases are found. (OK?)

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 should be expanded. [Do we want to say this in light of the USAID cuts, reduced \$ in FY97 PB, etc?]

Improving Program Coordination. One of the most challenging aspects of the U.S. effort is effective coordination among a host of Agencies with varied missions and activities. In order to ensure that efforts are productive, the Agencies supporting international activities must develop a mechanism for coordinating U.S. programs in a systematic and efficient manner.

F. TRANSLATION OF RESEARCH ADVANCES INTO PRACTICE

Insert Quote

An important element in our fight against AIDS is ensuring that research advances are translated into the care of HIV positive persons. The increasing presence of HIV in every community necessitates that all health care providers become knowledgeable about assessing risk, promoting prevention, and caring for people with HIV.

An example of the importance of such efforts is the translation of the research finding in AIDS Clinical Trial Group 076, which found that the use of AZT by pregnant women during pregnancy and childbirth and its application to newborns for the first six weeks of life can reduce the risk of perinatal transmission of HIV by two-thirds. Translation of these results required actions by the Centers for Disease Control and Prevention, which prepared guidelines for physicians caring for pregnant women and for consumers; the Health Resources and Services Administration, which provided guidance to grantees on coverage of such services; the Health Care Financing Administration, which provided similar guidance to State Medicaid Directors.

1. Record of Achievement

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

- The National Institutes of Health (NIH) supports a broad range of efforts including a "Clinical Alerts" mechanism for the dissemination of clinical trials results to health professionals, the media, and the public;
- DHHS supports and directs the International HIV/AIDS Clinical Conference Call series, which disseminates critical, state-of-the-art clinical care information to primary care providers via live worldwide audio tele-conferencing;
- NIH supports publicly available computerized databases such as AIDSDRUGS, AIDSTRIALS, and AIDSLINE;
- The toll-free 1-800 TRIALS-A AIDS Clinical Trials Information Service (ACTIS) is co-sponsored by NIH, CDC, and FDA;

- The Centers for Disease Control and Prevention disseminates information through the National AIDS Hotline (1-800-342-AIDS); its toll-free 1-800-HIV-0440 HIV/AIDS Treatment Information Service (ATIS); and the AIDS Information Clearinghouse;
- The CDC also issues guidelines for health professionals through its *Morbidity and Mortality Weekly Report*;
- The Agency for Health Care Policy and Research (AHCPR) has published a series of HIV-related clinical practice guidelines for clinicians and companion pamphlets for their patients; and,
- The Health Resources and Services Administration directs a nationwide system of AIDS Education and Training Centers that provide state of the art HIV clinical information to health care providers. HRSA also has developed guidances for its Ryan White CARE Act grantees and funds an AIDS warmline that responds to questions from clinicians across the country.

2. Future Opportunities for Progress

There are opportunities for improvement in translating research advances into practice. They include:

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/AIDS must be expanded. [How do we reconcile decrease in AETCs?] An AHCPR-supported study indicated that primary care physicians may miss significant HIV-related symptoms during patient examinations.¹¹ Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.¹² Reference Kittahare (sp?) article.

Disseminating Guidelines. One of the most difficult tasks for clinicians and patients is interpreting the patchwork of data and articles regarding treatments and converting it into a therapeutic strategy for their patients. With every research breakthrough, this task becomes more difficult. It is essential that practical information for practicing clinicians and their patients be provided in a timely manner.

The Federal government currently supports a number mechanisms for periodically assessing advances in clinical care. It is essential

that these assessment efforts continue and that crucial information be widely disseminated. This will require collaboration with industry, government, and professional groups.

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

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

Footnotes

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

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

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

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

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

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

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

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

4. Heiner Grosskurth, Frankc Mosha, James Todd, Extra Mwijarubi, Arnould Clokke, Kesheni Senkoro, Philippe Mayaud, John Chagalucha, Angus Nicoll, Gina ka-Gina, James Newell, Kokuugonza Mugeye, David Mabey, Richard Hayes. Impact of Improved Treatment of Sexually Transmitted Diseases on HIV Infection in Rural Tanzania: Randomized Controlled Trial. *The Lancet*, Vol. 346, August 26, 1995.
5. Maria Wawer, *Science*. 9.08.95, vol. 269, No. 5229
6. Personal communication from CDC Division TB Elimination.
7. Alan B. Stone, and Penelope J. Hitchcock. Vaginal Microbicides for Preventing the Transmission of HIV. *AIDS* 1994, 8 (suppl 1):S285-S293.
8. Housing and the HIV/AIDS Epidemic: Recommendations for Action. National Commission on AIDS. Washington, D.C. July 1992.
9. *HIV/AIDS Policy Guidance*. U.S. Agency for International Development. September 1995.
10. 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.
11. 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.
12. 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)