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August 6, 1996

Jeff --

Attached are two new versions of the intro and prevention sections.

Version #1: Incorporates JL shortened intro, adds RS quotes and accomplishments, slightly pares down previous version, and responds to edits from PF, RS, JL, SD, MC, LR.

Version #2: Takes out a lot of previous text (in prevention), incorporates JL shortened intro, adds RS quotes and accomplishments.

I'm working on the rest of the document now. (Research on....)

After you have ^{read these} I would ~~1~~ like to get your comments and go over where we need to go from here.

Thanks,



To JL 11:15 am
(Prevention)
1:45 pm
(Research)

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Members of the Interdepartmental Task Force on HIV and AIDS

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, international activities, translation of research into practice, and civil rights.

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. Whilst 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 600,000 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 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

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.

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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.

Introduction

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'.

■ 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 also 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.

■ *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.

Improving Understanding of Modes of Transmission

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 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. Moreover, young people are becoming infected at an alarming rate; 50 percent of new infections are among persons under age 25. It is likely that many Americans, aged 25 to 44, for whom HIV is the leading cause of death, became infected as adolescents. Racial and ethnic minorities also are disproportionately represented among HIV infections. In 1995, African-Americans accounted for 40 percent of newly reported AIDS cases and Hispanics represented 19 percent of new cases. More than 50 percent of women with HIV/AIDS are African American or Hispanic. 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. Seroprevalence surveys provide information on the level of HIV infections in selected "sentinel" populations. As the Federal Agency with primary responsibility for monitoring the epidemic, 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. This surveillance system also provides essential data on HIV-related opportunistic infections.

There are, however, opportunities for refinement. Effective prevention intervention programs begin with sound information 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.

Prevention Research: Closing Gaps in Scientific Knowledge³

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. Experience has taught us that prevention efforts can be effective, when the intervention incorporates findings from both experience and relevant research. Many significant scientific questions exist in the field of HIV-related behavioral research. 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. Basic behavioral research, seeks to explain the determinants and causes underlying biological, behavioral, and social processes. HIV-related risk-taking behavior is often complex and influenced by a host of individual and environmental factors.

To capitalize on what is known and 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. For example, although much has been learned about the basic biology of substance abuse, greater understanding of the mechanisms underlying addictive behavior could assist in the development of new therapeutic approaches to addiction. This may in turn, reduce the number of new HIV infections.⁴ Although there is some information on relevant risk-taking behaviors, more information about knowledge, attitudes, decision-making processes, and beliefs about AIDS and other sexually transmitted diseases (STDs) is 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.⁵

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. We know from other behavior-influenced diseases (such as hypertension) and practices (such as smoking cigarettes and wearing seatbelts) that basic information about what motivates a person to exhibit these behaviors can be incorporated into intervention research to advance approaches which reduce unhealthy behaviors.

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. This theoretically based intervention research has identified several significant predictors of change in sexual and drug-using behaviors among gay men, adolescents, and heterosexual adults.⁶ Studies have shown that community-based HIV risk reduction programs that are gender-relevant and culturally-sensitive can be effective.⁷ A recent study has also provided a reason for optimism that the spread of HIV can be contained among injecting drug user populations when there is early community outreach and access to sterile injection equipment. Keep??⁸

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. One high priority area is research on interventions that lead to sustained behavioral change and reduced recidivism. Another area for investment is research on cultural barriers and strategies to reach populations resistant to certain behavioral interventions. A third area is research on the effectiveness of treatment for drug abuse, mental illness, and alcoholism in reducing HIV risk behavior.

Agencies supporting intervention and behavioral research must include scientists from a broad range of disciplines in their planning activities and improve their data-sharing and collaborative efforts with Agencies responsible for implementing prevention programs. 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.

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

way to those on the front lines of the epidemic. Community-based organizations, which are responsible for developing a large portion of the prevention programs, often do not or cannot, take advantage of current knowledge about program effectiveness.

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. Presently, the Federal government supports a range of programs that address the disparate needs of a number of at-risk populations. However, resource allocation pressures among many community-based organizations has resulted in gaps in program areas. 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.

Insert RS paragraph on minority CBOs 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 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

expanded 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. There is also substantial evidence that use of non-injectable drugs such as alcohol and crack cocaine can adversely influence risk-taking behavior. SAMHSA supports the urgent need for the integration of substance abuse prevention and treatment and HIV prevention services for those who use drugs, however, SAMSHA recognizes that there is a "hardcore" segment of the population that refuses treatment and will not practice HIV prevention. The need to encourage HIV prevention and treatment for this population is critical.

Fundamental to the success of an integrated approach would be the continued expansion of educational activities to prevent substance abuse and increased outreach efforts to encourage active substance abusers to seek treatment. We also need to ensure that sufficient drug treatment services are available for a range of addictions for those in need.

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.^{9,10} 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.

HIV positive people are at very high for developing active tuberculosis (TB) disease. People infected with both HIV and TB are more likely to develop active TB disease than people who are infected only with TB. 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.¹¹ 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.

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. 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.

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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 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. Incorporating effectiveness measures must become a routine part of all Federally-funded programs. It is only through sound evaluations that we will be able to determine whether our efforts have been effective in slowing the epidemic. Achieving this will also require careful examination of what programs should be continued, what activities need to be initiated, and an awareness that a reconfiguration of some program priorities may be required.

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

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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, international activities, translation of research into practice, and civil rights.

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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. Whilst 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 600,000 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.

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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

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.

Insert RS language on minority CBOs 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 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 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

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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.

2/6/96 JS edits to make Prevention Shaker.

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■ Record of Accomplishment

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There have ~~also~~ 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 have a clearer understanding of those who are becoming infected and what behaviors are placing people at risk for infection. Recent

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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. ~~Moreover, young people are becoming infected at an alarming rate; 50 percent of new infections are among persons under age 25. It is likely that many Americans, aged 25 to 44, for whom HIV is the leading cause of death, became infected as adolescents. Racial and ethnic minorities also are disproportionately represented among HIV infections. In 1995, African-Americans accounted for 40 percent of newly reported AIDS cases and Hispanics represented 19 percent of new cases. More than 50 percent of women with HIV/AIDS are African American or Hispanic. 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. ~~Seroprevalence surveys provide information on the level of HIV infections in selected "sentinel" populations. As the Federal Agency with primary responsibility for monitoring the epidemic, 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. This surveillance system also provides essential data on HIV-related opportunistic infections.~~

There are, however, opportunities for refinement. Effective prevention intervention programs begin with sound information 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.

6. Prevention Research: Closing Gaps in Scientific Knowledge³

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. ~~Experience has taught us that prevention efforts can be effective, when the intervention incorporates findings from both experience and relevant research. Many significant scientific questions exist in the field of HIV-related behavioral research.~~ 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. ~~Basic behavioral research, seeks to explain the determinants and causes underlying biological, behavioral, and social processes. HIV-related risk-taking behavior is often complex and influenced by a host of individual and environmental factors.~~

To capitalize on what is known and 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. ~~For example, although much has been learned about the basic biology of substance abuse, greater understanding of the mechanisms underlying addictive behavior could assist in the development of new therapeutic approaches to addiction. This may in turn, reduce the number of new HIV infections.⁴ Although there is some information on relevant risk-taking behaviors, more information about knowledge, attitudes, decision-making processes, and beliefs about AIDS and other sexually transmitted diseases (STDs) is 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.⁵

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. ~~We know from other behavior-influenced diseases (such as hypertension) and practices (such as smoking cigarettes and wearing seatbelts) that basic information about what motivates a person to exhibit these behaviors can be incorporated into intervention research to advance approaches which reduce~~

unhealthy behaviors.

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. ~~This theoretically-based~~ intervention research has identified several significant predictors of change in sexual and drug-using behaviors among gay men, adolescents, and heterosexual adults.⁶ Studies have shown that community-based HIV risk reduction programs that are gender-relevant and culturally-sensitive can be effective.⁷ A recent study has also provided a reason for optimism that the spread of HIV can be contained among injecting drug user populations when there is early community outreach and access to sterile injection equipment. Keep??⁸

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. One high priority area is research on interventions that lead to sustained behavioral change and reduced recidivism. Another area for investment is research on cultural barriers and strategies to reach populations resistant to certain behavioral interventions. A third area is research on the effectiveness of treatment for drug abuse, mental illness, and alcoholism in reducing HIV risk behavior.

Agencies supporting intervention and behavioral research must include scientists from a broad range of disciplines in their planning activities and improve their data-sharing and collaborative efforts with Agencies responsible for implementing prevention programs. 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.

We know from efforts in other countries that HIV-related social marketing efforts can be successful. However, we have not been as effective as we could be in disseminating information about effective strategies so that this knowledge can be employed in the design and implementation of prevention interventions. There are good models for prevention interventions that are not making their way to those on the front lines of the epidemic. Community-based organizations, which are responsible for developing a large portion of the prevention programs, often do not or cannot, take advantage of current knowledge about program effectiveness.

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. ~~Presently, the Federal government supports a range of programs that address the disparate needs of a number of at-risk populations. However, resource allocation pressures among many community-based organizations has resulted in gaps in program areas.~~ ^{Nov 21/96} 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.

Insert RS paragraph on minority CBOs 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 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 ~~expanded~~ 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. There is also substantial evidence that use of non-injectable drugs such as alcohol and crack cocaine can adversely influence risk-taking behavior. SAMHSA supports the urgent need for the integration of substance abuse prevention and treatment and HIV prevention services for those who use drugs, however, SAMHSA recognizes that there is a "hardcore" segment of the population that refuses treatment and will not practice HIV prevention. The need to encourage HIV prevention and treatment for this population is critical.

Fundamental to the success of an integrated approach would be the continued expansion of educational activities to prevent substance abuse and increased outreach efforts to encourage active substance abusers to seek treatment. We also need to ensure that sufficient drug treatment services are available for a range of addictions for those in need.

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.

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HIV transmission is underway and should continue.

HIV positive people are at very high for developing active tuberculosis (TB) disease. ~~People infected with both HIV and TB are more likely to develop active TB disease than people who are infected only with TB.~~ 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." 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.

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. 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

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Draft for ONAP Review, 7.22.96

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 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. ~~Incorporating effectiveness measures~~ must become a routine part of all Federally-funded programs. It is only through sound evaluations that we will be able to determine whether our efforts have been effective in slowing the epidemic. Achieving this will also require careful examination of what programs should be continued, what activities need to be initiated, and an awareness that a reconfiguration of some program priorities may be required.

RESEARCH

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President Clinton, December 5, 1995

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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:

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³This section focus 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.

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

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.

Clinical Effectiveness Research. 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 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

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.

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 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

Option #2 Re-write: Shorter Version
August 6, 1996, 10:00 am (c:\....\final\text3.g96)

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RESEARCH

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2. Future Opportunities for Progress

Despite these advances, many complex biomedical and behavioral challenges remain. Identifying the most promising scientific avenues and having the appropriate structures and processes in place to ensure that the Nation capitalizes on these opportunities requires a considered and coordinated effort.

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. The law requires that the OAR develop a yearly NIH plan and budget for AIDS research and receive directly from the President and the Office of Management and Budget (OMB) a consolidated appropriation for AIDS activities at NIH. This single appropriation allows the OAR to effectively prioritize research resources on the basis of sound scientific judgment and provides flexibility for pursuing the most promising research opportunities.

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

Add RS language about the Levine Report

While NIH supports a significant portion of HIV-related research, other Agencies support a broad spectrum of research related to HIV and AIDS and have responded with research initiatives that bring to bear their unique capabilities and strengths.

This research is often carried out collaboratively. For example, the CDC, FDA, DOD, and NIH hold monthly discussions on protecting the country's blood supply. The DoD and NIH collaborate in the conduct of clinical trials, and strong linkages exist between basic and applied biomedical studies on HIV disease sponsored by the DoD, NIH, and VA. In addition, the CDC and VA jointly sponsor surveillance studies on the incidence of HIV-related opportunistic infections.

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.

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

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

Both approaches face significant obstacles and it is clear that 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. In the U.S. the infection rate among women is rising dramatically. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs¹². An easily available and inexpensive microbicide could provide a prevention option for millions of women worldwide.

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. Although epidemiological studies have demonstrated that the correct and consistent use of condoms will reduce the risk of acquiring and transmitting HIV and other STDs, there are many situations in which interpersonal, social, or cultural barriers interfere with a woman's ability to successfully negotiate condom use. The need for a method that can be employed by women is based on the prevalence of non-consensual sex, sex without condom use, and HIV risk behaviors that occur without partner knowledge.

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. To date, HIV research efforts have primarily focused on two specific populations, infants and adults.

There is however information indicating that HIV may behave differently in infected adolescents. Adolescent treatment approaches may vary from those used for adult or infants. Little definitive research has been conducted to date with HIV-positive adolescents, therefore, the specific impact of puberty on the

course of HIV infection has not yet been determined. Behavioral trends that play a key factor in treatment and prevention have also not been sufficiently studied.

Adolescents must 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.

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

Clinical Effectiveness Research. Due in part to the FDA's accelerated approval program¹³, the Federal government is now approving new treatments in record numbers and at record speed, but it is not always known whether a treatment confers a clinical benefit for the person. Specifically, while some treatments have shown promise based on surrogate markers and/or laboratory tests, data regarding long-term clinical effectiveness are unavailable. For example, we do not know the optimal stage in the course of HIV disease to begin treatment, for which patient groups, with which regimen, or with single or combination therapy. We also do not know when it is appropriate to switch or add therapies.

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

With the advent of accelerated approval by the FDA, it is incumbent upon the government to ensure that post-marketing effectiveness studies, currently mandated through regulation, are carried out. In order for the results to be relevant to as many persons as possible, it will be necessary that these studies include people representing a diversity of race, ethnicity, gender, age, and drug using behaviors. To develop a mechanism for conducting such studies, the Vice President has initiated discussions to examine possible options. Participants include pharmaceutical firms, public and private payors and insurers, researchers, 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. The Department of Defense has been successful in developing partnerships in the conduct of vaccine trials and this effort should be strengthened. As noted previously, microbicides (i.e., chemical barrier methods for preventing HIV transmission) are a promising approach, but will require preliminary Federal support before they reach a stage where the private sector can assume a lead role.

It is also unlikely that the free market system will push the implementation of head-to-head clinical trials of therapies that have been approved or are in development. However, information about these therapies is important to improving patient care and ensuring that the Nation's health dollars are wisely spent. The National Institutes of Health (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.

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Option #1 Re-write: Longer Version

August 6, 1996, 10:00 am (c:\....\final\text2.g96)

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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.

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RESEARCH¹²

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- Charged Vice President Gore to work with drug companies and AIDS researchers and advocates to accelerate AIDS drug development.

Record of Accomplishment: 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.

■ Future Opportunities for Progress

We must ensure that... identifies the Nation capitalizes on the most promising

Despite these advances, many complex biomedical and behavioral challenges remain. ~~Identifying the most promising scientific avenues, and having the appropriate structures and processes in place to ensure that the Nation capitalizes on these opportunities~~ requires a considered and coordinated effort.

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

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Amendments of 1993, provided the Office of AIDS Research (OAR) with new oversight and budget authorities. ~~The law requires that the OAR develop a yearly NIH plan and budget for AIDS research and receive directly from the President and the Office of Management and Budget (OMB) a consolidated appropriation for AIDS activities at NIH. This single appropriation allows the OAR to effectively prioritize research resources on the basis of sound scientific judgment and provides flexibility for pursuing the most promising research opportunities.~~

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

Add RS language about the Levine Report

~~While NIH supports a significant portion of HIV-related research, other Agencies support a broad spectrum of research related to HIV and AIDS, and have responded with research initiatives that bring to bear their unique capabilities and strengths.~~

~~This research is often carried out collaboratively. For example, the CDC, FDA, DOD, and NIH hold monthly discussions on protecting the country's blood supply. The DoD and NIH collaborate in the conduct of clinical trials, and strong linkages exist between basic and applied biomedical studies on HIV disease sponsored by the DoD, NIH, and VA. In addition, the CDC and VA jointly sponsor surveillance studies on the incidence of HIV-related opportunistic infections.~~

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

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

~~Both approaches face significant obstacles and it is clear that 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. ~~In the U.S. the infection rate among women is rising dramatically?~~ (Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs¹³.) An easily available and inexpensive microbicide could provide a prevention option for millions of women worldwide.

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. ~~Although epidemiological studies have demonstrated that the correct and consistent use of condoms will reduce the risk of acquiring and transmitting HIV and other STDs, there are many situations in which interpersonal, social, or cultural barriers interfere with a woman's ability to successfully negotiate condom use. The need for a method that can be employed by women is based on the prevalence of non-consensual sex, sex without condom use, and HIV risk behaviors that occur without partner knowledge.~~

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. ~~To date, HIV research efforts have primarily focused on two specific populations, infants and adults.~~

There is however information indicating that HIV may behave differently in infected adolescents. ~~Adolescent treatment approaches may vary from those used for adult or infants.~~ Little definitive research has been conducted to date with HIV-positive

adolescents, therefore, the specific impact of puberty on the course of HIV infection has not yet been determined. Behavioral trends that play a key factor in treatment and prevention have also not been sufficiently studied.

Adolescents must 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*

~~There is also a need for more adolescent-relevant information for clinicians and researchers. The Adolescent Medicine HIV/AIDS Research Network, 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) serves as an important model of collaboration in this area of research. This Network has been developed to improve our understanding of disease and health in adolescents. Several PHS agencies have cooperatively established the Adolescent Medicine HIV/AIDS Research Network. The Public Health Service should continue to develop, in collaboration with researchers, clinicians, and the infected and affected community, clinical practice guidelines and expeditiously disseminate the latest information on state-of-the-art therapies, options for trials and eligibility criteria for entry into them, and health care and prevention techniques to U.S. and international communities affected by HIV/AIDS. This work should continue.~~

Clinical Effectiveness Research. ^{FN} Due in part to the FDA's accelerated approval program¹⁴, the Federal government is now approving new treatments in record numbers and at record speed, but it is not always known whether a treatment confers a clinical benefit for the person. Specifically, while some treatments have shown promise based on surrogate markers and/or laboratory tests, data regarding long-term clinical effectiveness are unavailable. ~~For example, we do not know the optimal stage in the course of HIV disease to begin treatment, for which patient groups, with which regimen, or with single or combination therapy. We also do not know when it is appropriate to switch or add therapies.~~

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

optimally effective. *and the private sector*

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

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. ~~The Department of Defense has been successful in developing partnerships in the conduct of vaccine trials and this effort should be strengthened. As noted previously, microbicides (i.e., chemical barrier methods for preventing HIV transmission) are a promising approach, but will require preliminary Federal support before they reach a stage where the private sector can assume a lead role.~~

It is ~~also~~ unlikely that the free market system will push the implementation of head-to-head clinical trials of therapies that have been approved or are in development. However, information about these therapies is important to improving patient care and ensuring that the Nation's health dollars are wisely spent. The National Institutes of Health (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 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.

August 6, 1996

Jeff --

Attached are two new versions of the intro and prevention sections.

Version #1: Incorporates JL shortened intro, adds RS quotes and accomplishments, slightly pares down previous version, and responds to edits from PF, RS, JL, SD, MC, LR.

Version #2: Takes out a lot of previous text (in prevention), incorporates JL shortened intro, adds RS quotes and accomplishments.

I'm working on the rest of the document now. (Research on...)

After you have ^{read these} I would ~~like~~ like to get your comments and go over where we need to go from here.

Thanks,



August 7th, 1996

Received JL comments on
intro + PF (short version).

]

Jeff -

8/6/96

Here are the long
and 'short' versions
for the research
section.



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Message from the Director of the Office of National AIDS Policy

The epidemic of HIV and AIDS constitutes a public health crisis of unprecedented proportions. In 1993, the Office of National AIDS Policy (ONAP) was created by President Clinton to provide a national focus and direction for the government's response to HIV and AIDS. More recently, President Clinton asked ONAP to develop a comprehensive National 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, international activities, translation of research into practice, and civil rights.

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

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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. Whilst 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 600,000 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 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

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.

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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.

Introduction

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'.

■ 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

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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 duel 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 also 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.

■ 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.

Improving Understanding of Modes of Transmission

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 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. Moreover, young people are becoming infected at an alarming rate; 50 percent of new infections are among persons under age 25. It is likely that many Americans, aged 25 to 44, for whom HIV is the leading cause of death, became infected as adolescents. Racial and ethnic minorities also are disproportionately represented among HIV infections. In 1995, African-Americans accounted for 40 percent of newly reported AIDS cases and Hispanics represented 19 percent of new cases. More than 50 percent of women with HIV/AIDS are African American or Hispanic. 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. Seroprevalence surveys provide information on the level of HIV infections in selected "sentinel" populations. As the Federal Agency with primary responsibility for monitoring the epidemic, 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. This surveillance system also provides essential data on HIV-related opportunistic infections.

There are, however, opportunities for refinement. Effective prevention intervention programs begin with sound information 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.

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. Experience has taught us that prevention efforts can be effective, when the intervention incorporates findings from both experience and relevant research. Many significant scientific questions exist in the field of HIV-related behavioral research. 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. Basic behavioral research, seeks to explain the determinants and causes underlying biological, behavioral, and social processes. HIV-related risk-taking behavior is often complex and influenced by a host of individual and environmental factors.

To capitalize on what is known and 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. For example, although much has been learned about the basic biology of substance abuse, greater understanding of the mechanisms underlying addictive behavior could assist in the development of new therapeutic approaches to addiction. This may in turn, reduce the number of new HIV infections.⁴ Although there is some information on relevant risk-taking behaviors, more information about knowledge, attitudes, decision-making processes, and beliefs about AIDS and other sexually transmitted diseases (STDs) is 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.⁵

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. We know from other behavior-influenced diseases (such as hypertension) and practices (such as smoking cigarettes and wearing seatbelts) that basic information about what motivates a person to exhibit these behaviors can be incorporated into intervention research to advance approaches which reduce unhealthy behaviors.

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. This theoretically based intervention research has identified several significant predictors of change in sexual and drug-using behaviors among gay men, adolescents, and heterosexual adults.⁶ Studies have shown that community-based HIV risk reduction programs that are gender-relevant and culturally-sensitive can be effective.⁷ A recent study has also provided a reason for optimism that the spread of HIV can be contained among injecting drug user populations when there is early community outreach and access to sterile injection equipment. Keep??⁸

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. One high priority area is research on interventions that lead to sustained behavioral change and reduced recidivism. Another area for investment is research on cultural barriers and strategies to reach populations resistant to certain behavioral interventions. A third area is research on the effectiveness of treatment for drug abuse, mental illness, and alcoholism in reducing HIV risk behavior.

Agencies supporting intervention and behavioral research must include scientists from a broad range of disciplines in their planning activities and improve their data-sharing and collaborative efforts with Agencies responsible for implementing prevention programs. 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.

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

way to those on the front lines of the epidemic. Community-based organizations, which are responsible for developing a large portion of the prevention programs, often do not or cannot, take advantage of current knowledge about program effectiveness.

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. Presently, the Federal government supports a range of programs that address the disparate needs of a number of at-risk populations. However, resource allocation pressures among many community-based organizations has resulted in gaps in program areas. 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.

Insert RS paragraph on minority CBOs 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 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

expanded 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. There is also substantial evidence that use of non-injectable drugs such as alcohol and crack cocaine can adversely influence risk-taking behavior. SAMHSA supports the urgent need for the integration of substance abuse prevention and treatment and HIV prevention services for those who use drugs, however, SAMSHA recognizes that there is a "hardcore" segment of the population that refuses treatment and will not practice HIV prevention. The need to encourage HIV prevention and treatment for this population is critical.

Fundamental to the success of an integrated approach would be the continued expansion of educational activities to prevent substance abuse and increased outreach efforts to encourage active substance abusers to seek treatment. We also need to ensure that sufficient drug treatment services are available for a range of addictions for those in need.

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.^{9,10} 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.

HIV positive people are at very high for developing active tuberculosis (TB) disease. People infected with both HIV and TB are more likely to develop active TB disease than people who are infected only with TB. 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.¹¹ 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.

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. 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.

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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 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. Incorporating effectiveness measures must become a routine part of all Federally-funded programs. It is only through sound evaluations that we will be able to determine whether our efforts have been effective in slowing the epidemic. Achieving this will also require careful examination of what programs should be continued, what activities need to be initiated, and an awareness that a reconfiguration of some program priorities may be required.

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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.² 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

²This section focus^{os} 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.

2. Future Opportunities for Progress

Despite these advances, many complex biomedical and behavioral challenges remain. Identifying the most promising scientific avenues and having the appropriate structures and processes in place to ensure that the Nation capitalizes on these opportunities requires a considered and coordinated effort.

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. The law requires that the OAR develop a yearly NIH plan and budget for AIDS research and receive directly from the President and the Office of Management and Budget (OMB) a consolidated appropriation for AIDS activities at NIH. This single appropriation allows the OAR to effectively prioritize research resources on the basis of sound scientific judgment and provides flexibility for pursuing the most promising research opportunities.

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

Add RS language about the Levine Report

While NIH supports a significant portion of HIV-related research, other Agencies support a broad spectrum of research related to HIV and AIDS and have responded with research initiatives that bring to bear their unique capabilities and strengths.

This research is often carried out collaboratively. For example, the CDC, FDA, DOD, and NIH hold monthly discussions on protecting the country's blood supply. The DoD and NIH collaborate in the conduct of clinical trials, and strong linkages exist between basic and applied biomedical studies on HIV disease sponsored by the DoD, NIH, and VA. In addition, the CDC and VA jointly sponsor surveillance studies on the incidence of HIV-related opportunistic infections.

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

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

Both approaches face significant obstacles and it is clear that 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. In the U.S. the infection rate among women is rising dramatically. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs¹². An easily available and inexpensive microbicide could provide a prevention option for millions of women worldwide.

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. Although epidemiological studies have demonstrated that the correct and consistent use of condoms will reduce the risk of acquiring and transmitting HIV and other STDs, there are many situations in which interpersonal, social, or cultural barriers interfere with a woman's ability to successfully negotiate condom use. The need for a method that can be employed by women is based on the prevalence of non-consensual sex, sex without condom use, and HIV risk behaviors that occur without partner knowledge.

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. To date, HIV research efforts have primarily focused on two specific populations, infants and adults.

There is however information indicating that HIV may behave differently in infected adolescents. Adolescent treatment approaches may vary from those used for adult or infants. Little definitive research has been conducted to date with HIV-positive adolescents, therefore, the specific impact of puberty on the

course of HIV infection has not yet been determined. Behavioral trends that play a key factor in treatment and prevention have also not been sufficiently studied.

Adolescents must 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.

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

Clinical Effectiveness Research. Due in part to the FDA's accelerated approval program¹³, the Federal government is now approving new treatments in record numbers and at record speed, but it is not always known whether a treatment confers a clinical benefit for the person. Specifically, while some treatments have shown promise based on surrogate markers and/or laboratory tests, data regarding long-term clinical effectiveness are unavailable. For example, we do not know the optimal stage in the course of HIV disease to begin treatment, for which patient groups, with which regimen, or with single or combination therapy. We also do not know when it is appropriate to switch or add therapies.

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

With the advent of accelerated approval by the FDA, it is incumbent upon the government to ensure that post-marketing effectiveness studies, currently mandated through regulation, are carried out. In order for the results to be relevant to as many persons as possible, it will be necessary that these studies include people representing a diversity of race, ethnicity, gender, age, and drug using behaviors. To develop a mechanism for conducting such studies, the Vice President has initiated discussions to examine possible options. Participants include pharmaceutical firms, public and private payors and insurers, researchers, 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. The Department of Defense has been successful in developing partnerships in the conduct of vaccine trials and this effort should be strengthened. As noted previously, microbicides (i.e., chemical barrier methods for preventing HIV transmission) are a promising approach, but will require preliminary Federal support before they reach a stage where the private sector can assume a lead role.

It is also unlikely that the free market system will push the implementation of head-to-head clinical trials of therapies that have been approved or are in development. However, information about these therapies is important to improving patient care and ensuring that the Nation's health dollars are wisely spent. The National Institutes of Health (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.

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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 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.

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Message from the Director of the Office of National AIDS Policy

The epidemic of HIV and AIDS constitutes a public health crisis of unprecedented proportions. In 1993, the Office of National AIDS Policy (ONAP) was created by President Clinton to provide a national focus and direction for the government's response to HIV and AIDS. More recently, President Clinton asked ONAP to develop a comprehensive National 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, international activities, translation of research into practice, and civil rights. > on the

This is intended to be a living document that will require regular updating and adjustment as goals are reached and as new challenges

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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~~ ^{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

while

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 600,000 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.

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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

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.

Insert RS language on minority CBOs 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 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.

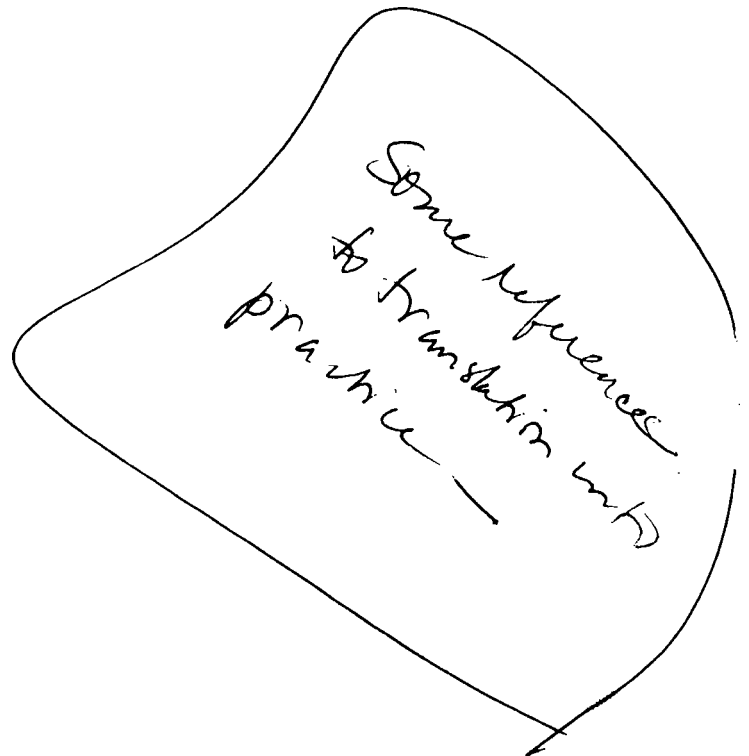
Given that prisoners are often at increased risk for HIV infection, offering educational programs during incarceration provides a unique opportunity to reach these persons. Research has shown that individuals who are well informed about HIV and substance abuse issues do modify their risk-taking behaviors.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

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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.



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.

add Keystone

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

How about early
ref. to Fed Plan
NIAH plan
for specific
priorities?

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.

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.

① **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.

② **Vaccine Development.** Several major challenges currently face the U.S. and the world in the HIV vaccine development effort. The first is to surmount the daunting scientific and social challenges and the second is to ensure the development and testing of promising vaccine candidates.

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

are pursuing approaches
Levine

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.

3 **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 would 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.

Clinical Effectiveness Research. 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 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

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.

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 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

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investment.

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 finance 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

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.

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*

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. Since January 1993 the Federal government has:

- Increased funding for the Ryan White CARE Act 134 percent in four years;
- Doubled funding for the AIDS Drug Assistance Program in the last two years;
- Increased funding for Housing Opportunities for People with AIDS 96 percent in four years;
- Preserved 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
- Revised 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 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 service resources were often directed toward meeting the acute care needs

of persons diagnosed with AIDS, rather than towards early preventive care for initial 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 finance 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.³ Thus, 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 Maternal and Child Health Programs.

Other sources of primary care supported by the Federal government

³ JL cite. Add Vancouver numbers.

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. The program provides coverage for hospitalizations, physician visits, x-rays and laboratory tests, home health care, nursing home care, and outpatient prescription drugs. In fiscal year 1996, Federal Medicaid spending for people living with AIDS is estimated at \$1.8 billion, nearly six times the amount expended on the Ryan White CARE Act.

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

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

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

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

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

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. It is the foundation upon which any program of care or services must be built. 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.¹⁴

People living with HIV and their families face significant obstacles locating affordable housing. The private market alone does not consistently meet their basic housing needs. Housing must often be provided in connection with specialized services that enhance an individual's or family's ability to live independently. In addition, people living with HIV must also overcome reduced

housing options due to unfounded fears and prejudice regarding AIDS.

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

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

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

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. Identifying HIV-positive prisoners and ensuring them access to quality care for incarcerated people is especially challenging. Prisoners do not have the choice of seeking care outside the prison setting and are dependent upon the prison staff to ensure that appropriate care is provided. They also may have difficulties regarding confidentiality, trust, and less access to research opportunities.

Improving access to appropriate HIV-related care in prisons must be a priority. At the Federal level, significant advances are being made in the quality of care, improved coordination, and developing models of care. Improving the quality of care at non-federal prisons will require improving the knowledge and skill of the health care teams in the prisons 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. For example, effort are already underway to improve linkages between discharge planning and Ryan White CARE Act programs, to assure a continuum of care and services for newly released HIV-positive prisoners.

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.

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.

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.

A Federal program that has achieved success in improving the

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

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

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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:

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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

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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

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.

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[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.]

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.;
- 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 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/AIDS in the areas of HIV prevention, research, care, civil rights, international activities, and translation of research into practice.

The National AIDS Strategy is intended to be a working document that requires regular updating and adjustment as goals are reached and new challenges emerge. This Strategy should provide 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 national and community-based organizations, state and local government, clinicians and researchers, members of the infected and affected community, and other individuals and organizations who can contribute to this historic document. This Strategy is being released, first, in draft form to allow for maximum input to the first of an ongoing national effort to chart and plan Federal efforts in response to the epidemic of HIV/AIDS.

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

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

Individuals living with HIV/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, patient and consumer advocates, health care professionals, community-based organizations, educators, religious leaders, and business leaders. The earlier insights provided by the National Commission on AIDS, the Institute of Medicine and National Research Council, the General Accounting Office, and the Office of Technology Assessment have also been extraordinarily helpful in developing the National AIDS Strategy.

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As a Nation, we face great challenges, but we are also facing equally challenging 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 in which 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 our 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 [usually fatal??] 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.

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[why mix 1994 and 1995???]. 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 shifted. The early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers. Today, men having sex with men represent

[slightly?] less than half of all new cases [anything on infections? i.e., and less than half of all new infections]. 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 AIDS were reported among [infants?].¹

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

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

The HIV epidemic continues to spread into suburban and rural areas, with especially dramatic increases in certain regions of the South and Midwest. Between January 1993 and December 1995 the largest numbers of AIDS cases (86,462) were reported from the South.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

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.

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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 **(re-add footnote; check for Vancouver numbers)**. People living with HIV are disproportionately dependent on the public sector for their health care. Nearly 50 percent of people living with AIDS are enrolled in Medicaid, including more than 90 percent of children with AIDS. In FY 1996, the Federal government spent \$1.8 billion on Medicaid benefits for people living with HIV and AIDS and another \$690 million on Medicare benefits. Social Security benefits for people disabled by HIV/AIDS total \$1.1 billion in FY 1996.

Globally, the toll of the pandemic 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 since the beginning of the pandemic, 6 million people have been diagnosed with AIDS worldwide and 27.9 million people have been infected with HIV. **[is this part of the 6 million? If so, the sentence should say "Since the beginning of the pandemic, 6 million people, including 1.6 million children, have been diagnosed with AIDS.]**and more than 1.6 million children have been developed 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, [prevention?] surveillance, and care. By [FY?]1995 that figure reached \$6.8 billion [I assume this includes entitlement spending. Does the FY85 include such spending?]. (See Appendix G).

In the past four years, under the leadership of President Clinton, spending for AIDS research, prevention, and care has increased by 47 percent. Funding for the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act alone has increased by 151 percent. Support for housing for people living with AIDS has increased by 91 percent. AIDS-related research funding has increased by 34 percent and AIDS prevention funding has increased by 24 percent. The National Institutes of Health Revitalization Act of 1993 created a 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, civil rights, international activities, and the translation of research into practice. They identify recent progress and future opportunities for further progress.

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.

I 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;
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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.

II 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 modes 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 Modes of Transmission

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.

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 Knowledge²

Factors that place individuals at risk for acquiring HIV infection entail a complex combination of behavioral, social, cognitive, and biological influences. 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 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 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. **[I would suggest**

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

replacing the rest with: "Once such models are developed, community-based organizations will require additional technical assistance and training in order to test those models in a "real-world" setting."] 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

[This paragraph seems redundant of the above. If you agree, I'd cut it and begin with the next paragraph.] 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.

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.

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?] advances 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.)

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 must continue to do so.

Insert RS language on minority CBOs and technical assistance.

Substance Abuse Prevention and Treatment. Injection drug abuse is

a major force driving growth in the epidemic. Approximately one-third of all new AIDS cases[not infections?] are directly or indirectly related to this mode of transmission. 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. Limiting the impact of substance abuse on the epidemic requires efforts on several fronts.

A central element to controlling the spread of HIV among substance abusers is enrollment into drug treatment programs. Substance abuse treatment is a highly effective form of HIV prevention. [add some stuff about what we've done to increase treatment slots, etc.]

We need to improve the integration of HIV prevention activities and substance abuse treatment and prevention programs. The epidemics of substance abuse and HIV infection are overlapping and highly interrelated, however, many care and prevention service programs for HIV and substance are not similarly integrated. It is vital to further strengthen efforts to integrate HIV prevention into current substance abuse programs and integrate substance abuse prevention into HIV 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.

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 [2000 percent?]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[will?] continue.

It is important that Federal and State efforts to reduce the

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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[particularly?] 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 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 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.

Prisoners. Those in prison are at high risk for both substance abuse and HIV infection. There is often a high prevalence of both 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. 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. 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.

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

I 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 of HIV as the [causal agent?] of AIDS;
- Development in March 1985 of an accurate test to determine exposure to HIV;
- Approval in September 1986 of of zidovudine (AZT), the first [what do they call them?] for treatment of HIV disease;
- Development by the Food and Drug Administration of a system of expedited review of treatments for life-threatening diseases, including HIV;
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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 two new diagnostic tests.)
- Supporting research that led to finding that use of AZT during

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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.