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FILE COPY

THE WHITE HOUSE

WASHINGTON

June 28, 1996

MEMORANDUM FOR CAROL RASCO

FROM: Patsy Fleming 

SUBJECT: Advisory Council assessment and recommendations

Attached is a series of documents from the Presidential Advisory Council on HIV/AIDS. They are:

- (1) An executive summary of a "progress report" on the Administration's efforts to implement prior recommendations. It is, on the whole, a very favorable report.
- (2) A detailed "progress report" assessing our response to each of their recommendations.
- (3) New recommendations approved at the April meeting of the Council.

Final review and editing within the Council was just completed. We are preparing a summary memo for the President, which we will send to you next week. Richard Sorian is working with Scott Hitt and the press office regarding the release of these documents. The CDC National AIDS Clearinghouse will be making them available.

As usual, we will be working with the relevant agencies to respond as favorably as possible to these recommendations. Much of that work is already under way.

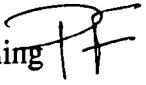
FILE COPY

THE WHITE HOUSE

WASHINGTON

JUN 28 1996

MEMORANDUM FOR CAROL RASCO

FROM: Patsy Fleming 

SUBJECT: Grandmothers Project

cc: Jeremy Ben-ami
Lyn Hogan

As you know, MC Smothermon is in our office as a Truman Fellow and has been working on this project. I want to bring you up to date on where we are at this point.

Two main issues need to be addressed:

Custodial - a need to be sure parental rights are maintained as long as possible, but also to facilitate the orderly and legal transfer of custody upon incapacitation or death of the parent.

Assistance - a need to assure that applicable federal and state benefits are available for the child(ren) and the custodial grandparent(s).

Three bills related to this issue were introduced in earlier Congresses. Representative Carolyn Maloney (D-NY) introduced the Standby Guardianship Bill and the Omnibus Foster Care Improvement Act. Senator William Cohen (R-ME) introduced a bill to recognize and provide assistance to grandparent caregivers. Representative Maloney's Standby Guardianship Bill was the only one which addressed AIDS issues specifically, but the others had important elements which are needed for all kinship guardians.

None of these bills made it out of committee. Both Senator Cohen and Representative Maloney had decided not to re-introduce, but MC has been talking with members of both staffs with some encouraging results. She has been asked to meet with the staff director and assistant of Cohen's Special Committee on Aging next week. I have written a letter to Maloney encouraging her to continue to address the vital issue of grandparent guardianship.

MEMO FOR CAROL RASCO

-2-

JUN 28 1996

The Federal Legislation Clinic, Georgetown University, is helping us with background and research. MC has met - or has meetings scheduled - with community people who have been working with kinship guardian and permanency planning issues for some time.

I am pleased with the progress made so far. MC will be with us until August 1, not long enough to deal completely with this complex issue, but we will have gone a long way in bringing people together to continue the process.

THE WHITE HOUSE

WASHINGTON

June 27, 1996

MEMORANDUM FOR JODIE TORKELSON

FROM: Patsy Fleming 
SUBJECT: Agency Representatives

I am writing to request your approval of agency representatives to work with the Office of National AIDS Policy.

Anthia Atwater is a contract employee through the Department of Housing and Urban Development, who is serving as a temporary receptionist.

Daniel C. Montoya works for the Health Resources and Services Administration's AIDS Policy Office. He is working with us in support of HRSA's role in the regional briefings we have been conducting across the nation and in responding to the care-related recommendations of the Presidential Advisory Council on HIV/AIDS.

Patricia Milon works for the Health Resources and Services Administration's Bureau of Primary Health Care. She visits our office about three days a month working on a project to improve linkages between HHS-funded HIV services and prevention programs with those of the Bureau of Prisons and other entities working with the incarcerated.

These activities would continue through December 31, 1996.

CP-
final signed
copy

THE WHITE HOUSE

WASHINGTON

May 6, 1996

MEMORANDUM FOR THE PRESIDENT

FROM: Carol H. Rasco, Assistant to the President for Domestic Policy
Patricia S. Fleming, Director, Office of National AIDS Policy

SUBJECT: Meeting of the Presidential Advisory Council on HIV/AIDS

Your Advisory Council on HIV/AIDS met on April 24-26 to review the Administration's response to date to its earlier recommendations and to develop a new set of recommendations regarding improving the Federal government's response to the epidemic. Final versions of the assessment and the recommendations are not yet available. We will share them with you when they are.

The meeting coincided with final congressional action on the year-long continuing resolution. As you can imagine, the successful repeal of the ban on HIV-positive service members and the substantial increases in funding for the Ryan White CARE Act were met with great enthusiasm. Councilmembers universally expressed deep appreciation for your leadership on both issues.

The assessment of the Administration's response was generally positive. Among the key points were:

- There was considerable praise for the leadership shown in holding the White House Conference on HIV/AIDS, the efforts to fight HIV-related discrimination, and the repeal of the Dornan amendment.
- There was strong support for the Administration's efforts to increase funding for a range of programs, including the Ryan White CARE Act, AIDS research, and prevention.
- Your defense of the Medicaid program was the source of considerable commendation and support. As you know, nearly 50 percent of people living with AIDS are on Medicaid, including over 90 percent of children with AIDS. The Council considered this of such high importance that it is sending you the attached letter to you as a special communication.

The Council expressed concern about the Administration's response in several areas:

- While praising the efforts of the White House and senior Administration officials in support of the consolidated budget authority of the NIH Office of AIDS Research, the Council is worried that these efforts are being undermined by some in the NIH leadership.

- The Council expressed the hope that funding for substance abuse treatment funds will increase at a faster pace since such treatment is a key form of HIV prevention. The Council did express appreciation for your leadership in pushing the Administration to pay closer attention to the growing interrelationship between the HIV and substance abuse epidemics. The meeting you called for at the White House Conference on HIV/AIDS to develop a government-wide strategy on this issue is scheduled for this August.

- The Council expressed "grave concerns that federal policy regarding needle exchange programs is not consistent with current knowledge and understanding regarding the impact of such programs on HIV prevention efforts."

- The Council was disappointed in the Administration's response related to funding for AIDS housing and called for increases in both FY 1996 and FY 1997. (The Housing Opportunities for People with AIDS (HOPWA) program is flat funded at \$171 million.)

- The Council continued to express opposition to the mandatory HIV testing policies of the State Department and the Peace Corps. The AIDS Policy Office will be meeting with these agencies to discuss a review of the public health rationale for them. The Council was pleased to learn that the Job Corps is doing away with its mandatory HIV testing program for residential students. Instead, all new students will be counseled about HIV and offered voluntary testing.

PRESIDENTIAL

April 29, 1996

ADVISORY

COUNCIL ON

HIV/AIDS

President William Jefferson Clinton
The White House
Washington, DC 20500

Dear Mr. President:

As members of your Advisory Council on HIV/AIDS, we are writing to you today to urge your continued support for the Medicaid program, which currently represents the sole source of health insurance for over 40% of people living with HIV/AIDS. We are extremely grateful to you for the leadership and forcefulness with which you have defended this program to date, and urge your continued vigilance. While we recognize that we have previously communicated our concerns to you regarding Medicaid, the tremendous level of activity on this issue since we last wrote, as well as the overall importance of this issue, compels us to offer this more detailed set of recommendations at this time.

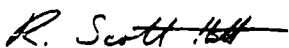
Most of the Medicaid proposals that have been introduced in the 104th Congress, as well as the proposal presented to Congress by the National Governor's Association, if passed, would be devastating for thousands of people living with HIV/AIDS whose care and treatment are financed by Medicaid. Specifically, the Council makes the following recommendations regarding all present and future reform proposals:

1. Block granting Medicaid would be a sweeping change that would diminish profoundly limit access to healthcare for people living with HIV/AIDS. Block granting of Medicaid in any form is unacceptable.
2. Sizable cuts to projected Medicaid growth would result in the loss of essential services and/or complete coverage for many. Without its status as an entitlement, a Medicaid block grant would provide care only until the allocated funding runs out. The cuts in Medicaid growth set by almost all current Congressional proposals guarantee that this would occur, thereby leaving thousands without coverage. In addition to protecting the overall funding level for Medicaid, we urge you to continue to insist that states be required to maintain their current level of financial participation in Medicaid.
3. Many states are moving to mandate enrollment in managed care programs for Medicaid recipients. Although it is possible to provide quality care for people with HIV/AIDS in managed care settings, these programs typically restrict access to services, particularly specialty care, as a means of limiting costs. Managed care models often result in disincentives to care for individuals with high-cost conditions, such as HIV/AIDS. Thus, Congressional reforms in this area -- as well as state waivers under consideration by Health Care Financing Administration -- must contain protections to guarantee medically necessary care and appropriate grievance procedures.
4. As biomedical research produces important changes in HIV treatment practices, the federal government must ensure that states make available to Medicaid beneficiaries the same access to new and cutting-edge therapies that individuals receive within the private health insurance system.

5. The federal government must insist that states remain responsive to the broad spectrum of vulnerable persons in need of health care by preserving guaranteed categorical eligibility. The federal government must retain financial and other incentives for states to cover the broadest possible range of low-income persons, including those whose medical expenses push them into poverty. Moreover, the federal government must not allow discrimination to be used as a means of denying health benefits. Health care access for all legal residents of the United States must be preserved.
6. People with AIDS require a broad range of services. Adequate health care coverage must include regular access to primary care, appropriate specialists, as well as inpatient hospitalization and outpatient care. Prescription drugs are perhaps the single most important life-sustaining benefit for people with AIDS. The federal government must take steps to ensure that this optional benefit continues to be available in all fifty states. Additionally, the federal government must protect community-based care as a cost-effective and humane optional service, which recognizes the importance of culturally appropriate care for specific populations.
7. Protecting current law as it relates to amount, duration and scope of services is among the most important actions you can take to ensure that Medicaid functions effectively for its beneficiaries. Future Medicaid law must continue to require that services provided by a state Medicaid plan be provided in a sufficient amount, duration and scope to reasonably achieve its purpose.
8. Due to the nature of AIDS and HIV-related care, even a nominal co-payment of five to ten dollars per prescription or physician visit can quickly become prohibitively expensive. Because Medicaid is a health care program for low-income people, increases in cost-sharing burdens on beneficiaries will severely restrict access to care.
9. Strong quality assurance and due process protections must remain in place to ensure that eligibility and treatment determinations are made in a timely manner, and to ensure that medically necessary and high quality treatment is provided.

As your Administration continues its deliberations and negotiations with Congress, we ask that you fight vigorously for these essential elements of the Medicaid program. As community leaders from across the country, we offer you our assistance in this regard, knowing that the basic health care needs of thousands of persons living with HIV/AIDS depends on your success.

Sincerely,



R. Scott Hitt, Chair

Members of the Presidential Advisory Council on HIV/AIDS

THE WHITE HOUSE
WASHINGTON

FILE COPY

March 20, 1996

MEMORANDUM FOR CAROL RASCO

FROM: Patsy Fleming 

SUBJECT: Rockefeller Foundation HIV Vaccine Efforts

This memo is in follow-up to your request for information on the Rockefeller Foundation's (RF) vaccine efforts discussed in Judy Mann's Washington Post article of January 26, 1996.

The RF's International AIDS Vaccine Initiative (IAVI) grew out of a series of Foundation-sponsored meetings to assess the scientific, logistical, and financial obstacles to developing a preventive HIV vaccine. The initiative also represents one of two schools of thought about the best path to take in developing a successful vaccine. Because it's important to understand the context from which this new initiative emerged, I'll begin with background information.

Background: Two Development Pathways

At present researchers hold two major views regarding the most promising approaches to vaccine development. Some scientists believe that we do not know enough about the virus to proceed and that we need to return to basic science to gather more information to guide us. Others believe that only clinical efficacy trials will provide the answers that really matter. This group believes that as long as we have a safe candidate we don't have to have resolved all of the scientific questions before proceeding and that in the face of a global emergency we must test candidate vaccines in people immediately. Both groups have valid arguments.

The issues driving this debate are scientific and social, with different parts of the world experiencing the epidemic in different ways. Some regions of the world have already experienced the devastating consequences of the epidemic while, in some regions 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. Given the state of scientific knowledge, there is some consensus that both the basic and empirical avenues can and should be pursued.

Federally, the National Institutes of Health (NIH) primarily supports the basic approach (FY 95 -- approximately \$112 million) and Department of Defense supports the empirical approach (FY 95 -- approximately \$20 million.)

The International AIDS Vaccine Initiative (IAVI)

The Rockefeller Foundation's International AIDS Vaccine Initiative seeks to promote rapid

empirical testing and to support activities to encourage private market participation. The projected strategies of this two-pronged effort are:

1. Supporting targeted research and development by:

- developing candidate vaccine approaches that have promise but are underexplored (in the RF's opinion);
- developing candidate vaccines from HIV subtypes found in areas of the world where the epidemic is spreading most rapidly; and
- ensuring that candidates are safe, effective, and progress readily into ethically conducted clinical trials.

2. Creating a more enabling environment for HIV vaccine development by:

- creating a credible market in developing countries today for vaccines developed in the future (i.e., using international loan mechanisms to guarantee a market for promising products);
- reducing the potential costs of liability exposure (i.e. establishing a vaccine injury compensation program or vaccine insurance strategy); and
- improving the legal and regulatory environment (i.e. harmonizing international regulatory procedures).

IAVI will be seeking the financial and political support from a broad range of organizations, including national governments, international agencies, non-governmental agencies, industry, and private individuals.

These efforts are just beginning; an Executive Director for the project began work at the beginning of February.

Federal Efforts

The Federal government is taking steps that can complement IAVI efforts. Specifically:

■ Vice President Gore's Meeting with Pharmaceutical Company Leaders

At the White House Conference on HIV and AIDS the President asked the Vice President to meet with industry leaders and leading government researchers to identify ways to accelerate the development of vaccines, therapeutics, and microbicides.

The meeting produced forthright discussion and several follow-up steps, including commitments on the part of the Administration to: (1) work with international organizations, such as the World Bank, to increase investment in AIDS vaccine development and trials worldwide, and (2) facilitate ongoing discussions between the government and the

pharmaceutical industry to identify promising areas of research that government can support in order to stimulate private sector investment.

■ External Evaluation of the NIH's AIDS Research Program

The external evaluation mandated by OAR's 1993 authorizing legislation includes an assessment of the NIH vaccine effort. The report recommended restructuring the entire NIH vaccine effort with oversight provided by non-governmental scientists. It also recommended that enhanced coordination among U.S. government agencies, pharmaceutical and biotechnology companies, foreign countries, and international organizations be facilitated through the Office of National AIDS Policy.

■ Future Planning and Coordination

Increased coordination of Federal efforts is being facilitated through two mechanisms, the National Strategy for HIV and AIDS and the coordinated government-wide research budget and plan.

Both these efforts required departments agencies to link their objectives to budget allocations. This provides a mechanism to better assess efforts department-wide, improve coordination, and influence budget commitments.

THE WHITE HOUSE

WASHINGTON

MAR - 4 1996

MEMORANDUM TO CAROL RASCO

FROM: PATSY FLEMING 

SUBJECT: Needle Exchange Programs

The largest proportion of new AIDS cases is now related to injection drug use. HIV is transmitted through the sharing of used needles and syringes that contain HIV infected blood. Health guidelines have long recommended against the sharing of injection equipment, but such equipment is not readily available because of legal restrictions on over-the-counter sale of needles and syringes.

To address this problem, many community organizations around the country have developed needle exchange programs as a form of AIDS prevention. They have -- sometimes in violation of local ordinances -- offered clean needles in exchange for used needles from addicts. There are about 70 needle exchange programs across the United States operating in 46 cities in 21 states. Some are operated by local health departments.

Legislation enacted in 1987 disallows the use of Federal funds for needle exchange programs (unless for research purposes) until the Surgeon General determines that needle exchange programs decrease HIV transmission and do not increase injection drug use.

A series of research studies have concluded that the criteria outlined in this legislation can in fact be met. The most recent and most thorough of these studies was one issued recently by the National Academy of Sciences. It concluded:

- Needle exchange programs increase the availability of sterile injection equipment, resulting in a lower number of contaminated needles in circulation. (Therefore, the logical assumption is that needle exchange programs reduce transmission of HIV.)
- There is no credible evidence that drug use is increased among participants as a result of programs that provide legal access to sterile equipment. In fact, exchange programs can be seen as outreach programs to substance users who ultimately are brought into treatment for their addiction.

Despite this scientific evidence, there is considerable controversy about the morality of needle exchange programs. A growing number of communities have embraced this approach, others have rejected it. One key policy question is *whether localities can choose to use Federal funds for needle exchange programs. The other question is whether government officials can say that needle exchange programs funded with state, local or private funds are effective strategies in blocking HIV transmission.* (N.B. In my public speaking, this is what I say.)

MAR - 4 1996

Many in the public health community argue that needle exchange programs are our most effective weapon in reducing HIV transmission among substance users. They are not asking that the Federal government adopt this approach nationwide. They are asking only that the restriction on *local* decisions on use of federal funds for this purpose be lifted (for example, in the use of substance abuse block grant money). They recognize that if the Public Health Service lifts the funding restrictions, Congress may reimpose or even tighten them. But they also believe it is important for you to show leadership by publicly acknowledging the effectiveness of needle exchange programs. This would strengthen those in the public health community who want to use local funds for such programs.

There are three possible approaches to this issue:

- (1) Oppose needle exchange programs as too controversial and as sending the wrong message regarding drug use. This would run counter to leading public health opinion.
- (2) Lift the restrictions by having the Surgeon General or, since we don't have one, the Secretary, make a determination that the criteria set forth in existing statute have been met. This may well result in a determination in favor of lifting the restrictions and could lead to even more restrictive legislation. However, such a determination would make clear to the country that this is an option that should be considered. Even if the restrictions are lifted, *the decision to adopt needle exchange programs would remain a local one.*
- (3) Applaud the National Academy of Sciences report as a major contribution to the public debate on this issue. Acknowledge that needle exchange programs seem to work in preventing HIV transmission and encourage states and localities as well as community based organizations to consider them in the context of broad-scaled harm reduction and substance abuse treatment efforts. But whatever the science may say, this remains a divisive issue socially and politically. It should be a community decision, not a Federal decision. We are supporting research that will give communities the information they need to make this decision. This approach, while not discouraging local initiatives, would not free up Federal funds for these efforts.

THE WHITE HOUSE

WASHINGTON

April 8, 1996

MEMORANDUM FOR THE PRESIDENT AND THE FIRST LADY

FROM: Carol H. Rasco, Assistant to the President for Domestic Policy
Patricia S. Fleming, Director, Office of National AIDS Policy *PSF*

SUBJECT: Amendment regarding mandatory HIV testing of newborns

cc: Jennifer Klein

We are writing to bring you up to date on the status of congressional consideration of the issue of mandatory HIV testing of newborns. House-Senate conferees met last week to try to resolve differences regarding an amendment on HIV testing of newborns that was added to the Ryan White CARE Act reauthorization bill during House consideration. However, no final conclusion was reached.

Coburn-Waxman Amendment

The House amendment, sponsored by Reps. Coburn (R-OK) and Waxman (D-CA), would trigger mandatory HIV testing of newborns if certain conditions are not met. It would require the Secretary of Health and Human Services to determine, within two years, if HIV testing of newborns is the standard of care when the HIV status of the mother is unknown. If it is the standard of care, the Secretary must then determine, after another 18 months, that newborn testing is occurring voluntarily in 95 percent of the infants born to mothers who have not been tested. If the Secretary determines that 95 percent of such newborns have not been voluntarily tested, then mandatory HIV testing of newborns would be required in those states not in compliance. The states would have three-and-a-half years to reach the 95 percent level through voluntary testing.

Leading medical groups (such as the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the Pediatric AIDS Foundation) oppose this amendment and support voluntary HIV testing of pregnant women. In addition, AIDS advocacy organizations are nearly universally opposed to this amendment.

Testing of Pregnant Women

During Senate consideration of the Ryan White CARE Act, an amendment offered by Senator Kassebaum was approved that would require states to adopt the Public Health Service's guidelines making routine counseling and voluntary testing of all *pregnant women* the standard of care. The emphasis on the prenatal period, of course, has the greatest potential for preventing transmission to newborns. Newborn testing will have virtually no impact on HIV transmission to newborns. Prenatal HIV testing would permit HIV infected mothers to take AZT during pregnancy and childbirth, which has been demonstrated to

reduce the likelihood of transmission by as much as two-thirds.

It is worth noting that there are already encouraging results confirming that the combination of routine HIV counseling, voluntary testing, and AZT by choice is highly effective at reducing perinatal transmission. A study from North Carolina indicates that, after being counseled about HIV, most women choose to be tested and that, if positive, most choose to take AZT. The rate of perinatal transmission fell from 21 percent of all infants born to HIV-positive mothers in 1993 to just 8.5 percent in 1994, on a par with the original NIH study. Results from hospitals in major urban centers -- such as Miami, Atlanta, and Harlem, show similar high rates of testing and AZT use.

Current Status

Discussions in conference have focused on possible changes to the Coburn-Waxman amendment, such as changing the trigger for mandatory HIV testing of newborns to a failure to achieve a 50 percent reduction in perinatal transmission. But the underlying mandatory nature of the amendment remains.

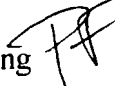
The Administration has deliberately not taken a position on Coburn-Waxman. Instead, we have consistently emphasized the importance of implementing the PHS recommendations for voluntary prenatal testing as the most effective intervention and the various HHS agencies have taken major steps to assure that testing and treatment are readily available to those women who need it. At the White House Conference on HIV/AIDS on December 6th, you stated that this is an issue that should be left to the public health officials to resolve, not politicians.

It is not clear how the conferees will resolve this issue, but it is quite possible that the final bill will contain something along the lines of the Coburn-Waxman amendment. While all the AIDS groups oppose the amendment, it is quite likely that they will be very divided over the issue of whether the CARE Act should be vetoed if it comes with a mandatory testing amendment. Some will consider reauthorization of Ryan White to be a higher priority; others will be more concerned about the precedent of signing mandatory testing legislation. At this time, we are giving no indication of future action until it is clear what the conference will do.

THE WHITE HOUSE
WASHINGTON

APR - 4 1996

MEMORANDUM FOR CAROL RASCO

FROM: Patsy Fleming 

SUBJECT: HIV in Prisons

This is in response to your request for information regarding prisoners and HIV.

There are two levels of concern with regard to prisoners with HIV: 1) federal policies as they affect prisoners in federally run institutions, and 2) access to appropriate services in state and local prisons.

(1) The Office of National AIDS Policy is working with the Justice Department and HHS toward the following goals for federal prisons:

- (a) a consistent and appropriate standard of care provided for all prisoners;
- (b) appropriate HIV prevention programs in all prisons;
- (c) a rational system of HIV testing (current policy is to mandatorily test prisoners on discharge; testing of those at or during incarceration is not based on a systematic approach -- whether voluntary or mandatory); and
- (d) appropriate discharge planning of HIV positive prisoners so they are linked to other federally funded HIV-related services programs in their communities.

We have convened a meeting of relevant agency officials scheduled for April 23 to address these issues.

(2) The overwhelming majority of prisoners with HIV are in state and local facilities where appropriate standards of care and prevention can be influenced only indirectly. Setting good policies as models at the federal level is one step. In addition, the Centers for Disease Control and Prevention supports prevention programs and HIV counseling and testing in state and local prisons and HRSA, through Ryan White CARE Act funds, supports services programs for prisoners and ex-offenders.

I have attached a summary of the article that will appear in the next issue of the MMWR. The full article will be available later today. I will fax that to you as soon as I receive it.

Attachment

Following is a synopsis of a Morbidity and Mortality Weekly Report (MMWR) article that will be available late today.

**HIV/AIDS education and prevention programs in adult prisons
and jails and juvenile confinement facilities--United States, 1994
April 5, 1996**

By the end of 1994, at least 4,588 inmates in U.S. adult prisons and jails had died of AIDS and at least 5,279 adult inmates were living with AIDS in prisons and jails, according to a recent survey. The high rate of AIDS cases in correctional facilities (almost 6 times the rate in the U.S. adult population) underscores the need for HIV education and prevention programs in these settings. The survey also found high rates of gonorrhea in juvenile detention centers, suggesting that adolescent inmates may also be at risk for HIV. HIV prevention programs in prisons and jails are vital to community prevention efforts and can have an impact both inside and outside prison walls. Correctional facilities offer a unique opportunity for reaching men and women at high risk for HIV infection with information about how to protect themselves and others from HIV. While several facilities have developed successful education programs, including peer counseling, survey results indicate the opportunity for prevention is frequently missed. Less than 1/10 of facilities were providing peer-led programs, which may be more effective than traditional approaches because of inmates' distrust of prison and public health officials. Communities should work with prison authorities to explore this and other options for HIV education and prevention.

March 28, 1996

MEMORANDUM FOR CAROL RASCO

FROM: Patsy Fleming 
SUBJECT: Meeting with Norman Lear

I. PURPOSE OF THE MEETING

To meet with Norman Lear regarding his offer to provide \$500 million in private sector matching funds for HIV-related research to find a cure.

II. BACKGROUND

A. Structure of the Donation

1. Matching Private Dollars to Federal Dollar

A matching approach is problematic. There are legal issues. Moreover, the Administration is strongly committed to finding a cure and a vaccine and has increased funding for HIV-related research by 34 percent; the President proposes spending \$1.5 billion in FY 97.

It would be extremely productive to support activities that the government cannot support.

2. Alternative Models

a. A Gift to the Government

This would be helpful in funding programs and projects that are not currently funded or are underfunded. But this approach would most likely result in loss of control of where the money goes. Other models for a public/private partnership can be explored.

b. The Aaron Diamond Model

Irene Diamond, using only private funds, has established a first-rate, well-respected research institute that has contributed to scientific progress in

understanding HIV.

Mr. Lear could replicate the Aaron Diamond model, or could possibly add funds to their general accounts, or donate funds earmarked for specific projects.

B. Substance

Funds could productively be donated in the following areas.

1. Biomedical prevention

Many scientists believe that the prevention of sexually transmitted HIV infection, as well as the prevention of STDs in women and infants, will depend on the development of a safe, effective, female-controlled mechanical and chemical barrier methods (microbicides) that will block HIV transmission.

There are promising microbicide candidates available right now. Studies for these agents could be conducted in a relatively brief period of time.

Worldwide, over 80 percent of HIV infections are acquired heterosexually, and the risk of becoming infected or infecting others is substantially increased by the presence of other STDs. Microbicides could provide an easily available and inexpensive protection option for millions of women worldwide. This approach could also protect heterosexual men.

In addition, there appears to be an increase in the prevalence of the E clade of HIV which is more easily transmitted through heterosexual sex, thereby heightening the need for protection options.

2. Vaccines

Vaccine development is an area that receives solid Federal support, but is also an area that could benefit from increased support in the private sector.

The Rockefeller Foundation has recently established the International AIDS Vaccine Initiative (IAVI) to promote rapid empirical testing and to support activities to encourage private market participation. The projected strategies of this two-pronged effort are: (a) supporting targeted research and development, and (b) creating a more enabling environment for HIV vaccine development.

The IAVI is a nascent effort and would be open to discussing funding opportunities.

3. Young Researchers

Currently, it is extremely challenging for young researchers to obtain consistent NIH

support due in part to funding levels and the tremendous competition for grants. Supporting these young researchers and their innovative ideas could build a larger pool of talented researchers for the future.

4. Prevention

One of most promising ways to slow the spread of this epidemic is to prevent infections. We know that prevention programs work. However, more creative activities can be supported if they do not use federal dollars.

There is a critical need for basic behavioral research sexual and drug use behaviors. In addition, support for explicit, population-targeted social-marketing activities could be extremely beneficial in developing prevention programs and products that could reach those being most affected by the epidemic, young gay and bisexual men, women, and people of color. Drawing upon the experience and talent of the entertainment industry to develop innovative and effective prevention messages could be developed, and help those most affected.

March 28, 1996

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In addition, there appears to be an increase in the prevalence of the E clade of HIV which is more easily transmitted through heterosexual sex, thereby heightening the need for protection options.

2. Vaccines

Vaccine development is an area that receives solid Federal support, but is also an area that could benefit from increased support in the private sector.

The Rockefeller Foundation has recently established the International AIDS Vaccine Initiative (IAVI) to promote rapid empirical testing and to support activities to encourage private market participation. The projected strategies of this two-pronged effort are (a) supporting targeted research and development, and (b) creating a more enabling environment for HIV vaccine development.

The IAVI is a nascent effort and would be open to discussing funding opportunities.

3. Young Researchers

Currently, it is extremely challenging for young researchers to obtain consistent NIH

support due in part to funding levels and the tremendous competition for grants. Supporting these young researchers and their innovative ideas could build a larger pool of talented researchers for the future.

4. Prevention

One of most promising ways to slow the spread of this epidemic is to prevent infections. We know that prevention programs work. However, more creative activities can be supported if they do not use federal dollars.

There is a critical need for basic behavioral research sexual and drug use behaviors. In addition, support for explicit, population-targeted social-marketing activities could be extremely beneficial in developing prevention programs and products that could reach those being most affected by the epidemic, young gay and bisexual men, women, and people of color. Drawing upon the experience and talent of the entertainment industry to develop innovative and effective prevention messages could be developed, and help those most affected.

THE WHITE HOUSE
WASHINGTON

FEB 27 1996

MEMORANDUM FOR CAROL H. RASCO

FROM Patricia S. Fleming *PSF*
SUBJECT White House Leadership Conference on Youth, Drug Use and
Violence March 7, 1996

I was pleased to learn that you are participating in this important conference, which will address some of the most difficult issues facing American youth today.

I am writing to urge you to include HIV as part of the group discussion that you will chair. As you know, one quarter of all new HIV infections is among teenagers and AIDS is the leading cause of death for persons ages 25 to 44.

Just as alarming and as relevant to this conference, however, is the number of HIV infections attributable to drug use. CDC estimates that as many as 50 percent of all new HIV infections may be among injection drug users. Substance abuse problems that contribute to the spread of HIV are not limited to injecting drug use. The use of alcohol and marijuana adversely influence risk taking and sexual behaviors. CDC studies conducted every two years in high schools (grades 9 through 12) consistently indicate that by the twelfth grade, approximately three-fourths of high school students have had sexual intercourse. Moreover, many students report using alcohol or drugs when they have sex and, in the most recent survey, 1 in 62 high school students reported having injected an illegal drug.

For these reasons, I ask that you address the link between HIV and drug use during your session at the conference next week.

If you have questions or need information on this issue, please call me or LaHoma Romocki at 202-632-1090.

THE WHITE HOUSE
WASHINGTON

FEB 27 1996

MEMORANDUM FOR THE HONORABLE HENRY G. CISNEROS

FROM Patricia S. Fleming 
SUBJECT White House Leadership Conference on Youth, Drug Use and
Violence March 7, 1996

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THE WHITE HOUSE
WASHINGTON

FEB 27 1996

MEMORANDUM FOR THE HONORABLE DONNA E. SHALALA

FROM

Patricia S. Fleming



SUBJECT White House Leadership Conference on Youth, Drug Use and
Violence March 7, 1996

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THE WHITE HOUSE
WASHINGTON

FEB 27 1996

MEMORANDUM FOR THE HONORABLE RICHARD W. RILEY

FROM Patricia S. Fleming 
SUBJECT White House Leadership Conference on Youth, Drug Use and
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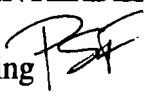
If you have questions or need information on this issue, please call me or LaHoma Romocki at 202-632-1090.

THE WHITE HOUSE

WASHINGTON

February 26, 1996

MEMORANDUM FOR THE INTERDEPARTMENTAL TASK FORCE ON HIV & AIDS

FROM: Patricia S. Fleming 
SUBJECT: Membership on HIV-Related Committees

In October 1995, I requested that members of the Interdepartmental Task Force on HIV & AIDS complete the attached questionnaire in order to determine the racial and ethnic composition of HIV-related Federal advisory committees, workgroups, ad hoc committees, grant review committees, etc. This information was requested by the Office of Minority Health (OMH)/Department of Health and Human Services (DHHS) as part of follow-up activities related to the DHHS-sponsored national minority AIDS conference held in September 1994. OMH has asked the Office of National AIDS Policy for assistance in compiling this information as it related to HIV/AIDS activities which occurred in Fiscal Year 1995.

As discussed previously, this information will assist in the development of a national minority HIV strategic plan (including the racial/ethnic composition of Federal committees), being developed through a joint effort between the Federal government and community-based representatives. We believe it is important to provide accurate and timely information as a means to enhance and maintain the close working relationship with minority communities which has developed over the past several years.

I would appreciate your responding directly to OMH by March 15, 1996. The contact person at OMH is Mr. Matthew Murguia, Deputy Director, Division of Policy and Data. Mr. Murguia's address is:

Office of Minority Health/DHHS
5515 Security Lane, Suite 1000
Rockville, MD 20852
FAX: 301-443-8280

Please use the attached format (modified if necessary) for developing your responses and attach a list of committee members. Please call Mr. Murguia directly at 301-443-9923 if you have any questions. Thank you in advance for your assistance.

THE WHITE HOUSE

WASHINGTON

MEMORANDUM FOR GREG SIMON FEB 22 1996

FROM: Patsy Fleming 

SUBJECT: Follow-up to Vice President's meeting with drug companies

In reviewing our notes from Tuesday's meeting, there appear to be at least seven areas of follow up based on the Vice President's comments and/or issues that arose during the discussion.

(1) Establishment of the four-way dialogue regarding post-FDA-approval clinical effectiveness trials.

While I think there is considerable enthusiasm for the concept, the devil will be in the details and in holding some of the companies to their apparent commitment to participate in this effort. There are three immediate steps that can be taken:

(a) A lead person within the Administration must be named to develop the government's position on this subject. I suggest that Phil Lee is probably the most appropriate person, given his official position and the fact that he has already initiated some dialogue with foundations and HMOs on this subject.

(b) We need to meet with the other two parties who are players: the third party payors and the patient advocates. This could be done by you, by my office, or by HHS. This would probably require separate meetings with each group as we begin to test the waters about their concerns.

(c) A few years ago, the Keystone Center conducted one of their dialogues on the implications of expedited approval. Abby Dilley of Keystone has spoken with Jeff Levi (who participated in that original dialogue) about Keystone's interest in doing a follow-up: looking specifically at the impact of expedited approval on our knowledge of how best to use drugs licensed under that process. All four elements needed for the clinical trials proposal participated in the original dialogue. This could be a vehicle -- either through a totally independent Keystone effort or through a co-sponsored activity between Keystone and the White House -- for resolving many of the policy implications of our concept.

(2) How do we determine the gaps in our scientific effort -- and how do we fill them?

This seemed to be a recurring question on the part of the Vice President. I think that the Office of AIDS Research at NIH is structurally designed to play this role and has made great strides in accomplishing it. I propose a briefing for the Vice President by Bill Paul, the director of OAR, along with several members of the Levine Committee, which is just

FEB 22 1996

completing a comprehensive external review of the NIH's research effort. I think this can help identify specific areas where the Vice President's intervention might move the process along.

(3) What is the threshold for private investment in the "next generation" of drugs?

This may have been the most interesting question that was left unresolved at the meeting. All parties seemed eager to praise the collaboration between NIH and the private sector, but I think it remains unclear how far NIH must take a concept before private sector interest (and capital) will step in to bring the concept to full development. This could be the focused discussion of another meeting of drug companies with the Vice President -- perhaps with a different (or at least modified) cast of players. (We should try to get the actual top people at these companies involved.) And the answer to this question is very different for small companies than for large ones -- and we may want to focus on the smaller biotech firms initially.

(4) Improving the development of pediatric indications of AIDS drugs.

Dr. Kessler has agreed to take the lead on this issue. I think an initial meeting, convened by the Vice President's office but co-chaired by Dr. Kessler, would get this initiative moving. It should be a more focused group: perhaps limited to the Pediatric AIDS Foundation, which has been spearheading this issue, the American Academy of Pediatrics, and several drug companies for whom this has been an issue.

(5) International support for vaccine development.

The Vice President indicated an interest in pushing international organizations, especially the World Bank, to invest more in vaccine development. This can be expanded to include microbicide development. We can also develop a short list of other potential funders to approach.

(6) Support for microbicide development.

The Vice President's strong support for microbicide development had a very positive impact on both the private and public sector representatives at the meeting. We need to find more public ways for the Vice President to express that support. We may also need to remind NIH that this is a priority for the Vice President.

(7) Additional views from participants.

The Vice President urged participants to forward additional views. A general thank you letter reminding them of that request would be helpful.

—

This needs
to be faxed
today

Thanks J
Done

For 456-6231

—

DRAFT

1: Simon. 222

February 22, 1996

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DRAFT

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**OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT**

750 17th Street, N.W.
Washington, DC 20503

Phone: 202-632-1090
Fax: 202-632-1096

FACSIMILE COVER SHEET

TO: Greg. Simon

FAX NUMBER: 456-6231

FROM: Patricia Fleming

DATE: 2-22-96

PAGES INCLUDING COVER SHEET: 3

COMMENTS:

THE WHITE HOUSE
WASHINGTON

FEB 4 1985

FILE COPY

MEMORANDUM FOR CAROL H. RASCO

FROM: Patsy Fleming

PF

SUBJECT: Update on Report on HIV/AIDS and Adolescents

This memorandum is to update you on progress with the report to the President on AIDS and adolescents.

Status

The report is in final review at the Department of Health and Human Services and should be ready for the printer by February 20. Comments have been quite positive and helpful in honing the central message of the report. A copy of the report is attached.

Rollout Strategy

We are planning to release the report to the public on March 5. We have tentatively reserved a room at the National Press Club to conduct a press conference. I would like the press conference to include two members of Congress (one Democrat and one Republican), a young adult, an educator, and representatives of the National AIDS Fund and the Until There's A Cure Foundation both of whom helped with the report. We will also involve several national youth organizations.

Attachment

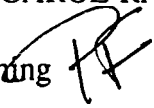
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THE WHITE HOUSE
WASHINGTON

FILE COPY

FEB 13 1996

MEMORANDUM FOR CAROL RASCO

FROM: Patsy Fleming 

SUBJECT: OAR controversy

I have also received many of the letters you have regarding the single appropriation. There is some confusion in the community about what is happening -- in part because the legislative issues have been complex, in part because the Administration is not speaking as clearly with one voice as we would like.

The single appropriation for the Office of AIDS Research has been controversial since its inception in 1993. While supported by the top leadership in the Administration, some institute directors at NIH have quietly worked connections on the Hill and in the scientific community to oppose it. Representative Porter, Chair of the House Labor-HHS Appropriations Subcommittee has been one of the critics of the single appropriation; Senator Specter, his Senate counterpart, has been more supportive.

The House Labor-HHS bill did not include the single appropriation for OAR. The Senate bill did. The Continuing Resolution that funds NIH for the full year requires that the money be spent under the terms and conditions of the House bill. However, in a floor statement, Porter said that he did not consider the issue of OAR resolved. Unfortunately, all the lawyers at HHS and OMB have concluded that the language of the legislation is very clear and a single appropriation cannot be assumed.

OMB and HHS, using the underlying authorizing statute that gives OAR its budgetary authority, have used the apportionment authority of the OMB to continue OAR's authority. In other words, even though there is no single appropriation, the apportionment of funds for NIH for AIDS research are being allocated to the institutes based on the decisions of the OAR, which are, in turn, based on the OAR's plan and budget for FY 1996. In other words, OAR continues to have significant authority at the front end of the budgeting process. What is lost without the single appropriation is the opportunity to shift funds at the *end* of the appropriations process that will permit more rapid response to fast breaking scientific developments.

The community's concerns have been two-fold. First, they have been slow in coming around to our understanding of the legislative restrictions. I think progress has been made in that

FEB 13 1996

regard now that all of our friends on the Hill (e.g., Pelosi's staff) share this interpretation. Second, they feel that the Administration has not been strong enough in its support for OAR during the appropriations process. They have a point here: while the White House and OMB have been vocal, the message from NIH has not always been clear.

The meeting at Nancy-Ann Min's office with Kevin Thurm and John Callahan of HHS and Harold Varmus and Bill Paul of NIH resulted in full agreement for public support of the OAR. Earlier today, Donna Shalala gave a strong statement on this issue to science reporters. It was agreed that the Secretary would send a letter to various community groups restating the firm position of the Administration on this issue and would also send a letter to Porter and Specter urging further consideration of the single appropriation. In addition, Varmus and Paul will be co-signing a letter to the editor on this subject to *Nature*, which had run a story that started some of this controversy.

It was also agreed that there would be a working group created to develop a longer term strategy regarding protecting the single appropriation in FY 1997 and in the reauthorization process.

n:\oar.chr

THE WHITE HOUSE
WASHINGTON

FILE COPY

MEMORANDUM FOR JEREMY BEN-AMI

DATE: February 9, 1996
FROM: Patsy Fleming
SUBJECT: National Strategy for HIV and AIDS

Attached is draft copy of the National Strategy for HIV and AIDS for your review and comment. In this draft the appendices are organized by department in order to more easily facilitate individual department reviews. In the final document, agency and department efforts will be organized by substantive area (i.e., prevention, research, care and services, translation of science into practice, international activities, and civil rights).

THE WHITE HOUSE
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THE WHITE HOUSE
WASHINGTON

FILE COPY

MEMORANDUM FOR CLAUDIA COOLEY

DATE: February 8, 1996
FROM: Patsy Fleming
SUBJECT: National Strategy for HIV and AIDS

Attached is a draft copy of the National Strategy for HIV and AIDS, including the HHS agency and office appendices. The following copies are included:

1. One draft copy with cover letter and all HHS appendices
 2. One draft copy *for each* HHS agency along with the agency's individual appendix.
- The agencies and offices included are the:

National Institutes of Health;
Centers for Disease Control and Prevention;
Health Care Financing Administration;
Health Resources and Services Administration;
Substance Abuse and Mental Health Administration;
Agency for Health Care Policy and Research;
Food and Drug Administration;
Indian Health Service;
Office of International Health;
Office of Population Affairs; and
Agency for Children and Families

(The CDC and SAMSHA also have an additional cover memo as special assistance is needed from these agencies. Extra copies are also attached to this memo.)

For this review, agency appendices are organized by agency (e.g., NIH, CDC, etc.). In the final document, agency and department efforts will be organized by substantive area (i.e., prevention, research, care and services, translation of science into practice, international activities, and civil rights).

All department comments are due back to the Office of National AIDS Policy by no later than February 15, 1996. The timeline for completing the strategy is extremely tight and we will be moving ahead with revisions as quickly as possible.

If you have any questions do not hesitate to contact me.

Date: February 8, 1996

To: CDC

From: Jane Sanville, Office of National AIDS Policy

Re: CDC Review of National Strategy for HIV and AIDS

There are several areas we need your help with, specifically:

Text:

- Confirmation of accuracy for all epidemiological and demographic data.
- Is the national prevention goal theoretically achievable (i.e., reducing infections each year until there are no new infections).

Appendix:

- In Redlined text there are specific questions.
- Is it possible to condense some of the description information under the goal of monitoring the epidemic?

Date: February 8, 1996

To: SAMSHA

From: Jane Sanville, Office of National AIDS Policy

Re: SAMSHA Review of National Strategy for HIV and AIDS

There are several areas we need your help with, specifically:

Text:

- Information on the extent of AOD-related behaviors -- the text reads: There is substantial evidence that use of alcohol and other substances can adversely influence risk-taking behavior. It is estimated that x% of the population is affected by alcohol and other drugs in addition to injection drug use.

Appendix:

- In Redlined text there are specific questions.

THE WHITE HOUSE
WASHINGTON

FILE COPY

February 7, 1996

MEMORANDUM TO CAROL RASCO

FROM: Patsy Fleming
SUBJECT: NGA Medicaid Proposal

I want to bring to your immediate attention the very strong concerns being raised by the AIDS community to the National Governors' Association proposal to restructure Medicaid. I have attached a copy of a letter sent to the President today by a coalition of national groups, press releases from the AIDS Action Council and Human Rights Campaign on this subject, and material provided by Tim Westmoreland of Georgetown University Law Center.

As you know, the President has displayed enormous political courage in standing against the tide for dismantling of Medicaid. He has been particularly effective in communicating to the AIDS community and to the nation as a whole the critical importance of Medicaid to Americans living with AIDS. For this, the President and his Administration have garnered very strong support from the community for his actions.

In that light, the proposal by the NGA has many in the community quite alarmed. They have raised several key issues:

- **Definition of Disability.** By dropping the current federal definition of disability and allowing states to decide who is disabled, the NGA plan could create tremendous inequities for people with HIV and AIDS. Because of the high cost of their care, people with HIV/AIDS are an unattractive population to cover.
- **Medically Needy.** Because of their high medical costs, many people with AIDS who are Medicaid beneficiaries are classified as "medically needy." Under the NGA plan, such individuals could be denied both mandatory and optional benefits, including prescription drugs.
- **Statewideness of Benefits.** By eliminating requirements that benefits be provided statewide with comparable duration and scope, the NGA plan would allow states to arbitrarily limit or eliminate coverage of certain services -- i.e., prescription drugs -- to certain categories of beneficiaries -- i.e., people with HIV/AIDS.

- **Right of Private Action.** As you know, people with HIV/AIDS have been and continue to be subject to extraordinary levels of discrimination. In fact, AIDS related discrimination is the leading reason for bias investigations by the HHS Inspector General. The NGA plan replaces the federal right of private action with a state-based system. By the time such a convoluted system were completed, a person with AIDS could very well be deceased.
- **Cost-Sharing.** Again, because of the high cost of services - especially drugs -- the imposition of percentage cost-sharing can be prohibitively expensive for people with HIV/AIDS. Current rules limiting such cost-sharing to "nominal" amounts has protected these individuals from this impact. The NGA plan, however, would allow for larger charges.

FILE COPY

February 6, 1996

MEMORANDUM FOR THE INTERDEPARTMENTAL TASK FORCE ON HIV AND AIDS

FROM: Patricia S. Fleming
Director, Office of National AIDS Policy

SUBJECT: Review of Draft of the National Strategy for HIV and AIDS

As you remember, as a result of our meetings last year each member of the Interdepartmental Task Force on HIV/AIDS (IDTF) was asked to develop individual department and agency plans for HIV/AIDS, linking goals and objectives to budget levels and identifying areas of unmet need.

The individual plans you submitted were carefully studied. Your considerable knowledge and suggestions regarding promising areas for Federal effort were reviewed, as were the comments and counsel of others experienced with combatting this epidemic (i.e., the Presidential Advisory Council on HIV and AIDS, participants at the White Conference on HIV and AIDS, and many HIV positive persons and their families, friends, and caregivers.) The ideas and concerns raised pointed to a consensus on several issues. I believe this document builds on this consensus and articulates the goals and objectives of the entire Federal government.

Please review the attached draft and your appendix carefully. You should:

- Check the budget figures carefully and make any necessary changes. (These budget figures will be cross-checked with OMB figures.)
- Information that was missing or unclear has been 'redlined'. Please be certain to provide this information.
- Check for the accuracy of department and agency names, program titles, and acronyms.
- Make sure that your comments are clear. Comments are due back to the Office of National AIDS Policy **BY NO LATER THAN FEBRUARY 15, 1996**. If you have any questions please call Jane Sanville at (202) 632-1090.

Thank you for your assistance in developing this first-ever National Strategy for HIV and AIDS.

Page 2, MEMORANDUM FOR THE INTERDEPARTMENTAL TASK FORCE ON HIV AND AIDS

Distribution:

Gloria Guttierrez, Department of Commerce
William Perry, Department of Defense
William Modzleski, Department of Education
Corlis Moody, Department of Energy
Claudia Cooley, Department of Health and Human Services
Jacquie Lawing, Department of Housing and Urban Development
Eleanor D. Acheson, Department of Justice
Frederick Drayton, Department of Labor
Anne Keatley Solomon, Department of State
Alex Rodriguez, Department of Treasury
Susan Mather and Abid Rahman, Department of Veterans Affairs
Nils M. Daulaire, Agency for International Development
Chuck J. Supple, Corporation for National Service
Richard Turman, Office of Management and Budget
Fred Garcia, Office of National Drug Control Policy
Michael Grant, Office of Personnel Management
Charles Baquet, Peace Corps
Charlotte Brittian, Social Security Administration
Joseph Duffey, U.S. Information Agency

THE WHITE HOUSE

WASHINGTON

FILE COPY

FEB - 5 1996

MEMORANDUM TO JENNIFER KLEIN

FROM: PATRICIA S. FLEMING, DIRECTOR, OFFICE OF NATIONAL AIDS POLICY

SUBJECT: MOTHERS' VOICE INVITATION

A copy of the attached invitation to the First Lady from Mothers' Voices was sent to the Office of National AIDS Policy for our information.

We have worked closely with this organization and they are a highly credible and effective group in advancing the national response to HIV and AIDS. Mothers' Voices met with the President during 1993 and had a very productive meeting. In addition, Eileen Mitzman, a member of the Board of Directors, was one of the two community representatives to introduce the President at the White House Conference on HIV and AIDS.

I would strongly recommend that the First Lady accept this invitation if at all possible.

Thank you.

Enclosure

History of The Mothers' Voices Luncheon

Disturbed by the nation's wavering commitment, stagnant resources and fragmentation within the AIDS movement, five individuals decided that they wanted to know more about how they could join the battle against the enlarging epidemic. In so doing, they concluded that it was time to bring together a group who had not been engaged, in an organized way, in the battle against the killer. They decided mothers needed to join together as a united voice. In 1991, the founders produced a Mother's Day card that was distributed to hundreds of organizations with the simple message: ***On this Mother's Day help us fight for what we care most about in our lives, the health and well being of our children...It's time to find a cure!*** Letters and unsolicited financial support poured in. The response from thousands of individuals from all over the country was overwhelming.

Realizing that they had struck a responsive cord, Mothers' Voices was launched in a restaurant in lower Manhattan. Over 200 women, concerned with ending the plague came together in the belief that the sense of loss and grief, could be transformed to hope and empowerment. They pledged to build a nationwide constituency of mothers to work for increased government funding for prevention, treatment and a cure.

1992 *Attendees:* 250

Master of Ceremonies: **Ellen Levine**, Editor-in-Chief REDBOOK

Speakers: **Mary Fisher**, Founder of Family AIDS Network
Dr. Mathilde Krim, Founder of American Foundation of AIDS Research
Jeanne White-Ginder, Mother of **Ryan White**
Daniel Bross, Executive Director of AIDS Action Council
Eileen Mitzman, Mother who lost her daughter **Marni** to AIDS in 1991

1993 *Attendees:* 700 at the Marriot Marquis, NYC

Keynote Address: **Matilda Raffa Cuomo**

Master of Ceremonies: **Ellen Levine**, Editor-in-Chief REDBOOK

Extraordinary Voice Award Honorees: **Tammy Boccomino**, Mother with AIDS
Dorothy Feagins, Mother of daughter with AIDS
Carol DiPaolo, Mother of **Joey DiPaolo**
Toukie Smith, Sister of **Willi Smith**
Eileen Mitzman, AIDS activist

1994 *Attendees:* 950 at the Waldorf Astoria, NYC

Keynote Address: Congresswoman **Nita M. Lowey**

Master of Ceremonies: **Ron Silver** and **Ernie Anastos**

Extraordinary Voice Award Honorees: **Jeanne Moutoussamy-Ashe**, Widow of **Arthur Ashe**
Kenneth Cole, Business leader and AIDS activist
Susan Sarandon, AIDS activist
Pamela Shaw, Educator and Activist

1995 *Attendees:* 1050 at the Waldorf Astoria, NYC

Keynote Address: **Anna Quinlen**

Master of Ceremonies: **Paula Zahn**

Extraordinary Voice Award Honorees: **Susan DeLaurentis**, Co-Founder, The Pediatric AIDS Foundation
Susan Zeegan, Co-Founder, The Pediatric AIDS Foundation
Mike Shriver, Founder and E.D. of Mobilization Against AIDS
Sandra Isham Vreeland, Poet and mother living with AIDS

MOTHERS' VOICES
165 West 46th Street
Suite 1310
New York, NY 10036
Phone: (212) 730-2777
Fax: (212) 730-4378

November 17, 1995

Mrs. Hillary Rodham Clinton
The White House
1600 Pennsylvania Avenue
Washington DC 20500

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Speaking from the Heart about AIDS®

MOTHERS'
VOICES

Dear Mrs. Clinton:

We are writing to invite you to be the keynote speaker at our fifth annual *Mothers' Voices* benefit luncheon at the Waldorf-Astoria Hotel in New York City on Thursday, May 9, 1996.

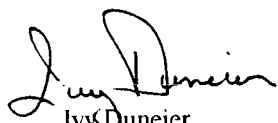
In 1991 five individuals driven by their own personal conviction to make a difference in the fight to end AIDS, created a Mother's Day AIDS awareness card campaign. This was the beginning of a nationwide movement of mothers to unite to end the AIDS epidemic. Since then, hundreds of thousands of mothers have responded to the annual campaign. Our first *Extraordinary Voices awards luncheon* held in 1991 in New York City was attended by 100 women. Four years later, approximately one thousand New York women attended our annual luncheon benefit. The *Extraordinary Voices awards luncheon* celebrates mothers who have found their voice and use it to advocate on the behalf of their children, hoping to create a world without AIDS. *Mothers' Voices* newsletter, *Speaking from the Heart*, is distributed to more than 25,000 families and 3,000 community-based organizations around the country.

Mothers' Voices believes that every child deserves the chance of a lifetime. We are committed to building a national advocacy movement of mothers to become an army of new voices working for the end to the epidemic that is snuffing out the lives of our children. By mobilizing the moral authority of mothers to speak out against the barriers to conquering this killer, we will work for public policies that advance AIDS prevention, expanded research leading to better treatments, and ultimately, a cure. Given the opportunity and resources, mothers as educators and advocates are our best hope of ending AIDS.

We believe that, given the opportunity and resources, mothers as educators and advocates are our best hope to assuring the end this epidemic. We would be very honored if you would consider our request to be the keynote speaker at this year's luncheon. The luncheon begins with a VIP reception at 11:30am, followed by the program at 12 noon. Of course, we will do all we can to accommodate you and your schedule requirements.

We will be in touch with your office in a few weeks to ascertain the possibility of your availability to address the leaders of our rapidly expanding movement. We are hopeful that your response will be favorable.

Respectfully yours,


Ivy Duneier
Board President


Ellen Levine
Board Member

encl: "The History of the Mothers' Voices Luncheon"

THE WHITE HOUSE

WASHINGTON

FEB - 1 1996

MEMORANDUM FOR GORDON ADAMS

FROM: Patsy Fleming 

SUBJECT: FY 1997 budget

cc: Carol H. Rasco

I want to take this opportunity to raise with you two important areas of concern to me with regard to AIDS funding in the FY 1997 budget.

DEPARTMENT OF DEFENSE

As you know, each year the Department of Defense requests very low levels of funding for its AIDS research programs, and Congress increases those levels. The President has expressed his strong support for a continued role in AIDS research by DoD. This should be reflected in the Administration's budget request.

As I understand it, the current FY 1996 funding level is at \$31.56 million. I strongly urge that the FY 1997 request include the same amount or more. DoD is playing a critical role in vaccine research, and is making important contributions in epidemiology and therapeutics research as well. The President requested that an interdepartmental HIV/AIDS research plan and budget be prepared under the leadership of Dr. William Paul at NIH. Thus, we can be assured that DoD's efforts will be coordinated with the work of other Federal agencies in this area.

USAID

I also want to urge that sufficient funds be given to USAID in the FY 1997 budget request that will permit USAID to maintain or increase its commitment to both bilateral and multilateral programs, including UNAIDS. The U.S. contributes approximately 25 percent of the budget of UNAIDS and has provided tremendous leadership in the shaping of the program. In addition, USAID has set up programs in developing countries focusing specifically on HIV/AIDS activities within the broader context of U.S. foreign policy goals including democratization and sustainable economic development. U.S. funds are used as leverage for soliciting funds from other nations. A reduction could jeopardize that leverage. To reduce or withdraw support from our bilateral and multilateral programs now places in jeopardy our position as a world leader, compromises critical U.S. foreign policy goals and limits the political influence we have gained thus far in the global campaign to stop HIV/AIDS.

n:\fy97adam

FILE COPY

**THE WHITE HOUSE
WASHINGTON**

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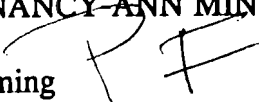
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THE WHITE HOUSE
WASHINGTON

FILE COPY

January 31, 1996

MEMORANDUM TO ~~NANCY ANN MIN~~ AND GORDON ADAMS

FROM: Patsy Fleming 

SUBJECT: Suggested Revisions in DoD Signing Statement

Thank you for sending the draft signing statement for the DoD authorization bill. Based on our meeting today, I have several suggestions for ways to strengthen the text. I would suggest the following:

"The Act specifically includes two provisions affecting members of the Armed Forces and their families to which I remain strongly opposed. As I have mentioned before, I am very concerned by the provision requiring the involuntary separation of military personnel who are living with the Human Immunodeficiency Virus (HIV), when such a departure is not medically required. This provision is blatantly discriminatory and highly punitive to service members and their dependents. Individuals living with HIV can and do lead full and productive lives, provide for their families, and contribute to the well being of our nation. The men and women affected by this provision serve their country with honor and should be allowed to continue to do so. Therefore I am, today, asking the Congress to repeal this provision before a single service member is discharged from the Armed Forces. I have also directed the Secretary of Defense and the Secretary of Veterans Affairs to utilize all possible means to provide these service members and their families with additional benefits to ameliorate the burden this legislation will place on them."

THE WHITE HOUSE
WASHINGTON

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THE WHITE HOUSE
WASHINGTON

FILE COPY

January 30, 1996

MEMORANDUM FOR JENNIFER KLEIN

FROM: Jeff Levi 

SUBJECT: Briefing materials

Attached are most of the materials you requested. Still to come:

- Summary of PHS guidelines on prenatal testing
- Q&A on ACTG recompetition

Richard Sorian will be getting those to you. (I'm out of the office all day but can be paged.)

TALKING POINTS

DISCHARGE OF HIV-POSITIVE MILITARY PERSONNEL

Background

The President intends to sign the conference agreement on H.R.1530, the National Defense Authorization Act. The legislation includes important reforms in military acquisition rules, an increase in pay for military personnel, and other issues vital to the national interest. It also contains a provision, opposed by the President, requiring the retirement or discharge of personnel who are HIV-positive.

Key Points

- The President and his Administration have vigorously opposed this provision. The President cited it as one of the reasons for his veto of the earlier version of this legislation.

I find the provision to be deeply offensive. It flies in the face of medical advice and singles out one group of Americans for differential treatment and discrimination.

These men and women are willing and able to continue serving their nation. This provision is an insult to their commitment. They have served an average of 10 years in the Armed Forces and more than 80 percent of them volunteered to serve their country.

- During the negotiations over the revised version of the legislation, the Administration aggressively sought to have this provision omitted from the final legislation. Sadly, these efforts were not successful.
- The overall legislation is vitaly necessary for the national security of the U.S. I fully understand the need for the President to sign this legislation.
- The Administration intends to take the following steps to mitigate the effect of the legislation on the men and women of the Armed Forces who would be adversely affected by this legislation:
 - The Administration will work closely with a members of Congress from both parties to pursue legislation to reverse this policy before it takes effect in six months.
 - The Office of National AIDS Policy, the Department of Defense, and the Department of Veterans' Affairs are working to identify all possible benefits that can be provided to these individuals and their families to ameliorate the effects of this legislation.



**HUMAN
RIGHTS
CAMPAIGN**

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pager 800 386 5996

News

FOR IMMEDIATE RELEASE

Friday, Jan. 26, 1996

GOP EXTREMISTS PLACED DISCRIMINATORY MEASURE IN DEFENSE BILL, HRC SAYS

Dorman, Lott Pushed Ugly Provision to Discharge HIV+ Troops

Washington — Republican extremists are responsible for a discriminatory HIV measure in the defense spending bill expected to be passed by the Senate on Friday, the Human Rights Campaign charged. HRC called on enlightened members of Congress to roll back this unnecessary provision.

"GOP presidential candidate Bob Dorman and Senate Republican Whip Trent Lott of Mississippi pushed this outrageous measure through, despite the protests of more moderate members of their own party," said Daniel Zingale, HRC's political director. "The blame for this ugly amendment belongs squarely with them."

Rep. Dorman, of California, wrote the measure, which would force the Pentagon to discharge all service members with the virus that causes AIDS. The provision would also deny these men and women many of the valuable benefits available to service members discharged for other medical conditions.

"There is absolutely no reason to treat people with HIV any differently from service members with other chronic medical conditions, such as heart disease or diabetes," Zingale said. "This measure will remove trained, experienced, healthy and productive people from the armed forces. Even the Pentagon has said it doesn't want this provision."

A total of 1,149 service members would be affected by the measure, which calls for their discharge within six months.

White House spokesman Mike McCurry said Thursday that President Clinton has reservations about the HIV provision but plans to sign the bill. The \$265 billion authorization passed the House on Wednesday.

Currently, HIV-positive service members may serve their country as long as they can perform their duties, but they are not deployed overseas. The same policy is applied to service members with other chronic medical conditions such as diabetes, asthma, heart disease or cancer.

The Human Rights Campaign also objects to a provision in the bill that would ban abortions at overseas military hospitals. Clinton had objected to this and the HIV provision when he vetoed an earlier version of the defense bill in December. Congress then went back and removed some of the other provisions the president opposed.

The Human Rights Campaign is the largest national lesbian and gay political organization, with members throughout the country. It effectively lobbies Congress, provides campaign support and educates the public to ensure that lesbian and gay Americans can be open, honest and safe at home, at work and in the community.

THE WHITE HOUSE

WASHINGTON

The Clinton Administration and HIV/AIDS

In 1992, when he ran for President of the United States, Bill Clinton said he would "provide the leadership this country needs for a loud, clear, and consistent war on AIDS." In his first three years in office, the President has translated that pledge into action, turning around more than a decade of governmental policies that were regarded as at best apathetic and at worst hostile to those living with HIV/AIDS. Following are the highlights of the Administration's HIV/AIDS-related actions taken since January 20, 1993.

AIDS Advisory Council. The President has created a 30-member Presidential Advisory Council on HIV and AIDS to provide him and his Administration with expert outside advice on the ways in which the Federal government should respond to the HIV/AIDS epidemic. Specifically, the Council is charged with making recommendations in the areas of AIDS-related research, prevention, and care.

AIDS Funding. The President has placed AIDS programs among his investment priorities. In the three budgets he has submitted to the Congress, the President has increased total government funding for AIDS research, prevention, and care by 40%, including a 108% increase for the Ryan White CARE Act programs.

Anti-Discrimination. The Justice Department and the Equal Employment Opportunity Commission have vigorously enforced provisions of the Americans with Disabilities Act that prohibit discrimination against people with HIV/AIDS. The EEOC has received more than 900 charges alleging employment discrimination against people with HIV and AIDS and has resolved 789 charges, obtaining monetary benefits of over \$6.1 million. The Health Care Financing Administration (HCFA) has taken action on nearly 20 complaints of denial of care by health care facilities or providers to persons with HIV/AIDS and new efforts are being made to address discrimination in nursing homes.

Blood Safety. The Food and Drug Administration (FDA) held ground-breaking public meetings on the use of new technologies to reduce the risk of HIV transmission by blood product transfusion. The Administration has received the Institute of Medicine report examining the issues surrounding transmission of HIV throughout the blood supply before 1987. The Department of Health and Human Services has named the Assistant Secretary for Health to be the Department's blood safety director, with overall responsibility for ensuring the IOM's recommendations are carried out and the coordination and oversight of the Public Health Service's blood safety programs.

Consumer Protection. The FDA is working with community organizations to prevent fraudulent activities aimed at people living with HIV disease. To date, 10 FDA-funded coalitions throughout the country -- including representatives from the community, health professionals, and law enforcement agencies -- have been established to educate and protect people with HIV and AIDS from fraudulent products.

Data Gathering. The Department of Health and Human Services (HHS) is supporting three major efforts directed at gathering and analyzing services provided to persons with HIV disease. The "AIDS Cost and Services Utilization Survey," the "HIV Cost and Services Utilization Survey," and the "Hospital Cost and Utilization Project," will provide an important data base on the cost of AIDS care and the use of health care services by people living with HIV.

Dental Care. The AIDS dental reimbursement program was expanded to address the lack of dental care available to low-income and under-insured individuals living with HIV/AIDS. The program, which reimburses accredited dental schools and post-doctoral dental training programs for uncompensated costs incurred in providing oral health care to HIV-positive individuals, includes 124 institutions in 35 states.

Disability Eligibility. The Social Security Administration published revised regulations expanding the list of health manifestations that will be considered in determining eligibility due to HIV/AIDS for Social Security and Supplemental Security Income disability benefits. The agency also revised its rules to allow physicians and other health professionals to provide information to Social Security field offices, which then can make immediate disability findings.

Drug Approval. The FDA has approved or provided new labelling indications for fifteen new products to treat HIV or HIV-related conditions while dramatically reducing the time it takes for drug review and approval.

Drug Development. HHS created the National Task Force on AIDS Drug Development, an historic partnership between government, industry, academia, medicine, and AIDS-affected community organizations to identify and eliminate barriers to the rapid development of drugs for HIV and HIV-related conditions. The Task Force has issued 45 specific recommendations, many of which are currently being implemented.

Early Intervention. The Agency for Health Care Policy and Research issued clinical practice guidelines for health care professionals to assist in the evaluation and management of early HIV infection. The guidelines stress the importance of prevention of HIV-related opportunistic infections and the link between prevention and early diagnosis and care. A quick reference guide for physicians and consumer guides for adults, adolescents, and the parents of children with HIV infection was also made available. The U.S. Public Health Service provided support for a new campaign by the National Minority AIDS Council to promote the use of prophylactic treatment to prevent the occurrence of pneumocystis carinii pneumonia in people with HIV.

Health Benefits. Federal medical assistance programs serve nearly 50% of people living with AIDS and more than 90% of children with AIDS. Medicaid is the largest single payer of direct medical services, paying an estimated 25% of the aggregate cost of AIDS-related care. Under Title II of the Ryan White CARE Act, 18 states operate health insurance continuation programs that allow low-income people with HIV to continue their private health insurance.

Home Care. AIDS-specific Medicaid home care waivers are in place in 15 states, allowing

States to provide targeted home and community-based services to people with HIV/AIDS. In 1995, those programs will serve at least 21,170 individuals. HHS also is developing prototype waivers to help other States gain quick approval of future waiver applications.

Housing. In the last two years, the Department of Housing and Urban Development's (HUD) Housing Opportunities for People with AIDS (HOPWA) program has provided \$300 million to communities with a high incidence of HIV infection to provide housing assistance to people living with HIV/AIDS. HUD also has established the National Office of HIV/AIDS Housing to assist low-income people with HIV/AIDS to pay for housing. President Clinton cited the proposal to cut \$30 million from HOPWA as one of the reasons for his veto of the fiscal year 1995 rescissions bill.

International Cooperation. The U.S. is actively cultivating international cooperation in HIV/AIDS prevention and care through participation in the United Nations' new Joint Programme on HIV/AIDS. Representatives of the U.S. participated in the Tenth International HIV/AIDS Conference in Yokohama, Japan, and the World AIDS Summit in Paris and is participating in regional conferences for Latin America and the Caribbean, Asia, and Africa. The U.S. Agency for International Development sponsored the Third HIV/AIDS Prevention Conference in Washington DC, which allowed for an exchange of information among diverse prevention and care groups from around the world and resulted in an agenda of effective prevention measures to be pursued worldwide. Through USAID, the U.S. is the largest bilateral donor in international assistance for prevention HIV/AIDS transmission, providing more than \$120 million annually.

Mental Health. HHS awarded the first Federal grants to develop mental health services for persons living with HIV/AIDS and their families and partners. Approximately 260,000 mental health counseling sessions for people with HIV were reported during the last six months of 1994. Approximately 100,000 individuals with HIV also received mental health services under the Ryan White CARE Act.

Minority Communities. The Public Health Service convened the National Congress on the State of HIV in Racial and Ethnic Communities, bringing together individuals and organizations to develop plans to alter the course of HIV in those communities. The National Institutes of Health (NIH) added four new sites to its AIDS Clinical Trials Group at institutions that serve predominantly minority populations.

Perinatal Transmission. An NIH-sponsored clinical trial (ACTG 076) provided strong evidence that use of AZT by HIV-positive pregnant women dramatically reduced the rate of HIV transmission from mother to infant. The FDA expeditiously approved changes in labelling indications for AZT to include treatment of HIV-infected pregnant women. The U.S. Public Health Service issued guidelines in August 1994 on using AZT during pregnancy to reduce the risk of perinatal HIV transmission. In July 1995, CDC published PHS recommendations for routine HIV counseling and voluntary HIV testing for all pregnant women in the U.S. Widespread implementation of these recommendations will enable women to seek and receive

the care they need for themselves and to reduce the risk of transmitting HIV to their infants by as much as two-thirds.

Policy Coordination. To provide a central focus for governmental efforts against HIV/AIDS, the President created the Office of National AIDS Policy within the White House, to advise him on AIDS policy issues and coordinate interdepartmental activities. An Interdepartmental Task Force on HIV/AIDS, chaired by National AIDS Policy Director Patricia Fleming, was created to assist in that effort.

Prevention. CDC has initiated a comprehensive community planning process for HIV prevention programs, placing control of such programs in the hands of local community organizations rather than having them dictated by the Federal government. CDC also initiated an unprecedented review of government-funded HIV/AIDS prevention activities conducted by panels of individuals from outside of the government. In January 1994, the Centers for Disease Control and Prevention (CDC) launched the Prevention Marketing Initiative aimed at young adults (ages 18-25) to change behaviors that contribute to the transmission of HIV. The initiative features production of frank, forward-thinking public service announcements promoting both abstinence and the consistent and correct use of latex condoms.

Research Organization. The President signed the National Institutes of Health Revitalization Act of 1993, placing full responsibility for planning, budgeting, and evaluation of the AIDS research program at NIH in the Office of AIDS Research. Dr. William Paul, an internationally acclaimed immunologist, was appointed to head that office and has developed the first comprehensive plan and budget for AIDS research.

Ryan White CARE Act. In the three budgets he has sent to Congress, the President has increased funding for the Ryan White CARE Act by 108%, fulfilling the President's promise to fully fund that program. During the last two years, the number of metropolitan areas eligible for assistance under Title I of the Ryan White CARE Act has increased from 25 to 49. Preliminary data indicate that approximately 360,000 clients were served under Title I of the Act. Eighty percent of U.S. metropolitan areas report providing new or expanded Ryan White services to people living with HIV, including HIV/AIDS drug assistance; services for women, children, and other special needs populations; and expanded rural services. All 54 states and territories are currently funded under Ryan White Title II, serving an estimated 296,000 clients with those funds. Title III(b), which pays for counseling, testing, and early intervention services, including treatment, served more than 175,000 clients, including a large number of women and minorities. Currently, 144 community-based organizations, located in 33 states, the District of Columbia, and Puerto Rico, are supported with Title III(b) funds. Title IV develops comprehensive coordinated care systems linked to clinical research in more than 80 communities, meeting the unique needs of children, youth, women, and families. Reauthorization of the Ryan White CARE Act is a top priority for the Administration in 1995.

Treatment. The NIH Preclinical AIDS Drug Screening Program has screened 72,000 potential agents for treatment of HIV disease and approved six compounds for Phase I clinical trials. NIH

clinical trials involve more than 45,000 HIV-infected individuals. Several promising HIV protease inhibitors and potent combination drug regimens are slated to begin Phase III efficacy trials in the near future. Thousands of other HIV-positive individuals are receiving promising investigational therapies through clinical trials and various expanded access programs.

Vaccines. The NIH has significantly expanded its basic research efforts to design new approaches to developing AIDS vaccines. It is now evaluating 14 vaccine candidates to identify those that might be appropriate for efficacy trials. The Department of Defense is also developing and testing several candidate HIV vaccines to protect U.S. military personnel.

Veterans. The Department of Veterans Affairs (VA) provides care to nearly 17,000 veterans with HIV-related diseases. The VA operates four specialized AIDS Clinical Units in New York City, Miami, West Los Angeles, and San Francisco medical centers. AIDS research is conducted at 85 medical centers, comprising over 800 individual research projects. Specialized AIDS Research Centers dedicated to conducting HIV research are located in New York City; Durham, NC; San Diego CA; and Atlanta. VA AIDS research is funded by about \$6 million in VA research funds and over \$24 million in extramural grants. VA also maintains a national AIDS data base to track the epidemic within the veterans' population.

Water Safety. The Centers for Disease Control and Prevention and the Environmental Protection Agency issued guidance for vulnerable populations recommending steps to purify drinking water to protect against *Cryptosporidium*, which can be fatal to those with compromised immune systems. These agencies have also conducted research and outreach about threats of water-borne diseases to such individuals through funding and hosting several workshops and training programs.

Women and AIDS. The NIH created a Women's Interagency HIV Study to identify the nature and rate of HIV disease progression in women. NIH requires that women and members of minority groups be included in all NIH supported biomedical and behavioral research involving human subjects. NIH has initiated a major research effort to develop female-controlled barrier methods, including vaginal compounds, to prevent HIV transmission.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service



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First 500,000 AIDS Cases — United States, 1995

As of October 31, 1995, a total of 501,310 persons with acquired immunodeficiency syndrome (AIDS) had been reported to CDC by state and territorial health departments; 311,381 (62%) had been reported as having died. The AIDS surveillance case definition was substantially expanded in late 1987 and again in 1993 to reflect increased knowledge of the natural history of human immunodeficiency virus (HIV) and to remain consistent with the clinical management of HIV disease (1,2). This report presents rates of reported AIDS cases for 1994 and describes the temporal changes in the characteristics of persons reported with AIDS during three periods corresponding to changes in the AIDS case definition—1981–1987, 1988–1992, and 1993–October 1995—and how this information can be used to plan local, state, and national prevention programs.*

Of the cumulative AIDS cases, 50,352 (10%) were reported during 1981–1987, 203,217 (41%) during 1988–1992, and 247,741 (49%) during 1993–October 1995. The proportion of AIDS cases among females increased from 8% of cases reported during 1981–1987 to 18% during 1993–October 1995 (Table 1). The proportion of cases among whites decreased from 60% to 43%, and the proportion among blacks and Hispanics increased from 25% to 38% and from 14% to 18%, respectively. During 1994, the rates per 100,000 population for blacks and Hispanics (101 and 51, respectively) were substantially higher than rates for whites (17), American Indians/Alaskan Natives (12), and Asians/Pacific Islanders (6).

The proportion of cases among persons who reported injecting-drug use increased from 17% during 1981–1987 to 27% during 1993–October 1995, and the proportion of cases attributed to heterosexual transmission increased from 3% to 10%. Cases among men who have sex with men decreased from 64% to 45%.

During 1994, the rates per 100,000 population for reported AIDS cases were 48 in the Northeast, 31 in the South, 29 in the West, and 13 in the Midwest.[†] However, during 1988–1992 and 1993–October 1995, the largest numbers of cases (65,926 and 86,462, respectively) were reported from the South, which also accounted for the largest proportionate increase of reported cases (31%). The proportionate increases in

*Single copies of this report will be available free until November 22, 1996, from the CDC National AIDS Clearinghouse, P.O. Box 6003, Rockville, MD 20849-6003; telephone (800) 458-5231 or (301) 217-0023.

[†]Northeast=Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont; Midwest=Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin; South=Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia; West=Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and Wyoming.

TABLE 1. Number and percentage of persons with AIDS, by selected characteristics and period of report — United States, 1981–October 1995

Characteristic	1981–1987		1988–1992		1993–October 1995		Cumulative	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Sex								
Male	46,317	(92.0)	177,807	(87.5)	204,356	(82.5)	428,480	(85.5)
Female	4,035	(8.0)	25,410	(12.5)	43,383	(17.5)	72,828	(14.5)
Age group (yrs)								
0– 4	653	(1.3)	2,766	(1.4)	2,013	(0.8)	5,432	(1.1)
5–12	100	(0.2)	669	(0.3)	616	(0.2)	1,385	(0.3)
13–19	199	(0.4)	758	(0.4)	1,343	(0.5)	2,300	(0.5)
20–29	10,531	(20.9)	38,662	(19.0)	41,861	(16.9)	91,054	(18.2)
30–39	23,269	(46.2)	92,493	(45.5)	111,992	(45.3)	227,754	(45.4)
40–49	10,491	(20.8)	47,088	(23.1)	64,990	(26.2)	122,569	(24.4)
50–59	3,690	(7.3)	14,537	(7.2)	18,413	(7.5)	36,640	(7.3)
≥60	1,419	(2.8)	6,244	(3.1)	6,513	(2.6)	14,176	(2.8)
Race/Ethnicity								
White, non-Hispanic	30,104	(59.8)	102,551	(50.5)	105,516	(42.6)	238,171	(47.5)
Black, non-Hispanic	12,794	(25.4)	63,319	(31.2)	94,158	(38.0)	170,271	(34.0)
Hispanic*	7,039	(14.0)	35,213	(17.3)	45,135	(18.2)	87,387	(17.4)
Asian/Pacific Islander	309	(0.6)	1,339	(0.7)	1,809	(0.7)	3,457	(0.7)
American Indian/ Alaskan Native	67	(0.1)	433	(0.2)	783	(0.3)	1,283	(0.3)
HIV-exposure category								
Men who have sex with men	32,246	(64.0)	110,934	(54.6)	111,257	(44.9)	254,437	(50.8)
Injecting-drug use	8,639	(17.2)	49,093	(24.2)	67,708	(27.3)	125,440	(25.0)
Men who have sex with men and inject drugs	4,193	(8.3)	14,252	(7.0)	13,984	(5.6)	32,429	(6.5)
Hemophilia	505	(1.0)	1,744	(0.9)	2,009	(0.8)	4,258	(0.8)
Heterosexual contact	1,248	(2.5)	12,335	(6.1)	24,958	(10.1)	38,541	(7.7)
Transfusion recipients	1,285	(2.6)	3,894	(1.9)	2,521	(1.0)	7,700	(1.6)
Perinatal transmission	608	(1.2)	3,084	(1.5)	2,432	(1.0)	6,124	(1.2)
No risk reported	1,628	(3.2)	7,881	(3.9)	22,872	(9.2)	32,381	(6.4)
Region†								
Northeast	19,544	(38.8)	62,282	(30.6)	74,769	(30.2)	156,595	(31.2)
Midwest	3,770	(7.5)	20,352	(10.0)	24,914	(10.1)	49,036	(9.8)
South	12,960	(25.7)	65,926	(32.4)	86,462	(34.9)	165,348	(33.0)
West	13,550	(26.9)	46,675	(23.0)	53,729	(21.7)	113,954	(22.7)
U.S. territories	516	(1.0)	7,889	(3.9)	7,566	(3.1)	15,971	(3.2)
Vital status								
Living	2,779	(5.5)	32,144	(15.8)	155,006	(62.6)	189,929	(37.9)
Deceased	47,573	(94.5)	171,073	(84.2)	92,735	(37.4)	311,381	(62.1)
Total‡	50,352	(100.0)	203,217	(100.0)	247,741	(100.0)	501,310	(100.0)

*Persons of Hispanic origin may be of any race.

†Northeast=Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont; Midwest=Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin; South=Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia; West=Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and Wyoming.

‡Includes persons for whom sex, race/ethnicity, or region are missing.

reported cases from 1988–1992 to 1993–October 1995 for the Midwest, Northeast, and West were 22%, 20%, and 15%, respectively.

During 1993–October 1995 in the South and Midwest, higher proportions of cases among adolescents and young adults (aged 13–29 years) occurred in small (50,000–499,999 population) metropolitan statistical areas (MSAs) and non-MSAs (rural areas) (27% and 24%, respectively) compared with 9% in the Northeast and 11% in the West. During this time period, among cases in adolescent and young adult men who have sex with men, 25% of 8481 cases in the South occurred in persons who resided in small MSAs and rural areas, 21% of 2870 in the Midwest, 9% of 3311 in the Northeast, and 9% of 5706 in the West. Among adolescent and young adult injecting-drug users, 30% of 531 cases in the Midwest occurred among persons residing in small MSAs and rural areas, 23% of 2370 in the South, 17% of 930 in the West, and 8% of 3304 in the Northeast. The proportion of cases among adolescents and young adults residing in small MSAs and rural areas that resulted from heterosexual transmission was highest in the South (32% of 2842), followed by the Midwest (22% of 678), the West (18% of 691), and the Northeast (7% of 1745).

During 1993–October 1995, most AIDS cases among adolescent and young adult men who have sex with men occurred among whites in all four regions (Midwest, 57%; West, 56%; South, 49%; and Northeast, 42%). Black adolescent and young adult men who have sex with men accounted for 39% of cases in the South, 37% in the Midwest, 36% in the Northeast, and 14% in the West. These proportions were higher than those for cases among black adolescent and young adult men who have sex with men reported during 1988–1992 (South, 31%; Midwest, 30%; Northeast, 31%; and West, 12%).

Reported by: Div of HIV/AIDS Prevention, National Center for Prevention Svcs, CDC.

Editorial Note: The World Health Organization estimates that 18 million adults and 1.5 million children have been infected with HIV, resulting in approximately 4.5 million AIDS cases worldwide (3). The theme for the 1995 World AIDS Day (December 1) is "Shared Rights, Shared Responsibilities." The findings in this report document both the magnitude and evolving nature of the AIDS epidemic in the United States, and underscore that HIV-prevention programs must be planned and implemented collaboratively by persons with diverse skills, training, and experience.

In addition to describing the overall magnitude of the epidemic—approximately one half million cases, nearly half of which have been reported since 1993—this report highlights changes in the epidemiologic patterns during 1993–October 1995 compared with those during earlier periods. In particular, although men who have sex with men continue to account for the largest proportion of cases, the AIDS epidemic is increasing more rapidly among injecting-drug users and persons infected through heterosexual contact with a partner at risk for or known to have HIV infection or AIDS (4,5). The increase in AIDS cases resulting from heterosexual transmission also is reflected in the increase in cases reported among women. The proportions of AIDS cases reported during 1993–October 1995 that are attributed to these risk behaviors will increase as records of persons who were reported initially without risk are reviewed and the risk is identified (6). Geographic patterns also have changed, as reflected by increases occurring among persons in the South. Finally, regardless of transmission mode or region, the epidemic continues to affect blacks and Hispanics disproportionately.

Although the AIDS epidemic in the United States was recognized initially in the Northeast and West (7), and rates remain highest in the Northeast, the findings from AIDS surveillance document that the greatest proportionate increases in the HIV epidemic have occurred in the South and Midwest—areas that account for the largest proportion of the total U.S. population. These regional variations, especially in adolescents and young adults, underscore the importance of developing HIV-prevention programs based on local trends in the epidemiology of HIV transmission. In the South and Midwest, more detailed characterization of the epidemiologic patterns in small cities and rural areas is particularly important for developing effective regionwide prevention programs.

The disproportionate impact of the epidemic among racial/ethnic minorities is reflected by rates of reported AIDS cases that are six and three times higher for blacks and Hispanics, respectively, than for whites. Rates for HIV infection and the proportions of men who have sex with men and injecting-drug users with AIDS who are black and Hispanic also vary substantially by region (8). For example, Hispanics account for lower proportions of reported cases of AIDS among adolescents and young adult men who have sex with men in the Midwest and South than in the Northeast and West. Because race and ethnicity are not risk factors for HIV transmission, programs to prevent HIV transmission among racial/ethnic minorities should be based on underlying social, economic, and cultural factors that influence risk behaviors (8).

Because of the regional and local variations in the AIDS epidemic in the United States, HIV-prevention efforts must be directed at the local level. In 1993, a CDC advisory committee review of HIV-prevention programs emphasized the importance of 1) enhancing the capacity of local and state agencies to collect and analyze information relevant to the specific and unique aspects of HIV transmission in their communities, 2) strengthening the behavioral and social science bases of HIV-prevention activities, and 3) ensuring that HIV-prevention strategies and interventions reflect the preferences and needs of the affected communities for whom they are intended (9). As a result, in 1994, CDC initiated the HIV Prevention Community Planning process (10) that has provided resources for collaboration between health departments and planning groups that are representative of the local communities. These resources facilitate HIV-prevention programs that are based on scientific data (including data from HIV/AIDS surveillance, seroprevalence surveys, vital statistics, and behavioral research) and knowledge of the community norms and practices. This approach is consistent with the focus of World AIDS Day and emphasizes the necessity of shared participation in HIV-prevention planning and program implementation.

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July 1995

CDC HIV/AIDS PREVENTION

CENTERS FOR DISEASE CONTROL AND PREVENTION

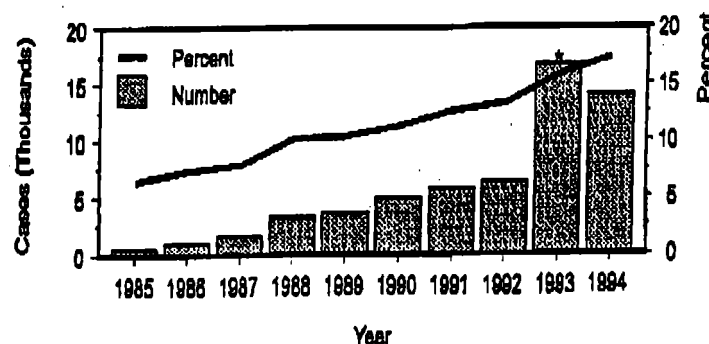
Women, Children, and HIV/AIDS

CDC tracks HIV infection and AIDS in two groups increasingly affected by the epidemic-- women and children--through a number of surveillance programs. Information on the status of HIV/AIDS in these groups is critical to plan and evaluate prevention programs, to determine health care resource needs, and to better target services and care to those who need them.

Women and Children Increasingly Affected by AIDS

Through December 1994, CDC received reports of 58,428 cumulative cases of AIDS among adult and adolescent women (13 years of age and older) in the U.S. Women account for more and more AIDS cases--they were only 7% of all AIDS cases in 1985, but jumped to 18% in 1994. AIDS is now the fourth leading cause of death among women 25-44. And AIDS is actually increasing faster in women than it is in men. In 1994 alone, 14,081 women were reported with AIDS. Women of childbearing age account for the vast majority of those cases: 84% were reported in women 15-44 years old.

FIGURE 1. Number and percentage of AIDS cases among women aged ≥13 years -- United States, 1985-1994



* The AIDS surveillance case definition was expanded in 1993.

In 1994, most women with AIDS were infected through injecting drug use--41%. But nearly as many--38%--were infected through heterosexual contact with an infected partner. An additional 19% were initially reported with no specific HIV exposure. Historically, when these cases are investigated, it is found that most of these women--66%--have been exposed through heterosexual sex. Heterosexual contact is the most rapidly increasing transmission category for women. Comprehensive HIV prevention programs for women must address their multifaceted prevention needs.

The epidemic in children is closely associated with the epidemic in women. CDC has received reports of more than 5,500 cases among children who were infected with HIV through perinatal transmission (from mother to child during pregnancy, labor, or delivery) or by breastfeeding. In 1994, 1,017 pediatric AIDS cases were reported, an 8% increase from the number reported in 1993. Of these, 92% were mother-to-child transmission. For HIV-infected women of childbearing age, the possibility of perinatal transmission adds an additional important dimension to HIV prevention.

Racial/Ethnic and Regional Variations

- ▲ In 1994, women of color accounted for more than three-fourths of all AIDS cases among women: African-American women represented 57% and Hispanic women 20%.
- ▲ The Northeast accounted for the largest percentage of AIDS cases among women: 44%. The South followed with 36%; the West, 9%; Midwest, 7%; and Puerto Rico and U.S. territories, 4%.
- ▲ Most women with AIDS were from urban areas, but the South reported more than 10% of cases from smaller towns and rural areas.
- ▲ Of all AIDS cases among women, 61% were reported from just 5 states: New York (26%), Florida (13%), New Jersey (10%), California (7%), and Texas (5%).
- ▲ HIV infection in childbearing women varies by region. From 1989 to 1993, prevalence decreased in the Northeast from 4.1 to 3.4 per 1,000. In the South, it increased from 1.6 in 1989 to 2.0 in 1991, and has been stable since.

In 1993, an estimated 7,000 HIV-positive women gave birth in the U.S. That's 1 out of every 625 live births. Not every baby born to an infected mother is also infected. Without preventive treatment, the mother-to-child transmission rate is 15-30%, or about 1,000-2,000 infants in 1993.

AZT Can Reduce Perinatal Transmission

A breakthrough study last year showed that some pregnant women who are infected with HIV but don't yet have any signs of AIDS can reduce the chances of transmitting HIV to their babies by as much as two-thirds if AZT therapy is begun early in pregnancy, continued through labor and delivery, and provided to the child for the first 6 weeks of life.

Based on these findings, the Public Health Service (PHS) issued recommendations in August 1994 on using AZT to reduce the risk of perinatal transmission. And in July 1995, to provide pregnant women the opportunity to learn their HIV status as early in pregnancy as possible, PHS issued guidelines calling for routine counseling and voluntary HIV testing for all pregnant women. If women do not receive prenatal care, or if for any reason their HIV status is unknown at the time of delivery, the guidelines

recommend that HIV testing be offered to them or their babies at or shortly after delivery. Implementing these guidelines will reduce the number of children who get AIDS. Just as important, targeted prevention programs for women are critical for the health of both women and children. The best way to prevent infection in babies is to prevent infection in women.

Evaluating Prevention Efforts

It is critical that resources are directed where they do the most good. To do that, the impact of prevention programs must be continuously monitored and changes made to most effectively target messages and activities. And surveillance is essential to know where HIV infection is decreasing, stabilizing, and increasing so that programs can be directed where they are most needed. In collaboration with community-based organizations, state and local health departments, and other federal and private-sector organizations, CDC is committed to ensuring that both the implementation and evaluation of HIV prevention programs for women and children continue to be priorities in the fight against AIDS.

WOMEN'S INTERAGENCY HIV STUDY (WIHS)

UPDATE

OVERVIEW

The WIHS is a collaborative, multi-site, longitudinal study designed to investigate comprehensively the impact of infection with HIV on women in the United States. The study population includes approximately 2,000 HIV-infected women and 500 women at high-risk of acquiring HIV who were age 13 years or older at the time of enrollment. The WIHS operates in tandem with its sister study, the HIV Epidemiology Research Study (HERS) sponsored by the Centers for Disease Control and Prevention (CDC), which is currently following patients in study sites located in Baltimore MD, Detroit MI, New York City NY, and Providence RI.

Since the study's inception in August 1993, study research questions have been elucidated; standardized protocols and data collection instruments developed; site-specific infrastructure built; and the extent of homology with the HERS defined, including designation of research questions to be studied using joint WIHS/HERS data. Formal enrollment began in October 1994 and was completed in late 1995. The six month follow-up of early enrollees began in April 1995. The projected date of completion for the original WIHS study is July 31, 1997.

BACKGROUND

In 1992, NIAID issued a Request for Applications (RFA) to support clinical sites for the study of HIV disease progression in women in the U.S. The study objectives were to:

- (1) determine the spectrum and course of the clinical manifestations of HIV infection in women
- (2) determine the pattern and rate of decline of CD4⁺ cells in women and the relationship of CD4⁺ cell changes to other immunologic and virologic parameters and to the clinical manifestations of HIV
- (3) investigate infectious, treatment-related, endocrine, nutritional, health utilization, socioeconomic, and substance-abuse cofactors that may be related to the rate and type of HIV disease progression
- (4) determine the rate of HIV seroconversion among high-risk HIV-uninfected women.

In August 1993, four awards were made by the NIAID under a cooperative agreement (grant) mechanism, each with a four-year period of performance. The awards include:

- a New York City Consortium under Bronx-Lebanon Hospital/Montefiore Medical Center, with two subcontracts (Beth Israel Hospital, Mt. Sinai Medical Center)
- a Washington DC Consortium under Georgetown University Medical Center, with five subcontracts (Howard University Medical Center, George Washington University Medical

Center, Whitman-Walker Clinic, Montgomery County Health Department, and Inova Health System of Northern Virginia)

- a **San Francisco Consortium** under University of California, San Francisco, with three subcontracts (San Francisco General Hospital, Highland Hospital AIDS Clinic, East Bay AIDS Center)
- a **Los Angeles Consortium** under UCLA School of Medicine/Los Angeles County-USC Medical Center, with six subcontracts (Charles Drew University of Medicine/Martin Luther King Medical Center, AIDS Healthcare Foundation and Southwest Community-Based AIDS Treatment Group, the Santa Barbara County Department of Health Services, T.H.E. Clinic for Women, Prototypes/W.A.R.N., and the University of Hawaii).

A fifth site, a **Chicago Consortium**, was funded in January 1994, under Chicago-Cook County Hospital, with three subcontracts (University of Illinois at Chicago, Rush Presbyterian-St. Luke's Medical Center, and Northwestern Memorial Hospital). A sixth site, State University of New York (SUNY) at Brooklyn, was added in May 1994, using previously-awarded, investigator-initiated grant monies.

The National Institute of Child Health and Human Development (NICHD) assumed sponsorship of the Los Angeles Consortium in August 1994. It also provides supplemental funding for the SUNY Brooklyn WIHS site. The National Institute of Dental Research (NIDR) and Agency for Health Care Policy and Research (AHCPR) also provide ancillary support to the WIHS. In October 1995, the National Institute on Drug Abuse (NIDA) and the National Cancer Institute (NCI) began providing significant ancillary budgetary support to the study.

The NIAID provides ancillary support to the HERS clinical sites through an interagency agreement with the CDC. The New England Research Institute (NERI) provides statistical and data management support for both the WIHS and the HERS under a contract awarded by the NIAID in April 1993.

The WIHS prospective cohort study is designed to answer the following questions:

- (1) What are the types, incidence, and predictors of AIDS-defining and HIV-related conditions and other clinical conditions?
- (2) What are the predictors of incidence and clinical course of cervical neoplasia and HPV-mediated cervical disease?
- (3) What are the predictors of incidence, prevalence, and course of disease of genital infections?
- (4) Are there different trends over time in substance use according to HIV serostatus? according to immune status among HIV-infected women?
- (5) Are there different trends over time in sexual behavior according to HIV serostatus?
- (6) Are there different trends over time in psychosocial outcomes according to HIV serostatus?
- (7) Among HIV-seropositive women, what are the predictors of clinical disease progression as defined by onset of AIDS-defining or HIV-related conditions?

- (8) Among HIV-seropositive women, what are the predictors of length of survival from AIDS diagnosis? from HIV-associated illnesses? from CD4 thresholds?
- (9) Among HIV-seropositive women, what is the rate of change and what are the predictors of rate of change of immunologic/virologic markers?

STRENGTHS OF THE WIHS

1. The cohort includes a truly comprehensive cross-section of women at risk for HIV, including the full spectrum of ethnicity and race, as well as the mechanisms of initial HIV infection.
 - The WIHS participant cohort consists of HIV-infected women who represent ALL stages of HIV infection and HIV-seronegative women who are at risk. Of the first 2250 women enrolled, approximately 56% are African American; 24% Latina; 18% White, non-Hispanic; and 2% other. Approximately 30% of the cohort were exposed to HIV through their own injection drug use.
2. The WIHS cohort will allow a very precise scientific evaluation of those factors associated with HIV disease progression by employing state-of-the-art technologies, including viral load, precise immunologic markers, and importance of co-infecting organisms, which will be performed prospectively, in this current era of anti-retroviral therapies.
3. Every attempt has been made to study the social context in which these women must function. Issues of access to health care, victimization by physical and/or emotional abuse, impact of child-care responsibilities, and other aspects of social science are actively being studied.
4. A comprehensive biologic tissue, serum, and cell bank has been developed, which will allow on-going scientific study for years to come.
5. The WIHS cohort has allowed for the development of numerous additional scientific "sub-studies," which use the infra-structure of the cohort, funded by NIAID, with additional funding provided by other Institutes within the NIH (NICHD, NIDR, NIDA, NCI) allowing a significant increase in the breadth of our work, in a context of cost-effectiveness.
6. The WIHS cohort has developed mechanisms of patient accrual and retention, which may be used as models for design and implementation of diverse types of future studies in women, people of color, and low income communities.
 - Creative means have been employed to assure recruitment and retention of this large cohort, many of whom come from settings which are traditionally conducive to non-compliance, including poverty and drug use. Thus, transportation to and from the study visit has been provided, along with on-site child care, provision of food, provision of monetary incentive fees and gifts, access to social services, and access to other support services. These mechanisms will be studied and may be employed in future studies dealing with various women's health issues and recruitment of low income men.

FUTURE DIRECTION

A scientific review of the WIHS was held in January 1996 to obtain expert advice on the appropriate strategy to study the nature of HIV disease progression in women. Specifically, the panel was asked to consider the scientific issues that should be addressed by the WIHS and make recommendations concerning future priorities. The recommendations emanating from this panel will be taken into consideration during the renewal phase of the WIHS.

MEMORANDUM FOR CAROL RASCO

FROM: Patsy Fleming

SUBJECT: New development in AIDS treatment

Today and over the next several days there will be considerable interest on the part of the press and the AIDS community in new data being released on studies of a new class of AIDS drugs called protease inhibitors. Two companies -- Merck and Abbott -- are in something of a competition to get headlines and FDA approval for this new treatment. Approval of these products could come as early as the spring.

The data being discussed are based on the use of protease inhibitors in late-stage AIDS. Most of the data have not been made public. However, at a meeting convened by Phil Lee last week, we did learn that there is preliminary evidence that the use of this drug prolongs life for those with end stage disease.

This is very exciting and holds great promise. However, we must be cautious about overinterpreting results from two studies of short duration (six months) in late stage patients. We should also be cautious about making assumptions regarding the value of these drugs in *earlier* stages of HIV disease.

There will be several concerns associated with this promising development:

(1) Initially, neither company will have sufficient production capacity to meet the likely demand. Sales initially will be limited to those who have taken the drug under the companies' expanded access programs. There will be desperate calls for government help to increase production capacity. I know that Phil Lee has been talking with the companies and others about this issue.

(2) The prices of the two protease inhibitors have not yet been made public, but it will not be inexpensive. Furthermore, they may need to be taken in combination with existing, expensive therapies. We will work with HCFA to assure Medicaid coverage of this drug. This will also place additional pressure on the drug purchase assistance program funded under Title II of the Ryan White CARE Act -- a program that is already very short of cash in many states. We

have been talking with HRSA and OMB about increasing the percentage of Title II funds (now limited to 50%) that can be used for drug purchase as one mechanism to free up resources, if states so choose.

(3) Finally, the NIH will have to work with the drug companies to conduct follow up studies to assure that we learn the full *clinical* value of this drug at all stages of disease. Discussions within NIH are already underway about how to design and finance these studies.

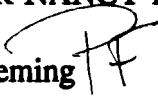
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THE WHITE HOUSE

WASHINGTON
January 30, 1996

FILE COPY

MEMORANDUM FOR NANCY-ANN MIN

FROM: Patsy Fleming 
SUBJECT: FY 1997 AIDS budget

cc: Carol H. Rasco

I know that your work on the FY 1997 budget is under way, and I wanted to take this opportunity to share with you some funding and programmatic priorities of my office for the coming fiscal year.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HRSA:

- Funding levels for the Ryan White CARE Act must continue to increase. I believe that we must come in with a total number that is higher than the President's FY 1996 request -- reflecting our understanding that (despite Congress's failure to approve the full 1996 request) the increased burden of the epidemic requires additional funding. I support the Department's request for \$776.7 million for all CARE Act titles (compared with the President's FY 1996 request of \$746.7 million).

I am especially concerned about the fact that under Title II a number of states have run out of funds for their drug purchase assistance programs well before the end of their grant period, resulting in either total cessation of the program or dramatically reduced coverage. This can be addressed both through increased funding for Title II *and* some programmatic changes.

- In the absence of a reauthorization bill, which could still be on hold when this budget is submitted, it will be important to request language as part of the appropriation that will give the CARE Act programs some of the flexibility and focus sought in the reauthorization. This includes:

- For Title I, eliminating eligibility for the "hamlets" and permitting the use of supplemental funds to hold harmless the formula grants to Title I cities.

- For Title II, permitting states to spend less than 50 percent of their funds on consortia (with the specific approval of HRSA) if additional funds are needed to sustain the drug purchase program. In addition, states should be given some direction in setting priorities for the drug purchase program -- in the absence of the reauthorization bill's requirement that HRSA develop a model formulary. Priority in

the drug purchase programs should be given to life sustaining and disease prevention therapies. (This would address the problem that some states have chosen to eliminate coverage for opportunistic infection treatment and prophylaxis -- the treatments most likely to prolong life -- while assuring coverage for anti-retrovirals, some of which are of limited or unproven clinical value.)

- The President established the goal of eliminating transmission of HIV to newborns in his White House Conference speech. We should have language in our budget proposal that summarizes the efforts of all the HRSA programs to implement the program to use AZT therapy to prevent perinatal transmission. To the degree possible, it would be useful for HRSA to identify the amount of money being spent in each program on this effort.
- I strongly urge that our FY 1997 budget request seek the restoration of funding to the 1995 level of \$16 million for the AIDS Education and Training Centers.

Centers for Disease Control:

- We must continue to seek increases for prevention at the CDC. One of the recommendations of the Presidential Advisory Council on HIV/AIDS has been that prevention be added to the list of investment priorities. While I still hope that will happen, in the meantime, it is important to demonstrate our seriousness in implementing the President's call to reduce the number of new infections each year until there are no new infections by requesting *at least the same increase* we sought for FY 1996, \$34.7 million.
- Within that funding level, we should also recognize the shifting demographics of the epidemic through the targeting of funds. It is of great importance to me that we address the intimately related problems of substance abuse and HIV. CDC staff report that new data not yet released show that 50 percent of all new infections are among injection drug users. And we know that use of other substances, including alcohol, can lead to HIV transmission. In addition to work CDC is doing with grantees to gain greater attention to substance abuse through the community planning process, we also should use the budget as a vehicle.

It is my understanding that the five-year grant cycle for directly funded community based organizations expires at the end of FY 1996. I suggest two options for the future of these funds (approximately \$40 million):

Option 1: A new round of grants to directly funded CBOs would be issued -- this time with a focus on CBOs serving substance abusers. This would address the community's expressed desire for continuation of the direct funding approach, while also addressing new aspects of the epidemic.

Option 2: The funds allocated for direct funding of CBOs could be put into the "pot" for community planning, but these funds could be distributed competitively among the states as a supplement to their regular award for CBOs conducting substance abuse and HIV prevention. There is a precedent for this. In FY 1995 additional funds became available and CDC awarded them to states for addressing certain priority areas.

- As you know, the Performance Partnership Grants proposal has been the source of great consternation within the community. At its December meeting, the Presidential Advisory Council on HIV/AIDS asked that this proposal be withdrawn. Given that this proposal is not likely to go anywhere in this Congress (Senator Kassebaum has indicated that she does not want to include HIV programs in her grant consolidation legislation), our acknowledgement of this reality in our budget proposal would help significantly with the community and the Council. Movement in this area is extremely important to me.

This is not to say that we cannot administratively propose (and clearly state in the budget) our intention to implement key elements of the original PPG proposal. These, to me, would be:

- (1) A commitment to develop and use performance measures for HIV prevention programs. Given the President's challenge to have a prevention strategy that reduces new infections each year, we must have a way of measuring our progress toward that goal.

- (2) Greater flexibility in the use of HIV prevention funds at the state or local level. Currently, the community planning process only has jurisdiction over counseling and testing funds and health education/risk reduction funds. The surveillance dollars are treated separately. One of the key issues many community planning groups face is that they need better surveillance and epidemiologic data to target their local prevention efforts. As in the PPG proposal, it will be critical to maintain a standard database in HIV/AIDS surveillance. But some flexibility should be given communities to shape their surveillance to local needs.

SAMHSA:

- My concern with substance abuse and HIV makes the future of the SAMHSA block grant even more important. I hope we can see a significant increase in funding for the SAMHSA block grant. This is directly related to HIV prevention, since drug treatment is one of the most effective forms of HIV prevention.

- As proposed by SAMHSA, the FY 1997 budget would reduce significantly the amount of money targeted for AIDS demonstrations. This is a result of the plan to move expiring demonstrations into one large pot. We will not be able to explain this apparent decrease unless there is language that makes it very clear that our intention is for HIV-related

programs to receive the highest priority among the demonstrations funded. As presented by SAMHSA, this is not the case.

NIH:

- AIDS research has always done well in the President's requests. We must continue this trend. NIH must have sufficient funds to maintain their commitment base. At the same time, NIH must be able to address new opportunities in therapeutics as whole new classes of drugs come on line and pursue vaccine and microbicide development. At a minimum, AIDS research should receive the same percentage increase as the total NIH budget.
- Regardless of the outcome of the FY 1996 discussions regarding the single appropriation for AIDS through the Office of AIDS Research, the President's budget must present the request for 1997 through the OAR. This is a commitment by the President that was strongly reiterated at the White House Conference on HIV and AIDS. This will be especially important in FY 1997 as the OAR implements the recommendations of the group conducting the external review of the NIH research programs.

DEPARTMENT OF DEFENSE

- I will be communicating directly with Gordon Adams, but I hope you can assist us in making sure that the AIDS budget for the DOD will reflect at least current spending levels -- so that we will not, once again, look as though we are depending on Congress to fund the important vaccine and therapeutics research under way at DOD.

USAID

- I will also be communicating directly with Gordon Adams about USAID but I hope you can assist in assuring that USAID's commitment to both bilateral and multilateral programs, including UNAIDS, will be maintained or increased in FY 1997.

As always, thank you for your support on these matters.

THE WHITE HOUSE
WASHINGTON

FILE COPY

January 30, 1996

MEMORANDUM TO CAROL RASCO

FROM: Patsy Fleming *PF*
SUBJECT: National Defense Authorization Act

In preparation for our meeting today, this memo lays out the background of the issue of HIV-positive military personnel and several options we could pursue on this issue.

Background

As you know, the conference agreement on the National Defense Authorization Act (H.R.1530) includes a provision sponsored by Rep. Robert Dornan (R-CA) requiring the involuntary separation of all military personnel who are infected with the human immunodeficiency virus (HIV). Such individuals would be required to be retired or discharged within six months of enactment. All future individuals identified as HIV-positive would be similarly separated within six months of the date of those test results.

The immediate effect would be the discharge of 1,049 current members of the Armed Forces. Under a policy adopted by the Department of Defense in 1986, such individuals are now permitted to remain in the military and are restricted to stateside duties. These men and women (approximately 10 percent of the total are female) are healthy, well-functioning individuals who are not impaired in their ability to perform their duties.

Options for Action

There are several options that should be considered when the legislation reaches the White House. They are:

(1) **Veto Option.** The DoD is recommending that the President sign the revised bill and the White House Office of the Press Secretary has announced that the President intends to sign it. However, there is still time to reverse this decision and adopt a very targeted veto strategy.

Under this strategy, the President would veto the revised bill for one reason only: the continued presence of this highly discriminatory and possibly unconstitutional provision affecting the lives of members of the Armed Forces. The President would make clear that he is not seeking to reopen many of the difficult issues on which both parties have compromised. He is only asking that the Congress remove this provision and send him back the same bill for his signature.

Pluses: Such an approach would make clear the President's unwillingness to approve blatantly discriminatory legislation that would adversely affect the lives of service members and their families. It would be consistent with his past statements and policy decisions on this subject. This option is strongly favored by national AIDS organizations, members of the President's Advisory Council on HIV and AIDS, national gay/lesbian organizations, and other groups favoring civil rights.

Minuses: By overruling his advisors, the President could appear indecisive. It could inflame relations with members of Congress who have been told the bill will be signed. And it could result in the same legislation coming back to the President for his signature. It could also appear that the President is favoring a small group of individuals over the needs of all military personnel and their families.

(2) Signature/Repeal Option. The President could go ahead with plans to sign the revised bill and announce his immediate support for legislation to repeal this provision before the six-month window is closed. This is an option that has been discussed in the media and has strong support among constituency groups.

Senator Nunn has spoken out forcefully against the Dornan Amendment as have numerous other Democrats in both the House and Senate. There are also numerous Republican members of both houses of Congress who have expressed disdain for the Dornan Amendment and/or support for repeal. They include: Sens. Cohen, Jeffords, Warner, Stevens, Kassebaum, McCain, Specter, Mack, Chafee, Campbell, Snowe, and Hatch and Reps. Morella, Gunderson, Torkildsen, Hobson, Forbes, Frelinghuysen, Foley, Flanagan, Campbell, Bilbray, Gilman, Kelly, and Boehlert.

Pluses: Such a strategy clearly puts us on the side of the service members and makes clear the President's disdain for this provision. If successful, it would ameliorate much if not all of the damage created by signing the legislation.

Minuses: There is no guarantee -- and not even a strong likelihood -- that repeal would be successful. Rep. Dornan and others could block such legislation in the House and Sen. Helms and others could filibuster it in the Senate. Many constituency groups view this as a hollow promise.

(3) Legal Options. If the President signs the legislation, there are several legal options that could be pursued. They are:

(a) Justice Department Review. The Department of Justice could review the provision with regard to its constitutionality. While such an opinion would assist those who are likely to challenge the provision in court it appears likely that DoJ will find a Constitutional basis for the provision.

(b) Legal Challenges. It is highly likely that one or more legal challenges including a request for an injunction will be made against this legislation. Such challenges do not have to await actual discharge of personnel. Any written or oral statements by the President regarding his lack of support for this provision would assist those who challenge the provision in court.

(c) Administration Participation. If court challenges are made, the Administration will face a difficult decision -- whether to defend the provision in court. There is precedent for refusing to do so and leaving it to House and Senate to defend the law.

(4) Administrative Options. In the event that legal and legislative efforts fail to eliminate this provision, there are several things that can be done to ameliorate the situation for these individuals and their families. The DoD has prepared an options list that covers such issues as income, health care coverage, transition benefits, and job placement (See Attachment). In summary, the key decisions are:

(a) Implementation. DoD is fully supportive of utilizing the entire six months provided under the law while allowing those who choose to retire to do so.

(b) Financial Resources. Under the Dornan Amendment, HIV-positive personnel receive an "involuntary" or "administrative" separation from the Armed Forces. Under such classification, they receive only a lump sum payment of about \$30,000. However, if we choose to grant a "disability separation" they would receive slightly more money (\$35,000). Finally, if we choose to grant a "disability retirement" (which requires action by the DVA) they would receive an annual income ranging from 30% to 100% of their current pay.

(c) Health Care Coverage. The Dornan Amendment would provide health benefits to the separated service members but not to their dependents. Only by granting these individuals a "disability retirement," would we provide their dependents with health care coverage.

(d) Transition Benefits. Beyond transition assistance, job training, and financial counseling, there are limited ways to assist with reemployment. Placement into civil service positions (which also would carry FEHB health coverage) would be problematic because of current limits on FTEs, requirements that veterans and those discharged for downsizing be given preference, and plans to draw down the civilian DoD workforce by 100,000 by 2001.

Position Statement

I strongly support a targeted veto strategy. In the absence of a veto, I recommend aggressive pursuit of a legislative remedy while preparing to support legal challenges to this law. In the meantime, we must also adopt as many administrative remedies as possible in case those options do not succeed so that we mitigate the harm that will be done to these service members.

THE WHITE HOUSE
WASHINGTON

FILE COPY

January 29, 1996

MEMORANDUM TO JENNIFER KLEIN

FROM: Patricia S. Fleming 

SUBJECT: DRAFT REPORT ON ADOLESCENTS AND HIV/AIDS

I am sending you this draft report on adolescents and HIV/AIDS for your review. It has been reviewed by the senior officials at the Department of Health and Human Services and will be sent to the individual agencies for their review tomorrow. Our schedule calls for this review period to end at close of business Friday, February 2. Release is tentatively scheduled between February 28 and March 6.

Thank you for taking a look at this.

THE WHITE HOUSE
WASHINGTON

FILE COPY

January 29, 1996

MEMORANDUM TO NANCY-ANN MIN

FROM:

Patricia S. Fleming 

SUBJECT: DRAFT REPORT ON ADOLESCENTS AND HIV/AIDS

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Thank you for taking a look at this.

cc: Richard Turman

THE WHITE HOUSE
WASHINGTON

FILE COPY

January 29, 1996

MEMORANDUM TO JEREMY BEN-AMI

FROM: Patricia S. Fleming *PSF*

SUBJECT: DRAFT REPORT ON ADOLESCENTS AND HIV/AIDS

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THE WHITE HOUSE
WASHINGTON

FILE COPY

January 29, 1996

MEMORANDUM TO CAROL H. RASCO

FROM: Patricia S. Fleming *PSF*

SUBJECT: DRAFT REPORT ON ADOLESCENTS AND HIV/AIDS

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Thank you for taking a look at this.

THE WHITE HOUSE
WASHINGTON

FILE COPY

January 26, 1996

MEMORANDUM FOR CAROL RASCO

FROM: Patsy Fleming *PF*

SUBJECT: Discharge of HIV positive personnel

As I understand it, the forced (involuntary) separation of HIV-positive personnel before they are disabled has, primarily, economic implications. These servicemembers will become unemployed -- and may well have great difficulty finding new employment. If they were permitted to continue in service until they were medically disabled, they could receive medical retirement benefits of 30% of their pay. While these servicemembers will lose their current medical benefits and will not have access to DOD research trials, they *will* be eligible for full veterans medical benefits and will be able to receive HIV-related care in the VA system. They will also be eligible for CHAMPUS.

I have convened a meeting this afternoon with DOD, VA, OMB, and DPC staff (Molly Brostrom) to discuss these issues in detail so we can minimize to the fullest extent possible the negative impact of this provision.

FILE COPY

THE WHITE HOUSE
WASHINGTON

JAN 26 1996

MEMORANDUM TO NANCY ANN MIN

FROM: Patricia S. Fleming,  Director, Office of National AIDS Policy

SUBJECT: Suggested language regarding the DoD Reauthorization Bill

Following is the proposed language we discussed for the President's message upon signing the National Defense Authorization Act (H.R.1530). Thanks for your help on this.

"As I mentioned in my veto message for the earlier version of this bill, I am very concerned by the provision requiring the retirement or discharge of military personnel who are living with the human immunodeficiency virus (HIV). I am disappointed that members of Congress did not see fit to remove this discriminatory provision from the final legislation. As long as these men and women are willing and able to serve their country, such action is unnecessary. I will strongly support efforts to repeal this provision as quickly as possible. In the meantime, my Administration will do everything in its power to assure that such personnel receive all benefits to which they are entitled."

n:min.mmo

THE WHITE HOUSE
WASHINGTON

FILE COPY

JAN 24 1996

MEMORANDUM FOR DISTRIBUTION LIST

FROM: Patricia S. Fleming, Director, Office of National AIDS Policy

SUBJECT: Presidential Advisory Council Recommendations

At its December 8 meeting, the Presidential Advisory Council on HIV/AIDS approved a number of recommendations regarding Federal HIV/AIDS policy and programs. I am enclosing a copy of these recommendations and ask that you share them with the relevant officials in your agency for consideration.

The President appointed the advisory council in the hope that its diverse membership from around the nation would provide new ideas and insights into improving the government's response to the epidemic. It is the President's hope that we are as responsive as possible to these recommendations.

My office will be in touch soon with your staff to discuss how we can move forward in responding to the Council.

Thank you for your cooperation.

Enclosure

Distribution List:

The Honorable Jesse Brown, Secretary of Veterans Affairs
The Honorable Henry Cisneros, Secretary of Housing and Urban Development
The Honorable William Perry, Secretary of Defense
The Honorable Janet Reno, Attorney General
The Honorable Alice Rivlin, Director, Office of Management and Budget
The Honorable Donna Shalala, Secretary of Health and Human Services

xc: Dr. Helene Gayle, Director, Center for HIV/STD/TB, CDC
Dr. Eric Goosby, Director, OHAP
Dr. Kathleen Hawk, Director, Bureau of Prisons
Dr. David Kessler, Commissioner, FDA
Dr. Phillip R. Lee, Assistant Secretary for Health
Dr. Alan Leshner, Director, NIDA
Ms. Doris Meissner, Director, Immigration and Naturalization Service
Dr. Joseph O'Neill, Associate Administrator for AIDS, HRSA
Dr. William Paul, Director, Office of AIDS Research
Dr. David Satcher, Director, CDC
Mr. Ciro Sumaya, Administrator, HRSA
Dr. Michael Trujillo, Director, Indian Health Service
Dr. Bruce Vladeck, Administrator, HCFA

FILE COPY

THE WHITE HOUSE
WASHINGTON

JAN 24 1996

MEMORANDUM FOR THE HONORABLE JESSE BROWN

FROM: Patricia S. Fleming *PSF*

SUBJECT: Veterans with AIDS

I recently received a disturbing letter from a young African-American female veteran with AIDS. She has described a situation that is difficult to understand, given the excellent care usually afforded our veterans.

Would you please look into this matter for me? Please respond directly to Ms. Elease Dewey and send me a copy.

Thank you for your assistance.

Enclosure

n:\veterans

THE WHITE HOUSE
WASHINGTON

January 24, 1996

FILE COPY

MEMORANDUM FOR PHIL LEE

FROM: Patsy Fleming *PF*

SUBJECT: Thursday's meeting on AIDS research

The following is a complete list of who will be attending the meeting at 3 p.m. on Thursday. Please let me know about additional people who need to be cleared in for the later meeting.

White House:

Carol H. Rasco, Assistant to the President for Domestic Policy
Patsy Fleming, Director, Office of National AIDS Policy
Jeff Levi, Office of National AIDS Policy
Jane Sanville, Office of National AIDS Policy
Joe Sestak, National Security Council

HHS:

Phillip R. Lee, Assistant Secretary for Health
William Paul, Director, OAR
Jack Whitescarver, Deputy Director, OAR
Wendy Wertheimer, OAR
Anthony Fauci, Director, NIAID
Theresa Toigo, Acting Deputy Commissioner for HIV/AIDS, FDA
Helene Gayle, Director, Center for HIV/STD/TB, CDC

VA:

Ken Kizer, Assistant Secretary for Health
Michael Hughes
Paul Hoffman
Susan Mather

Energy:

Steven Golson

Defense Department:

Don Burke

John Mazzuchi, Principal Director of the Office of the Deputy Assistant Secretary for
Clinical Services

Joseph Osterman, Director of Environmental and Life Sciences, Office of the Deputy
Director of Defense Research and Engineering

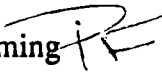
THE WHITE HOUSE
WASHINGTON

January 18, 1996

FILE COPY

MEMORANDUM FOR CAROL H. RASCO

FROM:

Patsy Fleming 

SUBJECT:

Video request

Attached is a request for a video taping by the President for the March meeting sponsored by the CDC for state and community leaders in HIV prevention. This is, in a sense, the annual convention on HIV prevention. It would be an important opportunity for the President to reaffirm his commitment in this area and to provide support for the tremendous work these folks are doing.

VIDEO REQUEST PROPOSAL**Date: 01/18/96**

___ ACCEPT**___ REJECT****___ PENDING**

TO: Stephanie Streett
Deputy Assistant to the President &
Director of Scheduling

Anne Walley
Deputy Assistant to the President &
Director of Scheduling

FROM: Carol H. Rasco, Assistant to the President for Domestic Policy

REQUEST: Video message for the Centers for Disease Control and Prevention
"HIV Prevention Community Planning Co-Chairs Meeting"

PURPOSE: This annual CDC meeting of 800+ participants from all 50 states is a prime opportunity to indicate the Administration's strong support for AIDS prevention and for partnership with states and communities.

DATE AND TIME: Conference opens March 7, 1996.

SOURCE OF PAYMENT: Centers for Disease Control and Prevention

BACKGROUND: Approximately 800 AIDS prevention leaders from all 50 states, DC, and Puerto Rico will attend this meeting in Atlanta GA. This is a one-time usage.

DURATION: Three to five minutes

REMARKS ATTACHED: Script is attached to the request.

STAFF CONTACT: Richard Sorian, Office of National AIDS Policy, 632-1090

ORIGIN OF PROPOSAL: Office of National AIDS Policy

Centers for Disease Control and Prevention Video

- This video is for the opening of the Centers for Disease Control and Prevention "HIV Prevention Community Planning Co-Chairs Meeting"
- The video allows the President to demonstrate the Administration's strong commitment to AIDS prevention and to partnership with states and communities.
- Approximately 800 community leaders in HIV/AIDS prevention will be meeting for two days in Atlanta GA to discuss a series of issues related to prevention of AIDS. The Community Planning Process was launched by the Clinton Administration in 1993 to improve local input to prevention programs.

DRAFT SCRIPT

Centers for Disease Control and Prevention Video

The PRESIDENT:

It's a pleasure to join you today for the annual HIV Prevention Community Planning meeting. I'm sorry I can't be there with you in person.

I'd like to thank Dr. Satcher and Dr. Gayle and their team of committed public health professionals for their remarkable leadership in our national fight against HIV and AIDS.

And let me thank each and every one of you for your work on the front lines of this epidemic. In community after community across this great nation, you provide the thoughtful leadership and passionate commitment that is needed to turn the tide in this epidemic.

I am proud of the work we have done together to create the community planning process. In its short history, this effort has already transformed HIV prevention from a top-down bureaucratic approach to a bottom-up community effort. Working in partnership we have provided millions of Americans with the kind of honest, targeted information they need to protect themselves and their loved ones from HIV.

But you and I know that the job is not yet done. Not when forty to sixty thousand Americans are still becoming infected with HIV each year. Not when seventy to eighty thousand of our brothers and sisters are being diagnosed with AIDS every year. And not when more than one hundred Americans are dying of AIDS every day.

We have a lot more to do and I am confident that with you leading the way we will reverse these truly troubling trends.

In December, at the historic White House Conference on HIV and AIDS, I called on our public health professionals to work toward a very important goal -- to reduce the number of HIV infections each and every year until there are none.

THE PRESIDENT:

It will take a national effort, beginning in communities like yours, to achieve that important goal. And we will need the help of businesses, schools, churches, and other community organizations to get there.

We all recognize that changing behavior is very difficult. And this is especially true among young people. I am troubled by the continued rise in new infections among teenagers. Too many young people seem to believe they are either bulletproof or doomed to a life of misery. In either case, they take risks with their health and increasingly those gambles are resulting in deadly consequences. We've got to break that death spiral and we've got to do it now.

We also must do more to break the grip that illegal drugs have on too many Americans. And we must strengthen the link between AIDS prevention and drug abuse prevention efforts.

My Administration remains committed to leading the fight against AIDS. Our recently released national plan makes clear that that fight includes three important elements: a search for a cure and a vaccine; comprehensive care for all those who are living with HIV and AIDS; and a continued effort to reduce new infections through prevention.

Together we can reach those goals and change the future of our country.

Thank you and God bless you.

THE WHITE HOUSE
WASHINGTON

FILE COPY

February 7, 1996

MEMORANDUM FOR DISTRIBUTION

FROM: Patricia S. Fleming, ^{PSF} Director, Office of National AIDS Policy

SUBJECT: Draft Report "Youth and HIV/AIDS: An American Agenda"

Attached is a revised copy of a draft report to the President entitled, "Youth and HIV/AIDS: An American Agenda." It is scheduled for release on March 5, 1996. Please have your relevant staff review and provide my office with your comments/clearance by close of business February 13. Please ask that the comments be specific and include suggested replacement language. If you or your staff have any questions, please direct them to Richard Sorian of my staff at (202) 632-1090.

Thank you.

Distribution List:

Helene Gayle, Centers for Disease Control and Prevention
William Paul, National Institutes of Health
Ciro Sumaya, Health Resources and Services Administration
David Kessler, Food and Drug Administration
Nelba Chavez, Substance Abuse and Mental Health Services Administration

THE WHITE HOUSE
WASHINGTON

JAN 17 1996

MEMORANDUM FOR THE PRESIDENT

THROUGH Carol H. Rasco *CR*
Assistant to the President for Domestic Policy

FROM Patricia S. Fleming *PSF*
Director, Office of National AIDS Policy

SUBJECT The Global AIDS Epidemic

Over the past several months, I have participated in two significant international events. I represented the U.S. at a meeting of the governing board for the new United Nations Programme on HIV/AIDS (UNAIDS) and I gave a speech at the 9th International Conference on AIDS and STDs in Africa. On both occasions, I was reminded of the terrible effects of the AIDS epidemic worldwide. This memo is to brief you on these issues and efforts being made to alleviate them.

Scope of the International HIV/AIDS Pandemic

While HIV/AIDS continues to be a serious problem in the U.S., in many developing countries the epidemic is much more advanced. One million people in the U.S. have been infected with HIV; another 18 million people around the world suffer the same fate. Over three-quarters of worldwide HIV infection occurs through heterosexual transmission. At the global level, women and men are affected by HIV in almost equal numbers, usually in the prime of their economically productive years. By the year 2000, experts estimate that as many as 40 million people around the world will be HIV positive. Ninety percent will live in developing countries. Close to five million children will have been orphaned in this decade alone with estimates that the numbers will increase to 15 million worldwide by the year 2000.

Implications for Development

The pandemic's social and economic toll in the developing world is becoming increasingly apparent. As in the U.S., the health care costs for people with HIV/AIDS over the course of their illness is very high. Some countries currently spend one-quarter to one-half of their health budget on AIDS-related care, with studies indicating that this could rise to as much as 80 percent in parts of Africa and Asia by the year 2010. Socio-economic studies have shown decreases in overall domestic savings and investment levels, negative effects on foreign investments, reductions in the volumes of imports and exports, and reduction in receipts from tourism.

MEMORANDUM FOR THE PRESIDENT

Page 2

The epidemic is having serious effects on other areas of society. Industries such as mining and trucking in Southern Africa are already experiencing major labor shortages due to high HIV prevalence among workers. Some countries are reporting evidence of human rights abuses. Organized prostitution rings have been coercing young girls into having unprotected sex resulting in thousands of new infections. Civil strife and war have also resulted in the abuse of women and children including rape, fostering the spread of HIV and isolating individuals from their communities and families. High infection rates among police and military personnel are threatening not only internal and national security but social and political stability.

The Role of the United States

The U.S. has been a major source of bilateral and multilateral funds for international HIV/AIDS activities. The Agency for International Development, the Centers for Disease Control and Prevention and their non-governmental partners, and the National Institutes of Health have provided unparalleled technical assistance to AIDS programs in developing countries since 1986. If U.S. development assistance is reduced by the levels proposed by Congress, I am convinced that it will have a direct and immediate impact on the ability of the world to overcome the challenge of HIV, due not only to the diminished U.S. contribution, but also the political leverage that we bring to bear as a world leader. I am also convinced that important U.S. foreign policy goals including democratization, economic development and peacekeeping may be compromised as the number of AIDS cases worldwide escalates.

UNAIDS

Currently, a major effort towards greater coordination of resources allocated for HIV/AIDS within the UN system is underway. The governing bodies of WHO, UNICEF, UNDP, UNFPA, UNESCO and the World Bank have formed a new, joint and co-sponsored program which became operational on January 1, 1996. UNAIDS will strengthen national capacity through policy development and research, technical support, advocacy and coordination at county, intercounty and global levels. As one of the donor countries providing strong leadership on this new program, the U.S. has an obligation to commit the resources it has promised and see the initiative through. The U.S. is contributing approximately 25 percent of the budget and has provided significant leadership in the shaping of the program. A global appeal will solicit additional support from nontraditional donor countries as well as encourage developing countries to increase contributions from their own national budgets. We have high hopes that this program will make a difference.

Lessons and Challenges

We have learned many valuable lessons in our struggle against HIV/AIDS. We have learned that HIV/AIDS is not "an outbreak, but part of the human condition" according to Dr. Peter Piot, Executive Director of UNAIDS. We have learned that condoms will never be

MEMORANDUM FOR THE PRESIDENT**Page 3**

enough; risk behaviors and the circumstances that lead people into them are complicated and dynamic. We have learned that we need to lower the social, cultural, religious and moral constraints on our ability to talk openly about human sexual behavior and raise the low status of women that impedes their capacity to negotiate safe sex with their partners. We have learned that we need to empower women around the world by increasing their access to economic resources and education. We also have learned that we need to end the marginalization and stigmatization of gay men, commercial sex workers, poor people and injecting drug users that limit their access to information, condoms, health care and social support for behavior change.

As the epidemic has progressed, so has our knowledge and understanding about what we need to do to prevent and control its spread. We must continue to build on successes exemplified by USAID's program in Thailand which has seen a decline in infection rates over the past several years. We are working with countries to improve services and education for people with sexually transmitted diseases which has been shown to reduce HIV transmission dramatically.

We have made important gains over the past decade and with your continued support, we can maintain our global leadership in bringing this pandemic to an end.

THE WHITE HOUSE
WASHINGTON

FILE COPY

JAN 17 1996

MEMORANDUM FOR THE PRESIDENT

THROUGH Carol H. Rasco
Assistant to the President for Domestic Policy

FROM Patricia S. Fleming *PSF*
Director, Office of National AIDS Policy

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MEMORANDUM FOR THE PRESIDENT

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The epidemic is having serious effects on other areas of society. Industries such as mining and trucking in Southern Africa are already experiencing major labor shortages due to high HIV prevalence among workers. Some countries are reporting evidence of human rights abuses. Organized prostitution rings have been coercing young girls into having unprotected sex resulting in thousands of new infections. Civil strife and war have also resulted in the abuse of women and children including rape, fostering the spread of HIV and isolating individuals from their communities and families. High infection rates among police and military personnel are threatening not only internal and national security but social and political stability.

The Role of the United States

The U.S. has been a major source of bilateral and multilateral funds for international HIV/AIDS activities. The Agency for International Development, the Centers for Disease Control and Prevention and their non-governmental partners, and the National Institutes of Health have provided unparalleled technical assistance to AIDS programs in developing countries since 1986. If U.S. development assistance is reduced by the levels proposed by Congress, I am convinced that it will have a direct and immediate impact on the ability of the world to overcome the challenge of HIV, due not only to the diminished U.S. contribution, but also the political leverage that we bring to bear as a world leader. I am also convinced that important U.S. foreign policy goals including democratization, economic development and peacekeeping may be compromised as the number of AIDS cases worldwide escalates.

UNAIDS

Currently, a major effort towards greater coordination of resources allocated for HIV/AIDS within the UN system is underway. The governing bodies of WHO, UNICEF, UNDP, UNFPA, UNESCO and the World Bank have formed a new, joint and co-sponsored program which became operational on January 1, 1996. UNAIDS will strengthen national capacity through policy development and research, technical support, advocacy and coordination at county, intercounty and global levels. As one of the donor countries providing strong leadership on this new program, the U.S. has an obligation to commit the resources it has promised and see the initiative through. The U.S. is contributing approximately 25 percent of the budget and has provided significant leadership in the shaping of the program. A global appeal will solicit additional support from nontraditional donor countries as well as encourage developing countries to increase contributions from their own national budgets. We have high hopes that this program will make a difference.

Lessons and Challenges

We have learned many valuable lessons in our struggle against HIV/AIDS. We have learned that HIV/AIDS is not "an outbreak, but part of the human condition" according to Dr. Peter Piot, Executive Director of UNAIDS. We have learned that condoms will never be

MEMORANDUM FOR THE PRESIDENT

Page 3

enough; risk behaviors and the circumstances that lead people into them are complicated and dynamic. We have learned that we need to lower the social, cultural, religious and moral constraints on our ability to talk openly about human sexual behavior and raise the low status of women that impedes their capacity to negotiate safe sex with their partners. We have learned that we need to empower women around the world by increasing their access to economic resources and education. We also have learned that we need to end the marginalization and stigmatization of gay men, commercial sex workers, poor people and injecting drug users that limit their access to information, condoms, health care and social support for behavior change.

As the epidemic has progressed, so has our knowledge and understanding about what we need to do to prevent and control its spread. We must continue to build on successes exemplified by USAID's program in Thailand which has seen a decline in infection rates over the past several years. We are working with countries to improve services and education for people with sexually transmitted diseases which has been shown to reduce HIV transmission dramatically.

We have made important gains over the past decade and with your continued support, we can maintain our global leadership in bringing this pandemic to an end.

THE WHITE HOUSE
WASHINGTON

FILE COPY

January 17, 1996

MEMORANDUM FOR CAROL RASCO

FROM: Patsy Fleming 

SUBJECT: Goals for 1996

Long-term goals:

(1) *Develop a comprehensive strategy for addressing the link between substance abuse and HIV transmission.* This includes better integration of HIV prevention with substance abuse prevention, development of Administration policies regarding harm reduction for substance abusers, and improved research on effective interventions and models for HIV prevention among substance abusers.

(2) *Improve the government's efforts to find a cure, a vaccine, and a microbicide to prevent HIV transmission.* This includes an interdepartmental research plan to better integrate research efforts across the government and the Vice President's meeting with the private sector regarding increased investment in HIV-related pharmaceutical development.

(3) *Improve communication between the government and affected communities and increase the visibility of the Administration's AIDS-related efforts.* The centerpiece of this effort will be town meetings to be held across the country. The town meetings will help to continue the dialogue fostered at the White House Conference on HIV and AIDS between the Administration and the affected communities regarding effective strategies to address all aspects of the epidemic.

Short-term goals:

(1) Release of the *report on the state of the epidemic among adolescents.* (February)

(2) Release of the government-wide *national plan for combatting AIDS.* (late February)

FILE COPY

**THE WHITE HOUSE
WASHINGTON**

January 5, 1996

MEMORANDUM FOR DISTRIBUTION LIST

FROM: Patsy Fleming, Office of National AIDS Policy

SUBJECT: NIH-related budget issues

We talked with Dr. Steve Schnittman of the NIH Division of AIDS at the National Institute for Allergy and Infectious Disease (NIAID) to get further information on the impact of the budget impasse on AIDS research. We learned the following:

- Enrollment in AIDS clinical trials has been suspended as of yesterday. An estimated 8-to-10,000 people are currently enrolled (they will get all the services they need). An average of 25 people enroll in these trials each day. Only those who had completed the initial tests required to enroll in a trial will be allowed to enroll. All others must wait.
- Approximately 100 AIDS research units around the country involved in recruiting and enrolling patients in research programs are running out of money. Fifteen units ran out of money on Jan. 1, and many more will run out of money at the end of this month if the impasse continues.
- NIAID has stopped work on all new AIDS drug trials. There are approximately 40 trials in development at any one time.

One example of the impact of this suspension is an agreement between NIH and Merck to begin a licensing trial of a new protease inhibitor (one of the promising new AIDS drugs that have received so much press attention) in mid-January. Without that trial, Merck cannot license the drug and begin providing it to the public.

Another example is a pediatric trial of the drug 3TC by Glaxo-Wellcome. Enrollment in that trial has been suspended and there are not yet enough patients in the trial to yield the data necessary to prove the efficacy of the drug in children with HIV.

Hope this is helpful. Call me if you need more information.

Distribution list:

Jeremy D. Benami
William A. Halter
Lawrence J. Hass
John A. Koskinen

Carol H. Rasco
Stephen B. Silverman

Info sent to all ACTG/CPCRA/DAIRI
sites 1/4/96

From: Jack Killen:exec:niaid
To: {actg.broadcast@karloff.fstrf.org}:unix,
{mci.cpcra@karloff.fstrf.org}:unix,blandry:ess,Jim Neaton:unix,
jbray:ess,{durakos1@westat.com}:unix,{6870061}:mci,{4742263}:mci
cc: prab, trp, actgstaff:ess, cpcrastaff:ess,jack,ocpr:31,dgk
Subj: SUSPENSION OF NEW SUBJECT ACCRUAL

As you know, the impasse in federal budget negotiations continues, with no end in sight. Until a clearer picture of the fiscal 1996 budget emerges, it is therefore necessary for us to further restrict the activities of DAIDS-sponsored clinical trial groups in order to ensure the safety of subjects already enrolled into ongoing clinical trials. These restrictions will place the following limits on the support provided by the statistical center and operations office contractors:

No new subjects may be enrolled in trials. (This means no new subject identification numbers will be issued; subjects with numbers already issued may be entered.)

Support for the development of new protocols and for all other activities not directly related to the monitoring, conduct, and analysis of ongoing clinical trials will be suspended.

Conference calls will be limited to those necessary for the management of clinical trials with currently enrolled subjects and other calls which may be necessary for the protection of the safety of subjects already on study.

The restrictions will remain in place until we can be confident that resources needed to ensure the safety of enrolled subjects are not totally exhausted before the end of the budget impasse. If you have specific questions, please call either Steve Schnittman (301-496-8210) or Jim Balsley (301-402-2300). You should also feel free to contact me.

We regret having to take these steps, but thank you for your understanding and support.

**OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT**

750 17th Street, N.W.
Washington, DC 20503

Phone: 202-632-1090
Fax: 202-632-1096

FACSIMILE COVER SHEET

TO: Distribution list

FROM: Patsy Fleming

DATE: January 5, 1996

PAGES INCLUDING COVER SHEET: 3

Distribution list:

Jeremy D. Benami
William A. Halter
Lawrence J. Hass
John A. Koskinen
Carol H. Rasco
Stephen B. Silverman

THE WHITE HOUSE
WASHINGTON

July 26, 1996

MEMORANDUM TO THE DOMESTIC POLICY COUNCIL

FROM: CAROL RASCO *CR*

SUBJECT: SEPTEMBER MEETINGS

I am writing to inform you of two upcoming Council meetings - **September 17, 1996** to discuss the implementation of the President's Memorandum on federal family work arrangements and **September 30, 1996** to discuss the Partnerships for Stronger Families initiative. Both meetings will be held from 5 p.m. - 6 p.m. in the Roosevelt Room.

Family-Friendly Workplace Meeting - September 17, 1996

As you may recall, the President's June 21, 1996 Memorandum reiterated his belief that honoring and supporting the concerns of family members in the workplace is vital to good government. The Memorandum directs each executive department and agency to review their personnel practices and develop a plan of action to utilize the flexible policies already in place and, to the extent feasible, expand their ability to provide their employees a broader range of options. On September 17th, we will discuss the federal strategy in place to complete this task. For more information, please see the attached memorandum from Elaine Kamarck and myself that gives guidance for your departmental response, due November 18, 1996.

Partnerships for Stronger Families Meeting - September 30, 1996

Most of your agencies are heavily engaged in the Partnerships for Stronger Families (PSF), an effort to make the federal government more responsive to and supportive of community based plans to serve children and families. We have set the September 30th meeting as an opportunity for each of the five interagency action teams to report to the Council on their progress. Details on the specific goals of each of the teams can be found on the attached fact sheet.

Additional information will be sent to you prior to each of these meetings. Please ask your staff to hold both of these dates on your schedule. I would greatly appreciate your personal participation, if your schedule permits. If you do have a conflict, we will be accepting substitutes only at the Assistant Secretary level. If you have any questions or concerns, please feel free to contact Jeanine Smartt at (202) 456-5228. Thank you.

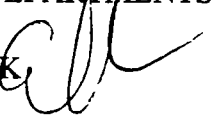
Attachments:

- A. Memorandum from Carol Rasco and Elaine Kamarck
- B. Partnerships for Stronger Families Fact Sheet

THE WHITE HOUSE
WASHINGTON

July 26, 1996

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

FROM: CAROL RASCO AND ELAINE KAMARCK  

SUBJECT: FAMILY-FRIENDLY WORK ARRANGEMENTS

As you know, the President's June 21, 1996 Memorandum reiterated his commitment to families in the federal workplace. The Memorandum directed all heads of executive departments and agencies to review their personnel policies and programs and develop a plan of action that provides employees more flexibility to meet family demands. To this end, attached please find a suggested format for your department's response, including options that will assist you in assessing your efforts. This review should build on your outline submitted in response to the July 11, 1994 Memorandum in which you were asked to establish a program to encourage and support the expansion of flexible family-friendly work arrangements.

This review is meant to assist you as well as the Administration in assessing how we can best serve our employees and their families. In responding to the questions, please identify any barriers that you may have faced while implementing your agency's family-friendly work arrangements.

By Monday, November 18, 1996 we would like a report that details your agency's accomplishments and ongoing efforts, following the format provided herein. In addition, Carol Rasco will be hosting a meeting with the Domestic Policy Council on September 17, 1996 to discuss these policies.

The White House contacts for this initiative are Lisa Mallory at the National Performance Review (202-632-0150 ext.147) and Jeanine Smartt at the Domestic Policy Council (202-456-5228). By August 15, 1996 please provide them with the name of the person(s) that will serve as representative(s) for your department or agency.

We appreciate your immediate attention to this matter.

Attachments:

- A. June 21, 1996 Presidential Memorandum
- B. July 11, 1994 Presidential Memorandum
- C. Suggested Format for Response

PARTNERSHIPS FOR STRONGER FAMILIES

The goal of Partnerships for Stronger Families is to make the federal government a more responsive and supportive partner in efforts to implement comprehensive community-based initiatives to serve children and families. Many promising domestic initiatives of the Clinton administration have been designed to support community-developed strategies including the Empowerment Zone/Enterprise Community Program and the National Performance Review's State and Local partnerships. This effort will take lessons learned from those models and others across the country and pursue systemic change to make federal practices more supportive of community efforts.

Partnerships is an interagency effort, coordinated by several White House offices including the Domestic Policy Council, the National Performance Review, the Community Empowerment Board, and the Office of Management and Budget. Federal agency staff have formed five action teams to pursue a concrete agenda for administrative action in 1996. The teams and their initial mandates are:

- 1. Building Capacity: Technical Assistance** Mission: to inventory federal technical assistance to communities in children and family services and to consider ways to improve interagency coordination and make TA more responsive to customer needs.
- 2. Accountability: National Indicators** Mission: to develop options for a system of national indicators of family and child well-being, possibly modelled on the Index of Leading Economic Indicators.
- 3. Financing: Flexibility** Mission: to explore federal funding and regulation of efforts to integrate services to children and families, to recommend improvements, and to explain to communities how to maximize federal funding and flexibility.
- 4. Information Dissemination** Mission: to inventory federal clearinghouses, web sites and 800 numbers providing information to communities on programs for children and families and to recommend ways to integrate these resources into an easy-to-use reference system — on the World Wide Web and through non-electronic means.
- 5. Promoting Intergovernmental Partnerships** Mission: to examine how a single federal point of contact for states and communities might be implemented, using the HUD/Connecticut MOU as a model and learning opportunity.

The teams are currently holding their initial meetings and have been asked to submit work plans by the end of May indicating reasonable goals for action in 1996. Participating agencies include Health and Human Services, Housing and Urban Development, Agriculture, Labor, Education and Justice. Each agency is participating on all five teams. Team chairs are Assistant Secretaries or other high-level agency officials. The initiative is being managed by a Steering Committee consisting of the Team Chairs and representatives of the various White House offices.

(7/9/96)

For file.

THE WHITE HOUSE
WASHINGTON

SCHEDULING REQUEST PROPOSAL

Date: 10/02/96

☐ ACCEPT

☐ REJECT

☐ PENDING

TO: Patti Solis
Special Assistant to the President and Director of Scheduling for the
First Lady

FROM: Carol H. Rasco, Assistant to the President for Domestic Policy
Patricia S. Fleming, Director, Office of National AIDS Policy
Marsha Scott, Deputy Assistant to the President for Political Affairs

REQUEST: Tea/meeting with the First Lady and AIDS orphans, their grandparents
who are now taking care of the children, and people in the community
serving this group.

PURPOSE: To demonstrate support for AIDS orphans and their grandparent
caretakers and highlight Administration efforts.

BACKGROUND: The tea would take place while the AIDS Memorial Quilt is in
Washington. The event would highlight the plight of AIDS orphans. It
is estimated that 80,000 American children will be orphaned as result
of AIDS by the year 2000. Many of these children are ultimately cared
for by grandparents who are not only suffering the loss of their own
child but are also coping with new parenting responsibilities. This
would be an opportunity to announce several initiatives to address
problems with laws and administrative requirements that can
discontinue public assistance benefits after the death of the parent.

This proposal is an alternative to the radio address scheduling request.
Our preference is for the radio address.

PREVIOUS
PARTICIPATION: None.

DATE AND TIME: Between October 11 - October 13

DURATION: 45 minutes

LOCATION: White House.

PARTICIPANTS: The President, the First Lady, Patsy Fleming, Carol Rasco, Donna Shalala, 2-3 children orphaned by AIDS, 4-6 grandparents, 1-2 community program people.

OUTLINE OF EVENTS: The First Lady would meet with a small group of orphans, their grandparents, and people working on programs serving this group. Each person would briefly relate their experience, what would help them, what programs have helped them. The First Lady would turn to Administration officials to announce new grants awards, efforts to remedy administrative problems, and a commitment to the issue.

REMARKS: Yes. Brief introductory remarks.

MEDIA: Yes. Open press.

PRESIDENT: Yes, if possible.

FIRST LADY: Yes.

VICE PRESIDENT: Yes, if possible.

MRS. GORE: Yes, if possible.

RECOMMENDED BY: Carol Rasco, Patsy Fleming, and Marsha Scott

CONTACT: Jeff Levi, Office of National AIDS Policy, 632-1090.

THE WHITE HOUSE
WASHINGTON

January 31, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed, Assistant to the President for Domestic Policy *BR*
Patricia S. Fleming, Director, Office of National AIDS Policy *PSF*

SUBJECT: Follow up to the December meeting of the Presidential HIV/AIDS Advisory Council

We are pleased to transmit to you the most recent recommendations of the Presidential Advisory Council on HIV and AIDS following its meeting of December 15-17.

A copy of the Council's recommendations is attached. These recommendations, in summary, ask for the following:

- Continued leadership by the Administration for funding for AIDS research, prevention, treatment, and housing as well as protection of Medicare and Medicaid.
- Continued advocacy for funding for AIDS Drug Assistance Programs and HUD's Housing Opportunities for People with AIDS program.
- Greater focus by the Federal Bureau of Prisons on the needs and rights of federal prisoners living with HIV/AIDS.
- Greater support for AIDS treatment programs focused on Native American communities.
- Administration leadership in working with states and the private sector on reducing the cost of AIDS drugs.

The Council also approved a resolution commending you and the Office of National AIDS Policy for formulating the first-ever National AIDS Strategy, which you received from Patsy Fleming on December 17. The Council also sent a letter to Secretary Shalala urging her to support Federal funding for needle exchange programs to reduce the spread of HIV among intravenous drug users, their sexual partners, and their children.

The steps we will take in the coming months to address these concerns are as follows:

- Your fiscal 1998 budget includes across-the-board increases in funding for AIDS research, prevention, treatment, and housing. While these increases are smaller than in previous years, they are significant in the context of your balanced budget proposal.

- Your budget maintains the Federal guarantee of Medicare and Medicaid coverage for people with disabilities including people living with HIV/AIDS. However, the proposed per capita cap concerns many AIDS advocates because of its potential to reduce benefits to costly patients.
- The Federal Bureau of Prisons and the Department of Defense are working on addressing the inclusion of HIV/AIDS issues in all services of the Federal Bureau of prisons and Department of Defense prisons and briggs (including D.C. jails).
- The Office of National AIDS Policy is convening a roundtable discussion of AIDS issues related to the Native American community on February 11.
- The Department of Health and Human Services is working with the states and others to find ways to reduce the cost of AIDS drugs to government programs.
- The Department of Health and Human Services will report to Congress on or about February 15 on Federally-sponsored research into the effectiveness of needle exchange programs to reduce HIV transmission without encouraging use of illegal drugs.

Presidential Advisory Council on HIV/AIDS
Fifth Full Council Meeting
December 15 - 17, 1996

REPORT FOUR

RECOMMENDATIONS

•National AIDS Strategy Resolution

The Council commends the President and the Office of National AIDS Policy for demonstrating leadership in developing the Federal Government's first national comprehensive strategy for dealing with the HIV/AIDS epidemic. While there are clearly significant issues regarding the epidemic which still must be addressed, the National AIDS Strategy provides a foundation for the Federal Government's response to HIV/AIDS in the year ahead. Specific implementation tactics and strategies must be developed.

The Council believes that in order to have any realistic chance of achieving the President's stated goals of finding a cure, developing a vaccine, and reducing annual new infections to zero, other important issues such as how to decrease infections among intravenous drug users must be addressed more comprehensively.

The Council intends to continue to ensure that all crucial issues are dealt with and to ensure that the actions of relevant Federal Agencies are consistent with the National AIDS Strategy and with the recommendations of this Council.

IV.A. Leadership Recommendation

Background

During the debate over the FY1997 budget, President Clinton exercised leadership critical to the lives of people living with HIV and at risk for HIV by protecting Medicaid and Medicare, holding out for increases in funding for research, prevention and care, and by seeking budget amendments for the AIDS Drug Assistance Program and HOPWA as the need for increased funding became apparent.

The FY 1998 budget debate will require the same level of leadership from the President and his Administration. Our nation faces the continuing challenge of assuring access to new and promising treatments for HIV, the opportunity that new avenues of treatment and vaccine research offer, the need to expand prevention efforts to more Americans at risk, and the need to assure that people with HIV have housing that addresses their needs.

Recommendation IV.A.1.

That in his FY 1998 budget request, the President continue to protect Medicaid and Medicare, and seek increases in funding for research, prevention, care and services — including the Ryan White Care Act and HOPWA. In particular, because of the availability of new drug therapies, ADAP funding must be increased, and not in competition with funding for the care system. Increased funding will be essential until new financing systems can be developed among private and public health payers to cover the cost of the new therapies.

In the international arena, the President should seek increases in funding for USAID programs relating to the global epidemic.

Recommendation IV.A.2.

That the Vice-President continue the dialogue which he has established with the major manufacturers of HIV/AIDS drugs and that the issue of international provision of basic medications for the prevention and treatment of opportunistic infections and other HIV/AIDS associated medical conditions be added to their agenda.

IV.B. AIDS/Prison Issues

Background

Citizens incarcerated in the United States prisons system have a constitutional right to quality health care appropriated social services, and humane living conditions.

This issue was first addressed in the 1991 NCOA report in the Federal Bureau of Prisons.

In 1995 the ONAP revisited this issue so that the needs of the HIV-infected prison population were not neglected.

“HIV infected prisoners who are not provided adequate medical care while incarcerated become sicker and can impose an unnecessary burden on the health care delivery system upon release. Moreover, without proper prevention education, prisoners and formerly incarcerated persons will continue to engage in risky behavior and thereby increase the possibility of new transmissions. People of Color have been particularly hard hit by the expanding HIV/AIDS epidemic and they also experience high rates of incarceration.¹

“For prisoners with HIV/AIDS locked away in federal, state, and local prisons and jails, a short prison term can become a death sentence because of lack of medical care, little

¹ 1996, Policy Statement, NORA Working Group on Incarcerated Populations.

psychosocial support, discrimination, stigmatization, and harassment from both corrections staff and other prisoners. Studies have shown that prisoners with HIV/AIDS live half as long as similar IDU populations on the outside. Women prisoners with HIV/AIDS are the fastest growing and most medically underserved prison population. Compassionate release or medical parole is out of reach for most prisoners with full-blown AIDS (and other life threatening illnesses).²

Historically, prison infirmaries have not been equipped to deal with the specialized needs of inmates with HIV/AIDS and infections associated with HIV disease such as multiple-drug-resistant tuberculosis. In an effort to address these concerns, we recommend the following:

Recommendation IV.B.1.

The Council requests a comprehensive and specific report be from the Federal Bureau of Prisons, and the Department of Defense, within 90 days, addressing the inclusion of HIV/AIDS issues in all services of the Federal Bureau of Prisons and DoD prisons and brigades (including D. C. Jails). This should minimally include the following:

- a. Content and frequency of prison staff educational efforts paying particular attention to issues of; women at-risk for HIV, substance use, prevention, and the medical management of HIV disease.
- b. Accessibility of all FDA approved HIV/AIDS therapeutic modalities for prison inmates with HIV/AIDS, and numbers of prisoners availing themselves of these therapies.
- c. Availability of mainstream clinical drug trials for prison inmates, the nature of any access barriers -- and means to remove such barriers, and numbers, sites and principal investigators of these programs.
- d. The status of quality assurance criteria and certifications, (including nondiscrimination guidelines) with a demonstrable high level of compassionate care available for the ill and dying.
- e. Description of case management for prison inmates with HIV/AIDS.
- f. Availability of voluntary peer education opportunities for HIV+ inmates. (Please include curriculum participation, site, and frequency statistics.)
- g. Accessibility of condoms and barrier protection against HIV transmission to prison

² 1996, HIV/AIDS in Prison Project, Catholic Charities, Judy Greenspan, author.

inmates.

- h. Specific details concerning the availability of ongoing (at least every 6 months) educational programs for incarcerated individuals regarding all aspects of HIV, including substance abuse issues and sexuality.
- I. Definition of the limits of jurisdiction which differentiate the authority of the federal government in all correctional facilities; District of Columbia, military, federal, state, and local correctional institutions, including federal funding streams.
- j. The scope of implementation of the seven major recommendations of the National Commission on AIDS (March, 1991).

Recommendation IV.B.2.

The Administration should direct the Secretary of Health and Human Services to develop oversight language appropriate for discharge planning (including accessing benefits) for ex-offenders with HIV/AIDS designed to assure their continuity of care through Probation Departments in various locales as well as the accessibility of appropriate linkages within the community.

IV.C. AIDS/Native American Issues

Background

During 1994 - 1995, extensive efforts were made in the public and private sector to insure and preserve HRSA assistance to special populations. Under the reauthorization, it appears to be discretionary for the Secretary to determine allocations to specific communities and projects.

Recommendation IV.C.1.

Therefore, the Council requests that the President instruct the Secretary of Health and Human Services to reassess the legislative intent of the reauthorized Ryan White CARE Act regarding needs of the Native American community to insure appropriate support for Native American care, infrastructure development, and coordination *on a national level*.

Background

Agreements ensuring the fulfillment of Native American health care needs are part of the traditional government-tribal relationship. In the instance of alcohol and substance abuse programs, IHS was instructed to develop memorandums of agreement with tribal

governments and the BIA to ensure that these three entities work together to reduce the effects of addiction in tribal communities. Memorandums of agreement include a specific tribal plan describing needs, availability of services, and prevention efforts. Similar memorandums are needed in dealing with HIV/AIDS. Local tribes have need to have ownership of direct client services for HIV case management on their Reservations; Native Case Management Programs need a commitment from IHS that they will work cooperatively with these programs, which are located on and off Reservations.

Recommendation IV.C.2.

Therefore, the Council requests that the Secretary of Health and Human Services instruct the Director of Indian Health Services to demonstrate within ninety-days the adequacy of *HIV* prevention, care, and treatment including access to needed drugs, for American Indians and Alaska Natives living on or near reservations. This should include documentation of needs assessments completed, barriers, and gaps identified and proposed solutions. It should also include a discussion of how IHS plans to work with the private non-profit sector to improve AIDS-related services.

Background

Programs providing Case Management Services to Native Americans need to ensure that the services are culturally relevant for this population. Criteria to evaluate the cultural relevancy of services may include such things as: Native Americans seated on the governing or policy-making body, insuring that 50% of the staff are native Americans, insuring that traditional tribal healing services are available onsite by referral. IHS needs to commit to complying with the *Buy Indian Act* for training IHS personnel in HIV/AIDS Case Management Services.

Recommendation IV.C.3.

Therefore, the Council requests that the Secretary of Health and Human Services instruct the Director of IHS to develop Case Management oversight guidelines which are appropriately oriented to the specific needs of Native American people with HIV/AIDS and assure the provision of health care and in a safe and culturally appropriate manner.

IV.D. AIDS/Service Issues

Recommendation IV.D.1

That the Administration take leadership in working with the states and the private sector to reduce the cost of pharmaceuticals to ADAP and Medicaid programs.

Recommendation IV.D.2

That the federal government working with the states expeditiously finance, and evaluate new demonstration projects that 1) enable funds to be used for very early access to HIV care services, and 2) assess the resulting impact on health status, life expectancy, client return to work and earned income, and net health care costs (new expenditures offset by lowered costs), on a lifetime and annual cost-of-care basis. These demonstrations should be financed with new funds, so as not to diminish access to care and treatment under current funding.

Recommendation IV.D.3

That the Office of National AIDS Policy create a mechanism for the public sector, the private sector, and the community to engage in a formal, facilitated dialogue process on how to set priorities for HIV care and services that assures the best use of resources and recognizes a context of shifting demands for services. This dialogue should be completed within six to eight months.

Recommendation IV.D.4

That the Office of National AIDS Policy work with the Secretary of HHS and the Secretary of Labor, the co-chairs of the Advisory Council on Consumer Protection and Quality in Health, to assure inclusion of the concerns of people living with HIV and their recommendations.



December 2, 1996

MEMORANDUM TO THE PRESIDENT

From: Carol H. Rasco
Patricia S. Fleming

SUBJECT: Background Information on AIDS

This memo provides the latest information on the AIDS epidemic and the key aspects of the Federal response.

I. State of the Epidemic

As of September 30, 1996, there were 566,002 reported AIDS cases and over 343,000 deaths. AIDS is now the leading cause of death among Americans aged 25 to 44. 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.

The highest rates of increase in new AIDS cases are among adolescents, injecting drug users, women, and people of color. CDC estimates that one-quarter of new HIV infections in the U.S. occur among young people under age 21. CDC also estimates that more than 36 percent of new AIDS cases are associated with injection drug use. Women now comprise 14 percent of cumulatively reported AIDS cases. As of December 1995, African-Americans and Hispanics comprised 52 percent of cumulative AIDS cases.

The HIV epidemic continues to spread into suburban and rural areas, with dramatic increases in certain regions of the South and Midwest. 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.

The U.S. epidemic is part of a global pandemic. Globally, the toll of the epidemic is much greater and threatens to reverse decades of economic and public health progress in developing countries. The World Health Organization estimates that 27.9 million people have been infected with HIV.

II. The Federal Response

Your Administration has been credited with making tremendous progress in the fight against AIDS. Progress since you took office includes:

- A 40 percent increase in NIH-supported AIDS research.
- A 158 percent increase in Ryan White AIDS Treatment grants.
- A 24 percent increase in CDC HIV prevention activities.
- A 96 percent increase for HUD's Housing Opportunities for People with AIDS program.
- Strengthening the Office of AIDS Research at the National Institutes of Health.
- As a result of Public Health Service guidelines recommending the use of AZT by HIV-positive pregnant women and their newborns, a 17 percent drop in the number of infants with perinatally-acquired HIV infection (from 1994 to 1995).
- Responding rapidly to FDA approval of a new class of AIDS therapies called protease inhibitors with increases in funding for State AIDS Drug Assistance Programs.
- Easing of Social Security disability rules to speed approval of eligibility.
- Creating the Office of National AIDS Policy at the White House and the Presidential Advisory Council on HIV/AIDS.

III. Research Developments & Opportunities for Progress

A. THERAPEUTICS

Implications of Viral Levels

NIH-sponsored research indicates that decreasing the amount of HIV in the blood can significantly slow how quickly a person becomes ill, and can also decrease the chance of transmission from mother to child. This finding has tremendous implications for therapy. Studies indicate that combination therapy (i.e., use of one or more anti-retroviral drugs), especially where a protease inhibitor (the newest class of anti-retroviral drugs) is used, provides the greatest benefit for the patients. However, this approach is new and we still do not know the best time to start therapy, to stop therapy, to change therapy, and how long these effects will last. More research is needed.

Discovery of New Receptors

The breakthrough discovery of new chemokine receptors (CCR5 and CXCR4 or fusin are receptors on the cell where HIV binds) has offered exciting new avenues for drug and vaccine development. Research indicates that people who have defective or missing receptors are much more resistant to becoming infected.

B. PREVENTION

In response to the recommendations from the Report of the NIH AIDS Research Program Evaluation Task Force, NIH is developing a comprehensive HIV prevention science agenda. Areas of focus will include:

Vaccines. We desperately need a vaccine that will control new infections both in the U.S. and abroad. New generations of vaccines, including DNA vaccines, are now in early development. Research efforts in the HIV vaccine arena will have important implications for developing vaccines for other diseases such as Tuberculosis.

Other Prevention Efforts. Preventing HIV infection through behavioral modification and/or a microbicide (a mechanical or chemical barrier method that blocks infection) also offers tremendous hope. Secretary Shalala has promised \$100 million over the next four years for microbicide research and development.

IV. Role of the Vice President

The Vice President has been intimately involved in developing the Forum for Collaborative HIV Research. This new public-private group is designed to catalyze collaborations among government researchers, pharmaceutical companies, third-party payors, and the community to capitalize on recent scientific advances and learn how to optimally use available treatment regimens.

The Vice President also has expressed interest in continuing efforts to expedite vaccine and microbicide research.

THE WHITE HOUSE

WASHINGTON

November 15, 1996

Dear Religious Leader:

On Sunday, December 1, people around the world will commemorate World AIDS Day. This is an opportunity for all of us blessed to live in the United States to reflect on the tremendous impact that HIV and AIDS have had on our nation's families, our communities, our country, and our planet.

More than 566,000 of our fellow Americans have been diagnosed with AIDS in the past 15 years and more than 330,000 of them have already lost their lives to this relentless disease. Every person with AIDS is someone's son or daughter, mother or father, friend or neighbor. And they are all children of God. Discrimination against people with AIDS violates our most basic national values.

I ask that, as a religious leader in your community, you take a moment this week to speak to your congregation about this very important subject. It is also an opportunity for you to address the scourge of drug abuse -- particularly among our young people, who all too often place themselves at risk of HIV and AIDS as a result of illegal drug use.

In the past few years, we have truly joined together as a nation to fight the AIDS pandemic. Religious leaders have helped to educate their congregations and communities about HIV and AIDS, to encourage compassion, and to care for those who are living with this disease. Religious institutions continue to play an important role in our national response to this tragedy.

The challenges that HIV and AIDS present are daunting. AIDS is the leading cause of death among Americans 25 to 44. Today, nearly half of all new HIV infections occur among people under the age of 21. Our young people need to know that they have the power to protect themselves and their friends through education and prevention. We also must remind our children that drugs are harmful to them and can lead to their early death, and not only from the drugs themselves. We must help our young people understand that they are at serious risk of becoming infected with HIV when they engage in illegal drug use. It is up to all of us to put an end to these twin epidemics.

In Ezekiel, Chapter 34, Verse 16, the Lord said: "I will seek that which was lost and bring again that which was driven away, and will strengthen that which was sick." This is the task before us all, and with God's help we shall succeed.

Sincerely,

Bill Clinton

THE WHITE HOUSE
WASHINGTON

February 3, 1997

MEMORANDUM FOR BRUCE REED

FROM: Patricia S. Fleming *PSF*
RE: Presidential Advisory Council on HIV and AIDS

Attached is the Memo to the President for your transmittal. Please forward.

cc: Elena Kagan

THE WHITE HOUSE
WASHINGTON

January 31, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed, Assistant to the President for Domestic Policy
Patricia S. Fleming, Director, Office of National AIDS Policy *PSF*

SUBJECT: Follow up to the December meeting of the Presidential HIV/AIDS Advisory Council

We are pleased to transmit to you the most recent recommendations of the Presidential Advisory Council on HIV and AIDS following its meeting of December 15-17.

A copy of the Council's recommendations is attached. These recommendations, in summary, ask for the following:

- Continued leadership by the Administration for funding for AIDS research, prevention, treatment, and housing as well as protection of Medicare and Medicaid.
- Continued advocacy for funding for AIDS Drug Assistance Programs and HUD's Housing Opportunities for People with AIDS program.
- Greater focus by the Federal Bureau of Prisons on the needs and rights of federal prisoners living with HIV/AIDS.
- Greater support for AIDS treatment programs focused on Native American communities.
- Administration leadership in working with states and the private sector on reducing the cost of AIDS drugs.

The Council also approved a resolution commending you and the Office of National AIDS Policy for formulating the first-ever National AIDS Strategy, which you received from Patsy Fleming on December 17. The Council also sent a letter to Secretary Shalala urging her to support Federal funding for needle exchange programs to reduce the spread of HIV among intravenous drug users, their sexual partners, and their children.

The steps we will take in the coming months to address these concerns are as follows:

- Your fiscal 1998 budget includes across-the-board increases in funding for AIDS research, prevention, treatment, and housing. While these increases are smaller than in previous years, they are significant in the context of your balanced budget proposal.

- Your budget maintains the Federal guarantee of Medicare and Medicaid coverage for people with disabilities including people living with HIV/AIDS. However, the proposed per capita cap concerns many AIDS advocates because of its potential to reduce benefits to costly patients.
- The Federal Bureau of Prisons and the Department of Defense are working on addressing the inclusion of HIV/AIDS issues in all services of the Federal Bureau of prisons and Department of Defense prisons and briggs (including D.C. jails).
- The Office of National AIDS Policy is convening a roundtable discussion of AIDS issues related to the Native American community on February 11.
- The Department of Health and Human Services is working with the states and others to find ways to reduce the cost of AIDS drugs to government programs.
- The Department of Health and Human Services will report to Congress on or about February 15 on Federally-sponsored research into the effectiveness of needle exchange programs to reduce HIV transmission without encouraging use of illegal drugs.

Presidential Advisory Council on HIV/AIDS
Fifth Full Council Meeting
December 15 - 17, 1996

REPORT FOUR

RECOMMENDATIONS

•National AIDS Strategy Resolution

The Council commends the President and the Office of National AIDS Policy for demonstrating leadership in developing the Federal Government's first national comprehensive strategy for dealing with the HIV/AIDS epidemic. While there are clearly significant issues regarding the epidemic which still must be addressed, the National AIDS Strategy provides a foundation for the Federal Government's response to HIV/AIDS in the year ahead. Specific implementation tactics and strategies must be developed.

The Council believes that in order to have any realistic chance of achieving the President's stated goals of finding a cure, developing a vaccine, and reducing annual new infections to zero, other important issues such as how to decrease infections among intravenous drug users must be addressed more comprehensively.

The Council intends to continue to ensure that all crucial issues are dealt with and to ensure that the actions of relevant Federal Agencies are consistent with the National AIDS Strategy and with the recommendations of this Council.

IV.A. Leadership Recommendation

Background

During the debate over the FY1997 budget, President Clinton exercised leadership critical to the lives of people living with HIV and at risk for HIV by protecting Medicaid and Medicare, holding out for increases in funding for research, prevention and care, and by seeking budget amendments for the AIDS Drug Assistance Program and HOPWA as the need for increased funding became apparent.

The FY 1998 budget debate will require the same level of leadership from the President and his Administration. Our nation faces the continuing challenge of assuring access to new and promising treatments for HIV, the opportunity that new avenues of treatment and vaccine research offer, the need to expand prevention efforts to more Americans at risk, and the need to assure that people with HIV have housing that addresses their needs.

Recommendation IV.A.1.

That in his FY 1998 budget request, the President continue to protect Medicaid and Medicare, and seek increases in funding for research, prevention, care and services — including the Ryan White Care Act and HOPWA. In particular, because of the availability of new drug therapies, ADAP funding must be increased, and not in competition with funding for the care system. Increased funding will be essential until new financing systems can be developed among private and public health payers to cover the cost of the new therapies.

In the international arena, the President should seek increases in funding for USAID programs relating to the global epidemic.

Recommendation IV.A.2.

That the Vice-President continue the dialogue which he has established with the major manufacturers of HIV/AIDS drugs and that the issue of international provision of basic medications for the prevention and treatment of opportunistic infections and other HIV/AIDS associated medical conditions be added to their agenda.

IV.B. AIDS/Prison Issues

Background

Citizens incarcerated in the United States prisons system have a constitutional right to quality health care appropriated social services, and humane living conditions.

This issue was first addressed in the 1991 NCOA report in the Federal Bureau of Prisons.

In 1995 the ONAP revisited this issue so that the needs of the HIV-infected prison population were not neglected.

“HIV infected prisoners who are not provided adequate medical care while incarcerated become sicker and can impose an unnecessary burden on the health care delivery system upon release. Moreover, without proper prevention education, prisoners and formerly incarcerated persons will continue to engage in risky behavior and thereby increase the possibility of new transmissions. People of Color have been particularly hard hit by the expanding HIV/AIDS epidemic and they also experience high rates of incarceration.¹

“For prisoners with HIV/AIDS locked away in federal, state, and local prisons and jails, a short prison term can become a death sentence because of lack of medical care, little

¹ 1996, Policy Statement, NORA Working Group on Incarcerated Populations.

psychosocial support, discrimination, stigmatization, and harassment from both corrections staff and other prisoners. Studies have shown that prisoners with HIV/AIDS live half as long as similar IDU populations on the outside. Women prisoners with HIV/AIDS are the fastest growing and most medically under served prison population. Compassionate release or medical parole is out of reach for most prisoners with full-blown AIDS (and other life threatening illnesses).²

Historically, prison infirmaries have not been equipped to deal with the specialized needs of inmates with HIV/AIDS and infections associated with HIV disease such as multiple-drug-resistant tuberculosis. In an effort to address these concerns, we recommend the following:

Recommendation IV.B.1.

The Council requests a comprehensive and specific report be from the Federal Bureau of Prisons, and the Department of Defense, within 90 days, addressing the inclusion of HIV/AIDS issues in all services of the Federal Bureau of Prisons and DoD prisons and briggs (including D. C. Jails). This should minimally include the following:

- a. Content and frequency of prison staff educational efforts paying particular attention to issues of; women at-risk for HIV, substance use, prevention, and the medical management of HIV disease.
- b. Accessibility of all FDA approved HIV/AIDS therapeutic modalities for prison inmates with HIV/AIDS, and numbers of prisoners availing themselves of these therapies.
- c. Availability of mainstream clinical drug trials for prison inmates, the nature of any access barriers -- and means to remove such barriers, and numbers, sites and principal investigators of these programs.
- d. The status of quality assurance criteria and certifications, (including nondiscrimination guidelines) with a demonstrable high level of compassionate care available for the ill and dying.
- e. Description of case management for prison inmates with HIV/AIDS.
- f. Availability of voluntary peer education opportunities for HIV+ inmates. (Please include curriculum participation, site, and frequency statistics.)
- g. Accessibility of condoms and barrier protection against HIV transmission to prison

² 1996, HIV/AIDS in Prison Project, Catholic Charities, Judy Greenspan, author.

inmates.

- h. Specific details concerning the availability of ongoing (at least every 6 months) educational programs for incarcerated individuals regarding all aspects of HIV, including substance abuse issues and sexuality.
- I. Definition of the limits of jurisdiction which differentiate the authority of the federal government in all correctional facilities; District of Columbia, military, federal, state, and local correctional institutions, including federal funding streams.
- j. The scope of implementation of the seven major recommendations of the National Commission on AIDS (March, 1991).

Recommendation IV.B.2.

The Administration should direct the Secretary of Health and Human Services to develop oversight language appropriate for discharge planning (including accessing benefits) for ex-offenders with HIV/AIDS designed to assure their continuity of care through Probation Departments in various locales as well as the accessibility of appropriate linkages within the community.

IV.C. AIDS/Native American Issues

Background

During 1994 - 1995, extensive efforts were made in the public and private sector to insure and preserve HRSA assistance to special populations. Under the reauthorization, it appears to be discretionary for the Secretary to determine allocations to specific communities and projects.

Recommendation IV.C.1.

Therefore, the Council requests that the President instruct the Secretary of Health and Human Services to reassess the legislative intent of the reauthorized Ryan White CARE Act regarding needs of the Native American community to insure appropriate support for Native American care, infrastructure development, and coordination *on a national level*.

Background

Agreements ensuring the fulfillment of Native American health care needs are part of the traditional government-tribal relationship. In the instance of alcohol and substance abuse programs, IHS was instructed to develop memorandums of agreement with tribal

governments and the BIA to ensure that these three entities work together to reduce the effects of addiction in tribal communities. Memorandums of agreement include a specific tribal plan describing needs, availability of services, and prevention efforts. Similar memorandums are needed in dealing with HIV/AIDS. Local tribes have need to have ownership of direct client services for HIV case management on their Reservations; Native Case Management Programs need a commitment from IHS that they will work cooperatively with these programs, which are located on and off Reservations.

Recommendation IV.C.2.

Therefore, the Council requests that the Secretary of Health and Human Services instruct the Director of Indian Health Services to demonstrate within ninety-days the adequacy of *HIV* prevention, care, and treatment including access to needed drugs, for American Indians and Alaska Natives living on or near reservations. This should include documentation of needs assessments completed, barriers, and gaps identified and proposed solutions. It should also include a discussion of how IHS plans to work with the private non-profit sector to improve AIDS-related services.

Background

Programs providing Case Management Services to Native Americans need to ensure that the services are culturally relevant for this population. Criteria to evaluate the cultural relevancy of services may include such things as: Native Americans seated on the governing or policy-making body, insuring that 50% of the staff are native Americans, insuring that traditional tribal healing services are available onsite by referral. IHS needs to commit to complying with the *Buy Indian Act* for training IHS personnel in HIV/AIDS Case Management Services.

Recommendation IV.C.3.

Therefore, the Council requests that the Secretary of Health and Human Services instruct the Director of IHS to develop Case Management oversight guidelines which are appropriately oriented to the specific needs of Native American people with HIV/AIDS and assure the provision of health care and in a safe and culturally appropriate manner.

IV.D. AIDS/Service Issues

Recommendation IV.D.1

That the Administration take leadership in working with the states and the private sector to reduce the cost of pharmaceuticals to ADAP and Medicaid programs.

Recommendation IV.D.2

That the federal government working with the states expeditiously finance, and evaluate new demonstration projects that 1) enable funds to be used for very early access to HIV care services, and 2) assess the resulting impact on health status, life expectancy, client return to work and earned income, and net health care costs (new expenditures offset by lowered costs), on a lifetime and annual cost-of-care basis. These demonstrations should be financed with new funds, so as not to diminish access to care and treatment under current funding.

Recommendation IV.D.3

That the Office of National AIDS Policy create a mechanism for the public sector, the private sector, and the community to engage in a formal, facilitated dialogue process on how to set priorities for HIV care and services that assures the best use of resources and recognizes a context of shifting demands for services. This dialogue should be completed within six to eight months.

Recommendation IV.D.4

That the Office of National AIDS Policy work with the Secretary of HHS and the Secretary of Labor, the co-chairs of the Advisory Council on Consumer Protection and Quality in Health, to assure inclusion of the concerns of people living with HIV and their recommendations.

THE WHITE HOUSE

WASHINGTON

DATE: 1/23/97

MEMORANDUM FOR Patsy Flemming
FROM: JIM DORSKIND
SPECIAL ASSISTANT TO THE PRESIDENT
DIRECTOR OF CORRESPONDENCE
AND PRESIDENTIAL MESSAGES
SUBJECT: Petitions from Various continents

I attach an example of 75, 674 petitions that we received regarding an issue in which you might be interested.

If you have any questions, I can be reached at 65460.

6-Boxes

75, 674



Dear President Clinton,

While I am in Washington, D.C., visiting the AIDS Memorial Quilt, I want you to know how saddened I am by the visual display of death and sorrow AIDS has brought and continues to bring to our fellow Americans. Your response to AIDS will be an important consideration when I cast my ballot this November. I believe it is imperative that the next President provide **leadership** on the AIDS epidemic that includes measures to prevent HIV transmission; **support** research for treatments, vaccines and a cure; and **commit** to provide Americans living with HIV and AIDS the care and housing they need to stay alive.

I will vote on November 5 for myself, for all those who have lost their battles with this disease, and for the hundreds of thousands of Americans living with HIV and AIDS who depend on Presidential leadership for hope for the future.

Your name (signed):

Stephen Nutt

Your name (printed):

STEPHEN NUTT

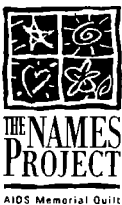
Address:

3125 S. 17th Street

City, State, Zip Code:

ARLINGTON, VA 22204

Remember them with your vote.



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Your name (signed):

Laura L. Guam

Your name (printed):

LAURA GUAM

Address:

3544 S. Stafford St.

City, State, Zip Code:

Arlington, VA 22206

Remember them with your vote.



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Your name (signed):

Susan Johnson

Your name (printed):

Susan Johnson

Address:

223 Round Table Dr

City, State, Zip Code:

San Jose CA 95128

Remember them with your vote.



THE WHITE HOUSE

WASHINGTON

November 15, 1996

Dear Religious Leader:

On Sunday, December 1, people around the world will commemorate World AIDS Day. This is an opportunity for all of us blessed to live in the United States to reflect on the tremendous impact that HIV and AIDS have had on our nation's families, our communities, our country, and our planet.

More than 566,000 of our fellow Americans have been diagnosed with AIDS in the past 15 years and more than 330,000 of them have already lost their lives to this relentless disease. Every person with AIDS is someone's son or daughter, mother or father, friend or neighbor. And they are all children of God. Discrimination against people with AIDS violates our most basic national values.

I ask that, as a religious leader in your community, you take a moment this week to speak to your congregation about this very important subject. It is also an opportunity for you to address the scourge of drug abuse -- particularly among our young people, who all too often place themselves at risk of HIV and AIDS as a result of illegal drug use.

In the past few years, we have truly joined together as a nation to fight the AIDS pandemic. Religious leaders have helped to educate their congregations and communities about HIV and AIDS, to encourage compassion, and to care for those who are living with this disease. Religious institutions continue to play an important role in our national response to this tragedy

The challenges that HIV and AIDS present are daunting. AIDS is the leading cause of death among Americans 25 to 44. Today, nearly half of all new HIV infections occur among people under the age of 21. Our young people need to know that they have the power to protect themselves and their friends through education and prevention. We also must remind our children that drugs are harmful to them and can lead to their early death, and not only from the drugs themselves. We must help our young people understand that they are at serious risk of becoming infected with HIV when they engage in illegal drug use. It is up to all of us to put an end to these twin epidemics.

In Ezekiel, Chapter 34, Verse 16, the Lord said: "I will seek that which was lost and bring again that which was driven away, and will strengthen that which was sick." This is the task before us all, and with God's help we shall succeed.

Sincerely,

A handwritten signature in black ink, reading "Bill Clinton". The signature is written in a cursive, flowing style with a long horizontal stroke at the end.

FILE COPY

THE WHITE HOUSE

WASHINGTON

November 1, 1996

MEMORANDUM FOR CAROL RASCO

FROM: Patsy Fleming 
SUBJECT: Grandparents Project Monograph

Background. When a parent dies or becomes incapable of caring for his or her child, frequently a family member (most often a grandparent) takes on the care of the child. Permanency planning difficulties were a recurrent theme during the ONAP regional briefings. In order to explore options for resolving these problems, DPC and ONAP staff met with Carol Williams, Associate Commissioner for the Children's Bureau, Administration for Children and Families, HHS on September 17.

Options for resolving current obstacles were explored; developing a monograph was proposed.

Monograph. We are working on a monograph that would provide technical assistance for the field on permanency planning and co-guardianship options available for HIV-positive and other terminally ill parents. The goal would be to influence the field by identifying model regulations and legislation that could be adopted at the state level, where many of the legal issues reside. The target audience would be service providers, state legislators, and advocates.

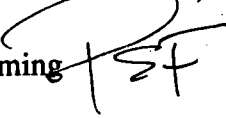
Jane Sanville (ONAP) met with ACF/HHS staff to work out the details. They agreed that those who are doing permanency planning for parents with HIV, and all other terminally ill parents, warranted special technical assistance. The monograph will be developed by HHS through their contracts with the ABA Resource Center and the Abandoned Infants Project in Berkeley. HHS is currently putting together a proposal for our review. I will keep you updated on its progress.

THE WHITE HOUSE
WASHINGTON

FILE COPY

NOV - 7 1996

MEMORANDUM FOR GARY WALTERS, CHIEF USHER, WHITE HOUSE

FROM: Patricia S. Fleming 
Director
Office of National AIDS Policy

RE: World AIDS Day Observance
December 1, 1996

I am writing to request your assistance with the annual White House observance of World AIDS Day on December 1.

As we have requested and you have done in previous years, we would like the lights to be dimmed from 7:45 p.m. to 8:00 p.m. on the East Portico, and any other possible locations. Last year, candles were placed in the windows facing Pennsylvania Avenue. I hope that you can do that again this year, using electric candles which would be easier to see.

Please let me know if this request will be honored. Thank you.

FILE

FILE COPY

THE WHITE HOUSE
WASHINGTON
September 24, 1996

MEMORANDUM FOR JEREMY BEN-AMI

FROM: Patsy Fleming *PF*
SUBJECT: Timeline for National AIDS Strategy

I'm writing in follow-up to our discussion regarding final release of the National AIDS Strategy. I have reviewed the steps in the process and have concluded that a December 1st release date for a final document is unworkable.

Having a final Strategy document ready for a December 1st release would require the schedule described below. It would call for the Presidential Advisory Council (PAC) members to submit their comments one month earlier than planned and would impose turnaround times for all involved parties (including the community, the Agencies, ONAP staff, etc.) that are virtually impossible to meet. As you can see, there are a number of 24-hour turnarounds. If one person fails to meet the deadline, the schedule collapses. Moreover, the rushed timeframe may leave the community and the PAC with the impression that we will not take their input seriously.

October 15	Comments back from the PAC
October 16	Incorporate PAC comments
October 17	Distribute to Agencies and WH simultaneously
October 23	Comments back from Agencies
October 24	Incorporate Agency comments
October 25	Final draft to copying center
October 28	Distribution to community
November 4	Comments back from community
November 5	Incorporate community comments
November 6	Distribute to Agencies and WH simultaneously
November 12	Comments back from Agencies
November 14	Complete incorporation of Agency comments
November 15	Final document to printer (printer requires 10 working days)
December 1	Release of final document

I suggest an alternative schedule that will allow the PAC to stay on schedule, not rush community input, and give us the opportunity to produce the best Strategy possible.

November 15	Comments back from PAC
November 20	Incorporation of PAC comments completed
November 21	Distribute to Agencies and WH simultaneously
November 29	Comments back from Agencies
December 6	Incorporation of Agency and WH comments completed
December 9	Final draft to copying center
December 12	Distribution and roll-out to community
December 15	Distribution to PAC at meeting
January 3	Comments back from community (15 working days for community review)
January 9	Incorporation of community comments completed
January 10	Distribute to Agencies and WH simultaneously
January 17	Comments back from Agencies
January 24	Incorporation of Agency comments completed
January 27	Final document to printer (printer requires 10 working days)
February 7	Release of final document

Let me know what you think.

FILE COPY

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20500

February 20, 1996

FEB 20 1996

MEMORANDUM FOR CAROL RASCO

FROM: JACK GIBBONS

SUBJECT: Meeting

DPC staff
www
LPF
Carol - I look forward to getting together with you on this. Jack

The Science Division has the principal liaison role for OSTP with the DPC. Dr. Ernest Moniz was recently confirmed as Associate Director for Science. His planned activities include many areas of mutual DPC-OSTP interest. I would like to get together with you and Ernie, fairly soon if possible, to discuss these areas of mutual interest and to explore options for collaboration. My staff will contact your office shortly to discuss scheduling.

It may be worth noting some of the issues that Ernie and his associates are actively pursuing or are evaluating for further development:



- a research agenda for enhancing the health of America's children, including examination of the basic behavioral and social science underpinnings of effective prevention programs.
- a portfolio of Federal social and behavioral science research.
- the evolving role and responsibilities of universities.
- the future of academic health centers in the context of health care reform.
- ethical issues in biomedical research, from embryo research to the use humans and animals in research.
- oversight of the President's Gulf War syndrome commission.
- support of science standards in education.
- food safety and nutrition.
- changes in immigration law as they relate to science and technology, particularly in academic settings.

Integrating some of this work with your concerns would likely be mutually beneficial. As one step, I request that the Associate Director for Science serve as a formal OSTP liaison with the DPC. I look forward to meeting with you.

cc: E. Moniz

THE WHITE HOUSE

WASHINGTON

August 13, 1996

INFORMATION

MEMORANDUM FOR THE PRESIDENT

FROM: Carol H. Rasco, Assistant to the President for Domestic Policy
Patricia S. Fleming, Director, Office of National AIDS Policy *PSF*

SUBJECT: HIV-related legislation

cc: The First Lady

Background:

The proposed HIV Prevention Act of 1996 (H.R. 3937), introduced August 1st by Rep. Tom Coburn (R-OK), has received some attention from conservative commentators recently. While it is unlikely to move this year, we thought it would be useful to summarize the Administration's position on the various issues this legislation raises.

As you know, Rep. Coburn was the author of legislation requiring mandatory HIV testing of newborns. This was opposed by most in the public health community, and a compromise was attached to the Ryan White CARE Act, which you signed in May, that would require mandatory testing of newborns in the year 2000 if states have not achieved a 95 percent acceptance rate of voluntary testing or have not reduced their rate of perinatal transmission by 50 percent. Reports from the International Conference on HIV/AIDS in Vancouver indicate that many health care providers are achieving high rates of voluntary testing and that the hoped for decline in perinatal transmission is beginning to be seen. (There already is a 10% decrease reported between 1994 and 1995.)

Key elements of H.R. 3937:

This new bill offered by Coburn would legislate in areas that have traditionally been left to public health professionals. In each area, the Centers for Disease Control and Prevention and state and local health departments already have the authority to act and in some cases they have. This is a case where rigidly legislated standards could result in inappropriate public health responses to a constantly evolving epidemic.

(1) *Requires reporting of the names of all individuals who test positive for HIV to state health departments.* This would be an intrusion on the discretion of the states to determine appropriate public health policies. Twenty-seven states already have names reporting policies and CDC provides additional funds to encourage states to adopt such a policy.

(2) *Requires states to have notification programs for sex and needle sharing partners of those*

who are HIV positive. This is unnecessary. The CDC already requires such programs as a condition of receipt of Federal prevention funds.

(3) Permits the involuntary testing of defendants in sexual assault cases -- both to inform the victim and as relevant information in a prosecution. Again, this is unnecessary. The Omnibus Crime Act of 1994 allows sexual assault victims to request HIV testing of an accused offender.

(4) Allows health care professionals to make HIV testing of patients a pre-condition for performing invasive procedures. This is counter to the current guidelines of the Public Health Service, which say it is critical that health professionals take universal precautions *for all invasive procedures regardless of the patient's HIV status.*

(5) Requires HIV positive health care workers to notify patients before performing invasive procedures. This policy already is reflected in PHS guidelines on HIV-infected health care workers; all states are required to adopt these policies.

(6) Establishes the sense of Congress that it is a felony for HIV positive individuals to engage in behaviors that an individual knows places others at risk, even if no transmission occurs. This is an issue for state criminal codes. There have already been numerous prosecutions under existing law in such cases.

Summary:

In summary, this legislation is unnecessary. Many of the provisions reflect existing policy while others would override the judgment of public health professionals and eliminate the flexibility they need to adapt policies based on new scientific knowledge.

None of Coburn's proposals would actually promote the behavior change necessary to reduce HIV transmission. Your Administration has made great strides in improving HIV prevention programs -- primarily through the introduction of a community planning process that gives states and localities much greater flexibility in their use of federal funds to target interventions based on the demographics of the epidemic in their jurisdiction. Funding has increased by \$85.1 million (or 17 percent) since 1993, and you have requested another \$33.5 million for FY 1997.

The legislation also fails to address the problem that far too many people with HIV do not know their status. The CDC estimates that only 62% of the 650,000-900,000 people with HIV in the U.S. do not know their status. With the growing consensus in the scientific community that the earliest possible intervention in the course of HIV infection is probably the most appropriate intervention, it will be critical to convince more people to take advantage of testing. This will require a combination of actions -- including stronger outreach to those at risk and a change in attitude toward testing by those most at risk to HIV. At the request of the Office of National AIDS Policy, the CDC and the Health Resources and Services Administration will be funding a project to examine how programs and policies related to encouraging people to seek HIV testing and care should be modified. This project is expected to be completed by the end of the year.

THE WHITE HOUSE

WASHINGTON

August 13, 1996

INFORMATION

MEMORANDUM FOR THE PRESIDENT

FROM: Carol H. Rasco, Assistant to the President for Domestic Policy
Patricia S. Fleming, Director, Office of National AIDS Policy *PSF*

SUBJECT: HIV-related legislation

cc: The First Lady

Background:

The proposed HIV Prevention Act of 1996 (H.R. 3937), introduced August 1st by Rep. Tom Coburn (R-OK), has received some attention from conservative commentators recently. While it is unlikely to move this year, we thought it would be useful to summarize the Administration's position on the various issues this legislation raises.

As you know, Rep. Coburn was the author of legislation requiring mandatory HIV testing of newborns. This was opposed by most in the public health community, and a compromise was attached to the Ryan White CARE Act, which you signed in May, that would require mandatory testing of newborns in the year 2000 if states have not achieved a 95 percent acceptance rate of voluntary testing or have not reduced their rate of perinatal transmission by 50 percent. Reports from the International Conference on HIV/AIDS in Vancouver indicate that many health care providers are achieving high rates of voluntary testing and that the hoped for decline in perinatal transmission is beginning to be seen. (There already is a 10% decrease reported between 1994 and 1995.)

Key elements of H.R. 3937:

This new bill offered by Coburn would legislate in areas that have traditionally been left to public health professionals. In each area, the Centers for Disease Control and Prevention and state and local health departments already have the authority to act and in some cases they have. This is a case where rigidly legislated standards could result in inappropriate public health responses to a constantly evolving epidemic.

(1) *Requires reporting of the names of all individuals who test positive for HIV to state health departments.* This would be an intrusion on the discretion of the states to determine appropriate public health policies. Twenty-seven states already have names reporting policies and CDC provides additional funds to encourage states to adopt such a policy.

(2) *Requires states to have notification programs for sex and needle sharing partners of those*

who are HIV positive. This is unnecessary. The CDC already requires such programs as a condition of receipt of Federal prevention funds.

(3) Permits the involuntary testing of defendants in sexual assault cases -- both to inform the victim and as relevant information in a prosecution. Again, this is unnecessary. The Omnibus Crime Act of 1994 allows sexual assault victims to request HIV testing of an accused offender.

(4) Allows health care professionals to make HIV testing of patients a pre-condition for performing invasive procedures. This is counter to the current guidelines of the Public Health Service, which say it is critical that health professionals take universal precautions *for all invasive procedures regardless of the patient's HIV status.*

(5) Requires HIV positive health care workers to notify patients before performing invasive procedures. This policy already is reflected in PHS guidelines on HIV-infected health care workers; all states are required to adopt these policies.

(6) Establishes the sense of Congress that it is a felony for HIV positive individuals to engage in behaviors that an individual knows places others at risk, even if no transmission occurs. This is an issue for state criminal codes. There have already been numerous prosecutions under existing law in such cases.

Summary:

In summary, this legislation is unnecessary. Many of the provisions reflect existing policy while others would override the judgment of public health professionals and eliminate the flexibility they need to adapt policies based on new scientific knowledge.

None of Coburn's proposals would actually promote the behavior change necessary to reduce HIV transmission. Your Administration has made great strides in improving HIV prevention programs -- primarily through the introduction of a community planning process that gives states and localities much greater flexibility in their use of federal funds to target interventions based on the demographics of the epidemic in their jurisdiction. Funding has increased by \$85.1 million (or 17 percent) since 1993, and you have requested another \$33.5 million for FY 1997.

The legislation also fails to address the problem that far too many people with HIV do not know their status. The CDC estimates that only 62% of the 650,000-900,000 people with HIV in the U.S. do not know their status. With the growing consensus in the scientific community that the earliest possible intervention in the course of HIV infection is probably the most appropriate intervention, it will be critical to convince more people to take advantage of testing. This will require a combination of actions -- including stronger outreach to those at risk and a change in attitude toward testing by those most at risk to HIV. At the request of the Office of National AIDS Policy, the CDC and the Health Resources and Services Administration will be funding a project to examine how programs and policies related to encouraging people to seek HIV testing and care should be modified. This project is expected to be completed by the end of the year.

Elizabeth --

Thanks for reformatting.

Jen Klein will know how to get it to the First Lady, and she should have a copy of this since she works this issue for her.

Jeff

Sent by hand to
Elizabeth 8/13/96

6/25/96

THE WHITE HOUSE

WASHINGTON

JUN 24 1996

96 JUN 25 09:22

MEMORANDUM FOR THE PRESIDENT

FROM: Carol H. Rasco, Assistant to the President for Domestic Policy
Patricia S. Fleming, Director, Office of National AIDS Policy

SUBJECT: New AIDS treatments

Protease Inhibitors.

There has been considerable press attention recently regarding the promise offered by a new class of AIDS drugs called protease inhibitors. Most of these drugs have been licensed by the FDA under accelerated approval policies, coming to market in record time -- as short as 43 days for one of the four protease inhibitors.

In short-term studies with small numbers of patients, these drugs have been shown to suppress the replication of HIV to extremely low or, in some cases, undetectable levels. If replication of HIV can be held in check, there is an expectation that HIV can soon be treated as a chronic manageable disease. The effect of these protease inhibitors is greatest when taken in combination with other drugs, such as AZT. It is believed that finding the right combination taken early enough in the HIV infection process might even result in eradication of the virus in some individuals or completely block transmission from mother to fetus, though this has not yet been proven.

New Research Questions.

It is hard to describe the sense of hope and optimism that has been restored among people living with HIV. This enthusiasm is also felt within the scientific community. But it is important to remember that this is based on *short-term* results. We do not yet know the *durability* of this effect, whether these early results are generalizable to all persons with HIV infection, and the actual impact of these drugs on reducing mortality among people with HIV. Nor do we know the answers to some very important clinical questions relating to the most effective use of these drugs -- such as when in the course of HIV infection is the best time to start therapy, how long individuals should be treated, what is the optimal combination of drugs, and when one might need to change therapies when resistance develops.

The NIH has committed to answering these clinical effectiveness questions as rapidly as possible. This capacity to respond to emerging scientific questions underscores the importance of our support for the enhanced programmatic and budget authority of the NIH Office of AIDS Research.

JUN 24 1996

Access to Treatments.

* We are also committed to assuring that the benefits of our \$1.4 billion annual investment in AIDS research are translated into access to care for people with AIDS. These new drugs are expensive; the cost of these new combination therapies can be as high as \$10-12,000 a year. This highlights the importance of clinical effectiveness research into how best to use these new treatment regimens.

On the same day that the FDA approved the first protease inhibitor, you sent to Congress a \$52 million FY 1996 budget amendment increasing funding for the AIDS Drug Assistance Program, bringing to \$142 million the Federal commitment to this program. This was included in the final continuing resolution. On June 19, HCFA sent a letter to all state Medicaid directors informing them that treatment with protease inhibitors is now the standard of care, creating the expectation that states must include them in their formularies. (As you know, Medicaid covers nearly 50 percent of people with AIDS.) As it has become clearer that these drugs are going to be widely used, we are also working with OMB to try to identify still more funding in FY 1997 for the AIDS Drug Assistance Program.

→ *Muntz*

August 16, 1995

MEMORANDUM FOR MARSHA SCOTT

FROM: Jeff Levi 
SUBJECT: Some random ideas

cc: Richard Socarides

I enjoyed our lunch and would enjoy helping you think through how the Administration can link up better with the gay/lesbian community. Here are some thoughts (not in any order of importance) that have come to mind:

- You can't do this alone. You need to show that there is a commitment at every level of this Administration. What you accomplished with VA is a good example of spreading that commitment. Almost every cabinet agency has something it can do to address gay/lesbian concerns -- even if its as simple as having nondiscrimination policies for employees and in access to programs.
- Each of the relevant cabinet agencies should have a designated gay/lesbian liaison in the Office of the Secretary. The liaisons should have several functions: they should be the community's contact when access or information is needed; they should help identify what accomplishments we have already achieved for the gay/lesbian community; they should help identify (with the help of the community and/or on their own) additional policy and programmatic steps that can be taken to improve the department's relationship to the gay/lesbian community.
- The goal here should be the routinization of inclusion of the gay/lesbian community in each department's outreach and in program design. (This is, in reality, the most important contribution we could make. Access and inclusion needs to be inculcated into the bureaucracy -- this takes time, but once in place will outlast our time in office and will be hard for anyone else to dismantle.) Examples include: any agency doing work on family and medical leave should reach out to one of the gay/lesbian organizations so our definitions are inclusive; domestic violence programs should address gay/lesbian domestic violence issues, etc.
- Let's start making lists. There is far more that has been accomplished than is compiled in one place or has been reported in the press. We also need to think broadly in terms of what is a gay/lesbian issue -- sometimes it is important, even if the g-word or l-word isn't in it. (Breast cancer work comes most immediately to mind.)

- Let's not be passive in defining what is the gay/lesbian agenda. I'm not saying that we lecture the community about what ought to be on their agenda; but we shouldn't be limited by the official agenda presented to us by the organizational leadership. There are several reasons for that: (1) we need to broaden the basis on which we are going to be held accountable; (2) we need to educate the community's leadership about some of the things that can be done through the creative use of executive authority. This translates into our taking some initiatives that aren't asked for (e.g., the cabinet agency liaisons and any issues that might be identified through that process).
- Let's not fall for litmus tests. I don't think there is any one issue that is make or break in terms of reaching the gay/lesbian community that we are likely to wrong on. In fact, it's the opposite -- the issues that are important to gays and lesbians are often broader than those identified by the organizational leadership. First, don't forget the women: on issues of choice, women's health, and breast cancer our record is good and on the second two HHS has done some very good and important outreach and inclusion specifically for lesbians. (This was actually work Patsy started before she left HHS.) Other issues I'd identify include: hate crime, domestic violence, substance abuse, mental health services, social spending in general, Medicaid cuts in particular, Social Security and Medicare (yes, all those SAGE groups around the country), and -- not least -- we can also claim AIDS.
- We can use the Republican hatemongering to remind the community that they can't afford to take a chance by staying home. If we lost the White House, we lose a chance at any moral leadership against people who just haven't gotten around yet to legislating more fiercely against gays and lesbians -- but they will. (If HRCF and NGLTF can build their political support by inspiring fear of Helms and Dornan, so can we.)
- We need to reach beyond the official leadership. This can be done in several ways:
 - Work with the gay press, even though it is limited. Increase *your* visibility -- so there is a personality associated with g/l issues and the Administration. This can be done easily by (a) cultivating a relationship with the Blade (you'll be amazed at how it is picked up around the country) and (b) working with the press office to get special press releases (or even a regular column) out to the gay press -- so many of them simply reprint the releases.
 - Do cable access. Almost every community of any size now has gay cable access shows. It's informal, it's a chance to put a human face on who's working this issue.
 - Talk to someone younger about this internet stuff. There's tons of gay bulletin boards, etc. -- but I know nothing about them.
 - Find ways to be supportive of community organizations and leaders. I'm thinking of the community centers that are in most cities around the country -- or the gay/lesbian hotlines or anti-violence programs. There are several ways of reaching

them: one would be to include them, when relevant, in larger meetings of volunteers or community service organizations of this kind; another would be to find a reason to call these folks together (e.g., Justice could do a meeting of anti-gay/lesbian violence projects). These people have more direct access and communication with the grassroots than national leaders will ever have (at least until the major networks really cover this issue).

- Find some surrogates. We need a standard stump speech -- for you and for surrogates. There are some people (and we should develop a list that is both national and regional) who, even though they have no official positions at the moment, carry great influence with certain constituencies. Ginny Apuzzo is a logical person in terms of an incredible capacity to motivate and explain the world to the community. Tim Sweeney is probably the best organizer in the business. Again, these are people who are not tied to organizational agendas and therefore may be able to help us define more clearly for the g/l community why support for a perhaps imperfect Administration is critical in the larger political context.

THE WHITE HOUSE

WASHINGTON

July 8, 1996

MEMORANDUM FOR THE PRESIDENT

THROUGH: Carol H. Rasco 

FROM: Patricia S. Fleming, Director, Office of National AIDS Policy 

SUBJECT: Progress Report and Recommendations of the Presidential HIV/AIDS Advisory Council

On behalf of the Presidential Advisory Council on HIV/AIDS, I am pleased to share with you the executive summary of the Council's first progress report on the Administration's efforts to implement the Council's earlier recommendations. I am also forwarding a new set of recommendations passed at the Council's April 26th meeting, but just prepared for transmission.

Progress Report on the Administration's Response to the Epidemic

In sum, the Council has high praise for your Administration's AIDS efforts. The Council said that "this Administration has clearly made an unprecedented and laudable investment of funding, human resources, and genuine personal commitment. We commend the President's dramatically heightened responsiveness to the urgency of this epidemic." The Council is especially pleased with the strong commitment to increased discretionary spending on HIV/AIDS programs (a 43 percent increase in the first three years), support for the Ryan White CARE Act, vigorous resistance to the proposed dismantling of Medicaid, and the support for a strong and well-funded NIH Office of AIDS Research.

The Council is mindful, however, of the continued need for still stronger responses to various aspects of the epidemic. It is especially concerned that you and the Vice President maintain your high level of visibility on AIDS, saying it is needed to "combat complacency and inaction, wherever they exist." It seeks continued support for increased funding for discretionary programs — making special mention of the Housing Opportunities for People with AIDS program, which has been level-funded at \$171 million in the last three years despite the growing problem of homelessness among people living with HIV. (Secretary Cisneros has a FY 1997 budget amendment of \$25 million pending at the Office of Management and Budget.)

The Council is perhaps most critical in the area of prevention. While praising new initiatives such as community planning of prevention programs and a new set of public service announcements, and the Administration's support for increased substance abuse treatment funding, the Council expresses concern about the level of integration between substance abuse prevention and HIV prevention (the Public Health Service is sponsoring a meeting on

this subject in August, responding to your request at the White House Conference on HIV/AIDS) and it expresses the widely held view that "Federal policy regarding needle exchange...programs [is] not consistent with current knowledge regarding the impact of such programs on HIV prevention."

The Council had praise for the Vice President's efforts to establish an ongoing dialogue between the pharmaceutical industry and others affected by AIDS research. The Council also praises your support for microbicide research, saying "such compounds offer significant promise in preventing HIV transmission in a cost-effective and culturally sensitive manner." Secretary Shalala, speaking at the International AIDS Conference in Vancouver, has announced a new initiative in that regard.

Finally, the Council is quite pleased with the Administration's leadership in enforcing the Americans with Disabilities Act's prohibition of discrimination against people with HIV, the successful effort to overturn the Dornan amendment requiring the expulsion of HIV-positive service members, and endorsement of the Employment Non-Discrimination Act (ENDA), which prohibits discrimination based on sexual orientation. However, the Council looks for more action in addressing mandatory HIV testing policies as a condition of employment within the Federal government in the Foreign Service, the Peace Corps, and the military. (The Office of National AIDS Policy has worked with the Job Corps to eliminate its mandatory testing policies and is now working with the State Department regarding the Peace Corps and Foreign Service.)

New Recommendations for Action

This new set of 17 recommendations does not cover major new ground. The Council asks that:

- You and the Vice President serve as National Co-chairs and attend the display of the AIDS Memorial Quilt in October. (This request is pending.)
- Efforts are made to ensure broader access to HIV counseling and testing, including anonymous testing. (The FDA has recently approved home collection kits for HIV testing, which should increase access and privacy; there are various efforts under way to reassess how we can increase the number of people who are tested, given the new therapies that are available.)
- Access to and information about alternative therapies be improved. (The NIH Office of AIDS Research and Office of Alternative Medicine are working collaboratively in this regard.)
- Increased funding be provided for the Housing Opportunities for People with AIDS program (as mentioned above, a budget amendment is pending at OMB) and that a coordinated housing strategy be created (the Office of National AIDS Policy will convene a

group to address this).

- Increased attention be given to behavioral research, especially with regard to women and minorities and more effective dissemination of research findings to the field be assured. (This is part of the 1997 plan of the Office of AIDS Research and has received increased attention from the Centers for Disease Control and Prevention.)
- Access to clinical trials for children be improved and that drug manufacturers rapidly assess the applicability of new treatments for children. (The reauthorized Ryan White CARE Act makes provisions for closer linkage between services and clinical trials; FDA Commissioner Kessler has committed to working on the issue of more rapid availability of pediatric treatments.)
- Support for vaccines research be increased, including international collaborative efforts. (The FY 1997 budget includes increased funding for vaccine research.)

PRESIDENTIAL

ADVISORY

COUNCIL ON

HIV/AIDS

Executive Summary Progress Report

JUNE 7, 1996

The AIDS crisis has generated more than its share of advisory committees. Far too often, these committees, commissions, and councils have issued recommendations and detailed reports that have simply gone unheeded.

To avoid this all-too-frequent pattern--and to highlight the frank and continuing interchange between President Clinton and his Advisory Council on HIV/AIDS--we believe it is important to distribute not only our recommendations to the Administration, but also the Administration's responses, with our candid, independent evaluation of their responses.

This first progress report will be followed by others. Because the Council's evaluation process will constantly be evolving, this report is truly a work in progress, as are all of the efforts of the Council itself.

The differences between this report and those issued by previous national and/or Presidential councils addressing the AIDS crisis are illustrative of the differences between the councils themselves. President Clinton's AIDS Council, more than any of its predecessors, reflects the experience and expertise of those most impacted by the epidemic. Forty percent of the Council's members are HIV-positive. One-half are lesbian, gay, or bisexual. One-third are people of color. All Council members have personally been affected by the epidemic.

This Council is different in other ways as well. The Council has had unprecedented access to the President, top-level White House staff, and cabinet officials. To a degree that has surprised many Council members, Administration officials have rapidly addressed and implemented many of our recommendations. Even when the Administration has not been as responsive as we would have liked, our views as a Council, and those of others infected with or affected by HIV, have been heard and taken seriously.

While our access has been unusually broad, the scope of our mission has been more narrow than that of our predecessors. Our purpose has not been to advise the Nation, or Congress, but to advise the President on what his Administration can and should do to stop the spread of the epidemic; to find a cure and vaccine for HIV; to provide the best possible treatment and care to those who are infected; and to end HIV-related discrimination and intolerance. To augment that advisory role, the Council has established a process, which includes ongoing monitoring and evaluation, to ensure that appropriate Administration departments and agencies respond to our recommendations and are continuously held accountable for their responses.

We recognize that our work to date has yet to address a number of key issues. We encourage suggestions for future recommendations and welcome continued community input, especially from people living with HIV and their advocates. The Council believes that working with this Administration, we now have a significant opportunity to make a positive impact on national HIV/AIDS policy.

Overall, the Council has been impressed with the Administration's strong commitment to key items such as increased funding for the Ryan White CARE Act, vigorous resistance to the proposed dismantling of Medicaid, and support for a strong and well-funded Office of AIDS Research (OAR) at the National Institutes of Health (NIH). We believe that it is remarkable and laudable that the President has, during an era of flat Federal funding, helped to achieve a 43 percent increase in discretionary Federal AIDS funding during his first three years in office. However, the Council is disappointed with the Administration's lack of action on some of our recommendations, particularly regarding some of the more politically charged aspects of prevention and discrimination where greater courage and leadership are required.

This report contains our first two sets of recommendations (issued in July and December of 1995), the Administration's action in response to each recommendation, our evaluation of this response, and our proposed followup. It also includes our third set of recommendations, made in April 1996. We expect, in future months, to update these evaluations and to assess and distribute the Administration's responses to our third set of recommendations as well. We have developed recommendations in five subject areas: Presidential leadership, research, prevention, services, and discrimination. This report is presented accordingly.

Leadership:

The President's personal leadership and commitment in the battle against AIDS is clearly unmatched by his predecessors. By rapidly convening a national summit on AIDS at the Council's request, and by following our recommendation that he discuss HIV/AIDS with other broad audiences, the President has sent a much-needed message about the importance of the issue of AIDS to the American people. However, more visible leadership and direct involvement by the President, Vice-President, and cabinet officials are still needed to combat

complacency and inaction wherever they exist, both among the American people and within the Government. For years, various groups have called for a national plan on HIV/AIDS, and this Administration has expressed its willingness to develop such a plan. However, after almost four years, a National Plan on HIV/AIDS remains in development. The Council eagerly awaits the release of this plan.

Research:

The Council is pleased with the strong commitment made by the Administration in attempting to reorganize all HIV/AIDS research within the various Institutes of the NIH under the leadership and direction of the OAR. We believe that such reorganization ensures a more coordinated, efficient, and ultimately successful research endeavor. The President's strong and consistent support for the OAR is to be commended. However, action by the Congress in FY 1996 makes clear that further work is required to ensure that OAR can exercise its full budget authority in FY 1997 and beyond. The Council is also pleased by the rapidity with which the President called upon Vice President Gore to commence an ongoing dialogue between industry leaders and Government scientists in an attempt to expedite a more coordinated approach to drug, vaccine, and microbicide research and development. Such efforts must be continued, with inclusion of additional constituencies, including the AIDS-affected community, academic scientists, and others. The strong support articulated by the President in the area of microbicide research is greatly appreciated, as we believe such compounds offer significant promise in preventing HIV transmission in a cost-effective and culturally sensitive manner. Further investment will be required in the years ahead. The Council appreciates the Administration's concerns for inclusion of women, children, and all disenfranchised groups infected by HIV into clinical research studies. We look forward to specific actions to ensure that pediatric and gender-specific plans be required at the time of any new drug application to the Food and Drug Administration. In addition, future recommendations will be forthcoming from the Council in the areas of vaccine research and development and in behavioral research.

Prevention:

We were pleased that the President announced during his December 1995 White House Conference on HIV/AIDS his goal of ensuring an annual decrease in the number of new HIV infections in the United States of America. However, the Council continues to have grave concerns that much of the Federal HIV prevention strategy is underdeveloped, lacks focus, and is overly timid. We believe that a bold and carefully conceived plan, including generation of necessary political and societal support, is essential for achieving effective prevention strategies. The Council looks forward to working with the President and his Administration to develop such a plan and support for it.

The Council commends the Administration for its support of the prevention community planning process; its development of more direct public service announcements that discuss condoms and that seek to target high-risk populations such as young people of

color and gay and bisexual men; and its opposition to Congressional efforts to decrease access to substance abuse prevention and treatment programs. However, the Council continues to believe that Federal policy regarding needle exchange and the lack of integration/coordination of HIV prevention strategies with substance abuse treatment programs are not consistent with current knowledge regarding the impact of such programs on HIV prevention. Further, the Council supports increased priority for behavioral research and rapid distribution of key findings to front-line HIV prevention programs.

Services:

The Council is pleased with the Administration's continued support for increased funding for the Ryan White CARE Act. In particular, we applaud the Administration's leadership role in securing a \$105 million increase in funding for FY 1996. However, while the President's FY 1997 budget recognizes the continued need for increased AIDS funding, it still does not adequately respond to the growing need for services. Of particular concern to the Council is the Administration's failure to acknowledge in its FY 1997 budget the urgent need for increased funding for AIDS-specific housing through the Housing Opportunities for People with AIDS (HOPWA) Program. Since a growing proportion of people living with HIV/AIDS are homeless or at risk for homelessness, and the needs of this population continue to grow more complex, the Administration must make AIDS housing a higher priority.

The Council commends the President for his consistent leadership in defending the Medicaid program, which is the sole source of health care for nearly 50 percent of PWAs. The Administration has also taken a number of initial steps to develop national guidelines for managed care and Statewide Medicaid waivers, and is committed to using its limited administrative authority to encourage States to offer the broadest possible range of HIV/AIDS services and therapies through the Medicaid program. The Council urges the establishment of more formal managed care guidelines; rejection of managed care waiver applications that provide inadequate care for persons with HIV/AIDS; and the development of policy guidance related to coverage of the newly approved protease inhibitors. The Council cannot overemphasize the importance of the Administration's continued vigilance in this area, as well as in the area of health care provider training and education.

Discrimination:

The Administration's approach in this area has paradoxically been both notably strong and notably weak. The Administration's enforcement of the Americans with Disabilities Act, and the President's public words opposing discrimination based on HIV, race, sexual orientation, and other factors have been valuable and important. The Council particularly commends the President's real leadership in overturning the malicious Dornan Amendment, which would have expelled service members with HIV from the military and denied medical benefits to their families. We also strongly commend his support for the Employment Non-Discrimination Act, which would forbid employment discrimination based on sexual

orientation. The Council is profoundly concerned, however, that despite the Administration's positive words, the Federal Government is itself engaged in officially sanctioned HIV/AIDS-related employment discrimination in some departments. Thus, while we commend the Administration for reversing the policy of mandatory HIV testing and discrimination in the Job Corps, we urge the Administration to move swiftly to eliminate similar programs in the military, the State Department, and the Foreign Service, and to revise its arbitrary guidelines governing HIV-infected health care workers to bring them into accord with current public health consensus.

Conclusions:

In trying to assess the Administration's efforts to respond to the AIDS epidemic, the Council, and all Americans, are confronted with a difficult question: How do we judge and to what do we compare this Administration's efforts? When compared with that of previous administrations, this Administration has clearly made an unprecedented and laudable investment of funding, human resources, and genuine personal commitment. We commend the President's dramatically heightened responsiveness to the urgency of this epidemic. However, when compared with what truly needs to be done, this Administration's efforts are still insufficient. We must not become complacent, given the ongoing nature of this epidemic. The time for increased commitment, along with moral and political courage, is now.

Members:

R. Scott Hitt, *Los Angeles, CA*
Stephen Abel, *New York, NY*
Terje Anderson, *Burlington, VT*
Regina Aragón, *San Francisco, CA*
Mary Boland, *Newark, NJ*
Nicholas Bollman, *San Francisco, CA*
Tonio Burgos, *New York, NY*
Jerry Cade, *Las Vegas, NV*
Robert Fogel, *Chicago, IL*
Debra Fraser-Howze, *New York, NY*
Kathleen Gerus, *Sterling Heights, MI*
Edward Gould, *Encino, CA*
Phyllis Greenberger, *Washington, DC*
Bob Hattoy, *Washington, DC*
B. Thomas Henderson, *Austin, TX*

Carole laFavor, *Minneapolis, MN*
Jeremy Landau, *Santa Fe, NM*
Alexandra Levine, *Los Angeles, CA*
Steve Lew, *San Francisco, CA*
Helen Miramontes, *San Francisco, CA*
Altagracia Perez, *Los Angeles, CA*
Michael Rankin, *Oakland, CA*
H. Alexander Robinson, *Washington, DC*
Debbie Runions, *Nashville, TN*
Benjamin Schatz, *San Francisco, CA*
Richard Stafford, *Minneapolis, MN*
Denise Stokes, *Stockbridge, GA*
Sandra Thurman, *Atlanta, GA*
Charles Quincy Troupe, *Jefferson City, MO*
Bruce Weniger, *Atlanta, GA*

Copies of the full Progress Report can be obtained by calling the National AIDS Clearinghouse at 1-800-458-5231.

**REPORT THREE
APRIL 26, 1996
CONTINUED STEPS FOR PRESIDENTIAL
ACTION**

PREAMBLE

During the past few months, this Council has witnessed a heightened intensity by the Administration in the battle against HIV/AIDS. This renewed commitment has directly and indirectly contributed to a number of successes including increased funding for the Ryan White CARE Act, continued firm support for Medicaid and the repeal of the highly discriminatory provision of the Department of Defense reauthorization bill which would have irrationally and unfairly discharged HIV-positive military personnel.

While we are extremely encouraged by these victories, much remains to be done. It is imperative that we continue the momentum generated by these victories and redouble our efforts in the fight against HIV/AIDS.

At this time the Council offers its third set of recommendations.

A. LEADERSHIP

We urge the President and Vice President to accept the invitation to be National Co-chairs as well as attend the display of the AIDS Memorial Quilt in Washington, DC, this October.

B. SERVICES

1. The Administration should direct the Centers for Disease Control and Prevention (CDC) to take affirmative steps to ensure that CDC-funded HIV counseling and testing programs in all States and territories offer the option of anonymous testing that is geographically accessible and available to all who wish to be tested anonymously.

2. The Administration should issue an Executive Directive to the Director of the Office of Personnel Management (OPM) to add nutritional foods to those medical expenses covered under the Federal Employees Health Benefits Program, a fee-for-service plan.
3. The Administration should direct the Social Security Administration (and other appropriate agencies) to include and add the following reminder to the Social Security Notice of Disability Award: (specific wording to be developed by the Administration - this is our proposal).

IF YOU HAVE EXTENDED YOUR MEDICAL INSURANCE UNDER COBRA, YOUR EMPLOYER MUST BE GIVEN A COPY OF THIS LETTER NO LATER THAN----- (DATE OF LETTER PLUS 60 DAYS), AND SOONER IN MANY CASES, IF YOU ARE TO TAKE FULL ADVANTAGE OF YOUR COBRA INSURANCE. YOU MAY BE ELIGIBLE FOR AN ADDITIONAL 11 MONTHS OF COVERAGE AFTER THE FIRST 18 MONTHS AFTER YOUR COBRA COVERAGE HAS EXPIRED.

4. The Administration should recommend a substantial increase in the NIH Office of Alternative Medicine (OAM) budget for FY 1997.
5. The Administration should direct Medicaid and Medicare to determine which alternative/complementary therapies can be reimbursable immediately and directly to qualified health care providers. Medicaid and Medicare also should outline a plan for investigating whether other therapies are reimbursable directly to qualified medical and paramedical practitioners.
6. The Administration should direct OAM and OAR to act in concert to convene a working group consisting of representatives from countries doing alternative therapy research, HIV alternative therapy practitioners, conventional researchers, representatives from private insurance and pharmaceutical companies, and HIV-positive people using alternative therapies, to investigate new and innovative ways to research and make available to people therapies that anecdotally are being identified as treatments for HIV.

We acknowledge the Administration's achievement in obtaining level funding for housing to date. However, given the expanding epidemic level funding in the long run is not going to meet the developing needs.

7. The Clinton Administration should address the chronic underfunding of Housing Opportunities for Persons with AIDS (HOPWA) in FY97 and FY98 by expanding funding to keep up with the growing demand for housing and related support services in existing HOPWA jurisdictions, as well as the increase in the number of eligible jurisdictions overall. In particular, given the gravity of the situation, the President should include supplemental funds for HOPWA in any budget amendment or emergency supplemental funding request that he may submit to Congress in the next year.
8. The Administration should demonstrate strong White House leadership and commitment to AIDS housing by convening a series of high-level White House and cabinet level meetings by the Fall of 1996 to develop a coordinated, comprehensive HOPWA Revitalization Plan. At a minimum, these meetings would include representatives from Housing and Urban Development (HUD), Health and Human Services (HHS), Health Resources and Services Administration (HRSA), Office of Management and Budget (OMB), and the White House. These meetings, and the resulting HOPWA Revitalization Plan, should establish means and timetables to achieve full funding and timely reauthorization of HOPWA as a distinct HUD program, as well as improved interagency coordination and integration of AIDS housing services with other AIDS-related programs.

C. PREVENTION

1. We recommend that the President direct the Secretary of HHS, with the NIH, OAR, and the CDC, to develop a coordinated and comprehensive prevention science agenda that includes biomedical, behavioral, and social science interventions.
 - A. The NIH and OAR must make an increased commitment to research on sexual behavior and sexuality as indicators of high risk for HIV transmission. Basic research on the underlying mechanisms for sexual and drug-using behavior clearly related to HIV transmission must immediately be solicited and supported at increased levels.

- B. Due to the paucity of data, increased efforts should be made and funded to accurately assess the risk of oral sex. Studies should be funded to assess the potential safety and efficacy of anal usage of insertive condoms.**
- 2. The OAR should develop research initiatives that seek to identify successful models for behavior change in minority populations. Within communities of color, this population-based research should focus especially on women and gay men, the growing edge of this epidemic.**
 - 3. The limited availability of methadone and other effective substance abuse treatment modalities in many areas, especially rural regions, poses a major challenge for HIV prevention among needle users. The Secretary of HHS should order a formal review of federal regulations concerning access to methadone and other effective substance abuse treatment modalities, to consider ways in which those regulations might be changed to allow greater access to methadone without an adverse impact on substance abuse treatment.**
 - 4. The President should instruct the Secretary of HHS to ensure that federally funded research on HIV prevention interventions include specific mechanisms for rapid dissemination of findings, including resources to allow replication of programs with demonstrated effectiveness.**
 - a) Allocate funding for training of front-line prevention workers in application of relevant research findings.**
 - b) The Public Health Service should be directed to establish formal mechanisms for dissemination of accurate and up-to-date information to community and consumers in a way that is rapid, easily understandable, and widely accessible.**

D. RESEARCH

As the number of children infected with HIV continues to grow, it is increasingly important to assure their access to experimental therapies for HIV infection, and to newly licensed medications to treat the virus and the various opportunistic illnesses which may ensue. Additionally, ongoing research should be conducted to identify more efficacious interventions to decrease vertical transmission of HIV from mother to infant. Finally, despite a decreased incidence of HIV/AIDS among children, it is imperative that clinical trials for HIV-infected children continue to receive a high priority and adequate funding.

- 1. The Administration should require OAR to maintain an ongoing review of the numbers of children enrolled in NIH sponsored clinical trials, to ensure compliance with the right to access.**
- 2. The Administration should instruct the Food and Drug Administration (FDA) to place contingencies for full licensure on new drugs until safety and pharmacokinetic studies in children are completed and until the pediatric plan for the drug in question is presented by the sponsoring company.**

The consensus among scientists is that an effective vaccine to prevent AIDS is possible. Approximately 40,000 to 60,000 Americans still become newly-infected with HIV each year, despite extensive efforts to reduce risky human behaviors. The principal long-term and most cost-effective solution for the epidemic is a preventive vaccine, for which a high-priority, expedited research and development program is justified. Suitable organizational and administrative structures would facilitate such a program. Collaboration and cooperation are necessary between various governmental agencies, non-profit entities, academia, international organizations, industry and the public. International participation is essential.

The Presidential Advisory Council on HIV/AIDS is examining this issue closely, and will supplement the following initial recommendations as events ensue in this area, including progress in the ongoing efforts of the OAR to reform priorities and restructure AIDS research at the NIH.

- 3. Research and development for AIDS vaccines should receive a substantial increase in the proportion of funds devoted to it in the Federal biomedical research budget for AIDS.**
- 4. All agencies of the U.S. Government with experience in various phases of vaccine research and development -- including the NIH with its lead role in basic research, DOD, FDA, CDC, and the VA -- have valuable roles to play and should contribute their unique institutional expertise, capabilities, resources, and collaborative relationships in a coordinated and expedited Federal effort towards the common goal to produce an effective preventive vaccine for AIDS. In addition -- recognizing the need for public-private partnerships and the involvement of other nations in a global effort, and the relative advantage of private-sector, non-profit organizations in rapidly filling gaps in targeted vaccine research, product development, and testing -- the concept of an independent international AIDS vaccine initiative should be strongly encouraged and developed.**