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Crosswalk with PAC [Presidential Advisory Council] Recommendations - Fall 1996

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Pls find the draft recommendations crosswalk for the Council. Comments please.

Jane

Draft Draft

MEMORANDUM FOR THE PRESIDENTIAL ADVISORY ON HIV/AIDS (PACHA)

FROM: Patsy Fleming

SUBJECT: Recommendations Crosswalk for National AIDS Strategy

Please find attached the Recommendations Crosswalk for the National AIDS Strategy. ^{identifies} This document ~~intended to help the Advisory Council find where the~~ issues raised through ⁱⁿ ~~PACHA~~ ^{spell out} recommendations are addressed in the Strategy. Additional information about can also be found in the Administration's responses to the Advisory Council's recommendations.

If you have any questions please do not hesitate to call ^{me} ~~myself~~, Jeff Levi, or Jane Sanville at 202-632-1090.

Thank you for assistance in developing the first-ever National AIDS Strategy.

that

Draft Recommendations Crosswalk --

PACHA RECOMMENDATIONS - 7.28.95	NATIONAL AIDS STRATEGY (NAS)
I.A.1. The President himself must engage the American people through a National Summit that encompasses the scientific, medical, social, and political aspects of the AIDS epidemic. The summit, which should be held by the end of this year, should consider the impact of race, culture, poverty, disability, region, gender, sexual orientation, and age on our ability to develop an effective national AIDS strategy.	The discourse that began with the White House Conference on HIV and AIDS has continued, and the concerns raised by conference participants and in the follow-up regional briefings have informed the development of the Strategy. (p. 4)
I.A.2. The President should then proceed with an address declaring the battle against HIV a national priority and laying out his vision for ending the epidemic.	The President has outlined six national goals to guide our efforts. (pp. 3,6)
I.B.1. The President should continue his support of the Ryan White CARE Act and should endeavor to prevent the Congress from attaching unnecessary funding restrictions. He should also continue to vigorously support funding levels for the Ryan White CARE Act that <u>a</u> responsive to the rising caseloads and costs of delivering comprehensive services to people with HIV/AIDS and make the CARE Act a budget priority.	The Administration is committed to preserving funding the CARE Act programs (pp. 22-24).
I.B.2. The President must maintain a strong commitment to the entitlement status of the Medicaid program, including a willingness to veto any legislation that inadequately funds or transforms Medicaid into a block grant.	The Administrations's past and future commitment to preserve Medicaid funding is outlined on pages 22-24.
I.B.3. The President should continue to demonstrate strong support for the Housing Opportunities for Persons with AIDS (HOPWA) and other Federal housing programs that serve people living with AIDS. The President should make housing for people with AIDS (PWAs) and FY 1997 priority.	The Administrations's past and future commitment to preserve HOPWA funding is outlined on pages 22-24.

I.C.I. The President should make HIV prevention an investment priority during budgetary decision-making.	The President has proposed significant increases for HIV prevention in the FY 1997 budget (p. 10) and has identified five areas where we should focus future efforts (pp. 11-15).
I.D.I. The President should continue to show strong support for a coordinated Federal approach to HIV/AIDS research, including continued support for the Office of AIDS Research (OAR).	Support for a strong leadership and coordination of Federal research is a central element of the research section (p. 18).
I.E.I. In talking publicly about HIV, the President should vigorously speak out against HIV-related discrimination and condemn prejudice based on race/ethnicity and sexual orientation, which damage our efforts to combat AIDS. The President should strongly and visibly oppose any amendments to HIV-related legislation that are designed to divide the American people along line of sexual orientation, substance abuse history, race/ethnicity, or other factors.	The fourth goal of the National AIDS Strategy is to fight discrimination on all fronts including enforcing rights, protecting workers, opposing discriminatory legislation, and providing visible leadership (pp. 3, 6, 27-29).



PACHA RECOMMENDATIONS 12.8.95	NATIONAL AIDS STRATEGY
II.A.1 During his State of the Union Address, the President should renew his commitment to prevention/new infections, caring for people now living with HIV/AIDS, and finding a cure, a vaccine, and effective treatments for HIV. The President should, during this address, announce the immediate release of his updated national strategy on AIDS.	These goals are articulated throughout the NAS. Preventing new infections is one of the national goals (pp. 3,6) requiring multiple approaches (pp. 9-15). Caring for people now living with HIV is the third national goal (pp. 3,6) requiring an investment in care and services (pp. 22-25). Finding a cure, vaccine, and effective treatments is the first national goal (pp. 3,6) requiring commitment in four major areas (pp. 17-21).
II.A.2. To further accomplish the goals President Clinton outlined at the WHCA, the Clinton/Gore Administration should ensure that key Cabinet Secretaries initiate and maintain regular face-to-face meetings with HIV service providers, people living with HIV/AIDS, and their advocates to ensure consistent and ongoing communication and partnership with community members on the front lines of the AIDS epidemic.	The NAS is intended to be a living document that will require regular updating and regular consultation from the infected and affected communities. Developing an implementation plan and updating goals will require an ongoing dialogue and collaborative efforts between the public and private sectors (pp. 3-4).
II.B.1 Continue to support and defend the entitlement status and funding for Medicaid and Medicare, and continue to oppose any efforts to restrict eligibility and services for people living with HIV/AIDS.	The Administrations's past and future commitment to preserve Medicaid and Medicare funding is outlined on pages 22-24.
II.B.2 Direct that any waivers granted to States under the Medicaid program ensure access to a comprehensive continuum of care for people living with HIV/AIDS. To implement this policy, the President should direct the HCFA to establish national criteria by which to assess State waiver applications and to ensure that these criteria be consistent with current health care knowledge. These criteria also should be consistent with the provisions of the Americans with Disabilities Act (ADA), and State plans should be reviewed for this purpose by the HHS Office of Civil Rights.	The Administrations's commitment to preserve Medicaid funding is outlined on pages 22-24. (HCFA is currently reviewing all State Medicaid managed care waiver proposals to ensure continuity of care. See Administration's response to PACHA recommendations.)

II.B.3 Direct HCFA to ensure that State Medicaid programs cover HIV testing and counseling.	The Administrations's commitment to Medicaid is outlined on pages 22-24. The importance of the integrating HIV prevention -- including counseling and testing -- into primary care substance is discussed on p. 14. (HCFA is currently reviewing all State Medicaid managed care waiver proposals to ensure provision of a full range of services. See Administration's response to PACHA recommendations.)
II.B.4 Direct HCFA to report to the Council, at its next meeting, possible strategies to address the need to ensure that all Food and Drug Administration (FDA) approved drugs are covered under State Medicaid plans, even when prescribed for "off-label" indications. These strategies should address both policies and vigorous enforcement mechanisms.	Not directly discussed in the NAS -- the current Federal drug rebate law requires States to provide coverage for off-label uses of FDA-approved drugs, including those used in the treatment of HIV/AIDS.
II.B.5 The Administration should direct these Federal agencies that either finance or administer health care services (including but not necessarily limited to HCFA, the Department of Veteran's Affairs [VA], the Department of Defense, and the Department of Justice Bureau (for Prisons) to develop oversight guidelines for HIV managed health care programs. This will also require effective regulatory enforcement mechanisms.	Ensuring quality of care in Federally-supported programs is a major concern (p. 25).
II.B.6 The Administration should direct HRSA to develop a coordinated agency-wide approach that provides effective education, training, and technical assistance to HIV/AIDS providers and AIDS service organizations on health care management issues. Such an approach should include active participation by the private sector.	Improving program coordination (pp. 25, 35), providing guidance to improve quality of care (p. 25), and increased education and training (p. 34) are important steps to improving care. Developing an effective implementation plan for the strategy will require input from a variety of sectors, including the private sector (p. 3-4).
II.B.7. Before complementary therapies are widely used, the President should direct all appropriate agencies to support investigations of the efficacy of complementary therapies and provide increased financial support for this effort. Therapies shown to have benefit should be reimbursed under Medicaid.	The Report of the NIH AIDS Research Program Evaluation Task Force included a recommendation on complementary therapies. OAR will be working on implementing these recommendations in the year ahead (p. 18).

II.B.8. The President should continue to support full funding to a national network of AETC's, and direct HRSA to ensure that the work of the AETCs is coordinated with the community providers and planning groups.	The importance of maintaining the AETCs is discussed on page 34.
II.B.9. The Administration should direct HRSA to review and report to the Council at its next meeting the effectiveness of the Bureau of Health Professions' education activities specific to HIV/AIDS.	Not directly relevant to the NAS. However, the general issue of professional education is discussed on pages 25 and 34.
II.C.1. The CDC and the President should direct the Secretary of HHS to produce an annual estimate of HIV incidence based on seroprevalence studies and to work to ensure a reasonable relationship between epidemiological trends and CDC prevention funding. This report should specifically examine the demographic characteristics and geographic distribution of populations that experience disproportionate increase in new infections. - o The CDC should issue to the President an annual estimate of HIV incidence based on seroprevalence studies that provides a geographic analysis of the populations where there is a continuing disproportionate increase in new HIV infections. - o The President should direct the Secretary of HHS to ensure that resources are allocated to accomplish this task. - o The President should ensure that funding is adequate and responsive to the epidemiological trends, needs, and prevention infrastructure of affected communities.	Improving our understanding of trends in the epidemic, and targeting appropriate resource services in response to these changes, is discussed on pages 11-12.

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II.C.2. o The President should direct the CDC to develop a behavioral surveillance mechanism that will provide an analysis of patterns in risk-taking behavior; and o The President should direct the CDC to join with the National Institute on Drug Abuse (NIDA) and other relevant agencies to institute surveillance methods for detecting patterns of risk-taking behaviors in populations that show a continuing disproportionate increase in AIDS cases; and o He should direct the Secretary of HHS to coordinate the planning of an early warning system and ensure its ongoing use.	Understanding who is becoming infected and through what behaviors is critical to designing effective HIV prevention programs as well as targeting appropriate service resources (pp. 11-12).
II.C.3. The administration should pursue a comprehensive strategy to decrease HIV transmission related to injection drug use, which accounts for at least 50% of new HIV infections. In addition, high-risk sexual behavior while under the influence of drugs and/or alcohol accounts for another significant percentage of new cases of HIV disease. Strategies must explicitly address the sharing of injection drug use paraphernalia, as well as the high-risk sexual behavior associated with drug and/or alcohol use.	The importance of addressing substance abuse and integrating HIV prevention into substance abuse treatment is addressed on page 13. Issues related to enrolling more substance abusers into drug treatment, reducing the availability of illegal drugs, and preventing HIV transmission from the use of contaminated injection equipment and discussed on pages 13-14.
II.C.3.a. Increase access to effective substance abuse prevention and treatment research by: o Opposing congressional efforts to cut SAMHSA and other Federal funding for drug abuse treatment and prevention programs in FY 1996 appropriations. o Restoring budget requests for SAMHSA and other Federal funding for drug abuse treatment and prevention programs to at least the FY 1995 levels.	The President has fought hard for increased funding for substance abuse treatment. The importance of supporting substance abuse treatment is addressed on pages 13-14.
II.C.3.b. Revise the Department of Justice Model Drug paraphernalia Act, which serves as a model for State drug paraphernalia laws, to make it consistent with current reports, studies, and data relating to the access to sterile syringes as an effective intervention to counter HIV transmission among IDUs.	See Administration's response to PACHA recommendations.

II.C.3.c. The President should direct the Secretary of HHS to provide a recommendation (within 90 days) regarding the impact of needle-exchange programs on HIV infection and substance abuse. The recommendation should be based upon current reports, studies, and data on needle-exchange programs, and should develop and execute a plan to carry out the recommendations and indicate what programs and demonstration projects will be started or expanded.	Both CDC and NIH are supporting research to identify characteristics of successful needle exchange programs (p. 14). See also Administration's response to PACHA recommendations.
II.C.4. The President should reaffirm his support for community-based planning for prevention activities.	Strengthening community-based planning is one of the five major elements needed to meet the nation's prevention goal (pp. 11-13).
II.C.4.a. Direct the CDC to maintain HIV prevention programs independent of any consolidated grant programs, including the currently proposed Performance Partnership Grants.	Strengthening community-based planning is one of the five major elements needed to meet the nation's prevention goal (pp. 11-13). Also see Administration response to PACHA recommendations.
II.C.4.b. Direct the CDC to continue direct funding to community-based organizations.	CDC's prevention projects, many in partnership with States, local governments, and community-based organizations, have demonstrated that prevention programs are most effective when designed and implemented at the local level (p. 10). See Administration response to PACHA recommendations.

II.C.4.c. Direct the CDC, with the assistance of existing national minority organizations and other appropriate partners, to structure its technical assistance programs to address the prevention program development and infrastructure needs of populations that are currently experiencing an continued disproportionate increase in new infections.	The Administration has focused on the need to provide technical assistance on a number of fronts. First, the community planning process will require ongoing technical assistance from the CDC (p. 13) with particular attention to vulnerable populations (p. 15). In addition, as part of the Federal government's compliance with the Government Performance and Results Act, CDC and SAMHSA will continue to work with grantees to develop appropriate performance measures for HIV prevention programs (p. 12). And finally, the PHS will take the lead in ensuring that models of effective prevention interventions reach people developing and implementing prevention programs (p. 35). Also see Administration's response to PACHA recommendations.
II.C.5. Direct the Director of the Indian Health Service (IHS) to develop a comprehensive AIDS prevention and care plan for Indian Country (within 90 days) with the input from consumers of IHS services.	The Administration is committed to improving the care and prevention services in all Federally-sponsored programs (p. 25). Also see Administration's response to PACHA recommendations.
II.D.1. The Vice President's leadership and technological expertise should be sought to bring together the resources and expertise of various Government agencies, the private sector, community groups, and other nations in the effort to develop HIV vaccines and microbicide and to "reinvent" the Government's involvement in the development of these products.	The support of the Vice President has been instrumental in founding the Forum for Collaborative HIV Research (pp. 17,19,20) and developing the first Federal Plan for Biomedical Research on HIV and AIDS (pp. 17,18). His efforts will continue in the areas of microbicides and vaccines (p. 19).
II.D.2. The priority for funding by the OAR for microbicide research and development, as well as such funding within CDC, must be increased substantially, with a concomitant increase of full-time equivalents (FTE's) allocated for this priority.	The Administration is committed to advancing microbicide development (p. 19).
II.D.3. The Government should develop mechanisms to increase the pool of investigators in microbicide research and development, especially those involved in biomedical and behavioral aspects.	The Administration is committed to advancing microbicide development (p. 19) and increasing future support for basic research on behavior, interventions, social marketing, and program evaluation (p. 12).

II.D.4. In HIV/AIDS clinical research, the NIH must ensure the early and fundamental involvement of behavioral and social scientists in the process of initial study development, design, and implementation.	In response to the Report of the NIH AIDS Research Program Evaluation Task Force, NIH will be developing a comprehensive HIV prevention science agenda, combining biomedical and behavioral perspectives (p. 18). See also Administration's response to PACHA recommendations.
II.D.5. HHS should develop ongoing mechanisms to ensure the rapid translation of breakthrough research findings into clinical practice.	An important element in the fight against HIV and AIDS is ensuring that research advances are translated into improved HIV prevention programs and better care for HIV-positive persons. An entire section of the NAS focuses on the translation of research advances into practice (pp. 33-35).
II.D.6. A public health policy consensus panel should be convened by the Public Health Service by the end of April 1996 to assess the possible efficacy of available spermicide (e.g. nonoxynol-9) and other licensed products (e.g. chloerhexidine, benzalkonium chloride, diaphragms) to be used in "harm reduction" algorithms to decrease sexual transmission of HIV. The panel should include senior public health policy officials (CDC, FDA, HHS Secretary's Office), research agencies (NIH), community groups (women's health research advocates, commercial sex workers, interested foundations), academia, and industry. The meeting should also feature a review of the entire status of anti-HIV microbicide research.	The Administration is committed to advancing microbicide development (p. 19). See also Administration's response to PACHA recommendations.
II.D.7. The Council asks the FDA to comment by January 31, 1996, upon the proposed FDA regulations that require inclusion of women in all clinical trials of drugs for treatment of HIV/AIDS in which there is no known evidence of reproductive toxicity. When such toxicity has been documented, alternatives that allow the inclusion of women should be provided.	The Administration is committed to an increased focus in Federal research on vulnerable populations (p. 20). See also Administration's response to PACHA recommendations.

II.D.8. The FDA must require a sponsor to file a gender accrual analysis in the annual Investigational New Drug (IND) report, as stated in the final version of the proposed regulations published in the <i>Federal Register</i>, Vol. 60, No. 184, at 46794. In addition, for the New Drug Application (NDA) and the product licensing application (PLA), the regulations must require sponsors to analyze clinical data by gender and assess potential differences, including reporting on side effects by gender.	The Administration strongly supports an increased focus in Federal research on vulnerable populations (p. 20). See also Administration's response to PACHA recommendations.
II.D.9. The Secretary of HHS should publish for public comment by March 1, 1996, the proposed regulations regarding participation of pregnant women in clinical trials, with the following revision: A pregnant woman's inability to obtain consent from the father of the fetus should not disqualify her from participation in a federally funded clinical trial. This fact should be stated in the protocol consent form.	Not in the NAS -- current regulations address this concern.
II.E.1. The Administration should rescind mandatory HIV testing and/or discriminatory policies currently in place in the U.S. Foreign Service, the Peace Corps, the Job Corps, the State Department, and the military, when there is no compelling public health justification.	The Federal government is examining existing policies related to the exclusion of people living with HIV from Federal employment (p. 28).
II.E.2 The Secretary of HHS should instruct the CDC to (1) review its guidelines that arbitrarily restrict HIV-infected health care workers and that lead to discrimination against them, and (2) ensure that these guidelines are consistent with the prevailing scientific and public health knowledge on the issue.	See Administration's response to PACHA recommendations.
II.E.3. The Administration should oppose any congressional efforts to require that otherwise qualified military service personnel who test positive for HIV be discharged, including a veto of the Department of Defense Reauthorization Act if such a provision is included. In his veto message, the Council recommends that the President state that the veto is, in part due to the inclusion of this provision.	The Administration forcefully opposed the "Dornan Amendment" and will continue to in its efforts to protect the civil rights of people living with HIV (p. 28).

II.E.4. The Administration should direct the CDC, Immigration and Naturalization Service (INS), and the Department of State to monitor and coordinate the HIV testing of immigrants to ensure informed consent, pre- and post-test counseling, and appropriate legal and health referrals and to ensure that waivers of the HIV exclusion are granted on a priority basis when permitted by statute. Also, when permitted by statute, the INS and the Executive Office of Immigration Review (EOIR) should grant stays of deportation, suspension of deportations, extended voluntary departure, deferred action, and asylum based on the social group category of HIV-positive individuals.

See Administration's response to PACHA recommendations.

PACHA RECOMMENDATION - 4.26.96	NATIONAL AIDS STRATEGY
A. 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.	The NAS calls for Presidential leadership in a range of areas. (The President and First Lady have agreed to be National Co-Chairs of the October display of the AIDS Memorial Quilt.)
B.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.	The NAS stresses the importance of establishing community-based prevention priorities (pp. 12-13). (CDC's current guidelines encourage anonymous testing programs. See Administration's response to PACHA recommendations.)
B.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.	One of the national goals is to ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs (p. 24). (Coverage of medical foods is understood to be part of the "Flexible Services Option" of the fee-for-service contracts between OPM and service carriers. See Administration's response to PACHA recommendations.)
B.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.	The Administration has fought to make it easier to qualify for Social Security disability benefits for people living with HIV (p. 24). (The Administration is working with SSA to ensure that individuals are aware of the requirements for having their health benefits continued under COBRA. See Administration's response to PACHA recommendations.)
B.4. The Administration should recommend a substantial increase in the NIH Office of Alternative Medicine (OAM) budget for FY 1997.	The Report of the NIH AIDS Research Program Evaluation Task Force called for a strengthening of the scientific base for the assessment of complementary and alternative therapies for HIV disease. NIH is committed to implementing the Report's findings in the coming year (p. 18).

B.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.	One of the national goals is to ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs (p. 24). (Under Medicaid, states may offer a number of additional services, including "alternative medicine" options, at their discretion. See Administration's response to PACHA recommendations.)
B.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.	The Report of the NIH AIDS Research Program Evaluation Task Force called for a strengthening of the scientific base for the assessment of complementary and alternative therapies for HIV disease. NIH is committed to implementing the Report's findings in the coming year (p. 18).
B.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.	Maintaining consistent funding for the housing component of the services safety net will continue to be a national priority. The Administration has proposed to increase funding for HOPWA in FY 1997 by 96 percent since FY 1993 (pp. 23-24, 25).

B.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.	Maintaining consistent funding for the housing component of the services safety net will continue to be a national priority (pp. 23-24, 25). (ONAP is working with HUD to convene discussion with relevant agencies and community representatives to discuss access to housing for people living with HIV through HOPWA and other programs. See Administration's response to PACHA recommendations.)
C.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.	In response to the Report of the NIH AIDS Research Program Evaluation Task Force, NIH will be developing a comprehensive HIV prevention science agenda, combining biomedical and behavioral perspectives (p. 18).
C.1.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.	NIH and CDC both support increasing resources available for basic research on behavior, interventions, social marketing, and program evaluation (p. 12).
C.1.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.	Improving our understanding of modes of transmission (pp. 11-12) and developing a comprehensive NIH HIV prevention science agenda, including biomedical and behavioral aspects (p. 18) are key to critical to developing improved prevention strategies.
C.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.	The NAS discusses support for a broad range of prevention strategies, including research focusing on individual and community-level interventions (p. 12) with a special emphasis on vulnerable populations (pp. 15, 20). The NIH is also developing a comprehensive NIH HIV prevention science agenda, including biomedical and behavioral aspects (p. 18).

C.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.	The importance of enrolling more substance abusers into drug treatment is discussed on page 13.
C.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.	Improving the translation of research advances, including the dissemination of prevention models, is a major concern and addressed in Section F (Translation of Research Advances into Practice) of the NAS (pp. 33-35).
D.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.	The Administration is committed to an increased focus on vulnerable populations, including children and adolescents (p. 20). (The NIH has historically maintained detailed rolls of infants and children enrolled in clinical trials. See Administration's response to PACHA recommendations.)
D.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 Administration is committed to an increased focus on vulnerable populations, including children and adolescents (p. 20). (The FDA uses every opportunity to encourage pediatric studies throughout the development process to support pediatric-use labeling. See Administration's response to PACHA recommendations.)

D.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.	The Administration is committed to supporting biomedical approaches to prevention, including vaccines. In response to recommendations contained in the Report of the NIH AIDS Research Program Evaluation Task Force, NIH is establishing a strengthened trans-NIH vaccine research effort (p. 18).
D.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.	Federal vaccine research will be supported at both the NIH and DOD (p. 19). Moreover, the Vice President will continue high-level discussion to encourage private sector involvement in the development of both vaccines and microbicides (p. 19).

10/4

Hello Jeff --

-- Here's the crosswalk. Let me know what you think.

-- Scheduling request: Got ok from Jennifer, CHR's signature, and Wendy Heistad's signature. Faxed it over to Patti Solis with note that original will follow.

-- Messages/faxes -- Nothing urgent looking.

JL's Tim Westmoreland, 662-9595, re Medicaid and immigrants

David Care?, 410-786-3870, re/from? Judy Moore

Jay Coburn, AIDS Action, 986-1300, ext. 3021, re history of funding by CDC of CBO program

Thea Spires, HUD, 401-7991, Dianna Fortuna referred her to you

PFs: Douglas Morgan, NJ Dept. of Health, 609-984-5874, re correspondence.

Sharon Edwards, 544-6093, re trade bill

Have a good weekend.

... Hi Bopper



Draft Recommendations Crosswalk --

This document intended to help the PAC find where the issues raised through PAC recommendations are addressed in the Strategy. Additional information about can also be found in the Administration's responses to the Advisory Council's recommendations.

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PACHA RECOMMENDATIONS - 7.28.95	NATIONAL AIDS STRATEGY (NAS)
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I.B.2. The President must maintain a strong commitment to the entitlement status of the Medicaid program, including a willingness to veto any legislation that inadequately funds or transforms Medicaid into a block grant.	The Administrations's past and future commitment to preserve Medicaid funding is outlined on p. 22-24.
I.B.3. The President should continue to demonstrate strong support for the Housing Opportunities for Persons with AIDS (HOPWA) and other Federal housing programs that serve people living with AIDS. The President should make housing for people with AIDS (PWAs) and FY 1997 priority.	The Administrations's past and future commitment to preserve HOPWA funding is outlined on p. 22-24.

I.C.I. The President should make HIV prevention an investment priority during budgetary decision-making.	The President has proposed significant increases for HIV prevention in the FY 1997 budget (p. 10) and has identified five areas where we should focus future efforts (p. 11-15).
I.D.I. The President should continue to show strong support for a coordinated Federal approach to HIV/AIDS research, including continued support for the Office of AIDS Research (OAR).	Support for a strong leadership and coordination of Federal research is a central element of the research section (p.18).
I.E.I. In talking publicly about HIV, the President should vigorously speak out against HIV-related discrimination and condemn prejudice based on race/ethnicity and sexual orientation, which damage our efforts to combat AIDS. The President should strongly and visibly oppose any amendments to HIV-related legislation that are designed to divide the American people along line of sexual orientation, substance abuse history, race/ethnicity, or other factors.	The fourth goal of the National AIDS Strategy is to fight discrimination on all fronts including enforcing rights, protecting workers, opposing discriminatory legislation, and providing visible leadership (p. 3, 6, 27-29).

PACHA RECOMMENDATIONS 12.8.95	NATIONAL AIDS STRATEGY
II.A.1 During his State of the Union Address, the President should renew his commitment to prevention new infections, caring for people now living with HIV/AIDS, and finding a cure, a vaccine, and effective treatments for HIV. The President should, during this address, announce the immediate release of his updated national strategy on AIDS.	These goals are articulated throughout the NAS. Preventing new infections is one of the national goals (p.3,6) requiring multiple approaches (p. 9-15). Caring for people now living with HIV is the third national goal (p. 3,6) requiring an investment in care an services (p.22-25). Finding a cure, vaccine, and effective treatments is the first national goal (p.3,6) requiring commitment in four major areas (p.17-21).
II.A.2. To further accomplish the goals President Clinton outlined at the WHCA, the Clinton/Gore Administration should ensure that key Cabinet Secretaries initiate and maintain regular face-to-face meetings with HIV service providers, people living with HIV/AIDS, and their advocates to ensure consistent and ongoing communication and partnership with community members on the front lines of the AIDS epidemic.	The NAS is intended to be a living document that will require regular updating and regular consultation from the infected and affected communities. Developing an implementation plan and updating goals will require an ongoing dialogue and collaborative efforts between the public and private sectors (p.3-4).
II.B.1 Continue to support and defend the entitlement status and funding for Medicaid and Medicare, and continue to oppose any efforts to restrict eligibility and services for people living with HIV/AIDS.	The Administrations's past and future commitment to preserve Medicaid and Medicare funding is outlined on p. 22-24.
II.B.2 Direct that any waivers granted to States under the Medicaid program ensure access to a comprehensive continuum of care for people living with HIV/AIDS. To implement this policy, the President should direct the HCFA to establish national criteria by which to assess State waiver applications and to ensure that these criteria be consistent with current health care knowledge. These criteria also should be consistent with the provisions of the Americans with Disabilities Act (ADA), and State plans should be reviewed for this purpose by the HHS Office of Civil Rights.	The Administrations's commitment to preserve Medicaid funding is outlined on p. 22-24. (HCFA is currently reviewing all State Medicaid managed care waiver proposals to ensure continuity of care. See Administration's response to PACHA recommendations.)

II.B.3 Direct HCFA to ensure that State Medicaid programs cover HIV testing and counseling.	The Administrations's commitment to Medicaid is outlined on p. 22-24. The importance of the integrating HIV prevention -- including counseling and testing -- into primary care substance is discussed on p.14. (HCFA is currently reviewing all State Medicaid managed care waiver proposals to ensure provision of a full range of services. See Administration's response to PACHA recommendations.)
II.B.4 Direct HCFA to report to the Council, at its next meeting, possible strategies to address the need to ensure that all Food and Drug Administration (FDA) approved drugs are covered under State Medicaid plans, even when prescribed for "off-label" indications. These strategies should address both policies and vigorous enforcement mechanisms.	Not directly discussed in the NAS -- the current Federal drug rebate law requires States to provide coverage for off-label uses of FDA-approved drugs, including those used in the treatment of HIV/AIDS.
II.B.5 The Administration should direct these Federal agencies that either finance or administer health care services (including but not necessarily limited to HCFA, the Department of Veteran's Affairs [VA], the Department of Defense, and the Department of Justice Bureau for Prisons) to develop oversight guidelines for HIV managed health care programs. This will also require effective regulatory enforcement mechanisms.	Ensuring quality of care in Federally-supported programs is a major concern (p.25).
II.B.6 The Administration should direct HRSA to develop a coordinated agency-wide approach that provides effective education, training, and technical assistance to HIV/AIDS providers and AIDS service organizations on health care management issues. Such an approach should include active participation by the private sector.	Improving program coordination (p.25, 35), providing guidance to improve quality of care (p.25), and increased education and training (p.34) are important steps to improving care. Developing an effective implementation plan for the strategy will require input from a variety of sectors, including the private sector (p. 3-4).

II.B.7. Before complementary therapies are widely used, the President should direct all appropriate agencies to support investigations of the efficacy of complementary therapies and provide increased financial support for this effort. Therapies shown to have benefit should be reimbursed under Medicaid.	The Report of the NIH AIDS Research Program Evaluation Task Force included a recommendation on complementary therapies. OAR will be working on implementing these recommendations in the year ahead. (p.18) ??? Anything new re RWCA I & II policy statement re complementary therapies.
II.B.8. The President should continue to support full funding to a national network of AETC's, and direct HRSA to ensure that the work of the AETCs is coordinated with the community providers and planning groups.	The importance of maintaining the AETCs is discussed on p.34.
II.B.9. The Administration should direct HRSA to review and report to the Council at its next meeting the effectiveness of the Bureau of Health Professions' education activities specific to HIV/AIDS.	A progress was presented to the Council.????? - true?

II.C.1. The CDC and the President should direct the Secretary of HHS to produce an annual estimate of HIV incidence based on seroprevalence studies and to work to ensure a reasonable relationship between epidemiological trends and CDC prevention funding. This report should specifically examine the demographic characteristics and geographic distribution of populations that experience disproportionate increase in new infections. - o The CDC should issue to the President an annual estimate of HIV incidence based on seroprevalence studies that provides a geographic analysis of the populations where there is a continuing disproportionate increase in new HIV infections. - o The President should direct the Secretary of HHS to ensure that resources are allocated to accomplish this task. - o The President should ensure that funding is adequate and responsive to the epidemiological trends, needs, and prevention infrastructure of affected communities.	Improving our understanding of trends in the epidemic, and targeting appropriate resource services in response to these changes, is discussed on p.11-12.
II.C.2. o The President should direct the CDC to develop a behavioral surveillance mechanism that will provide an analysis of patterns in risk-taking behavior; and - o The President should direct the CDC to join with the National Institute on Drug Abuse (NIDA) and other relevant agencies to institute surveillance methods for detecting patterns of risk-taking behaviors in populations that show a continuing disproportionate increase in AIDS cases; and - o He should direct the Secretary of HHS to coordinate the planning of an early warning system and ensure its ongoing use.	Understanding who is becoming infected and through what behaviors is critical to designing effective HIV prevention programs as well as targeting appropriate service resources (p.11-12).

II.C.3. The administration should pursue a comprehensive strategy to decrease HIV transmission related to injection drug use, which accounts for at least 50% of new HIV infections. In addition, high-risk sexual behavior while under the influence of drugs and/or alcohol accounts for another significant percentage of new cases of HIV disease. Strategies must explicitly address the sharing of injection drug use paraphernalia, as well as the high-risk sexual behavior associated with drug and/or alcohol use.	The importance of addressing substance abuse and integrating HIV prevention into substance abuse treatment is addressed on p.13. Issues related to enrolling more substance abusers into drug treatment, reducing the availability of illegal drugs, and preventing HIV transmission from the use of contaminated injection equipment and discussed on pages 13 - 14.
II.C.3.a. Increase access to effective substance abuse prevention and treatment research by: o Opposing congressional efforts to cut SAMHSA and other Federal funding for drug abuse treatment and prevention programs in FY 1996 appropriations. o Restoring budget requests for SAMHSA and other Federal funding for drug abuse treatment and prevention programs to at least the FY 1995 levels.	The President has fought hard for increased funding for substance abuse treatment. The importance of supporting substance abuse treatment is addressed on p.13 - 14.
II.C.3.b. Revise the Department of Justice Model Drug paraphernalia Act, which serves as a model for State drug paraphernalia laws, to make it consistent with current reports, studies, and data relating to the access to sterile syringes as an effective intervention to counter HIV transmission among IDUs.	See Administration's response to PACHA recommendations.
II.C.3.c. The President should direct the Secretary of HHS to provide a recommendation (within 90 days) regarding the impact of needle-exchange programs on HIV infection and substance abuse. The recommendation should be based upon current reports, studies, and data on needle-exchange programs, and should develop and execute a plan to carry out the recommendations and indicate what programs and demonstration projects will be started or expanded.	Both CDC and NIH are supporting research to identify characteristics of successful needle exchange programs (p. 14). See also Administration's response to PACHA recommendations.

II.C.4. The President should reaffirm his support for community-based planning for prevention activities.	Strengthening community-based planning is one of the five major elements needed to meet the nation's prevention goal. (p.11-13)
II.C.4.a. Direct the CDC to maintain HIV prevention programs independent of any consolidated grant programs, including the currently proposed Performance Partnership Grants.	Strengthening community-based planning is one of the five major elements needed to meet the nation's prevention goal. (p.11-13) OK?? Also see Administration response to PACHA recommendations.
II.C.4.b. Direct the CDC to continue direct funding to community-based organizations.	See Administration response to PACHA recommendations.
II.C.4.c. Direct the CDC, with the assistance of existing national minority organizations and other appropriate partners, to structure its technical assistance programs to address the prevention program development and infrastructure needs of populations that are currently experiencing an continued disproportionate increase in new infections.	The Administration has focused on the need to provide technical assistance on a number of fronts. First, the community planning process will require ongoing technical assistance from the CDC (p.13) with particular attention to vulnerable populations (p. 15). In addition, as part of the Federal government's compliance with the Government Performance and Results Act, CDC and SAMHSA will continue to work with grantees to develop appropriate performance measures for HIV prevention programs (p.12). And finally, the PHS will take the lead in ensuring that models of effective prevention interventions reach people developing and implementing prevention programs (p.35). Also see Administration's response to PACHA recommendations.
II.C.5. Direct the Director of the Indian Health Service (IHS) to develop a comprehensive AIDS prevention and care plan for Indian Country (within 90 days) with the input from consumers of IHS services.	The Administration is committed to improving the care and prevention services in all Federally-sponsored programs (p. 25). Also see Administration's response to PACHA recommendations.

II.D.1. The Vice President's leadership and technological expertise should be sought to bring together the resources and expertise of various Government agencies, the private sector, community groups, and other nations in the effort to develop HIV vaccines and microbicide and to "reinvent" the Government's involvement in the development of these products.	The support of the Vice President has been instrumental in founding the Forum for Collaborative HIV Research (p. 17,19, 20) and developing the first Federal Plan for Biomedical Research on HIV and AIDS (p. 17, 18). His efforts will continue in the areas of microbicides and vaccines (p. 19).
II.D.2. The priority for funding by the OAR for microbicide research and development, as well as such funding within CDC, must be increased substantially, with a concomitant increase of full-time equivalents (FTE's) allocated for this priority.	The Administration is committed to advancing microbicide development (p. 19).
II.D.3. The Government should develop mechanisms to increase the pool of investigators in microbicide research and development, especially those involved in biomedical and behavioral aspects.	The Administration is committed to advancing microbicide development (p. 19) and increasing future support for basic research on behavior, interventions, social marketing, and program evaluation (p. 12).
II.D.4. In HIV/AIDS clinical research, the NIH must ensure the early and fundamental involvement of behavioral and social scientists in the process of initial study development, design, and implementation.	In response to the Report of the NIH AIDS Research Program Evaluation Task Force, NIH will be developing a comprehensive HIV prevention science agenda, combining biomedical and behavioral perspectives (p. 18). See also Administration's response to PACHA recommendations.
II.D.5. HHS should develop ongoing mechanisms to ensure the rapid translation of breakthrough research findings into clinical practice.	An important element in the fight against HIV and AIDS is ensuring that research advances are translated into improved HIV prevention programs and better care for HIV-positive persons. An entire of the NAS focuses on the translation of research advances into practice (p 33-35).

II.D.6. A public health policy consensus panel should be convened by the Public Health Service by the end of April 1996 to assess the possible efficacy of available spermicide (e.g. nonoxynol-9) and other licensed products (e.g. chloerhexidine, benzalkonium chloride, diaphragms) to be used in "harm reduction" algorithms to decrease sexual transmission of HIV. The panel should include senior public health policy officials (CDC, FDA, HHS Secretary's Office), research agencies (NIH), community groups (women's health research advocates, commercial sex workers, interested foundations), academia, and industry. The meeting should also feature a review of the entire status of anti-HIV microbicide research.	The Administration is committed to advancing microbicide development (p. 19). See also Administration's response to PACHA recommendations.
II.D.7. The Council asks the FDA to comment by January 31, 1996, upon the proposed FDA regulations that require inclusion of women in all clinical trials of drugs for treatment of HIV/AIDS in which there is no known evidence of reproductive toxicity. When such toxicity has been documented, alternatives that allow the inclusion of women should be provided.	The Administration is committed to an increased focus in Federal research on vulnerable populations (p. 20). See also Administration's response to PACHA recommendations.
II.D.8. The FDA must require a sponsor to file a gender accrual analysis in the annual Investigational New Drug (IND) report, as stated in the final version of the proposed regulations published in the <i>Federal Register</i>, Vol. 60, No. 184, at 46794. In addition, for the New Drug Application (NDA) and the product licensing application (PLA), the regulations must require sponsors to analyze clinical data by gender and assess potential differences, including reporting on side effects by gender.	The Administration strongly supports an increased focus in Federal research on vulnerable populations (p. 20). See also Administration's response to PACHA recommendations.
II.D.9. The Secretary of HHS should publish for public comment by March 1, 1996, the proposed regulations regarding participation of pregnant women in clinical trials, with the following revision: A pregnant woman's inability to obtain consent from the father of the fetus should not disqualify her from participation in a federally funded clinical trial. This fact should be stated in the protocol consent form.	Not in the NAS -- current regulations address this concern.

II.E.1. The Administration should rescind mandatory HIV testing and/or discriminatory policies currently in place in the U.S. Foreign Service, the Peace Corps, the Job Corps, the State Department, and the military, when there is no compelling public health justification.	The Federal government is examining existing policies related to the exclusion of people living with HIV from Federal employment (p. 28).
II.E.2 The Secretary of HHS should instruct the CDC to (1) review its guidelines that arbitrarily restrict HIV-infected health care workers and that lead to discrimination against them, and (2) ensure that these guidelines are consistent with the prevailing scientific and public health knowledge on the issue.	See Administration's response to PACHA recommendations.
II.E.3. The Administration should oppose any congressional efforts to require that otherwise qualified military service personnel who test positive for HIV be discharged, including a veto of the Department of Defense Reauthorization Act if such a provision is included. In his veto message, the Council recommends that the President state that the veto is, in part due to the inclusion of this provision.	The Administration forcefully opposed the "Dornan Amendment" and will continue to in its efforts to protect the civil rights of people living with HIV (p. 28).
II.E.4. The Administration should direct the CDC, Immigration and Naturalization Service (INS), and the Department of State to monitor and coordinate the HIV testing of immigrants to ensure informed consent, pre- and post-test counseling, and appropriate legal and health referrals and to ensure that waivers of the HIV exclusion are granted on a priority basis when permitted by statute. Also, when permitted by statute, the INS and the Executive Office of Immigration Review (EOIR) should grant stays of deportation, suspension of deportations, extended voluntary departure, deferred action, and asylum based on the social group category of HIV-positive individuals.	See Administration's response to PACHA recommendations.

PACHA RECOMMENDATION - 4.26.96	NATIONAL AIDS STRATEGY
A. 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.	The NAS calls for Presidential leadership in a range of areas. (The President and First Lady have agreed to be National Co-Chairs of the October display of the AIDS Memorial Quilt.)
B.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.	The NAS stresses the importance of establishing community-based prevention priorities (p. 12-13). (CDC's current guidelines do not prohibit anonymous testing programs. See Administration's response to PACHA recommendations.)
B.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.	One of the national goals is to ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs (p. 24). Coverage of medical foods is understood to be part of the "Flexible Services Option" of the fee-for-service contracts between OPM and service carriers. (Coverage of medical foods is understood to be part of the "Flexible Services Option" of the fee-for-service contracts between OPM and service carriers. See Administration's response to PACHA recommendations.)
B.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.	The Administration has fought to make it easier to qualify for Social Security disability benefits for people living with HIV (p. 24). (The Administration is working with SSA to ensure that individuals are of the requirements for having their health benefits continued under COBRA. See Administration's response to PACHA recommendations.)

B.4. The Administration should recommend a substantial increase in the NIH Office of Alternative Medicine (OAM) budget for FY 1997.	The Report of the NIH AIDS Research Program Evaluation Task Force called for a strengthening of the scientific base for the assessment of complementary and alternative therapies for HIV disease. NIH is committed to implementing the Report's findings in the coming year (p. 18).
B.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.	One of the national goals is to ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs (p. 24). (Under Medicaid, states may offer a number of additional services, including "alternative medicine" options, at their discretion. See Administration's response to PACHA recommendations.)
B.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.	The Report of the NIH AIDS Research Program Evaluation Task Force called for a strengthening of the scientific base for the assessment of complementary and alternative therapies for HIV disease. NIH is committed to implementing the Report's findings in the coming year (p. 18).
B. 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.	Maintaining consistent funding for the housing component of the services safety net will continue to be a national priority. The Administration has proposed to increase funding for HOPWA in FY 1997 by 96 percent since FY 1993 (p. 23-24, 25).

B.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.	Maintaining consistent funding for the housing component of the services safety net will continue to be a national priority (p. 23-24, 25). (ONAP is working with HUD to convene discussion with relevant agencies and community representatives to discuss access to housing for people living with HIV through HOPWA and other programs. See Administration's response to PACHA recommendations.)
C.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.	In response to the Report of the NIH AIDS Research Program Evaluation Task Force, NIH will be developing a comprehensive HIV prevention science agenda, combining biomedical and behavioral perspectives (p. 18).
C.1.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.	NIH and CDC are both support increasing resources available for basic research on behavior, interventions, social marketing, and program evaluation (p. 12).
C.1.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.	Improving our understanding of modes of transmission (p. 11-12) and developing a comprehensive NIH HIV prevention science agenda, including biomedical and behavioral aspects (p. 18) are key to critical to developing improved prevention strategies.
C.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.	The NAS discusses support for a broad range of prevention strategies, including research focusing on individual and community-level interventions (p. 12) with a special emphasis on vulnerable populations (p. 15, 20). The NIH is also developing a comprehensive NIH HIV prevention science agenda, including biomedical and behavioral aspects (p. 18).

C.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.	The importance of enrolling more substance abusers into drug treatment is discussed on p. 13.
C.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.	Improving the translation of research advances, including the dissemination of prevention models, is a major concern and addressed in Section F (Translation of Research Advances into Practice) of the NAS (p. 33-35).
D.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.	The Administration is committed to and increased focus on vulnerable populations, including children and adolescents (p. 20). (The NIH has historically maintained detailed rolls of infants and children enrolled in clinical trials. See Administration's response to PACHA recommendations.)
D.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 Administration is committed to and increased focus on vulnerable populations, including children and adolescents (p. 20). (The FDA uses every opportunity to encourage pediatric studies throughout the development process to support pediatric-use labeling. See Administration's response to PACHA recommendations.)

D.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.	The Administration is committed to supporting biomedical approaches to prevention, including vaccines. In response to recommendations contained in the Report of the NIH AIDS Research Program Evaluation Task Force, NIH is establishing a strengthened trans-NIH vaccine research effort (p. 18).
D.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.	Federal vaccine research will be supported at both the NIH and DOD (p. 19). Moreover, the Vice President will continue high-level discussion to encourage private sector involvement in the development of both vaccines and microbicides (p. 19).

Executive Summary Progress Report

JULY 8, 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 are 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.

THE WHITE HOUSE
WASHINGTON
August 29, 1996

MEMORANDUM FOR PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

FROM: Patsy Fleming *PF*

SUBJECT: Correction to Progress Report

In responding to Recommendation II.E.2. regarding the guidelines on HIV-infected health care workers, we erred in stating that "the Secretary of HHS has asked for a review of these guidelines." The correct response is:

CDC is currently holding internal discussions about whether or not to formally review the health care worker guidelines. It is standard CDC procedure to routinely assess whether or not to conduct more formal reviews for all guidelines because of advances in science, environmental changes, or policy changes. Based on the outcome of the internal discussions, a decision will be made later this year.

I apologize for any confusion this may have created.

n: council.hcw

PRESIDENTIAL
ADVISORY
COUNCIL ON
HIV/AIDS

PROGRESS REPORT

Implementation of Advisory Council Recommendations

July 8, 1996

**I. Recommendations made on
July 28, 1995**

I.A. Leadership

Recommendation I.A.1.

The President himself must engage the American public through a National Summit that encompasses the scientific, medical, social, and political aspects of the AIDS epidemic. This summit, which should be held by the end of this year, should consider the impact of race, culture, poverty, disability, region, gender, sexual orientation, and age on our ability to develop an effective national AIDS strategy.

Administration's Response

The December 6, 1995, White House Conference on HIV/AIDS was a rapid response to an important recommendation. It was a truly historic event that has been followed through with continued dialogue and outreach to the HIV-affected communities across the country, in particular through the series of town meetings being held.

Assessment of the Response

The first White House Conference on HIV/AIDS was a prompt and substantive response to this recommendation. During the past year, the Administration's commitment to fighting HIV/AIDS has been clearly more visible.

Followup Action Recommended

See Recommendation A.2 in Section II.

Recommendation I.A.2.

The President should then proceed with an address declaring the battle against HIV a national health priority and laying out his vision for the ending of this epidemic.

Administration's Response

At the White House Conference, the President addressed the American people about the high priority that the fight against AIDS has for this Administration—and the importance of the epidemic to American society in general. In addition, the President directed that a number of important followup steps occur to show the continued commitment of the Administration to addressing this epidemic. This included asking the Vice President to work with the pharmaceutical industry to promote greater private sector involvement in AIDS research; asking that a transgovernmental plan and budget for AIDS research be developed under the leadership of

Dr. William Paul, Director, Office of AIDS Research (OAR), National Institutes of Health (NIH); and asking that the Centers for Disease Control and Prevention (CDC) host a national meeting on the interrelationship of substance abuse and HIV. The Vice President has held a meeting with the pharmaceutical industry and is now engaging in additional followup; Dr. Paul has presented the Federal plan to the White House; and the CDC meeting is scheduled for this summer.

Assessment of the Response

The President began this process with his speech at the White House Conference. That address provided a well-constructed blueprint for an appropriate national response to the HIV/AIDS epidemic.

Followup Action Recommended

The Council is awaiting the Administration's more detailed and comprehensive national strategy on AIDS.

I.B. Services

Recommendation I.B.1.

The President should continue his support of the Ryan White CARE Act and should endeavor to prevent the Congress from attaching unnecessary funding restrictions. He should also continue to vigorously support funding levels for the Ryan White CARE Act that are responsive to the rising caseloads and costs of delivering comprehensive services to people with HIV/AIDS and make the CARE Act a budget priority.

Administration's Response

The President's support for the CARE Act has been consistent and clearly articulated to the public and Congress. The President spoke out several times against the divisive tactics and amendments offered by Senator Jesse Helms. Administration officials at all levels made clear to Congress the Administration's position opposing all negative and extraneous amendments. It is unfortunate that the Republicans' distraction with the fight over Medicaid and the budget delayed completion of action on the CARE Act reauthorization, a measure for which there was such strong bipartisan support, but we are pleased to see it finally enacted into law.

The President continues to show strong leadership in support for increased funding for the CARE Act in the current fiscal year as well as FY 1997. Throughout the budget negotiations, funding increases for the CARE Act programs were a top priority. As a result of this persistence, CARE Act funding increased \$105 million in FY 1996. This includes a budget amendment made by the President last month requesting an additional \$52 million earmarked

for the hard-pressed AIDS Drug Assistance Program (ADAP) under Title II.

Assessment of the Response

The Council commends the Administration's continued efforts to expand funding for the CARE Act. In particular, we are pleased with the Administration's leadership role in obtaining a \$52 million emergency appropriation for ADAP and its strong advocacy for an additional \$53 million in FY 1996. The President has also requested a \$69 million increase for the CARE Act in his FY 1997 budget request. We also commend the President for his leadership in building bipartisan support for the Ryan White CARE Act renewal and funding increases.

Followup Action Recommended

While these funding increases are vital, the Council recognizes that they are modest relative to the critical need for CARE Act-funded services, especially in light of new drug developments. CARE Act programs will continue to play an essential role in ensuring access to these new therapies and must therefore receive substantial increases in funding in future years.

Recommendation I.B.2.

The President must maintain a strong commitment to the entitlement status of the Medicaid program, including a willingness to veto any legislation that inadequately funds or transforms Medicaid into a block grant.



Administration's Response

The President has fulfilled his commitment to protect Medicaid as an entitlement by vetoing legislation that would have gutted the Medicaid program. In his statement explaining his veto, the President mentioned the importance of Medicaid for people with AIDS as one of the reasons for opposing Republican efforts to make drastic cuts in and to block-grant the Medicaid program.

Assessment of the Response

The President's leadership was strong and effective, particularly his ability to create bipartisan support for Medicaid and Medicare.

Followup Action Recommended

We will continue to work with the Administration to turn back future challenges to Medicaid and Medicare.

Recommendation I.B.3.

The President must continue to demonstrate his strong support for the Housing Opportunities for Persons with AIDS (HOPWA) and other Federal housing programs that serve people living with AIDS. The President should make housing for people with AIDS (PWAs) a FY 1997 priority.

Administration's Response

The President has demonstrated his support for housing programs in the FY 1996 budget cycle. HOPWA has been protected from cuts, while many other housing programs have faced severe reductions. In the context of what is occurring with other housing programs, this is a tremendous victory. In the context of the rising need for housing services, it is recognized by the Administration that flat funding is insufficient. The Administration is examining ways to mitigate this in the context of the FY 1997 budget.

Assessment of the Response

Congress has imposed major cuts in many housing programs. AIDS housing programs have not been cut in this fiscal year, in large part due to the Administration's support of HOPWA. However, while flat funding is remarkable in the current fiscal climate, it is entirely inadequate in the overall context of the HIV/AIDS epidemic.

Followup Action Recommended

The Council strongly supports the proposals by Housing and Urban Development (HUD) Secretary Henry Cisneros to reprogram \$15 million within the FY 1996 HUD budget to provide additional funding for HOPWA and to amend the President's FY 1997 budget to add an additional \$50 million to funding for housing programs serving PWAs. The Council will work with the Administration on this effort. The Council recognizes the need to address the significance of housing for people with HIV/AIDS and the need to integrate housing services into a continuum of care.

I.C. Prevention

Recommendation I.C.1.

The President should make HIV prevention an investment priority during budgetary decision making.

Administration's Response

The President's commitment to HIV prevention programs remains strong. While the Congress failed to grant his request for additional prevention funding in FY 1996, once again the President is seeking a \$35 million increase in prevention spending in FY 1997.

Assessment of the Response

The Council commends the President for his commitment to HIV prevention funding, evidenced by his request for an increase in both FY 1996 and FY 1997.

While HIV prevention efforts have essentially received flat funding for the past several years substantial increases are needed in order to adequately address prevention efforts. In the face of the current congressional budgetary and political realities, the Council acknowledges that adequate funding is unlikely. Nonetheless, we believe that this goal is imperative.

Followup Action Recommended

The Council urges that the President continue his advocacy for prevention, understanding its central role in ending the HIV/AIDS epidemic, by vigorously working for congressional passage of his requested FY 1997 increase.

I.D. Research

Recommendation I.D.1.

The President should continue to show strong support for a coordinated Federal approach to HIV/AIDS research, including continued support for the Office of AIDS Research (OAR).

Administration's Response

Both the President and the Vice President have been active in support of a coordinated Federal approach to HIV/AIDS research. The President requested preparation of The Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS, which is a transgovernmental plan and budget prepared under the leadership of Dr. William Paul,

Director, OAR.

The Vice President has been engaged in discussions with the pharmaceutical industry and others regarding a better public/private collaboration in various areas of HIV/AIDS research—from vaccine and microbicide development to clinical effectiveness trials.

The Administration has staunchly supported its request for a consolidated budget for AIDS research at the NIH. House Republicans continue to be adamant in their opposition to providing the OAR with its full statutory authority (i.e., a consolidated budget and authority to shift funds during the fiscal year). Senior Administration officials at the White House, the Department of Health and Human Services (HHS), and the NIH continue to press our case for restoration of this important authority in FY 1996 and for a continuation of that authority in FY 1997 and beyond, through the NIH reauthorization bill.

I.E. Combating Discrimination/Social Prejudice

Recommendation I.E.1.

In talking publicly about HIV, the President should vigorously speak out against HIV-related discrimination and condemn prejudice based on race/ethnicity and sexual orientation, which damage our efforts to combat AIDS. The President should strongly and visibly oppose any amendments to HIV-related legislation that are designed to divide the American people along lines of sexual orientation, substance use history, race/ethnicity, or other factors.

Administration's Response

The President has spoken out against HIV-related discrimination throughout his term. He was eloquent in his response to Senator Jesse Helms's divisive tactics during the Ryan White CARE Act debate. The President has most recently endorsed passage of the Employment Non-Discrimination Act, which would ban employment discrimination based on sexual orientation. All enforcement arms of the Administration have been working effectively and collaboratively in challenging HIV-related discrimination.

The Justice Department and the Equal Employment Opportunity Commission (EEOC) are vigorously enforcing 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 to the affected parties. 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.

Assessment of the Response/Action To Be Taken

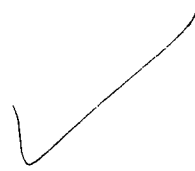
The President is to be commended for his clear and vocal leadership in speaking against HIV-related discrimination. Strong antidiscrimination efforts and vigorous condemnation of prejudice-based discrimination must be continued.

II. Recommendations made on December 8, 1995

II.A. Leadership

Recommendation II.A.1.

During his State of the Union Address, the President should renew his commitment to ending the AIDS epidemic and to committing our Nation's resources to preventing new infections, caring for people now living with HIV/AIDS, and finding a cure, a vaccine, and effective treatments for HIV. The President should, during this address, announce the immediate release of his updated national strategy on AIDS.



Administration's Response

During his State of the Union Address, the President focused on the health-related issue of greatest importance to people living with AIDS: the battle over Medicaid and Medicare. In that context, he renewed his pledge to protect Medicaid as an entitlement and to fight unreasonable cuts in funding. He mentioned people living with HIV/AIDS as a group that needed the protections Medicaid offered. The President has also mentioned the importance of Medicaid to people living with HIV/AIDS in other contexts as well. The National Strategy on HIV/AIDS is in final review. It is the Administration's hope to have a document ready for release in June.

Assessment of the Response

The President did mention AIDS in his State of the Union Address, although only in the context of health care.

Followup Action Recommended

It is important that the President continue to remind the Nation that much remains to be done in the battle against HIV/AIDS.

It is essential that the President and his Administration strategize on how to systematically communicate, in all contexts, the impact of the HIV/AIDS pandemic on the Nation and the world.

The President should continue to affirm his commitment to ending the AIDS epidemic and to committing the Nation's resources to preventing new infections, caring for people now living with HIV/AIDS, and finding a cure, a vaccine, and effective treatments for HIV.

Recommendation II.A.2.

✓ To further accomplish the goals President Clinton outlined at the White House Conference on HIV/AIDS, the Clinton/Gore Administration should ensure that key Cabinet Secretaries initiate and maintain regular face-to-face meetings with HIV service providers, people living with HIV/AIDS, and their advocates to ensure consistent and ongoing communication and partnership with community members on the front lines of the AIDS epidemic.

Administration's Response

The Office of National AIDS Policy has initiated a series of regional town meetings featuring senior Administration officials and members of the Presidential Advisory Council on HIV and AIDS. The chief purpose of these meetings is to continue the dialogue with HIV service providers, people living with HIV/AIDS, and their advocates. Meetings have been held in Dallas/Fort Worth, New York, Newark, NJ, Miami/Fort Lauderdale, San Diego, and San Francisco. Further meetings are planned for Chicago, Cleveland, Los Angeles, and Durham, NC.

In addition, Administration officials are continuing their ongoing dialogue with national and community leaders. For example, HUD Secretary Cisneros holds regularly scheduled meetings with AIDS housing advocates. HHS Secretary Shalala has had many such meetings. There is also considerable consultation between the HIV community and sub-cabinet officials.

Assessment of the Response

Progress has been made on this recommendation. Cabinet Secretaries and senior officials are actively involved in ongoing discussions with HIV service providers and persons affected by HIV/AIDS. The regional meetings being conducted are commendable.

The meeting between Vice President Gore, Government scientists, and industry representatives was an outstanding beginning to the dialogue that must continue about HIV treatment, microbicides, and vaccines.

Followup Action Recommended

A mechanism should be put in place to ensure that suggestions and ideas from regional meetings are disseminated to interested and affected parties. Relevant and appropriate recommendations should be incorporated into the national strategy on AIDS. The Council urges all relevant Cabinet Secretaries to take a more proactive approach to regular face-to-face meetings with HIV service providers, people living with HIV/AIDS, and their advocates.

II.B. Services

Recommendation II.B.1.

Continue to support and defend the entitlement status and funding for Medicaid and Medicare, and continue to oppose any efforts to restrict eligibility and services for people living with HIV/AIDS.

Administration's Response

The President has successfully fought to maintain the entitlement status of Medicaid; he has blocked attempts to make drastic cuts in Medicaid spending; he has opposed the block-granting of this program; he has supported a guaranteed package of benefits; and he has opposed attempts to remove the private right of action against inadequate State Medicaid programs.

Assessment of the Response

The continuing evolution of the variety of proposed changes makes our continued vigilance in following this issue essential. The Administration's strong opposition to the proposed changes that have come to date is acknowledged and supported by the Council.

Followup Action Recommended

The Council should continue monitoring changes in Medicaid and Medicare as they are proposed in legislation.

Recommendation II.B.2.

Direct that any waivers granted to States under the Medicaid program ensure access to a comprehensive continuum of care for people living with HIV/AIDS. To implement this policy, the President should direct the HCFA to establish national criteria by which to assess State waiver applications and to ensure that these criteria be consistent with current health care knowledge. These criteria also should be consistent with the provisions of the Americans with Disabilities Act (ADA), and State plans should be reviewed for this purpose by the HHS Office of Civil Rights.

Administration's Response

HCFA is currently reviewing all State Medicaid managed care waiver proposals to ensure continuity of care for Medicaid beneficiaries with HIV/AIDS, including education and outreach efforts during the managed care process, and procedures for disenrollment from

HMO programs if continuity and quality cannot be provided through such arrangements. These general criteria have already been applied in several State waiver reviews (e.g., New York, California, and Florida). HCFA is now developing monitoring guidelines to evaluate and promote improvement in Medicaid managed care waiver programs serving people with HIV/AIDS, as well as guidelines for the content and coordination of home care services provided in managed care settings.

During consideration of waiver applications, HCFA has worked closely with relevant community representatives with concerns about a specific State's proposal. In addition, all relevant agencies of HHS—such as the Office for Civil Rights and the Bureau of Primary Health Care at the Health Resources and Services Administration (HRSA)—have an opportunity to review State waiver applications. The HRSA AIDS Program Office will also review waivers with a special focus on HIV/AIDS issues and will, through its HIV/AIDS Managed Care Group, contribute to the development of the national monitoring guidelines being developed by HCFA.

Assessment of the Response

The Council acknowledges HCFA's work in establishing criteria that, while not yet in final form, have been used on a case-by-case basis in reviewing waiver applications.

Followup Action Recommended

We continue to desire that these criteria become "formalized" to ensure they are applied to all future waiver applications and that waivers approved include enforcement procedures to ensure that minimum standards of care are met. The Council will remain engaged in monitoring waivers being sought, with the goal that these waivers fully protect people with HIV/AIDS.

Recommendation II.B.3.

Direct HCFA to ensure that State Medicaid programs cover HIV testing and counseling.

Administration's Response

Medicaid may cover counseling and testing in the context of routine care for Medicaid clients. In addition, HCFA now leads a cross-cutting effort within HHS to provide outreach and information to Medicaid-eligible women regarding the potential benefits of HIV counseling and testing and, if appropriate, AZT treatment for pregnant women. HCFA has also sent policy guidance to State Medicaid directors that promotes full coverage and access for HIV counseling and testing services and AZT treatment pursuant to the results of AIDS Clinical Trials Group 076 protocol.

Assessment of the Response

The Council suggests this recommendation be incorporated into any reviews of standards of care and treatment that are developed over time.

HCFA appears to be using all its available tools under current law to ensure that all Medicaid-eligible persons are offered HIV testing and counseling. The greatest need is to persuade Medicaid providers and physicians to offer testing and counseling as an element of routine preventive medicine.

Followup Action Recommended

The Council requests that HCFA (1) keep the Council regularly informed about the extent to which this goal is being achieved, and (2) propose new measures that would further this goal.

Recommendation II.B.4.

Direct HCFA to report to the Council, at its next meeting, possible strategies to address the need to ensure that all Food and Drug Administration (FDA)-approved drugs are covered under State Medicaid plans, even when prescribed for "off-label" indications. These strategies should address both policies and vigorous enforcement mechanisms.

Administration's Response

The Federal drug rebate law requires States to provide coverage for off-label uses of FDA-approved drugs, including those used in the treatment of HIV/AIDS. A policy guidance similar to that issued regarding AZT for pregnant women is being developed for State Medicaid directors to promote full coverage and access to the newly approved protease inhibitors.

Assessment of the Response

As new therapies become available for HIV, it will be imperative for HCFA to communicate the resulting new standards of care to States, thus ensuring HIV drug reimbursement in participating States.

Followup Action Recommended

The Council will continue to work with the Administration on this issue to ensure that States pay for all approved drugs if they have agreed to drug reimbursement.

Recommendation II.B.5.

The Administration should direct those Federal agencies that either finance or administer health care services (including but not necessarily limited to HCFA, the Department of Veterans' Affairs [VA], the Department of Defense, and the Department of Justice Bureau of Prisons) to develop oversight guidelines for HIV managed care programs. This will also require effective regulatory enforcement mechanisms.

Administration's Response

See response to Recommendation II.B.2. regarding HCFA's policies. While the VA provides guidance to its clinicians regarding standards of care for people with HIV, it does not restrict the discretion of the practicing physician to determine a treatment protocol for an individual patient. Most HIV-related care in the VA system is delivered by infectious disease specialists who serve as the primary care providers for people with HIV.

The Office of National AIDS Policy has convened a working group of Federal agencies with programs affecting the incarcerated, including the Bureau of Prisons, with the express purpose of developing a standard of care for prisoners with HIV disease.

Assessment of the Response

This recommendation requires development of policies, procedures, and support to be used by community organizations, as managed care develops over time. Thus, the vast array of actions required to fully implement this recommendation is a work in process. This is very important to ensure that treatment, over time, is accessible, effective, complete, and timely. The Indian Health Service should be included as one of the agencies covered under this recommendation.

Followup Action Recommended

The Council must ensure that ongoing progress continues and that community organizations, which have been central in providing health care for persons with HIV/AIDS, remain an integral part of any managed care system and continue to receive appropriate support as the managed care environment develops.

Recommendation II.B.6.

The Administration should direct HRSA to develop a coordinated agency-wide approach that provides effective education, training, and technical assistance to HIV/AIDS providers and AIDS service organizations on health care management issues. Such an approach should include active participation by the private sector.

Administration's Response

HRSA has instituted several activities in response to the managed care movement. These include:

- *Establishment of the HRSA Managed Care Priority Group, which formed a partnership with American Association of Health Plans, formerly, Group Health Association of America, and jointly planned a national conference, April 1-2, 1996, to address managed care issues that relate to HRSA's mission and programs.*
- *Formation of a subgroup of the HRSA AIDS Priority Committee/HRSA AIDS Coordinators to develop a strategy to address the issues of managed care and HIV/AIDS.*
- *Implementation activities by the Bureau of Primary Health Care that have resulted in the development of a comprehensive managed care program that gives training, technical assistance, supplementary grant support, and access to senior executives in the managed care industry. The program includes training in managed care operations and procedures to health center staff, on-site technical assistance, network development, self-assessment tools, and collaborative initiatives with other Federal agencies, State and local governments, national organizations, private sector providers, and others involved in serving underserved populations. The Title III(b) programs (early intervention services for HIV/AIDS) are included in these activities. Recently, the Bureau of Primary Health Care has developed an agreement to train State health officials involved in the administration of CDC grants on managed care issues and has also initiated bureau-wide staff training in managed care.*
- *Active involvement of the AIDS Education and Training Centers (AETC) program in providing HIV training to providers working in managed care settings.*
- *Rapid dissemination of findings from five Special Projects of National Significance (SPNS) grants. These are grants to design and evaluate HIV capitated care approaches. Findings from these grants will be disseminated to HRSA grantees and other HIV providers through presentations, training, fax-out bulletins, and technical assistance to individual grantees. The SPNS grantees have participated in Titles I, II, and III(b) training sessions or meetings during the past 12 months.*

Assessment of the Response

HRSA has been responsive in developing programs and plans for working with its grantees to understand the changing world of managed care and how they can continue to be essential care providers. Nevertheless, the vast array of actions necessary to fully implement this recommendation is a work in process. This is very important to ensure that treatment, over time, is accessible, effective, complete, and timely.

Followup Action Recommended

The Council must ensure that ongoing progress continues and that community organizations, which have been central to providing health care for persons with HIV/AIDS, remain an integral part of any managed care system. The Secretary of HHS needs to ensure that education, training, and technical assistance on managed care be made available to all grantees of the Ryan White CARE Act.

It will also be important to ensure, over time, that adequate monitoring and reporting systems are developed to enable the Secretary to assess whether and to what extent all managed care systems, including comprehensive health centers, provide the full range of high-quality care and services needed by clients with HIV/AIDS.

Recommendation II.B.7.

Because complementary therapies are widely used, the President should direct all appropriate agencies to support investigation of the efficacy of complementary therapies and provide increased financial support for this effort. Therapies shown to have benefit should be reimbursed under Medicaid.

Administration's Response

The NIH Office of Alternative Medicine (OAM) has awarded a number of grants in the area of alternative therapies for AIDS. In addition, the recent report of the NIH AIDS Research Program Evaluation Working Group contains a specific recommendation that NIH should "strengthen the scientific base for the assessment of complementary and alternative therapies for HIV disease." Under the law, Medicaid can cover only FDA-approved treatments. There is a pending policy statement for Ryan White CARE Act Titles I and II that would permit CARE Act funds to be used for complementary therapies.

Assessment of the Response

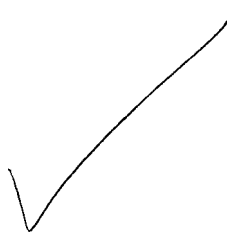
Both the Council and the report of the NIH AIDS Research Program Evaluation Working Group confirm the importance of complementary therapies in the management of HIV disease. This area of research is only now beginning to receive the attention it deserves.

Followup Action Recommended

We expect HRSA to implement its proposal to allow alternative and complementary therapies to be reimbursed under the Ryan White CARE Act. HHS should convene a working group to assess mechanisms to obtain third-party coverage, including Medicare or Medicaid, for complementary therapies. This evolving area will require continued monitoring by the Council.

Recommendation II.B.8.

The President should continue to support full funding to a national network of AETCs, and direct HRSA to ensure that the work of the AETCs is coordinated with community providers and planning groups.



Administration's Response

The President supported \$16.3 million for the national AETC program in FY 1996. The final appropriation for the AETCs was only at \$12 million. The President has requested \$16.3 million for the AETCs in his FY 1997 budget.

It is a priority of the AETC program to establish close working relationships with community providers and planning groups and to include community input in development of training activities and information dissemination plans. This has been accomplished more successfully in the epicenters, where the 15 main grantees are located, than in less affected areas. The proposed inclusion of the AETC program in the reauthorized Ryan White CARE Act will help to strengthen the relationship with these community providers.

Assessment of the Response

The Council commends the President's leadership in restoring funding for AETCs even though Congress reduced the final allocation from \$16.3 million to \$12 million in FY 1996.

While we agree that a closer working relationship has been developed by many AETC sites with local community providers and planning groups, other sites have been less successful.

We recognize the important function the AETC program plays in training health care providers in delivering quality, state-of-the-art care.

Followup Action Recommended

We support the President's request in his FY 1997 budget to restore funding for AETCs to \$16.3 million. The director of the AETC program should monitor the working relationship of each AETC with its associated planning councils, consortiums and other HIV coalitions in order to ensure more definitive and appropriate training efforts in all the regions.

Recommendation II.B.9.

✓ The Administration should direct HRSA to review and report to the Council at its next meeting the effectiveness of the Bureau of Health Professions' education activities specific to HIV/AIDS.

Administration's Response

A written progress report on this recommendation will be provided prior to the September meeting of the Council.

Assessment of the Response

The continuing inability of many health care providers to recognize and diagnose HIV infection, particularly in women, and provide state-of-the-art therapeutics is directly related to the need for ongoing education on HIV infection. In light of the funding decreases to both the AETC program and to overall health professions education, the Council is concerned about the impact on the diagnosis and care of HIV-infected persons.

Followup Action Recommended

The Council requests that the AIDS Program Office and HRSA's Bureau of Health Professions work together to respond to these concerns. A substantive written response, with recommendations for action, should be made available to the Services Subcommittee 30 days prior to the next Council meeting.

II.C. Prevention

Recommendation II.C.1.

✓ The CDC and the President should direct the Secretary of HHS to produce an annual estimate of HIV incidence based on seroprevalence studies and to work to ensure a reasonable relationship between epidemiological trends and CDC prevention funding. This report should specifically examine the demographic characteristics and geographic distribution of populations that experience disproportionate increases in new infections.

- The CDC should issue to the President an annual estimate of HIV incidence based on seroprevalence studies that provides a geographic and demographic analysis of the populations where there is a continuing disproportionate increase in new HIV infections.
- The President should direct the Secretary of HHS to ensure that resources are allocated to accomplish this task.
- The President should ensure that funding is adequate and responsive to the

epidemiological trends, needs, and prevention infrastructure of affected communities.

Administration's Response

It should be noted that CDC's prevention programs have been flat-funded by the Congress, despite the President's efforts to obtain significant increases. Therefore, decisions to invest additional resources in one area often result in difficult decisions to cut back in others.

CDC is working to derive annual HIV incidence estimates in selected subpopulations, including injection drug users (IDUs) and clients of sexually transmitted disease (STD) clinics. However, current methods have not succeeded in producing reliable HIV incidence estimates for the country as a whole.

As part of the community planning process, State and local health departments are expected to document that programming for HIV prevention reflects the local epidemiology. Grant applications are being reviewed with this in mind, and States and localities not following this portion of the guidance will be provided technical assistance. When necessary, CDC can and will require revisions in State plans.

Assessment of the Response

The Council is pleased that the CDC has determined that HIV incidence estimates within subpopulations must play a central role in the development of HIV prevention and education programs.

Followup Action Recommended

The Council recommends that the CDC continue to pursue means to achieve reliable national incidence estimates using data from surveillance systems and special studies, as needed, and that the Council be periodically updated on the progress in this area.

Furthermore, we recommend that the CDC report to the Council on its efforts to develop HIV seroincidence estimates, including adequacy, effectiveness, and efficiency of funding such efforts.

Finally, the Council supports the requirement for State and local health departments to document that programming for HIV prevention reflects the local epidemiology. We urge strong enforcement of this policy as well as the provision of relevant technical assistance.

Recommendation II.C.2.

- The President should direct the CDC to develop a behavioral surveillance mechanism that will provide an analysis of patterns in risk-taking behavior.
- The President should direct the CDC to join with the National Institute on Drug Abuse (NIDA) and other relevant agencies to institute surveillance methods for detecting patterns of risk-taking behaviors in populations that show a continuing disproportionate increase in AIDS cases.
- He should direct the Secretary of HHS to coordinate the planning of an early warning system and ensure its ongoing use.

Administration's Response

CDC agrees with the Council's recommendation to develop a behavioral surveillance mechanism to monitor patterns of risk-taking behavior. In addition, behavioral surveillance can monitor the adoption of protective behaviors that decrease the risk of HIV transmission. CDC is in the process of integrating standard HIV data elements in ongoing behavioral surveillance mechanisms, coordinating surveillance approaches for HIV with those for other STDs, and continuing expanded surveillance of persons reported with HIV infection and AIDS. CDC will soon solicit proposals for behavioral surveillance of subpopulations at particular risk for HIV infection, to be initiated in FY 1997. While surveillance does not fall within the mission of the NIH, program staff of NIDA will consult with CDC program staff to develop a better method to detect patterns of risk behavior.

In addition, the Substance Abuse and Mental Health Services Administration (SAMHSA) and CDC's National Center for Health Statistics (NCHS) are collaborating on an interagency agreement that would use SAMHSA's National Household Survey on Drug Abuse to collect new data. This includes incorporating NCHS's HIV/AIDS Risk Behaviors Module into the National Household Survey. CDC will also encourage local areas to use HIV surveillance or prevention funds for surveys of sexual behavior in the general population. As indicated above, State and local prevention partners are expected to direct their programs (and funds) in response to the epidemiology of the epidemic in their localities.

Assessment of the Response

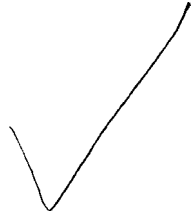
The Council commends the Administration's efforts toward fulfilling this recommendation. It is our understanding that the Administration has made progress toward this goal. We acknowledge that developing an effective behavioral surveillance mechanism presents difficult scientific challenges. Furthermore, once developed, efficient dissemination of the findings as a part of an "early warning system"—although critical—will require extensive planning.

Followup Action Recommended

The Council requests that we be briefed at our next full Council meeting on the Administration's efforts to date and plans for future efforts in this area and that appropriate members of the Council be included in the ongoing development of this necessary prevention tool.

Recommendation II.C.3.

The Administration should pursue a comprehensive strategy to decrease HIV transmission related to injection drug use, which accounts for at least 50 percent of new HIV infections. In addition, high-risk sexual behavior while under the influence of drugs and/or alcohol accounts for another significant percentage of new cases of HIV disease. Strategies must explicitly address the sharing of injection drug use paraphernalia, as well as the high-risk sexual behavior associated with drug and/or alcohol use.



Administration's Response

The need for a comprehensive approach to substance abuse and HIV transmission was recognized by the President in his remarks at the White House Conference on HIV/AIDS on December 6, 1995. In that speech, he directed the CDC to convene a meeting designed to develop a cross-governmental strategy. This meeting is scheduled for this summer. In addition, the White House Office of National AIDS Policy has convened a working group of the Interdepartmental Task Force on HIV/AIDS to consider these issues.

Assessment of the Response

See Recommendation II.C.3a-c.

Followup Action Recommended

See Recommendation II.C.3a-c.

Recommendation II.C.3.a.

Increase access to effective substance abuse prevention and treatment research programs by:

- Opposing congressional efforts to cut SAMHSA and other Federal funding for drug abuse treatment and prevention programs in FY 1996 appropriations.
- Restoring budget requests for SAMHSA and other Federal funding for drug abuse treatment and prevention programs to at least the FY 1995 levels.

- Supporting the continuation of specific funding for NIDA's AIDS demonstration projects.

Administration's Response

The President has fought for increased funding for substance abuse treatment and has opposed Congressional efforts to cut back dramatically on substance abuse funding. For FY 1997, the President has requested \$1.272 billion for the Substance Abuse Performance Partnerships, the principal source of Federal funding for substance abuse treatment. This is \$32 million above the FY 1995 spending level. The President's FY 1997 AIDS research budget request is contained in a consolidated account for the NIH OAR. The final level for projects proposed by NIDA will be determined by the Director of OAR in accordance with the priorities and objectives of the NIH Plan for HIV-Related Research.

Assessment of the Response

The Council commends the President for his support for expanded access to effective substance abuse prevention and treatment programs and the Administration's support of the Substance Abuse Performance Partnerships.

Followup Action Recommended

The Council recommends that the Administration actively support the reauthorization of SAMHSA programs and that the Director of the Office of National Drug Control Policy be engaged in communicating the importance of SAMHSA programs in our Nation's effort to reduce illicit drug use.

Representatives of the Council would like the opportunity to meet with the Director of the Office of National Drug Control Policy.

Recommendation II.C.3.b.

Revise the Department of Justice Model Drug Paraphernalia Act, which serves as a model for State drug paraphernalia laws, to make it consistent with current reports, studies, and data relating to the access to sterile syringes as an effective intervention to counter HIV transmission among IDUs.

Administration's Response

CDC and a variety of Federal and nongovernmental agencies sponsored a "Consultation on Recommendations for Model Laws and Regulations Related to the Sale, Possession, and Distribution of Syringes," held at the Carter Presidential Center in Atlanta, Georgia, on Thursday and Friday, May 16-17, 1996. Leaders from the fields of public health, substance abuse treatment, pharmacy, medicine, ethics, and criminal justice participated. Sponsors

included the Task Force for Child Survival and Development, the Kaiser Family Foundation, CDC, and the Georgetown/Johns Hopkins University Program on Law and Public Health. This meeting included a review of the Model Drug Paraphernalia Act. The Department of Justice will assess any changes in the model law based on the recommendations of the Secretary of HHS.

Assessment of the Response

We strongly commend the CDC for its leadership in convening this important meeting. We welcome the opportunity to engage in a dialogue with other public health, substance abuse treatment, pharmacy, medicine, ethics, and criminal justice professionals, as well as with State and Federal lawmakers to ensure that Federal and State laws regarding drug paraphernalia are consistent with current scientific knowledge.

Followup Action Recommended

The Council requests that it be briefed on what specific steps have been taken and those planned for the future.

Recommendation II.C.3.c.

The President should direct the Secretary of HHS to provide a recommendation (within 90 days) regarding the impact of needle-exchange programs on HIV infection and substance abuse. The recommendation should be based upon current reports, studies, and data on needle-exchange programs, and should include specific recommendations for programs and demonstration projects to implement needle exchange. The Secretary should develop and execute a plan to carry out the recommendations and indicate what programs and demonstration projects will be started or expanded.

Administration's Response

No action has been taken.

Assessment of the Response

The Council continues to have 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.

Followup Action Recommended

Council representatives intend to meet with the Secretary of HHS and the Assistant to the President for Domestic Policy as soon as possible to explore steps to bring Federal policy in line with current scientific knowledge.

Recommendation II.C.4.

✓ The President should reaffirm his support for community-based planning for prevention activities.

Recommendation II.C.4.a.

✓ Direct the CDC to maintain HIV prevention programs independent of any consolidated grant programs, including the currently proposed Performance Partnerships Grants.

Administration's Response

CDC will continue to support community-based planning for HIV prevention efforts and will work to coordinate HIV prevention programs with other prevention services and activities serving the same populations. The Administration has decided to keep the HIV prevention programs separate from the new Performance Partnerships Grant structure.

Assessment of the Response/Followup Action Recommended

The Council is pleased that the Administration has decided to maintain the strategically important approach of community-based planning for HIV prevention efforts, as focused and distinct efforts from other health planning needs. We urge the Administration to continue this policy. The Council supports the Administration's efforts to find ways to increase the coordination of HIV prevention efforts with related health concerns and facilitate effective and efficient health planning by State and local health departments.

Recommendation II.C.4.b.

✓ Direct the CDC to continue direct funding to community-based organizations.

Administration's Response

CDC has worked closely with community-based organizations over the past six years and views them as valuable partners in HIV prevention. CDC has extended the cooperative agreement for direct funding of HIV community-based organizations through March 1997. CDC will continue discussions with governmental and nongovernmental partners to determine the best ways to ensure that the HIV prevention needs of at-risk populations, currently

addressed by community-based organizations, will continue to be met beyond April 1997.

Assessment of the Response

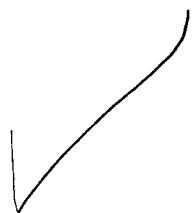
The Council supports the CDC decision to extend direct funding to community-based organizations through March 1997. We believe that this will allow for a natural transition and integration of these programs and organizations into the broad prevention efforts being developed in the HIV prevention planning process.

Followup Action Recommended

The Council recommends that this extension period be used to develop a strategic plan by which the communities, subpopulations, and programs that these organizations represent will continue to be served beyond 1997. The Council recommends that the direct funding of community-based organizations be maintained. Further, we recommend that the CDC clarify the relationships between directly funded community-based organizations and State/local health departments; develop clear guidance to ensure coordination between local planning groups, health departments, and community-based applicants for CDC funds; and provide support for program evaluation and accessible technical assistance.

Recommendation II.C.4.c.

Direct the CDC, with the assistance of existing national minority organizations and other appropriate partners, to structure its technical assistance programs to address the prevention program development and infrastructure needs of populations that are currently experiencing a continued disproportionate increase in new infections.



Administration's Response

CDC will continue to work through the National/Regional Minority Organizations (NRMOs) Grant Program to strengthen the capacity of existing NRMOs to work in partnership with CDC in the development of culturally competent HIV prevention programs for communities of color that are at increased risk for HIV infection. Beginning in FY 1994, activities for this program were refocused to concentrate on providing culturally competent and relevant technical assistance and training in organizational capacity building and programmatic development to organizations and agencies (primarily State and local health departments and minority community-based organizations) that offer HIV/STD prevention services to racial/ethnic minority populations. National organizations also provide tools and consultation to project areas to help assess technical assistance needs and priorities in support of HIV prevention community planning.

Assessment of the Response

The Council supports the CDC decision to continue its support of the NRMO Grant Program.

Followup Action Recommended

The Council requests that it be given an overview of what other partnerships the CDC has made in the effort to reach populations and subpopulations that are experiencing disproportionate increases in HIV infection rates (e.g., rural populations, young gay men, gay men of color, women, and IDUs). Additionally, we request that the CDC provide the Council with its assessment of the current NRMO technical assistance program and, if any changes or alterations are planned, ensure that the program is responsive to the current capacity-building and programmatic development needs of organizations serving the most highly impacted populations and subpopulations.

Recommendation II.C.5.

Direct the Director of the Indian Health Service (IHS) to develop a comprehensive AIDS prevention and care plan for Indian Country (within 90 days) with the input from consumers of IHS services.

Administration's Response

A review of the IHS AIDS prevention program is completed and will be available for the Council at its April meeting.

Assessment of the Response

We acknowledge the receipt of IHS's HIV/AIDS Prevention Program Report.

Followup Action Recommended

The Council requests an update on the implementation of the Summary of Findings and appendices contained in the IHS's HIV/AIDS Prevention Program Report, along with supporting documentation of consumers' input.

II.D. Research

Recommendation II.D.1.

The Vice President's leadership and technological expertise should be sought to bring together the resources and expertise of various Government agencies, the private sector, community groups, and other nations in the effort to develop HIV vaccines and microbicides and to "reinvent" the Government's involvement in development of these products.

Administration's Response

On February 20, 1996, Vice President Gore met with representatives of the pharmaceutical industry regarding expanded collaboration between the public and private sectors on AIDS research. The meeting included a discussion of the need for greater industry and Government involvement in the development of microbicides. The Vice President has expressed interest in a continued role in furthering this area of research and development.

Assessment of the Response

The meeting between Vice President Gore, Government scientists, and industry representatives was seen as a productive and useful first step in the process of reinventing the partnership between Government and private industry in the development of HIV vaccines, microbicides, and other new therapies.

Followup Action Recommended

It is imperative that this dialogue continue. Another meeting between the Vice President and other concerned groups should be convened by September 1 in order to keep the momentum for this partnership thriving. Furthermore, it is essential that community groups be included in future discussions, and that the Council be informed of these meetings.

Recommendation II.D.2.

The priority for funding by the OAR for microbicide research and development, as well as such funding within CDC, must be increased substantially, with a concomitant increase of full-time equivalents (FTE's) allocated for this priority.

Administration's Response

NIH funding for research on microbicides has increased over the past several years and will continue to increase. The priority accorded to this important area of research has been determined through the OAR planning process, which included consultation with NIH and

nongovernment scientists, clinicians, academicians, industry representatives, and AIDS community advocates. These experts reached a consensus on the scientific priorities included in the consolidated NIH Plan and Budget Request. OAR anticipates that this research will continue to receive high priority for funding.

At CDC, the Epidemiology Branch, Division of HIV/AIDS Prevention (DHAP), in collaboration with the Division of Reproductive Health, the Division of STD, and the Women's Health Program Office, coordinated a meeting in mid-April to discuss policy, research, and program issues concerning microbicide research relative to CDC's mission of HIV prevention. This meeting was attended by CDC researchers, outside consultants, and representatives from NIH and FDA. Regarding ongoing research, the CDC HIV/AIDS Epidemiology Branch, in collaboration with the Division of Viral and Rickettsial Diseases, is currently conducting a three-year prospective study of HIV in female genital tract secretions. Studies are also being conducted within the Epidemiology Branch to examine women's interpretation of HIV prevention messages as a function of relevant beliefs and goals concerning close relationships and potential biases in message interpretation due to contextual framing information and the hierarchical presentation of message content.

Assessment of the Response

The Administration is certainly moving in the right direction regarding this area, although these concrete increases have not yet been seen. The President has used his leadership to emphasize the importance of this area to the public. Two meetings have been held (CDC, 4/15/96, with Patsy Fleming, Director, Office of National AIDS Policy, and others in attendance, and the International Working Group on Microbicides, in Virginia, 4/11/96).

Followup Action Recommended

The Administration should require each relevant agency and NIH institute to provide, on an annual basis, information on specific funding and FTE allocations being applied for microbicide research. Tracking of this information should include the specific types and nature of the research being conducted.

Current efforts should be continued, and overall funding for microbicide research must significantly increase.

Recommendation II.D.3.

The Government should develop mechanisms to increase the pool of investigators in microbicide research and development, especially those involved in biomedical and behavioral aspects.

Administration's Response

Attracting new investigators into the field of AIDS research is a high priority for the NIH. Several mechanisms are already in place, such as the AIDS Loan Repayment Program, and others are under development. There are at present no special initiatives to increase investigators in any specific areas related to AIDS research, such as microbicides.

Assessment of the Response

While two recent meetings on microbicide research may have generated interest in this area by biomedical and behavioral researchers at the involved institutions, as yet there has been no evidence of specific mechanisms to increase the pool of investigators in this area.

Followup Action Recommended

The NIH, OAR, and CDC should issue Requests for Applications for training grants and for focused research projects related to microbicides.

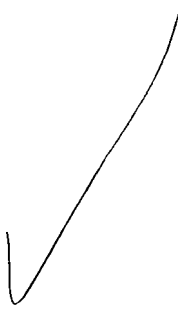
Federal agencies and institutes should track the monies being spent on training of potential investigators in the field of microbicide research.

Recommendation II.D.4.

In HIV/AIDS clinical research, the NIH must ensure the early and fundamental involvement of behavioral and social scientists in the process of initial study development, design, and implementation.

Administration's Response

The NIH has identified the issues of recruitment, retention, and adherence to clinical trial protocols and therapeutic regimens as important behavioral and social science research components of clinical research. These issues are critical to the outcome of these studies. The NIH is encouraging projects that link these important behavioral and clinical research issues. This is an important element of current NIH vaccine efficacy trials.



Assessment of the Response

This recommendation has not been implemented. The four recommendations listed in the Executive Summary of the NIH AIDS Research Program Evaluation Working Group Report (page 18) do not address this recommendation. However, NIH has identified the issue as an important component of clinical trial protocols and vaccine efficacy trials.

Followup Action Recommended

The Council will postpone recommendations for action until the report from the Behavioral, Social Science, and Prevention Area Review Panel of the NIH AIDS Research Program Evaluation Working Group is reviewed by the Council.

Recommendation II.D.5.

HHS should develop ongoing mechanisms to ensure the rapid translation of breakthrough research findings into clinical practice.

Administration's Response

The NIH has established a number of mechanisms to translate research findings to clinical practice. The NIH sponsors state-of-the-art and consensus conferences, coordinated through the NIH Office of Medical Applications of Research (OMAR), part of the Office of the Director of the NIH. A consensus meeting on behavioral research and HIV prevention is scheduled for this June. This is a critical tool for translation of science into practice.

OAR is also currently planning a consensus conference with OMAR regarding the use of antiretroviral therapy in light of the many new advances in therapeutic research, including the new protease inhibitors recently approved by the FDA. In addition, the NIH supports ongoing programs as well as new initiatives in the field of research information dissemination, including:

- Clinical Alerts to rapidly disseminate research findings to health care professionals, the media, and the public.*
- Clinical Alerts are available on-line on the MEDLARS system, provided to academic health science centers and hospitals, and transmitted via Internet. NIDA Community Alerts are designed to reach the drug abuse and drug abuse-related HIV/AIDS community with emerging issues of concern.*
- Computerized data bases, including those on the MEDLARS system (AIDSLINE, AIDSTRIALS, AIDS DRUGS, and DIRLINE), the toll-free (1-800-TRIALS-A) AIDS Clinical Trials Information Service (ACTIS), and the HIV-AIDS Treatment Information Service, provide the foundation for the global dissemination of information concerning basic research, clinical trials availability and results, and standards of care as well as other information of interest to HIV-infected individuals.*
- The National Library of Medicine (NLM) has provided awards to enable community-based organizations and public and health science libraries to design programs for improving access to AIDS information by targeted groups within their communities.*

- *The NLM and OAR developed a "Guide to NIH HIV/AIDS Information Services," a comprehensive listing of NIH-supported information services that assist care and service providers and their patients.*

Dissemination of information is a Public Health Service-wide function. For example, HRSA, through its direct contact with hundreds of providers through the Ryan White CARE Act and the community health centers programs, is able to disseminate new findings rapidly. In addition, the AETCs play an important role in translating new research findings into practice.

The CDC also works closely with community planning groups to provide them with information regarding the most effective behavioral intervention strategies. This has been identified as an important area of emphasis for additional technical assistance in the years ahead.

Assessment of the Response

Dissemination of information is a function of all agencies within the Public Health Service. However, in the area of behavioral and social science, there are no equivalent mechanisms for dissemination and translation of breakthrough research findings. Much of the behavioral and social science research findings are disseminated in the traditional manner, through journal publications. More rapid mechanisms for dissemination could facilitate community implementation of potentially more effective programs.

Followup Action Recommended

The Council will postpone action recommendations until the report from the Prevention Committee of the Working Group is reviewed by the Council.

Recommendation II.D.6.

A public health policy consensus panel should be convened by the Public Health Service by the end of April 1996 to assess the possible efficacy of available spermicides (e.g., nonoxynol-9) and other licensed products (e.g., chlorhexidine, benzalkonium chloride, diaphragms) to be used in "harm reduction" algorithms to decrease sexual transmission of HIV. The panel should include senior public health policy officials (CDC, FDA, HHS Secretary's Office), research agencies (NIH), community groups (women's health research advocates, commercial sex workers, interested foundations), academia, and industry. The meeting should also feature a review of the entire status of anti-HIV microbicide research.

Administration's Response

This recommendation is under active discussion. See the responses above under Recommendation II.D.2. regarding the CDC meeting as a potential precursor to the larger

meeting suggested here.

Assessment of the Response

The Council is concerned that this recommendation has not been carried out in the timeframe we suggested.

Followup Action Recommended

The urgency of this issue would mandate that our recommendation must be accomplished as soon as possible.

Recommendation II.D.7.

The Council asks the FDA to comment by January 31, 1996, upon the proposed FDA regulations that require inclusion of women in all clinical trials of drugs for treatment of HIV/AIDS in which there is no known evidence of reproductive toxicity. When such toxicity has been documented, alternatives that allow the inclusion of women should be provided.

Administration's Response

Earlier this year, FDA Commissioner Dr. David Kessler, asked Dr. Ruth Merkatz, Senior Advisor for Women's Health, to chair a working group to develop these proposed regulations. A proposal has been drafted and is beginning the review process within the FDA.

Assessment of the Response

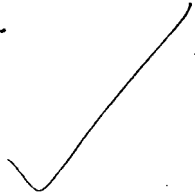
We acknowledge that the FDA has a working group on this issue.

Followup Action Recommended

A status report on this recommendation should be provided to the Council 30 days prior to the next Council meeting.

Recommendation II.D.8.

The FDA must require a sponsor to file a gender accrual analysis in the annual Investigational New Drug (IND) report, as stated in the final version of the proposed regulations published in the *Federal Register*, Vol. 60, No. 184, at 46794. In addition, for the New Drug Application (NDA) and the product licensing application (PLA), the regulations must require sponsors to analyze clinical data by gender and assess potential differences, including reporting on side effects by gender.



Administration's Response

The FDA received 13 comments on this proposed rule to the regulations. The FDA is currently evaluating the comments and drafting the final rule.

Assessment of the Response

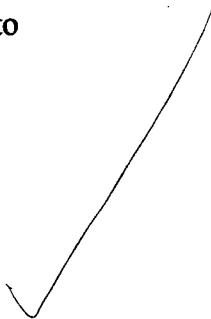
As of April 25, 1996, this had not been done.

Followup Action Recommended

A status report on this recommendation should be provided to the Council 30 days prior to the next Council meeting.

Recommendation II.D.9.

The Secretary of HHS should publish for public comment by March 1, 1996, the proposed regulations regarding participation of pregnant women in clinical trials, with the following revision: A pregnant woman's inability to obtain a written consent from the father of the fetus should not disqualify her from participation in a federally funded clinical trial. This fact should be so stated in the protocol consent form.



Administration's Response

Under current regulations, if a trial is for the health needs of the mother, the father's consent is not needed. Pending regulations address parental consent generally and are in final stages of review.

Assessment of the Response

Current policy (Code of Federal Regulations, Part 46.207) addresses this concern and does not preclude the inclusion of pregnant women in clinical trials.

Followup Action Recommended

This information should be widely disseminated.

II.E. Combating Discrimination/Social Prejudice

Recommendation II.E.1.

✓ The Administration should rescind mandatory HIV testing and/or discriminatory policies currently in place in the U.S. Foreign Service, the Peace Corps, the Job Corps, the State Department, and the military, when there is no compelling public health justification.

Administration's Response

On April 1, 1996, the Job Corps initiated a pilot program eliminating mandatory HIV testing for residential Job Corps applicants in Region VI. All applicants—residential and nonresidential—will be routinely counseled and offered voluntary HIV testing. After a three-month trial period, if successful, this program will be made national policy for the Job Corps.

Assessment of the Response

The progress by the Job Corps is encouraging and laudable. Unfortunately, the Council received no response from the Administration to our recommendation to eliminate policies of mandatory HIV testing and/or discrimination in the U.S. Foreign Service, the Peace Corps, the State Department, and the military absent a compelling public health justification for such policies.

Followup Action Recommended

The Council requests immediate clarification on the Administration's efforts to eliminate or justify mandatory testing and/or discrimination in the U.S. Foreign Service, the Peace Corps, the State Department, and the military.

Recommendation II.E.2.

✓ The Secretary of HHS should instruct the CDC to (1) review its guidelines that arbitrarily restrict HIV-infected health care workers and that lead to discrimination against them, and (2) ensure that these guidelines are consistent with prevailing scientific and public health knowledge on the issue.

Administration's Response

The Secretary of HHS has asked for a review of these guidelines.

Assessment of the Response

The Council is pleased that the Secretary has asked for a review of these arbitrary guidelines. However, the fact that the review is only now in process makes clear that this review is long overdue, especially in light of the National Commission on AIDS recommendations and other scientific studies and reports issued in the last several years.

Followup Action Recommended

The Council seeks confirmation that the review will be completed and that all changes necessitated by this review will be implemented during the current calendar year.

Recommendation II.E.3.

The Administration should oppose any congressional efforts to require that otherwise qualified military service personnel who test positive for HIV be discharged, including a veto of the Department of Defense Reauthorization Act if such a provision is included. In his veto message, the Council recommends that the President state that the veto is, in part, due to the inclusion of this provision.

Administration's Response

The President and the Administration strongly opposed enactment of the so-called "Dornan Amendment." Through the coordinated efforts of the White House, the Department of Defense, the Department of Veterans Affairs, and the Department of Justice—along with the advocacy of many community groups—repeal of this provision was accomplished before any service member had to be discharged. The Administration will continue to oppose efforts to reimpose this provision.

Assessment of the Response

The Council strongly advised the President to veto for the second time the DoD Reauthorization Act because it still contained the Dornan Amendment. While we opposed his decision to sign the bill, we commend the Administration's vocal opposition to the Dornan Amendment, its bold decision not to defend the law in court, and its leadership in obtaining legislative repeal of this law.

Followup Action Recommended

Continued vigilance will be required as similar amendments have been introduced in Congress.

Recommendation II.E.4.

The Administration should direct the CDC, Immigration and Naturalization Service (INS), and Department of State to monitor and coordinate the HIV testing of immigrants to ensure informed consent, pre- and post-test counseling, and appropriate legal and health referrals and to ensure that waivers of the HIV exclusion are granted on a priority basis when permitted by statute. Also, when permitted by statute, the INS and the Executive Office of Immigration Review (EOIR) should grant stays of deportation, suspension of deportations, extended voluntary departure, deferred action, and asylum based on the social group category of HIV-positive individuals.

Administration's Response

The Office of National AIDS Policy has worked closely with the relevant agencies in the Federal Government to ensure waivers for those attending the Summer Olympics in Atlanta and to permit transit visas for those passing through the United States on their way to the International Conference on AIDS in Vancouver. The Office will also work with the CDC to ensure appropriate oversight of HIV testing of potential immigrants.

While both EOIR and the INS are constrained by the need to approach and evaluate each application for asylum, stay or suspension of deportation, deferred action, or extended voluntary departure on its own legal and factual merits, the waiver process allows the flexibility to balance respect for individual rights with the need to protect the public health.

Because stays of deportation, voluntary departure, and deferred action status are forms of relief granted by an INS district director at his or her prosecutorial discretion, the district director must consider each case on the basis of its individual facts and not on the basis of membership in a social group. Similarly, EOIR's immigration judges and its Bureau of Immigration Appeals are charged by regulation with independent adjudication of individual cases. Thus, it is not possible to render these types of immigration decisions based on social group category. The INS will, however, consider applications for stays of deportation, voluntary departure, and deferred action status submitted by HIV-positive individuals in a manner consistent with applications submitted by aliens seeking to remain in the United States for other medical reasons. This includes reviewing all applications for relief where an individual alleges that deportation may result in his or her being unable to obtain life-sustaining treatment.

Finally, aliens with HIV who are seeking asylum or withholding of deportation may be able to qualify for recognition as members of a "particular social group" if the evidence in the individual case supports such a conclusion. (Courts have interpreted the phrase "particular social group" to mean a group of persons sharing a common, immutable characteristic that group members either cannot change or should not be required to change.) Withholding of deportation is available to persons whose life or freedom would be threatened on account of their membership in a particular social group. Aliens may be admitted on the basis of refugee status if they are able to document a well-founded fear of persecution on the basis of race, religion, nationality, membership in a particular social group, or political opinion and if they are able to satisfy the other elements of the statutory definition (the harm must emanate from the government of the refugee's country or an entity the government cannot or will not control, and the persecutor must seek to harm the asylum seeker specifically because of his or her membership in the social group). Finally, because asylum is a discretionary form of relief, the asylum seeker must demonstrate that he or she merits a favorable exercise of discretion. Humanitarian factors, such as an applicant's affliction with a serious medical condition, would generally weigh in the applicant's favor.

In sum, although the INS and EOIR are required to adjudicate requests for asylum, stay or suspension of deportation, deferred action, or extended voluntary departure on their individual merits and cannot grant such discretionary relief in a blanket fashion, where appropriate they will consider HIV infection as a factor weighing in favor of discretionary relief from deportation. Additionally, where consistent with statute, the INS and EOIR will recognize HIV infection as a characteristic that, depending on the practices of the government in the home country, can define a particular social group for purposes of determining eligibility for asylum and withholding of deportation.

Assessment of the Response

The Council is pleased by the Administration's clarification of INS policies regarding the granting of asylum relief from deportation to HIV-positive immigrants. This clarification allows for a more compassionate and sensible approach.

The Council remains concerned that informed consent, pre- and post-test counseling, and appropriate legal and health referrals for HIV-positive immigrants are not being monitored and coordinated by the INS. It is the INS that designates the doctors who conduct medical exams for immigration purposes.

Followup Action Recommended

Since the INS controls these "designated civil surgeons" and only the INS can instruct them to conduct appropriate health and legal service referrals to HIV-positive immigrants, the Council recommends that the INS take responsibility for the proper monitoring and coordination of all aspects of HIV testing, pre-and post-test counseling, and service referrals, using the CDC guidelines developed for these purposes.

The Discrimination Subcommittee will continue to monitor this issue to get further clarification from INS.

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.**

THE WHITE HOUSE
WASHINGTON

August 30, 1996

MEMORANDUM FOR PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

FROM: Patsy Fleming, Director, Office of National AIDS Policy

SUBJECT: Administration Response to Report Three (April 26, 1996)

I am pleased to transmit to you the responses of the relevant agencies to your most recent recommendations. As always, your reports are a useful tool in spurring new thinking and responsiveness on the part of the Federal government.

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.

Administration Response:

The President and First Lady have agreed to be National Co-Chairs of the October display of the AIDS Memorial Quilt. In addition, there will be participation by all levels of the Administration in the events of that weekend. (By tradition, the President and Vice President do not co-chair the same events.)

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.

Administration Response:

CDC's current program guidance to project areas funded for HIV Prevention (which includes all States and territories) states "Unless it is prohibited by State law or regulation, clients should be offered reasonable opportunities to receive HIV-antibody counseling and testing services anonymously. The availability of anonymous testing may encourage some persons at risk to seek services who would otherwise be reluctant to do so."

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.

Administration Response:

Coverage of medical foods is understood to be part of the "Flexible Services Option" of the fee-for-service contracts between OPM and insurance carriers. OPM is unaware of any individuals who have been denied coverage of medical foods, but will receive and address directly any problems in this regard. In an effort to clarify to all contractors OPM's intent, it is sharing a letter to the Director of the Office of National AIDS Policy (see attachment) with all its fee-for-service plans so they are "fully aware that OPM strongly supports use of the Flexible Services Option to cover the cost of any medically supervised use of medical foods in cases of AIDS patients."

In addition, the Health Care Financing Administration has recently communicated to all the state Medicaid directors the importance of covering medical foods as part of their benefits package (see attached letter). ONAP, OPM, and HCFA believe these actions will assure appropriate coverage of medical foods for people living with HIV/AIDS.

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.

Administration Response:

The Social Security Administration (SSA) supports the recommendation that individuals be made aware of the requirements for having their health benefits continued under COBRA. However, SSA does not think that adding language to the SSA disability award notice is the best approach to accomplish this.

While SSA does not know the exact number of individuals who are awarded SSA benefits and who also full under COBRA, SSA believes it is very small. Because it is not possible for SSA to determine whether a claimant is covered under COBRA, SSA believes it will create confusion if this notice is included in all disability award notices. SSA suggests consideration of other approaches to accomplish this end, including:

- Making copies of the COBRA pamphlet prepared by the Department of Labor available in SSA field offices so they can be distributed to interested members of the public;
- Providing a leaflet (enclosure) with SSA's award notice that explains the COBRA provisions and the need for the individual to provide a copy of the award notice to the plan administrator.

ONAP will work with SSA to pursue these options.

4. The Administration should recommend a substantial increase in the NIH Office of Alternative Medicine (OAM) budget for FY 1997.

Administration Response:

The FY 96 President's budget request for the NIH Office of Alternative Medicine was \$5.69 million. The President's FY 1997 budget request for the office is \$5.69 million.

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.

Administration Response:

One of HCFA's objectives is to assure that Medicaid eligible individuals living with HIV infection or AIDS have access to appropriate benefits under the Medicaid program. In partnership with the States, HCFA believes this objective can be met.

To this end, HCFA has advised States about the appropriate coverage of drugs for Medicaid eligible persons living with HIV/AIDS and to encourage States to ensure that appropriate services are provided those individuals. Generally, States are required to cover medically accepted indications of FDA approved drugs. As such, States are required to cover the recently FDA approved protease inhibitors.

Additionally, under Medicaid, states may offer a number of additional services at their discretion. For example, states may cover diagnostic, screening, preventive, and rehabilitative services, including any medical or remedial services, that are recommended by a physician or other licensed practitioner within the scope of their practice as defined by State law. There are some "alternative medicine" practitioners who are indeed licensed.

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.

Administration Response:

To address the issue of complementary and alternative medicine (CAM) for AIDS, the NIH AIDS Research Evaluation Task Force established a special subpanel of the evaluation, chaired by the Director of the Office of Alternative Medicine and comprised of researchers and advocates from across the country interested in these issues. The Subpanel also solicited input from interested proponents of CAM therapies. The Evaluation Task Force determined that the most meaningful and effective action for the NIH to take to advance the study of the potential benefits or harms of CAM use for HIV disease would be to strengthen the scientific basis for future CAM research in HIV disease. The evaluation recommended that the OAR should work in collaboration with the Office of Alternative Medicine in this regard. The Evaluation group also recommended that the OAR and OAM sponsor a workshop on the research methodology for the evaluation of the efficacy of CAM therapies for HIV disease and to provide information to assist individuals interested in CAM therapy research in preparing NIH grant applications and the process by which these grants are reviewed. The OAR has asked the Director of OAM to work with the NIH Institutes and Centers to prepare an implementation plan for the recommendations of the evaluation subpanel.

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.

Administration Response:

The President did submit a \$25 million dollar budget amendment for the HOPWA program for FY97, raising the President's request to \$196 million. This increase, if approved by Congress, will help lessen the impact of the reductions taking place in many existing HOPWA jurisdictions due to the increasing number of newly eligible jurisdictions.

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.

Administration Response:

The Secretary of Housing and Urban Development regularly meets with AIDS housing providers and residents to hear how HUD's programs, as well as other federal efforts, are working and how they could be improved and uses this information to improve HUD's response to the housing needs of persons living with HIV/AIDS. When appropriate, he conveys the information he receives to other departments through the Domestic Policy Council and the White House Office of HIV/AIDS Policy.

This fall, ONAP will work with HUD to convene discussions with relevant agencies and community representatives to discuss access to housing for people living with HIV through HOPWA and other 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.

Administration Response:

One of the major recommendations of the Evaluation Task Force in its recent review of the NIH AIDS research program was that the NIH develop an HIV Prevention Science Agenda "that is coordinated, comprehensive, and includes and combines biomedical, behavioral, and social interventions." The Committee also recommended that the OAR convene an HIV Prevention Science Advisory Group to advise the OAR Director on the development and implementation of this agenda. To implement these recommendations, the OAR will establish a Prevention Science Advisory Group under the auspices of the OAR Advisory Council (OARAC). The group will include representation from OARAC, the extramural science community, community organizations, and ex-officio members from other government agencies including the Centers for Disease Control and Prevention with expertise in biomedical and behavioral science-based approaches to HIV prevention. Additional input will be solicited from relevant NIH institutes and centers on an *ad hoc* basis. The Advisory Group will take the lead in the development of an NIH-wide prevention science plan highlighting scientific priorities for the agency, and will advise the OAR Director on related matters.

- 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.

Administration Response:

The NIH supports basic social sciences and behavioral research to strengthen the understanding of determinants and processes that influence HIV-related risk behaviors. As part of this approach, the NIH recognizes the importance of undertaking research on individual differences in human sexuality--social, cultural, cognitive, affective and neuropsychological--that have an impact on the sexual transmission of HIV. This includes studies that examine substance use and abuse by vulnerable groups within the context of sexual encounters and sexual abuse or coercion as determinants of risk taking. Multidisciplinary research that investigates the biobehavioral and sociobehavioral determinants and mechanisms of sexuality, including processes of sexual and gender identity formation is identified as an NIH AIDS investment area in the FY 1998 NIH Plan for HIV-related Research.

- 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.

Administration Response:

The NIH supports the development of strategies that enhance safe sex behaviors, including the development and evaluation of improved, acceptable, effective and safe physical and chemical barrier methods to prevent sexual transmission of HIV and STDs. NIH research encompasses both the biomedical and behavioral aspects of therapies, devices or other barrier approaches of HIV prevention such as condoms (including anal usage of insertive condoms and the female condom), dental dams, and microbicides. NIH has identified the evaluation of HIV transmission and acquisition in relation to local factors including intercurrent STDs, exogenous irritants and oral and anogenital inflammation as a strategic aspect of its AIDS research plan.

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.

Administration Response:

The NIH recognizes that racial and ethnic minority populations are disproportionately represented among cases of HIV/AIDS in the U.S. There has been a striking increase in the impact of HIV/AIDS on women and the rates of HIV transmission remain unacceptably high among gay men,

especially young gay men and gay men of color. The NIH recognizes that in order to be successful, preventive interventions must be targeted to specific populations and must take into account the cultural and social contexts in which individuals live. The NIH's primary behavioral prevention/intervention research portfolio will continue to focus on and produce useful information about populations at highest risk for HIV infection, including urban, disadvantaged, and predominantly ethnic minority populations. Within this portfolio, the NIH seeks to ensure that HIV preventive interventions reflect the most promising behavior change models, tailored to the specific needs of the most vulnerable populations.

CDC also conducts this research and already has research underway to identify and test behavioral interventions for communities of color. Because of CDC's strong ties with community members, State and local health departments and prevention programs, collaborative efforts can and have already been developed to conduct such research. For example, CDC is just completing a multi-site, community level intervention for women at risk for HIV and unwanted pregnancy. Over 80 percent of study participants are African American and intervention components are tailored specifically for this community. Importantly, this intervention focuses on not just one health threat to this population, but the interplay of multiple health threats including HIV, unwanted pregnancy, and STDs. Because of CDC's unique role, coordinating intervention models addressing multiple health threats is feasible and encouraged.

CDC also supports formative research on intervention models for young African American gay and bisexual men. This summer, CDC requested proposals to test behavioral intervention models for young men who have sex with men. In response, CDC received numerous proposals to work with minority men who have sex with men and anticipates funding a 5-year, multi-site intervention trial which will test intervention models for a range of communities of men who have sex with men, including communities of color.

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.

Administration Response:

The Department agrees that increasing the availability of effective substance abuse treatment modalities is critical to our progress in slowing the substance abuse and HIV/AIDS epidemics.

With respect to methadone, the Substance Abuse and Mental Health Services Administration (SAMHSA) agrees that the limited availability of methadone and other effective treatment modalities poses barriers among intravenous drug users. This recommendation is similar to the HIV setaside provision set forth in the substance abuse block grant which requires treatment access priority for injection drug users.

SAMHSA is working with the Food and Drug Administration to review current methadone regulations, particularly as they relate to the certification of clinics.

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.

Administration Response:

CDC believes the dissemination of intervention research finding is critical and therefore has placed a high priority on these activities. Indeed CDC has in place and continues to develop venues for dissemination of intervention research findings. Examples of existing venues include (1) sponsoring numerous conferences where program staff interact with intervention researchers (e.g. the annual HIV Prevention Community Planning co-chairs meeting); (2) the CDC Clearinghouse routinely distributes intervention program and research information; (3) the behavioral interventions; and (4) the provision of technical assistance to community planning groups on behavioral science issues. This year, CDC plans to fund a Request for Proposal, *Replication of Effective HIV Behavioral Interventions*, which encourages researchers and program staff to work together to transfer interventions with documented effectiveness.

- a) Allocate funding for training of front-line prevention workers in application of relevant research findings.

Administration Response:

CDC currently trains and assigns staff to State and local health departments to assist in HIV prevention efforts at the State and community level.

- 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.

Administration Response:

Currently, CDC manages a national AIDS public information system, consisting of mass media education efforts: the CDC National AIDS Hotline; the CDC National AIDS Clearinghouse; and partnerships with national organizations. This system helps ensure public and professional access to information about HIV and improve social support at the community level for individuals to maintain or adopt behaviors that will keep them from acquiring HIV. Additionally, in close cooperation with State and local health departments, CDC funds more than one hundred community based organizations and national/regional minority organizations to assist translating HIV prevention into community efforts.

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.

Administration Response:

The NIAID, NICHD, and NCI have historically maintained detailed rolls of infants and children enrolled in clinical trials sponsored and conducted by the NIH. The OAR is collaborating with HRSA and the Pediatric AIDS Foundation to link the NIH-sponsored clinical trial networks with HRSA-sponsored Ryan White grantees to enhance access to clinical trials and ensure better compliance with therapeutic research protocols. It should be noted that NIH-sponsored research demonstrated that administration of antiretroviral therapy in pregnant women and their babies reduces maternal-fetal HIV transmission. NIH is conducting follow-up studies of these children, and is pursuing additional prevention therapy protocols with newer agents. It can therefore be expected that the number of children born with HIV in the United States will continue to decline.

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.

Administration Response:

The FDA uses every opportunity to strongly encourage pediatric studies throughout the development process to support pediatric-use labeling. For each specific drug development situation, there are a variety of unique circumstances. In the case of the Abbott protease inhibitor, ritonavir, the sponsor submitted plans to study the drug in children and initiated the study prior to approval. However, concomitant adult trials enrolled much faster than the pediatric study, and therefore, yielded results much sooner, leading to a then unprecedented 72-day drug review and approval time. The pediatric study is continuing and is expected to yield sufficient data to include a pediatric-use statement in a labeling update. Examples such as these demonstrate the difficulties that arise in trying to meet the needs of different subject populations without increasing the drug's approval time.

While FDA is sympathetic to the needs of the children with HIV/AIDS, placing formal legal contingencies for approval of a new drug until safety and pharmacokinetic studies in children are

completed and until the pediatric plan for the drug is presented by the sponsoring company may limit its availability to others.

The FDA will continue to urge sponsors to include pediatric populations in their drug development plans, and encourage the submission of pediatric data under 21 CFR 201.57 (f)(9)(iv) for information in the labeling of marketed prescription drugs.

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.

Administration Response:

In FY 1996, the OAR allocated \$115,450,000 for HIV/AIDS vaccine research from the funds provided in the Continuing Resolution. At the level of the FY 1997 House Appropriations Committee allowance, the OAR estimates an allocation for HIV/AIDS vaccine research at \$123,725,000. This would represent an \$8.275 million increase for vaccine research or a 7.16% increase, well above the average increase projected for other NIH budget categories. In addition, in accord with recommendations from the recent evaluation of the NIH AIDS research program, a substantial proportion of the monies from the FY 1996 OAR Discretionary Fund were allocated to vaccine and vaccine-related immunological research. These funds are provided either to supplement existing grants in vaccine research where new opportunities exist or to initiate new research project grants (R01s) rated as excellent to outstanding by peer review groups.

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.

Administration Response:

At the White House Conference on HIV and AIDS in December 1995, the President requested that the Director of OAR chair a group to develop a Federal Biomedical Research Plan and Budget. A government-wide vaccine research agenda is thus a part of that overall plan, which was recently presented to the Vice President by the Director of OAR. The vaccine research portion of the plan represents input from the NIH, DOD, FDA, CDC and VA. In addition, many strong working relationships have developed across agencies. NIH works collaboratively with the DOD, CDC and VA on preparing international and domestic sites for potential phase II and phase III trials. International coordination of data collection by NIH (NIAID) international HIVNET sites will satisfy FDA

requirements to assure a seamless flow of data for vaccine advancement. NIH, CDC and DOD investigators are working closely with Thai government representatives to develop plans for expanded vaccine trials in Thailand. A meeting in Uganda is planned for September 1996 to discuss and formalize future collaborations for cohort development, training of staff, and vaccine trials in that country.

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PACHA RECOMMENDATION - 7.28.96	NATIONAL AIDS STRATEGY
✓ I.A.I. The President himself must engage the American people ...	The discourse that began with the White House Conference on HIV and AIDS has continued, and the concerns raised by WHCA and the follow-up regional briefings have informed the development of the Strategy. (p.4)
I.A.2. The President should then proceed with an address declaring the battle against HIV a national priority and laying out his vision for ending the epidemic.	Ending the epidemic will require the commitment of the public and private sectors on multiple fronts. The President has outlined six national goals to guide our efforts. (pp. 3,6)
✓ I.B.I. The President should continue his support of the Ryan White CARE Act	The past and future commitment to preserve funding the CARE Act programs is outlined on p. 22-24.
I.B.2. The President must maintain a strong commitment to the entitlement status of the Medicaid program, including a willingness to veto any legislation that inadequately funds or transforms Medicaid into a block grant.	The Administrations's past and future commitment to preserve Medicaid funding is outlined on p. 22-24.
✓ I.B.3. The President should continue to demonstrate strong support for ...	The Administrations's past and future commitment to preserve HOPWA funding is outlined on p. 22-24.
I.C.I. The President should make HIV prevention an investment priority during budgetary decision-making.	The President has proposed significant increases for HIV prevention in the FY 1997 budget (p. 10) and has identified five areas where we should focus our efforts (p.11 and pp. 11-15).
I.D.I. The President should continue to show strong support for a coordinated Federal approach to HIV/AIDS research, including continued support for the Office of AIDS Research (OAR).	Support for a strong leadership and coordination of Federal research is a central element of the research chapter (p.18).
I.E.I. In talking publicly about HIV, the President should vigorously speak out against HIV-related discrimination and condemn prejudice based on race/ethnicity and sexual orientation, which damage our efforts to combat AIDS. The President should strongly and visibly oppose any amendments to HIV-related legislation that are designed to divide the American people along line of sexual orientation, substance abuse history, race/ethnicity, or other factors.	The fourth goal of the National AIDS Strategy is to fight discrimination on all fronts including enforcing rights, protecting workers, opposing discriminatory legislation, and providing visible leadership. (pp. 3, 6, 27-29)

PACHA RECOMMENDATIONS 12.8.95	NATIONAL AIDS STRATEGY
II.A.I During his State of the Union Address, the President should renews his commitment to prevention new infections, caring for people now living with HIV/AIDS, and finding a cure, a vaccine, and effective treatments for HIV. The President should, during this address, announce the immediate release of his updated national strategy on AIDS.	These goals are articulated throughout the NAS. Preventing new infections is one of the national goals (p.3,6) requiring multiple approaches (p. 9-15). Caring for people now living with HIV is the third national goal (p. 3,6) requiring and investment in care and services (p.22-25). Finding a cure, vaccine, and effective treatments is the first national goal (p.3,6) will require a commitment in four major areas (p.17-21).
II.A.2. To further accomplish the goals President Clinton outlined at the WHCA, the Clinton/Gore Administration should ensure that key Cabinet Secretaries initiate and maintain regular face-to-face meetings with HIV service providers, people living with HIV/AIDS, and their advocates to ensure consistent and ongoing communication and partnership with community members on the front lines of the AIDS epidemic.	The NAS is intended to be a living document that will require regular updating. Developing an implementation plan and updating goals will require an ongoing dialogue and collaborative efforts between the public and private sectors. (p.3-4)
II.B.1 Continue to support and defend the entitlement status and funding for Medicaid and Medicare, and continue to oppose any efforts to restrict eligibility and services for people living with HIV/AIDS.	The Administrations's past and future commitment to preserve Medicaid and Medicare funding is outlined on p. 22-24.

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PACHA RECOMMENDATIONS - 12.8.95

II.B.2. Direct that any waivers granted to States under the Medicaid program ensure access to a comprehensive continuum of care for people living with HIV/AIDS. To implement this policy, the President should direct the HCFA to establish national criteria by which to assess State waiver applications and to ensure that these criteria be consistent with current health care knowledge. These criteria also should be consistent with the provisions of the Americans with Disabilities Act (ADA), and State plans should be reviewed for this purpose by the HHS Office of Civil Rights.

II.B.3. Direct the HCFA to ensure that State Medicaid programs cover HIV testing and counseling.

II.B.4. Direct HCFA to report to the Council, at its next meeting, possible strategies to address the need to ensure that all Food and Drug Administration (FDA) approved drugs are covered under State Medicaid plans, even when prescribed for "off-label" indications. These strategies should address both policies and vigorous enforcement mechanisms.

II.B.5. The Administration should direct these Federal agencies that either finance or administer health care services (including but not necessarily limited to HCFA, the Department of Veteran's Affairs [VA], the Department of Defense, and the Department of Justice Bureau for Prisons) to develop oversight guidelines for HIV managed health care programs. This will also require effective regulatory enforcement mechanisms.

II.B.6. The Administration should direct HRSA to develop a coordinated agency-wide approach that provides effective education, training, and technical assistance to HIV/AIDS providers and AIDS service organizations on health care management issues. Such an approach should include active participation by the private sector.

II.B.7. Before complementary therapies are widely used, the President should direct all appropriate agencies to support investigations of the efficacy of complementary therapies and provide increased financial support for this effort. Therapies shown to have benefit should be reimbursed under Medicaid.

II.B.8. The President should continue to support full funding to a national network of AETC's, and direct HRSA to ensure that the work of the AETCs is coordinated with the community providers and planning groups.

II.B.9. The Administration should direct HRSA to review and report to the Council at its next meeting the effectiveness of the Bureau of Health Professions' education activities specific to HIV/AIDS.

II.C.1. The CDC and the President should direct the Secretary of HHS to produce an annual estimate of HIV incidence based on seroprevalence studies and to work to ensure a reasonable relationship between epidemiological trends and CDC prevention funding. This

report should specifically examine the demographic characteristics and geographic distribution of populations that experience disproportionate increase in new infections.

- o The CDC should issue to the President an annual estimate of HIV incidence based on seroprevalence studies that provides a geographic analysis of the populations where there is a continuing disproportionate increase in new HIV infections.
- o The President should direct the Secretary of HHS to ensure that resources are allocated to accomplish this task.
- o The President should ensure that funding is adequate and responsive to the epidemiological trends, needs, and prevention infrastructure of affected communities.

II.C.2. o The President should direct the CDC to develop a behavioral surveillance mechanism that will provide an analysis of patterns in risk-taking behavior; and

o The President should direct the CDC to join with the National Institute on Drug Abuse (NIDA) and other relevant agencies to institute surveillance methods for detecting patterns of risk-taking behaviors in populations that show a continuing disproportionate increase in AIDS cases; and

o He should direct the Secretary of HHS to coordinate the planning of an early warning system and ensure its ongoing use.

II.C.3. The administration should pursue a comprehensive strategy to decrease HIV transmission related to injection drug use, which accounts for at least 50% of new HIV infections. In addition, high-risk sexual behavior while under the influence of drugs and/or alcohol accounts for another significant percentage of new cases of HIV disease. Strategies must explicitly address the sharing of injection drug use paraphernalia, as well as the high-risk sexual behavior associated with drug and/or alcohol use.

II.C.3.a. Increase access to effective substance abuse prevention and treatment research by:

- o Opposing congressional efforts to cut SAMHSA and other Federal funding for drug abuse treatment and prevention programs in FY 1996 appropriations.
- o Restoring budget requests for SAMHSA and other Federal funding for drug abuse treatment and prevention programs to at least the FY 1995 levels.

II.C.3.b. Revise the Department of Justice Model Drug paraphernalia Act, which serves as a model for State drug paraphernalia laws, to make it consistent with current reports, studies, and data relating to the access to sterile syringes as an effective intervention to counter HIV transmission among IDUs.

II.C.3.c. The President should direct the Secretary of HHS to provide a recommendation (within 90 days) regarding the impact of needle-exchange programs on HIV infection and substance abuse. The recommendation should be based upon current reports, studies, and data on needle-exchange programs, and should develop and execute a plan to carry out the

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recommendations and indicate what programs and demonstration projects will be started or expanded.

II.C.4. The President should reaffirm his support for community-based planning for prevention activities.

II.C.4.a. Direct the CDC to maintain HIV prevention programs independent of any consolidated grant programs, including the currently proposed Performance Partnerships Grants.

II.C.4.b. Direct the CDC to continue direct funding to community-based organizations.

II.C.4.c. Direct the CDC, with the assistance of existing national minority organizations and other appropriate partners, to structure its technical assistance programs to address the prevention program development and infrastructure needs of populations that are currently experiencing a continued disproportionate increase in new infections.

II.C.5. Direct the Director of the Indian Health Service (IHS) to develop a comprehensive AIDS prevention and care plan for Indian Country (within 90 days) with the input from consumers of IHS services.

II.D.1. The Vice President's leadership and technological expertise should be sought to bring together the resources and expertise of various Government agencies, the private sector, community groups, and other nations in the effort to develop HIV vaccines and microbicide and to "reinvent" the Government's involvement in the development of these products.

II.D.2. The priority for funding by the OAR for microbicide research and development , as well as such funding within CDC, must be increased substantially, with a concomitant increase of full-time equivalents (FTE's) allocated for this priority.

II.D.3. the Government should develop mechanisms to increase the pool of investigators in microbicide research and development, especially those involved in biomedical and behavioral aspects.

II.D.4. In HIV/AIDS clinical research, the NIH must ensure the early and fundamental involvement of behavioral and social scientists in the process of initial study development, design, and implementation.

II.D.5. HHS should develop ongoing mechanisms to ensure the rapid translation of breakthrough research findings into clinical practice.

II.D.6. A public health policy consensus panel should be convened by the Public Health Service by the end of April 1996 to assess the possible efficacy of available spermicide (e.g. nonoxynol-9) and other licensed products (e.g. chloerhexidine, benzalkonium chloride, diaphragms) to be used in "harm reduction" algorithms to decrease sexual transmission of

HIV. The panel should include senior public health policy officials (CDC, FDA, HHS Secretary's Office), research agencies (NIH), community groups (women's health research advocates, commercial sex workers, interested foundations), academia, and industry. The meeting should also feature a review of the entire status of anti-HIV microbicide research.

II.D.7. The Council asks the FDA to comment by January 31, 1996, upon the proposed FDA regulations that require inclusion of women in all clinical trials of drugs for treatment of HIV/AIDS in which there is no known evidence of reproductive toxicity. When such toxicity has been documented, alternatives that allow the inclusion of women should be provided.

II.D.8. The FDA must require a sponsor to file a gender accrual analysis in the annual Investigational New Drug (IND) report, as stated in the final version of the proposed regulations published in the *Federal Register*, Vol. 60, No. 184, at 46794. In addition, for the New Drug Application (NDA) and the product licensing application (PLA), the regulations must require sponsors to analyze clinical data by gender and assess potential differences, including reporting on side effects by gender.

II.D.9. The Secretary of HHS should publish for public comment by March 1, 1996, the proposed regulations regarding participation of pregnant women in clinical trials, with the following revision: A pregnant woman's inability to obtain consent from the father of the fetus should not disqualify her from participation in a federally funded clinical trial. This fact should be stated in the protocol consent form.

II.E.1. The Administration should rescind mandatory HIV testing and/or discriminatory policies currently in place in the U.S. Foreign Service, the Peace Corps, the Job Corps, the State Department, and the military, when there is no compelling public health justification.

II.E.2 The Secretary of HHS should instruct the CDC to (1) review its guidelines that arbitrarily restrict HIV-infected health care workers and that lead to discrimination against them, and (2) ensure that these guidelines are consistent with the prevailing scientific and public health knowledge on the issue.

II.E.3. The Administration should oppose any congressional efforts to require that otherwise qualified military service personnel who test positive for HIV be discharged, including a veto of the Department of Defense Reauthorization Act if such a provision is included. In his veto message, the Council recommends that the President state that the veto is, in part due to the inclusion of this provision.

II.E.4. The Administration should direct the CDC, Immigration and Naturalization Service (INS), and the Department of State to monitor and coordinate the HIV testing of immigrants to ensure informed consent, pre- and post-test counseling, and appropriate legal and health referrals and to ensure that waivers of the HIV exclusion are granted on a priority basis when permitted by statute. Also, when permitted by statute, the INS and the Executive Office of Immigration Review (EOIR) should grant stays of deportation, suspension of

deportations, extended voluntary departure, deferred action, and asylum based on the social group category of HIV-positive individuals.

PACHA CONTINUED STEPS FOR ACTION - 04.26.96

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.
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

- 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.

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.

Recommendations Crosswalk

Presidential Advisory Council Recommendations July 28, 1995	National AIDS Strategy (NAS) Responses, Accomplishments, and Future Opportunities September 1996
Prevention	P.9
The President should make HIV prevention an investment priority during budgetary decision making.	President Clinton has proposed to increase funding in the FY 1997 Budget for AIDS prevention at HHS by 27 percent (since FY 1993).
Research	P.16
The President should continue to show strong support for a coordinated Federal approach to HIV/AIDS research, including continued support for the Office of AIDS Research (OAR).	Since taking office in 1993, President Clinton has escalated AIDS research efforts by developing the first Federal Plan for Biomedical Research on HIV and AIDS to improve coordination of HIV-related research; and
	Facilitating creation of the Forum for Collaborative HIV Research to to identify opportunities for clinical effectiveness.
	As part of the Clinton Administration's continued commitment to HIV research through the OAR, the NIH's AIDS Research Task Force recommended to develop a comprehensive NIH HIV prevention science agenda, combining biomedical, behavioral, and social interventions; and to improve coordination among NIH-supported AIDS clinical trials programs.

	The President has requested \$449 million for the NIH overall, an increase of \$24 million for NIH supported AIDS research and an increase of \$4 million for AIDS research government-wide.
Services	Care & Services/P.22
The President should continue his support of the Ryan White CARE Act and should endeavor to prevent the Congress from attaching unnecessary funding restrictions. He should also continue to vigorously support funding levels for the Ryan White CARE Act that are responsive to the rising caseloads and costs of delivering comprehensive services to people with HIV/AIDS and make the CARE Act a budget priority.	President Clinton has signed the Ryan White CARE Act Amendments of 1996, and has proposed to increase Ryan White CARE Act funding by 157 percent since FY 1993.
	For FY 1997, President Clinton has sought \$896 million for the Ryan White Care Act.
The President must maintain a strong commitment to the entitlement status of the Medicaid program, including a willingness to veto any legislation that inadequately funds or transforms Medicaid into a block grant.	The President has fought to preserve the Medicaid guarantee of coverage for the more than 50% of people with AIDS and 90% of children with AIDS who rely on this program for their health coverage.
	The NAS, identifies the need to maintain the historic Federal-State partnership on Medicaid and acknowledges that proposals to block grant Medicaid would endanger care for people living with HIV and AIDS.
Combating Discrimination & Social Prejudice	Civil Rights/P.27

In talking publicly about HIV, the President should vigorously speak out against HIV-related discrimination and condemn prejudice based on race/ethnicity and sexual orientation, which damage our efforts to combat AIDS. The President should strongly and visibly oppose any amendments to HIV-related legislation that are designed to divide the American people along lines of sexual orientation, substance use history, race/ethnicity, or other factors.	The President led the successful effort to defeat the "Dornan Amendment" and continues to oppose its enactment.
	The President has acted to establish a HIV/AIDS education program for all Federal workers; and hosted the first ever White House Conference on HIV and AIDS.
	The Federal government will continue to exhibit strong enforcement of the Americans with Disabilities Act to enforce the civil rights of people living with HIV and AIDS. The joint effort of the HHS and the Justice Dept. aimed at access to nursing homes of people living with HIV is a significant effort in protecting the rights of those individuals.
	The Federal government is examining existing policies related to the exclusion of people living HIV from federal employment. The Director of the Office of AIDS policy is working with Federal Agencies to examine individual policies to determine whether they comply with Federal and health guidelines
	The Administration will continue to oppose, in the strongest terms possible, efforts by the Congress to discriminate against people living with HIV and AIDS.