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PACHA [Presidential HIV/AIDS Advisory Council] - Recommendations and Responses (Approach)

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President's Advisory Council on HIV/AIDS

Recommendations

Discrimination

I.E.1

Passed on: 7/28/95
Resolved? No

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 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 Response

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.

Further Council Comment 10/30/97

We are pleased that the President and the Vice-President have spoken out not only about HIV-related discrimination, but also about discrimination based on race and sexual orientation. We continue to hope that these sentiments will be translated into greater action, particularly with respect to the federal government's own policies of mandating HIV testing and employee discrimination.

II.E.1

Passed on: 12/8/95
Resolved? No

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.

Assessment of 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.

Follow-up 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.

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Progress

October 21, 1997 --- Todd sent a letter to Nancy Hendry, General Counsel, and David Gootnick, Director, at the Office of Medical Services for the Peace Corps discussing its policies regarding HIV positive applicants, staff, and volunteers.

October 31, 1997 --- Sandy received a letter from the Department of Defense (John Mazzuchi, Deputy Assistant Secretary for Clinical Services) regarding promotion opportunities for HIV infected Service personnel.

November 5, 1997 --- Daniel received a letter from the Department of State (William J. Burns, Executive Secretary) regarding HIV testing for Foreign Service personnel. Candidates for the Service are subject to mandatory HIV testing. A positive result will disqualify an individual from entry into the Service based on the belief that an HIV+ person is unable to serve in certain locations (due to lack of access to adequate medical facilities, exposure to other infectious diseases, and the potential need to administer live vaccines). The D.C. U.S. District court supported the policy of mandatory testing in a 1987 ruling. Foreign Service employees who become HIV+ subsequent to their entry into the Service are issued limited medical clearances, as are family members of employees. Foreign Service employees who develop AIDS are prohibited from overseas assignment. An appeals process does exist. Confidentiality is preserved in all cases.

Administration Response 4/1/96

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 HIV testing. After a three-month trial period, if successful, this program will be made national policy for the Job Corps.

Further Administration Response (DOL) 9/4/97

This is in response to your recent memo about the Job Corps HIV testing program. We met with the council in 1995. Following the line of the discussions at that meeting, we are changing from special mandatory testing to routine testing for HIV as is currently done for other blood tests such as for syphilis and anemia and other tests as for chlamydia and gonorrhea. All of these tests are done as essential components of the entrance medical examination.

It took us approximately 1 1/2 years to get approval from OMB for our health questionnaire which is administered to all applicants for admission and for the change stated above. During this time, we have piloted the revised HIV procedures, including HIV testing of nonresidents, in the 15 centers of the Dallas region. We have had phenomenal success in that approximately 10,000 students accepted the testing; about 6 first refused the test, but all accepted after counseling. The attached Change Notice (97-05) states the revised procedures we will institute in October 1997.

We feel it is exceedingly important to offer the HIV test, since prophylactic treatment for the infection is readily available, and we have given or referred for treatment all those with a positive test who need treatment as shown by clinical and/or laboratory evidence.

Further Council Comment 10/30/97

The Council is pleased by the Job Corps' recent announcement that applicants will now be admitted to the Job Corps irrespective of HIV status throughout the Job Corps program. We remain deeply troubled, however, by the failure of other of the other departments and programs we have cited either to eliminate their mandatory testing and/or employment discrimination policies, or to articulate a compelling public health rationale for such policies.

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Administration Response
11/5/97

The Foreign Service Act of 1980 directed the Secretary to establish a health care program to promote and maintain the physical and mental health of members of the Service and their families. Section 101 (4) of the Act specifies that "the members of the Foreign Service should be available to serve in assignments throughout the world." Based on the Act, worldwide availability is a criterion for entrance into the Foreign Service. To ascertain whether recipients of conditional offers of employment in the Foreign Service can meet the criterion of worldwide availability, they must undergo a medical examination prior to appointment. This has any of a variety of diseases and/or medical conditions that would preclude that individual from being able to serve anywhere in the world. Individuals who are determined to have such diseases or conditions are given limited medical clearances and thus disqualified from entrance into the Foreign Service, subject to the waiver process mentioned below. One part of the medical examination consists of laboratory studies that include both HIV and ELISA tests. An applicant who is determined by these tests to be HIV-positive is considered not to be available for assignment worldwide. HIV is only one of many medical problems or conditions that would disqualify an applicant from the Service because of the resulting limitations on worldwide availability.

In the Foreign Service context, there are three reasons why HIV positive individuals are not worldwide available medically, and thus must be identified in advance through mandatory testing:

- 1. ACCESS TO ADEQUATE MEDICAL FACILITIES: It is essential for a person infected with HIV to have quick access to high quality medical resources. Most overseas posts do not have access to the medical resources necessary to maintain the health of individuals infected with HIV. This is particularly important in today's medical environment where new HIV therapies can prolong life and improve the quality of life of HIV infected patients. Quality medical care has a positive impact on the evolution of the HIV infection in many individuals, especially those who are newly infected. Early diagnosis and prophylactic treatment of HIV related opportunistic infections is also paramount.*
- 2. ACTIVATION OF A LATENT HIV INFECTION: There is a strong suspicion among experts that exposure to other infectious diseases can activate latent HIV and cause progression to AIDS. The Office of Medical Services (M/DCP/MED) will therefore not support the assignment of a person infected with HIV to a post where there is a high incidence of infectious disease such as tuberculosis and infectious diarrhea.*
- 3. LIVE VACCINE: For many posts where the incidence of contagious diseases is high, vaccination with live vaccines is required. Live vaccines, however, are contraindicated in patients infected with HIV especially those whose immune systems have been weakened. Therefore, M/DGP/MED, in accordance with accepted sound medical practice, will not risk administering live virus vaccines to a person who is infected with HIV.*

The Department's policy of mandatory HIV testing was supported by the U.S. District Court for the District of Columbia in 1987. The district court was satisfied that the Department had serious grounds for concern about additional risks that persons with HIV encountered in many foreign posts due to inadequate diagnostic and treatment centers. The court stated: "The Rehabilitation Act does not require the Department of State to ignore the obvious relevance of HIV infection to its qualification of Foreign Service employees for long terms of worldwide duty abroad."

Foreign Service employees who become HIV positive subsequent to their entrance into the Foreign Service are issued limited medical clearances. In-service limited clearances are issued to individuals who have one or more medical conditions that require periodic and specialized medical evaluation and/or treatment, or whose medical condition would be aggravated by certain environmental conditions. Many conditions can result in a limited clearance, such as asthma, insulin dependent diabetes, coronary artery disease, chronic active hepatitis, and HIV, among others. When an employee holds a limited clearance, potential assignments are considered on the basis of the capability of local resources for monitoring and care of the medical condition or diseases and on whether or not service in that environment would place the person at increased risk. Every effort is made to find posts to which HIV-positive employees can be safely assigned, as is the case for employees with other medical conditions or diseases that result in limited clearances. HIV-positive employees may serve, and in fact are currently serving, overseas in countries where local health providers and medical facilities can follow their conditions.

Family members of applicants and family members of Foreign Service members who are found to be HIV positive are also issued limited medical clearances. The clearance status of an applicant's family does not have any effect on whether the applicant is accepted into the

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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.
Passed on:	12/8/95	
Resolved?	No	
<i>Administration Response</i>	<i>The Secretary of HHS has asked for a review of these guidelines</i>	
<i>Assessment of Response</i>	<i>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.</i>	
<i>Follow-up Action Recommended</i>	<i>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.</i>	
<i>Further Council Comment</i> 10/30/97	<i>The Council remains disturbed and baffled by the CDC's failure to review their guidelines or to announce a target date for doing so.</i>	
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.
Passed on:	12/8/95	
Resolved?	No	
<i>Administration Response</i>	<i>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.</i>	
<i>Assessment of Response</i>	<i>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.</i>	
<i>Follow-up Action Recommended</i>	<i>Continued vigilance will be required as similar amendments have been introduced in Congress.</i>	
<i>Further Council Comment</i> 10/30/97	<i>There are no new developments in this area. We continue to commend the Administration for the leadership it exercised on this issue.</i>	

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II.E.4

Passed on: 12/8/95
Resolved? No

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 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.

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Assessment of 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.

Follow-up 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.

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Recommendations

Administration Response

(DOJ)
4/23/96

Because the INS does not play a role with regard to the medical screening process undergone by aliens applying for a visa or for admission to the U.S., it is not the appropriate entity to monitor and coordinate HIV testing and counseling. (The INS does, however, test detainees upon request or those suspected of having HIV/AIDS. Additionally, INS provides pre- and post-test counseling to detainees deemed at risk.) The examination process is governed by HHS regulations. See 42 C.F.R. part 34. The Centers for Disease Control (CDC) publishes the technical regulations to be followed by physicians in performing medical exams and reporting the results. Thus, the initial part of the recommendation would more appropriately be directed to HHS and CDC.

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 deportation 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 U.S. 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 a member of a "particular social group" if the evidence in the individual cases supports such a conclusion*. 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 individuals 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 infections 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.

* 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.

Further Council Comment

10/30/97

To be provided by Steve Lew.

President's Advisory Council on HIV/AIDS

Recommendations

Leadership

I.A.1

Passed on: 7/28/95
Resolved? No

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.

Assessment of Response
7/8/96

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.

Follow-up Action
Recommended
7/8/96

See Recommendation A.2 in Section II.

Administration Response
12/6/96

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.

I.A.2

Passed on: 7/28/95
Resolved? No

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 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 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.

Follow-up Action
Recommended

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

President's Advisory Council on HIV/AIDS

Recommendations

II.A.1

Passed on: 12/8/95
Resolved? No

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 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 Response

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

Follow-up 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.

II.A.2

Passed on: 12/8/95
Resolved? No

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 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 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.

Follow-up 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.

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Administration Response
(DOJ)
4/23/96

The Department supports this recommendation; the Assistant Attorneys General for Policy Development and for Civil Rights are willing to participate in meetings to strengthen the Department's relationship with the HIV/AIDS Community.

III.A.1

Passed on: 4/26/96
Resolved? Yes

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, D.C. this October.

Administration Response
(ONAP)
8/30/96

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.)

IV.A.1

Passed on: 12/15/96
Resolved? No

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

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

Administration Response
(USAID)

HIV/AIDS funding for USAID continues to be relatively level, even in the face of rather drastic cuts to other assistance budgets including other health and family planning programs. Legislative language that has accompanied recent appropriations bills has been instrumental in maintaining consistent funding levels for HIV/AIDS. Over the past three fiscal years the HIV/AIDS funding for USAID has remained between \$121 million and \$117.5 with FY'97 and FY'98 levels expected to be at \$117.5 million.

While USAID and the HIV/AIDS program is appreciative of this consistent funding, the attached graph indicates the growing needs of the developing world vis-a-vis HIV and AIDS. It should also be noted that the annual domestic HIV/AIDS prevention budget is approximately \$700 million, well in excess of our U.S. HIV/AIDS assistance to more than 40 developing countries. (see graph)

Administration Response
(HUD)
5/21/97

The President's FY 1998 budget calls for an \$8 million increase in funding for the HOusing Opportunities for Persons with AIDS (HOPWA) program. This 4.1% increase over the FY96 appropriation only reveals part of the President's commitment to this program. In FY96, the President supported the 14.6% increase in funding for the HOPWA program that was eventually passed by both Houses of the Congress. Since his first year in office, the President, with the support of Congress, has succeeded in nearly doubling funding for housing and services for persons living with HIV/AIDS through the HOPWA program. While clearly a need for appropriate and safe housing for persons living with HIV/AIDS still exists throughout the nation, the housing and service needs of persons living with HIV/AIDS have been a priority at HUD.

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Administration Response (HHS) 4/5/97

In the FY 1998 budget request, the President has asked for \$1.036 billion for Ryan White CARE Act (RWCA) treatment activities. This is an increase of \$40 million (4 percent) over the FY 1997 level of funding. The new request includes:

- \$455 million for emergency relief grants to 40 cities and communities.
- \$432 million for formula grants to States (a \$15 million increase). Of this amount \$167 million is for the Drug Assistance Program (ADAP).
- \$85 million for discretionary grants to allow an additional five to ten thousand individuals who are infected with, or at-risk of, HIV infection to receive primary care services.
- \$40 million grants for coordinated HIV services and access to research for children, youth, women, and families.
- \$17 million for AIDS Education and Training Centers.
- \$7.5 million for the AIDS Dental Reimbursement program.

Although the level of support being presented for ADAP is the same in FY 1988 and FY 1997, (\$167 million), we feel that by providing a Title II increase to the overall State grant, States will be given the flexibility to provide the primary care services--AIDS drugs, insurance continuation--according to their own needs. States and local metropolitan areas are making difficult choices in setting priorities among competing needs for pharmaceutical treatments and other needs for health care and support services, including primary medical care necessary to ensure appropriate use of new therapies with clinical monitoring. Title I and II projects focus broadly on the development of systems of care with an emphasis on increasing access for disadvantaged and hard to reach populations and creating a continuum of care that both enrolls and retains people with HIV disease in care. The numbers of people needing care through CARE Act programs is increasing, and the populations now presenting in need of services (women, intravenous drug users, people of color) have historic barriers to accessing care. In addition to more complex and costly needs, States are increasingly reassessing their criteria for enrollment in and use of AIDS Drug Assistance Programs (ADAP) and have instituted clinical guidelines, caps, and more stringent financial criteria for enrollment. These are important trends that the Administration is monitoring in terms of identifying the need for services and ensuring that resources are maximized to serve those in need.

IV.A.2

Passed on: 12/15/96
Resolved? No

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

Administration Response 11/26/97

No response given to date.

IV.A.3

Passed on: 12/15/96
Resolved? No

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

Administration Response 11/26/97

No response given to date.

President's Advisory Council on HIV/AIDS

Recommendations

IV.A.4

Passed on: 12/15/96

Resolved? No

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

Administration Response
11/26/97

No response given to date.

IV.A.5

Passed on: 12/15/96

Resolved? No

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

Administration Response
11/26/97

No response given to date.

President's Advisory Council on HIV/AIDS

Recommendations

Miscellaneous

IV.M.1

Passed on: 4/5/97
Resolved? No

The President should forcefully oppose the HIV Prevention Act of 1997. Many provisions of this bill, including enforced mandates, interference with State and local control over health care policies, and the potential for institutional discrimination against people living with HIV/AIDS, will undermine rather than enhance our nations HIV prevention strategy.

Administration Response *(DD)* *10/13/97*

The Civil Rights Division agrees with the Council's recommendation to oppose the proposed HIV Prevention Act of 1997. The legislation, as drafted, violates the Americans with Disabilities ACT (ADA), because it conditions the receipt of medical and/or funeral-related services on the acceptance by the patient, or a decedent's representative, of mandatory testing for HIV/AIDS and the subsequent disclosure of those test results to sexual partners and health care and other professionals. For example, the bill would require that a corpse be tested for HIV/AIDS status before the decedent's family or representative could arrange for funeral and burial services.

The legislation is also abhorrent from a public policy standpoint. It discourages people from seeking voluntary HIV testing by requiring notification of sexual partners, health care professionals, state health care officials, and others regarding test results. Although the CDC has recommended partner notification as a primary prevention service, it has not sought to make partner notification mandatory, because it believes that the public interest is better served by ensuring that people seek testing under conditions that preserve their privacy and the confidentiality of their HIV status.

The legislation appears to create potential conflicts with the Ryan White Care Act, under which program entities may receive funding only if they ensure the confidentiality of HIV/AIDS information. The "sense of Congress" regarding confidentiality of HIV information, set forth in section 5 of the bill, stands in contrast to the provisions of the bill that mandate disclosure of HIV/AIDS status to a variety of persons.

Finally, the section of the legislation providing for the testing of certain indicted individuals is ambiguous in that it is not clear whether the victim of any crime, not just a sex crime, may request that a defendant be tested.

IV.M.2

Passed on: 4/5/97
Resolved? No

The Secretary of Health and Human Services should eliminate all regulations and requirements for mandated reviews by citizen review panels of the content of HIV prevention materials. HIV prevention materials produced or distributed with federal funding should be free of restrictions on content, subject only to review for scientific accuracy and cultural appropriateness for the targeted population. Grantees should be given great flexibility in utilizing the least burdensome methods of conducting these reviews.

Administration Response *11/26/97*

No response given to date.

President's Advisory Council on HIV/AIDS

Recommendations

VI.M.1

Passed on: 4/5/97
Resolved? No

The President should direct appropriate agencies to take all steps necessary to encourage scientific research, including clinical trials, to gauge the potential benefits and/or risks of medical marijuana use (including smoked marijuana) on chronic pain, nausea, glaucoma and other conditions due to illnesses such as AIDS, cancer and other chronic diseases.

Further, the President should direct that, pending the results of such research, the government refrain from any efforts to prosecute doctors who, in good faith, discuss the use of medical marijuana or recommend it for their patients.

Administration Response

(DD)
10/13/97

With regard to the background information provided in the Council's statement, the following changes are necessary in order to reflect the current status of the Arizona and California initiatives.

*On April 30, 1997, the U.S. District Court for the Northern District of California entered a preliminary injunction against the government in Conant V. McCaffrey, in which a group of California physicians and patients sued the Department of Justice, the Drug Enforcement Administration, the Department of Health and Human Services, and the Office of National Drug Control Policy. The lawsuit challenges the government's announcement that it would enforce the federal Controlled Substances Act (21 U.S.C. **801, et seq.) against physicians who recommend that their patients use marijuana pursuant to California Proposition 215.*

The preliminary injunction enjoins "defendants, their agents, employees, assigns, and all persons acting in concert or participating with them," from (1) threatening or prosecuting physicians, (2) revoking a physician's DEA registration to prescribe controlled substances, or (3) excluding them from participation in Medicare or Medicaid "based upon conduct relating to medical marijuana that does not rise to the level of a criminal offense." The preliminary injunction also covers "non-criminal activity related to those recommendations, such as providing a copy of a patient's medical chart to that patient or testifying in court regarding a recommendation that a patient use marijuana to treat an illness."

The second part of the recommendation, calling upon the President to direct the government to refrain from prosecuting doctors who prescribe marijuana for medical purposes, is inconsistent with the position taken by the government in ongoing litigation. This latter part of the recommendation should be deleted and replaced with language stating that the government is complying with the preliminary injunction while litigating the matter in court.

Moreover, the Department is concerned that the subjects of any clinical trials be notified of potential harmful effects and that they execute written waivers attesting that they have been notified. We therefore recommend the insertion, after "clinical trials," of the following language: "conducted in accordance with standard medical research practices".

President's Advisory Council on HIV/AIDS

Recommendations

Prevention

I.C.1

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

Passed on: 7/28/95

Resolved? No

Administration 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 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.

Follow-up 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.

Assessment of Further Response 8/13/97

(DRAFT)

The President failed to make HIV prevention an investment priority in the federal budget. The recent budget agreement with Congress removed protected status from all AIDS programs, including those that have previously been designated as investment priorities. The Council is deeply concerned that AIDS/HIV funding, including funding for programs to prevent HIV transmission, will suffer in the future, as AIDS competes with numerous other social programs for increasingly scarce discretionary funding. The Council urges the President to vigorously advocate with Congress to confer protected budgetary status on AIDS programs, including HIV prevention.

The Council applauds the President for proposing an increase to the CDC's HIV prevention budget for FY98. Despite this proposed increase, HIV prevention, which is among the most cost-effective health investments the federal government could make, remains badly underfunded. Indeed, the federal investment in HIV prevention represents but a tiny fraction of the annual cost of HIV disease to the federal government and to society at large. A substantial increase in HIV prevention spending will be needed if the President is to make good on his promise to the American people to reduce the number of new HIV infections each year until there are none.

Further Administration Response 10/31/97

HRSA, in a letter from Earl Fox, Acting Administrator, urges that recommendations relating to an HIV prevention priority should take into consideration the critical role of sexually transmitted diseases in HIV transmission and should address the national investment in the treatment and prevention of these diseases.

President's Advisory Council on HIV/AIDS

Recommendations

II.C.1

Passed on: 12/8/95

Resolved? No

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

Administration 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 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.

Follow-up 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.

Administration Response (CDC)

President's Advisory Council on HIV/AIDS

Recommendations

Assessment of Further Response 8/13/97

(DRAFT)

The urgency of this recommendation has only increased since it was initially issued. Advances in the treatment of HIV disease are prolonging life and slowing the progression of HIV disease, meaning that fewer individuals with HIV disease are captured by the AIDS surveillance system. Although the AIDS case reporting system is the most impressive public health surveillance system in the world, it has never effectively monitored the breadth of the epidemic, particularly new HIV infections, and is even less capable of doing so today. Reassessment of the nation's HIV/AIDS surveillance approaches is urgently required.

The Council applauds the CDC for convening an expert consultation earlier this year on the future of AIDS/HIV surveillance. At present, however, there has been little concrete progress on the followup actions previously recommended by the Council. There is no mechanism for providing a reliable annual estimate of HIV incidence, making it impossible to monitor the President's promise to reduce the number of new HIV infections annually until there are none. The CDC is currently unable to develop HIV seroincidence measures for key populations and has dismantled the only population-based serosurvey, the survey of childbearing women.

Moreover, no mechanism currently exists to ensure that there is a reasonable relationship between local epidemiology and the spending of CDC prevention funds by state and local health departments. Although epidemiologic relevance is one of the many criteria by which CDC judges state and local prevention plans, CDC has not clearly articulated its enforcement mechanisms for rectifying instances where spending departs from local epidemiology.

As with other initiatives related to HIV prevention, underfunding impedes the federal government's ability to undertake effective HIV/AIDS surveillance. Enhanced funding is required to enable CDC to effectively monitor the epidemic.

II.C.2

Passed on: 12/8/95
Resolved? No

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.

Administration 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.

President's Advisory Council on HIV/AIDS

Recommendations

<i>Assessment of Response</i>	<i>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.</i>
<i>Follow-up Action Recommended</i>	<i>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.</i>

<i>Assessment of Further Response</i> 8/13/97	<i>(DRAFT)</i> <i>Progress has been made in enhancing the nation's behavioral surveillance and research, but such efforts remain badly underfunded. No discernible progress has been made in developing an early warning system to help the country prevent outbreaks in new populations or in specific geographic areas.</i>
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II.C.3 Passed on: 12/8/95 Resolved? No	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.
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<i>Administration Response</i>	<i>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.</i>
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<i>Assessment of Response</i>	<i>See Recommendation II.C.3a-c.</i>
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<i>Follow-up Action Recommended</i>	<i>See Recommendation II.C.3a-c.</i>
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<i>Assessment of Further Response</i> 8/13/97	<i>(DRAFT)</i> <i>As indicated in the administration's initial response to this recommendation, the federal government convened a meeting of experts in Tampa in 1996 to discuss substance use and HIV prevention. The Council is unaware of any followup action that resulted from this meeting. Currently, the nation still lacks a comprehensive plan to address the behavior that is responsible for more than 50 percent of new HIV infections.</i>
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<i>Further Administration Response (HHS)</i> 10/22/97	<i>HRSA has supported and continues to be involved with the followup to the Tampa Forum on substance use and HIV prevention. SAMHSA, CDC, and HRSA have recently completed a Memorandum of Agreement to establish a task force of senior program managers to review the recommendations of the Forum, identify immediate cross cutting objectives and priorities, and to develop steps to put these recommendations into operation.</i>
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President's Advisory Council on HIV/AIDS

Recommendations

II.C.3.a Passed on: 12/8/95 Resolved? No	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 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 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.
Follow-up 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.
Assessment of Further Response 8/13/97	(DRAFT) As noted in the Council's initial assessment of the administration's response to this recommendation, the administration succeeded in opposing congressional efforts to cut drug treatment funding and in ensuring drug treatment funding at a level above FY95 spending. The Administration has not ensured continuation of specific funding for NIDA's AIDS demonstration projects. [Regarding the follow-up action recommended by the Council, the Council's Prevention Subcommittee has requested a meeting with the Director of the Office of National Drug Control Policy to discuss, among other things, his role in communicating the importance of SAMSHA programs.]
II.C.3.b Passed on: 12/8/95 Resolved? No	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 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 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.

President's Advisory Council on HIV/AIDS

Recommendations

Follow-up Action Recommended

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

Administration Response (DOJ) 4/23/96

In an attempt to arrive at a Departmental consensus on this recommendation, we sought input from the Criminal Division, the Drug Enforcement Agency, the Executive Office for U.S. Attorneys and from Office of Policy Development personnel involved in the formulation of drug policy. Based on these discussions, we have concluded that, pending the receipt and review of additional information relating to the impact of needle exchange programs on HIV infection and substance abuse, the Department is unable to support revising the Model Drug Paraphernalia Act (the Model Act) at this time.

Several components are concerned that revising the Model Act as the recommendations suggest would constitute a major departure from the law enforcement community's long-standing view that distribution of drug paraphernalia facilitates illicit drug use and undermines the message that such drug use is illegal. However, the Department is willing to revisit its position if current research reveals that needle exchange programs are effective in reducing HIV transmission and do not markedly increase the risk of substance abuse.

Accordingly, the Department suggests that the Advisory Council's recommendation that the Secretary of HHS provide a recommendation regarding the impact of needle exchange programs on HIV infection and substance abuse (See Section C(1) (c)) be implemented as rapidly as possible. We would further suggest that the Secretary's recommendation include an analysis of all of the available research including studies that have a bearing upon law enforcement interests and discuss other options -- such as increased availability of treatment, education or bleach distribution -- that might serve the public health interest without having a detrimental effect on law enforcement.

Assessment of Further Response 8/13/97

(DRAFT)

The Council is aware of no progress on this recommendation since the CDC's 1996 meeting at the Carter Presidential Center, referenced in the administration's initial response to this recommendation. The Secretary of HHS has made no recommendations to the Department of Justice on this matter, and DOJ has failed to revise the model act. The federal government's failure to act on this recommendation is unacceptable. As available data reveal, revisions to State laws (such as that undertaken by the State of Connecticut) that make drug laws consistent with current scientific knowledge, can serve as an important component of a comprehensive, effective plan to prevent HIV transmission from injection drug use. The Council urgently recommends that HHS and DOJ take action on this recommendation forthwith.

Further Administration Response (BOP) 10/22/97

The BOP would strongly object to supplying sterile needles or needle exchange programs within any prison or contract facility under the direction of the Federal Bureau of Prisons (Received in email to DCM from fcoleman@bop.gov).

II.C.3.c

Passed on: 12/8/95
Resolved? No

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 Response

No action has been taken.

Assessment of 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.

Follow-up 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.

President's Advisory Council on HIV/AIDS

Recommendations

Assessment of Further Response 8/13/97

(DRAFT)

Since the Council's original assessment of the Administration's response, which noted that no action had been taken, the Secretary of HHS issued a report in February 1997 in response to a request from the Senate Appropriations Committee. That report provides a comprehensive assessment of the overwhelming body of data demonstrating the effectiveness of needle exchange in reducing HIV infection rates and the absence of deleterious effects of needle exchange programs on rates of drug use. While carefully detailing the breadth of data supporting needle exchange as an effective component of a comprehensive strategy to prevent HIV transmission among injection drug users, the report stopped well short of lifting the existing ban on federal funding for such programs or of making specific recommendations for programs and demonstration projects.

As the Council observed in its original assessment, "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." Since making the recommendation above, the Council has specifically recommended that the administration lift the existing ban on federal funding for needle exchange by formally certifying that needle exchange programs reduce HIV transmission and do not cause an increase in drug use.

Further Administration Response 10/22/97

See Further Administration Comment II.C.3b

II.C.4

Passed on: 12/8/95
Resolved? No

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

Assessment of Response

Administration Response 8/13/97

(DRAFT)

The federal government's commitment to community planning has remained firm. After nearly four years' experience with this approach to prevention planning, the Council strongly recommends that the CDC implement measures to ensure the accountability of community planning. While the Council continues to endorse the need for local control in establishing prevention spending priorities, the CDC has the responsibility to ensure that federal prevention funding supports interventions that (a) are effective, and (b) reasonably relate to available epidemiologic data.

II.C.4.a

Passed on: 12/8/95
Resolved? No

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

Administration 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 Response

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.

President's Advisory Council on HIV/AIDS

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Assessment of Further Response 8/13/97

(DRAFT)

In accordance with this recommendation, the CDC has avoided folding HIV prevention into any consolidated grant programs. The Council urges the Administration to maintain this policy.

II.C.4.b

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

Passed on: 12/8/95

Resolved? No

Administration 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 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.

Follow-up 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.

Assessment of Further Response 8/13/97

(DRAFT)

The Council is pleased that the CDC has continued its direct support for community-based programs. In the future, the CDC needs to ensure that community-based organizations funded under this initiative are appropriately integrated into the local community planning process.

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.

Passed on: 12/8/95

Resolved? No

Administration 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 Response

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

President's Advisory Council on HIV/AIDS

Recommendations

Follow-up 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.

Assessment of Further Response 8/13/97

(DRAFT)
There has been no progress on the two followup action items previously identified by the Council. First, the Council has received no report that the CDC has made progress in identifying national or regional partners in preventing transmission in key populations, such as young gay men. Second, the CDC has not provided the Council with an assessment of its current NRMO technical assistance program.

II.C.5

Passed on: 12/8/95
Resolved? No

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 Response

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

Assessment of Response

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

Follow-up 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.

Assessment of Further Response 10/31/97

(DRAFT)
This has not occurred, despite repeated attempts to gain the attention and response of the Director. A recent Summit Meeting between the Office of National AIDS Policy and leaders in Indian Country, also failed to gain the attention of the Director. Indeed, it is even unclear at this time whether or not IHS is contracting with Indian owned services, as claimed.

[will call Jeremy Landau]

Further Administration Response (IHS) 11/26/97

The IHS and tribes have a Government to Government relationship as established through the United States Constitution, legislation and court decisions. This relationship is with Federally recognized Tribes and Tribal organizations. Also, in 1995 President Clinton signed a directive requiring tribal consultation before decisions are made concerning tribal trust resources. Based on these facts the IHS works closely with tribes and the organizations representing them in making decisions on how health care funds for American Indians and Alaska Natives are spent.

In addition, various health care and referral services are provided to Indian people in off-reservation settings through 34 urban programs. Authority to provide funds to these programs is in Title V of the Indian Health Care Improvement Act. In FY1998 the urban budget line item under this Title is \$25.7 million.

President's Advisory Council on HIV/AIDS
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III.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.
Passed on:	4/26/96	
Resolved?	No	
<i>Administration Response</i> <i>(ONAP)</i> <i>8/30/97</i>		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, 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.
<i>Assessment of Further Response</i> <i>10/31/97</i>		[Alexander to consult Mike Shriver] [Daniel to request info from agencies]

President's Advisory Council on HIV/AIDS

Recommendations

Further Administration Response 11/4/97

(The following information was received in a letter to Daniel from John M. Eisenberg, M.D., Administrator, Agency for Health Care Policy and Research (HCPR), HHS)

We believe this recommendation is on the right track. To enable a fully coordinated prevention science agenda, however, this recommendation should also encompass the relevant activities of the AHCPR and the scientific contributions of health services research. In the recent past, for example, ACHPR-sponsored research has demonstrated that:

- Preventive therapy for *Pneumocystis Carinii* pneumonia reduces hospitalization and improves outcomes in persons with HIV;*
- Primary care physicians often fail to recognize important clinical signs of HIV infection, such as Kaposi sarcoma;*
- Disadvantaged groups lag behind other patients in receipt of new HIV treatments; and that*
- Rural AIDS cases have risen dramatically among some groups, especially among women, blacks, and adolescents.*

The ACHPR also sponsors two other long-term efforts intended to foster greater understanding of, and lead to more effective prevention of, HIV and associated secondary infections. These include:

- The HIV Cost and Services Utilization Survey (HCSUS), a multimillion dollar longitudinal study gathered from a national sample of 3,000 HIV infected individuals from both urban and rural environs that examines the organization, delivery, costs, and outcomes of health services for people infected with HIV.*
- The ACHPR also houses the operations of the U.S. Preventive Services Task Force, an independent advisory panel that produces the "Guide to Clinical Preventive Services," an important mechanism to reach community clinicians with HIV/AIDS prevention strategies.*

Details of these and other relevant AHCPR-funded research on HIV/AIDS are listed below:

- AHCPR-Funded Study Finds Progression of HIV Disease Not Related to Race, Sex, or Drug Use (<http://www.ahcpr.gov/news/press/sept2.htm>)- Released 9/20/95*
- New Consumer Materials Aid in the Effort to Reduce the Number of Babies Born with HIV (<http://www.ahcpr.gov/news/press/hivchild.htm>)- Released 12/1/95*
- Doctors' and Nurses' Knowledge and Attitudes (<http://www.ahcpr.gov/data/colombo.htm>)*
- HIV/AIDS Research (<http://www.ahcpr.gov/research/mar96/dept3.htm>)*
- HIV/AIDS Research (<http://www.ahcpr.gov/research/jul96/dept3.htm>)*
- HIV/AIDS Research (<http://www.ahcpr.gov/research/may96/dept3.htm>)*
- HIV/AIDS Research (<http://www.ahcpr.gov/research/nov95/dept5.htm>)*
- HIV/AIDS Research (<http://www.ahcpr.gov/research/jan96/dept6.htm>)*
- HIV/AIDS Research (<http://www.ahcpr.gov/research/apr96/dept7.htm>)*
- HIV/AIDS Research (<http://www.ahcpr.gov/research/nov96/ra2.htm#head10>)*
- Health Insurance Coverage (<http://www.ahcpr.gov/data/acsus2.htm>)*
- Highlights from Recent AHCPR Research Findings (<http://www.ahcpr.gov/news/press/high195.htm>)- Released 10/8/96*
- Health Care Use (<http://www.ahcpr.gov/data/acsus3.htm>)*
- Clinical Studies (<http://www.ahcpr.gov/guide/medteprp/list2.htm#head2>)*

President's Advisory Council on HIV/AIDS Recommendations

III.C.1.a Passed on: 4/26/96 Resolved? No	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 (ONAP) 8/30/97	<i>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.</i>
Assessment of Further Response 10/5/97	<i>[Alexander to consult Mike Shriver] [Daniel to request info from agencies]</i>
III.C.1.b Passed on: 4/26/96 Resolved? No	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.
Assessment of Response 8/13/97	<i>(DRAFT) The Administration's response to the recommendation was non-responsive. There has been no progress on either of the items addressed by this recommendation.</i>
Administration Response (ONAP) 8/30/97	<i>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.</i>

President's Advisory Council on HIV/AIDS

Recommendations

III.C.2

Passed on: 4/26/96

Resolved? No

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 **(ONAP)** 8/30/97

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.

Assessment of Response 10/31/97

*[Alexander to consult Shriver]
[Daniel to request info from agencies]
[eventual response should note the lack of coordination between agencies involved in this field]*

III.C.3

Passed on: 4/26/96

Resolved? No

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.

Assessment of Response 8/13/97

*(DRAFT)
The Administration's response to this recommendation acknowledged the validity of the Council's concerns and indicated that SAMSHA and FDA were undertaking a review of current methadone regulations. The Council has not been provided with the results of any review and is unaware of whether such a review has, in fact, been made.*

President's Advisory Council on HIV/AIDS

Recommendations

Administration Response (ONAP) 8/30/97

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.

Administration Response (HHS) 10/30/97

Not having seen the Department's previous response to PACHA on this issue, the following text provides a more accurate assessment of the status of the referenced review and may provide more meaningful "feedback" to the Council. We have no comment on the needle exchange initiatives.

"The Institute of Medicine studied the Federal Regulation of methadone Treatment and issued a comprehensive report in 1995. The IOM report included many recommendations for changes to the existing regulation system. In response to the IOM report, FDA and SAMHSA, along with other Federal agencies, are developing a new system for overseeing narcotic treatment programs. The proposed new system will rely, for the most part, on non-government accreditation to assure that methadone treatment is provided by qualified entities. The accreditation based regulatory system is expected to increase clinical involvement in treatment, improve the quality and efficiency of treatment, and ultimately increase treatment capacity. The Department is in the final stages of evaluating this proposal and the announcement of a decision on how to proceed is expected soon.

"On November 17-19, 1997, the National Institutes of Health will convene a consensus development conference on "Effective Medical Treatment of Heroin Addiction." As part of that conference, NIH will determine the important barriers to effective use of opiate agonist in the treatment of opiate addiction in the U.S., including perceptions and the adverse consequences of opiate agonist use, as well as legal, regulatory, financial and programmatic barriers."

III.C.4

Passed on: 4/26/96
Resolved? No

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.

Assessment of Response 8/13/97

(DRAFT)

The Council is pleased that the CDC has funded a program concerning replication of effective HIV behavioral interventions, although the Council lacks sufficient information to evaluate the effectiveness of this program. In general, however, the federal effort in this area falls well short of what is needed to ensure that local prevention service providers have access to the latest prevention research findings.

Administration Response (ONAP) 8/30/97

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.

President's Advisory Council on HIV/AIDS Recommendations

III.C.4.a Passed on: 4/26/96 Resolved? No	Allocate funding for training of front-line prevention workers in application of relevant research findings.
<i>Assessment of Response</i> 8/13/97	<i>(DRAFT)</i> <i>The Administration's response to this recommendation was non-responsive. There has been no progress on this recommendation.</i>
<i>Administration Response</i> <i>(ONAP)</i> 8/30/97	<i>CDC currently trains and assigns staff to State and local health departments to assist in HIV prevention efforts at the State and community level.</i>
III.C.4.b Passed on: 4/26/96 Resolved? No	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.
<i>Assessment of Response</i> 8/13/97	<i>(DRAFT)</i> <i>The Administration's response specifically mentions the CDC National AIDS Hotline and the CDC National AIDS Clearinghouse. While these programs are clearly important, they represent a largely passive response to the need to ensure access to accurate, easily understandable, and up-to-date information to community educators and consumers. The Council strongly recommends that the CDC undertake more active efforts to disseminate accurate HIV-related information to the grassroots in a timely manner.</i> <i>[Daniel to seek info from CDC regarding (a) the CDC Hotline and AIDS Clearinghouse (number of users, evaluation data, etc.), and (b) whether the CDC has done an assessment of materials developed with federal money in order to ensure their accuracy, effectiveness and accessibility to community educators and consumers]</i>
<i>Administration Response</i> <i>(ONAP)</i> 8/30/97	<i>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.</i>

President's Advisory Council on HIV/AIDS

Recommendations

IV.C.1

Passed on: 12/15/96

Resolved? No

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

Administration Response (HHS) 4/5/97

In 1995, RWCA Title I and II providers reported serving 2,651 Native American clients (1995 Annual Administrative report). Additionally, during the period from June 1, 1995 - May 31, 1996 the AETC Program provided AIDS education and training to 1,115 Native American health care providers. A memorandum of agreement is being developed between HRSA and the Indian Health Services (IHS) to provide supplemental funding to the AETC program to conduct two major pilot HIV/AIDS educational programs (in Tennessee and Oregon) for Native American health care providers. The Special Projects of National Significance Program (SPNS) in September 1996 and February 1997, funded four organizations focusing specifically on the needs of Native Americans and Alaska Natives. These projects, which are headquartered in California, Alaska, and Arizona, are examining models to provide culturally appropriate care to Native Americans.

Moreover, the Indian Health Service is currently collaborating with the Division of HIV Services in HRSA to plan a major, collaborative meeting with Tribal and Urban program representatives to identify ways that training and technical assistance can be provided to tribal organizations in preparing applications for RWCA funds. The meeting planned for the latter part of June will also be used to explore ways that tribes and urban Indian programs can best work together on HIV/AIDS issues. Additionally, the Director, IHS, has requested the Office of National AIDS Policy convene a meeting of all Federal agencies that have programs impacting on American Indian/Alaska Native (AI/AN) people at risk for HIV infection. The purpose of the meeting would be to discuss ways in which the Federal Government can work with tribal organizations and urban Indian programs to identify the special HIV/AIDS needs of AI/AN populations and to develop specific, national strategies to meet these needs. The request also mentions the need for Bureau of Indian Affairs participation in this effort.

Further Administration Response 7/28/97

The HIV/AIDS Bureau in HRSA, in conjunction with the Indian Health Service, held a meeting on June 20, 1997, with representatives of tribal and urban Native American communities and organizations. The purpose of the meeting was to obtain advice from Native American communities concerning the types of technical assistance needed by organizations serving Native Americans to increase their access to Ryan White CARE Act funds. The meeting resulted in several recommendations made to HRSA for the provision of technical assistance strategies to enhance the access of affected population groups to Ryan White CARE Act funds. The meeting was also intended to be the beginning of a collaborative effort between HRSA and the IHS to explore ways that HRSA and the IS can best work with tribal and urban Native American programs in identifying HIV/AIDS issues affecting Native American communities and in continuing to identify strategies for provision of technical assistance under the Ryan White program to Native American communities.

President's Advisory Council on HIV/AIDS Recommendations

IV.C.2

Passed on: 12/15/96

Resolved? No

Agreements ensuring the fulfillment of Native American health care needs are part of the traditional government-tribal relationship. In the instance of alcohol and substance abuse programs, IHS was instructed to develop memorandums of agreement with tribal governments and the BIA to ensure that these three entities work together to reduce the effects of addiction in tribal communities. Memorandums of agreement include a specific tribal plan describing needs, availability of services, and prevention efforts. Similar memorandums are needed in dealing with HIV/AIDS. Local tribes have need to have ownership of direct client services for HIV case management on their Reservations; Native Case Management Programs need a commitment from IHS that they will work cooperatively with these programs, which are located on and

Administration Response
(HHS)
4/5/97

The IHS has not been asked to demonstrate the adequacy of its HIV/AIDS prevention and treatment program. If asked to do so the IHS will provide the needed information to show that it is providing the best care possible with available resources. The IHS shares information with non-profit organizations working with the non-profit sector, when ever possible partnerships are formed to improve the delivery of HIV/AIDS services to AI/AN clients. When available, the IHS uses Indian owned and managed organizations for services that must be contracted for in the private sector.

IV.C.3

Passed on: 12/15/96

Resolved? No

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

Therefore, the Council requests that the Secretary of Health and Human Services instruct the Director of IHS to develop

Administration Response
(HHS)
4/5/97

The IHS has developed culturally sensitive case management guidelines which are available through the CDC National AIDS Clearinghouse. A recent review of them has shown they need to be updated and this has been put on the work plan for the AIDS program. These guidelines are often modified at the local level to best meet the needs of the community being served. The Phoenix Area Indian Health Service is developing an HIV Center of Excellence. One of the goals of the Center is to enhance the ability of IHS and tribal health delivery systems to provide, culturally competent, medically appropriate HIV clinical care. This includes culturally sensitive case management and traditional treatments where appropriate.

V.C.1

Passed on: 4/5/97

Resolved? No

The Secretary of Health and Human Services should eliminate all regulations and requirements for mandated reviews by citizen review panels of the content of HIV prevention materials. HIV prevention materials produced or distributed with federal funding should be free of restrictions on content, subject only to review for scientific accuracy and cultural appropriateness for the targeted population. Grantees should be given great flexibility in utilizing the least burdensome methods of conducting these reviews.

Administration Response
8/13/97

(DRAFT)

There has been no progress on this recommendation since it was issued in April 1997.

President's Advisory Council on HIV/AIDS

Recommendations

Assessment of Response
8/13/97

(DRAFT)

There has been no progress on this recommendation since it was issued in April 1997. In proposed regulations published in the Federal Register, the CDC first proposed to lift the current content restrictions in [December 1992]. For nearly five years, these proposed recommendations have languished at HHS, even though no public health basis exists for the current restrictions. The Council urgently recommends that the administration immediately eliminate this impediment to frank, carefully targeted, effective HIV prevention programs.

VI.C.1

Passed on: 4/5/97
Resolved? No

The PACHA commends the Secretary of Health and Human Services and the Department of Health and Human Services on the Report to Congress on Appropriation for the Department of Labor, Health and Human Services Agencies: Needle Exchange Programs in America: Review of Published Studies and Ongoing Research which acknowledges the efficacy of syringe exchange programs to reduce the transmission of HIV.

WHEREAS, this report to the Congress confirms that syringe exchange programs reduce the rate of new HIV infections among injection drug users, and further confirms that such programs constitute a sound public health practice as part

Assessment of Response

President's Advisory Council on HIV/AIDS

Recommendations

Administration Response
(DQJ)
10/13/97

The Council recommends the prompt certification of syringe exchange programs in those communities that determine such programs to be appropriate. This recommendation raises issues under federal and state drug paraphernalia laws, which define "drug paraphernalia" to include syringes intended for use in illicit drug injection.

*The Mail Order Drug Paraphernalia Control Act, codified at 21 U.S.C. *863, can be interpreted not to affect needle distribution through certified exchange programs. Title 21, *863(f)(1) exempts "any person authorized by local, State, or Federal law to possess, manufacture, or distribute such items." Thus, if local, state, or federal law permits needle exchange programs, the federal paraphernalia law provides a corresponding exemption. Moreover, with respect to recipients of needles, the federal law does not prohibit simple possession of drug paraphernalia; it addresses only distribution, use of the mails, importation, or exportation.*

*By contrast, the Model Drug Paraphernalia Act, upon which most states base their laws, uses a different drafting approach and has no exemption analogous to the federal law. In order to accommodate this proposal, states that have not already done so would need to amend their paraphernalia laws. Options include (1) an exemption akin to the federal law at *863(f)(1), clarifying in the legislative history an intent to protect legitimate needle exchange programs, or (2) an explicit exemption to authorize needle exchange programs, with specified licensing or oversight. It may also be desirable to amend the federal law to include an explicit exemption to authorize needle exchange programs, setting forth a framework for a licensing or regulatory system.*

In addition to the statutory conflicts that the adoption of this recommendation would create, the certification of syringe exchange programs runs counter to existing Administration policy in this area. The Department has opposed the expansion of needle exchange programs until their impact on drug abuse and trafficking have been thoroughly studied and the results carefully analyzed. Revising the Model Drug Paraphernalia Act to comport with the Council's recommendation would constitute a dramatic break with the long-held position by the law enforcement community that the distribution of syringes facilitates illicit drug use and trafficking. Given that the use of injectable drugs, especially heroin, is on the rise across the nation, syringe exchange programs cannot be certified without very careful analysis. Although some studies present compelling evidence of reduced levels of HIV transmission among groups that are provided clean syringes, other studies, including those conducted in Vancouver and Montreal, show that needle exchange programs do not reduce HIV transmission. The research data therefore must be carefully reviewed and analyzed before such a significant change in policy regarding the enforcement of criminal drug laws is considered.

President's Advisory Council on HIV/AIDS

Recommendations

Prisons

IV.R.1a	The Council requests a comprehensive and specific report be from the Federal Bureau of Prisons, and the Department of Defense within 90 days, addressing the inclusion of HIV/AIDS issues in all services of the Federal Bureau of Prisons (including D. C. Jails) and DoD prisons and brigis. This should minimally include the following
Passed on: 12/15/96	
Resolved? No	
	a. Content and frequency of prison staff educational efforts paying particular attention to issues of women at-risk for HIV, substance use, prevention, and the medical management of HIV disease.

Administration Response (DOD) 3/26/97

In a letter to Eric Goosby, Acting Director of the Office of National AIDS Policy, on March 26, 1997, Jeanne B. Fites, Deputy Undersecretary of Defense for Program Integration, stated the following:

At its December 1996 meeting, the Presidential Advisory Council on HIV/AIDS approved a recommendation calling for the Department of Defense to provide a comprehensive report to the Council addressing HIV/AIDS programs and services in DoD correctional facilities.

The purpose of this letter is to inform you of the status of this report. The Department of Defense has begun working on the report. Implementation of DoD policies regarding HIV/AIDS and responsibility for operation of correctional facilities rests with each of the Military Departments. It has been necessary, therefore, to ask the Departments to provide a response to the concerns contained in the Advisory Council's recommendation. We are still awaiting input from several Military Departments. We anticipate completing and forwarding the report to you in mid-April.

I regret our delay in completing the report.

Federal Bureau of Prisons

There has been no response to date (November 22, 1997).

IV.R.1b	b. Accessibility of all FDA approved HIV/AIDS therapeutic modalities for prison inmates with HIV/AIDS and numbers of prisoners availing themselves of these therapies.
Passed on: 12/15/96	
Resolved? No	

Administration Response 11/26/97

No response given to date.

IV.R.1c	c. Availability of mainstream clinical drug trials for prison inmates, the nature of any access barriers -- and means to remove such barriers, and numbers, sites and principal investigators of these programs.
Passed on: 12/15/96	
Resolved? No	

Administration Response 11/26/97

No response given to date.

President's Advisory Council on HIV/AIDS

Recommendations

IV.R.1d

Passed on: 12/15/96

Resolved? No

d. The status of quality assurance criteria and certifications, (including nondiscrimination guidelines) with a demonstrable high level of compassionate care available for the ill and dying.

Administration Response
11/26/97

No response given to date.

IV.R.1e

Passed on: 12/15/96

Resolved? No

e. Description of case management for prison inmates with HIV/AIDS.

Administration Response

Description of case management for prison inmates with HIV/AIDS response.

Assessment of Response

We appreciate receiving a complete response from the Federal Bureau of Prisons to one out of ten items in this recommendation and look forward to other complete responses.

President's Advisory Council on HIV/AIDS

Recommendations

Administration Response (HHS) 4/5/97

The Health Resources and Services Administration (HRSA) has several programs to help address the HIV related needs of incarcerated populations. Historically over the last six years, numerous local communities and States, under Titles I and II of the Ryan White CARE Act, have identified HIV positive incarcerated individuals as a priority population in terms of linking those about to be released to essential health and supportive services in the community (such as primary care, drug reimbursement and housing) prior to their release. In addition, four programs received Title II CARE Act funding as Special Projects of National Significance to develop model programs that address the linkage of incarcerated and recently released inmates with HIV/AIDS and their families to community-based services. This combination of efforts has demonstrated considerable success in linking inmates to medical and community services, providing support to people who are trying to change behaviors and reacclimate to community norms, and reducing recidivism rates related to parole violations and medical compliance. A report was disseminated by HRSA in June 1995 entitled, "Progress and Challenges in Linking Incarcerated Individuals with HIV/AIDS to Community Services".

Recently, the Office of the Inspector General issued a draft report, "Audit of the Ryan White Comprehensive AIDS Resources Emergency Act of 1990, Title II, Administered by the Health Resources and Services Administration," which included a recommendation that HRSA issue specific guidance that CARE Act funds should only be used to supplement and enhance existing State programs, particularly State funded drug assistance programs and programs for inmates under the custody of the States. The Division of HIV Services, the organizational unit within HRSA that administers Titles I and II of the CARE Act, has established a Policy Review Board with responsibility to develop and disseminate program guidance and direction for grantees. It does so in conjunction with the Office of General Counsel, HRSA AIDS Advisory Council and Office of Grants Management, and with a public comment period.

The Division of HIV Services has a draft policy regarding services for incarcerated individuals with a clear understanding that such individuals are the responsibility of the institution and jurisdiction in which they are confined, not Federal CARE Act funding/programs. However, it also acknowledges that where other funding for pre-release case management and linkage services is unavailable, CARE Act funds may be used to provide case management services to HIV positive incarcerated individuals who are about to be released with the purpose of linking them to essential health and support services in the community. Such case management services typically include assessment of needs, development of a care plan, referral and follow-up to ensure access to needed service, and an ongoing reassessment of needs.

Additionally, the AIDS Education and Training Centers (AETC) Programs provide funding for training programs in correctional facilities. During the period June 1, 1995 - May 31, 1996, the AETC network conducted 289 programs on HIV/AIDS care in Federal, State and local correctional facilities. These educational and training programs were attended by 2, 863 health care providers from the correctional facilities.

During 1995 to 1996, several additional AETC HIV/AIDS training programs specifically were targeted to health care providers in Federal, State and local correctional facilities, were transmitted by satellite and down linked into correctional facilities. These programs were transmitted to an average of thirty-one States. The programs covered HIV/AIDS topics such as: oral management; medical management; wasting/opportunistic infections; antiretroviral therapy; and non viral opportunistic infections. Total attendance at these satellite presentations was 5, 811 correctional facility health care providers. Additional programs are scheduled for May and September 1997.

The AETC program also sponsors an HIV Clinical Conference Call Series which is available in the U.S. and internationally. This quarterly conference call brings together a panel of experts who discuss a current HIV topic and then takes calls from the audience on that topic. Health care providers from correctional facilities have been strongly encouraged to participate in these calls.

Administration Response (DOJ) 5/9/97

See VI.R.3 "Administration Response (DOJ)"

President's Advisory Council on HIV/AIDS

Recommendations

IV.R.1f Passed on: 12/15/96 Resolved? No	f. Availability of voluntary peer education opportunities for HIV+ inmates. (Please include curriculum participation, site, and frequency statistics.)
<i>Administration Response</i> 11/26/97	<i>No response given to date.</i>
IV.R.1g Passed on: 12/15/96 Resolved? No	g. Accessibility of condoms and barrier protection against HIV transmission to prison inmates.
<i>Assessment of Response</i>	<i>See April Report -- Item #4.</i>
<i>Administration Response</i>	
IV.R.1h Passed on: 12/15/96 Resolved? No	h. Specific details concerning the availability of ongoing (at least every 6 months) educational programs for incarcerated individuals regarding all aspects of HIV, including substance abuse issues and sexuality.
<i>Administration Response</i> (DOJ) 5/9/97	<i>The Department of Justice in their memo of May 9, 1997, indicates that "inmates receive education on the dangers of HIV and other sexually transmitted diseases during Admission and Orientation at each institution, and following any transfer."</i>
<i>Assessment of Response</i> 11/11/97	<i>This seems inadequate given this recommendation. We further request copies of curriculum used in such programs.</i>
<i>Follow-up Action</i> 11/11/97	<i>We further request copies of curriculum used in such programs and scheduling information regarding frequency of use.</i>
IV.R.1i Passed on: 12/15/96 Resolved? No	i. Definition of the limits of jurisdiction which differentiate the authority of the federal government in all correctional facilities; District of Columbia, military, federal, state, and local correctional institutions, including federal funding streams.
<i>Administration Response</i> 11/26/97	<i>No response given to date.</i>

President's Advisory Council on HIV/AIDS

Recommendations

IV.R.1j		j. The scope of implementation of the seven major recommendations of the National Commission on AIDS (March, 1991).
Passed on:	12/15/96	
Resolved?	No	
Administration Response (DOJ) 5/9/97	<i>We note at the outset that we have not had the opportunity to review the recommendations of the National Commission on AIDS and accordingly, are unable to comment on its implementation. However, we will be pleased to review and comment on any information that the Office of National AIDS Policy wishes to provide in this regard.</i>	
Assessment of Response 11/11/97	<i>The Department of Justice in their memo of May 9, 1997, indicates that they "have not had the opportunity to review the recommendations of the National Commission on AIDS (1992) and accordingly, are unable to comment on its implementation." We find this problematic.</i>	
Follow-up Action 11/11/97	<i>We request that the Office of National AIDS Policy to again forward them a copy of that report in conjunction with a re-forward of this set of recommendations and assessments.</i>	
IV.R.2		The Administration should direct the Secretary of Health and Human Services to develop oversight language appropriate for discharge planning (including accessing benefits) for ex-offenders with HIV/AIDS designed to assure their continuity of care through Probation Departments in various locales as well as the accessibility of appropriate linkages within the community.
Passed on:	12/15/96	
Resolved?	No	
Assessment of Response	<i>The response on the part of HHS regarding our request for information concerning Discharge Planning (Dec. '96), is hardly adequate, although the Federal Bureau of Prisons does comment upon this in its current report.</i>	
Administration Response (HHS) 4/5/97	<i>One of the least served and most needy of populations is that of the HIV infected ex-offender. The most effective method for reaching this population is through existing community based organizations providing linkages of health care services to under served populations. The Health Resources and Services Administration has funded through its program Special Projects of National Significance a model project that provides a partnership approach for engaging and retaining HIV infected ex-offenders and their families in primary and HIV-specific ambulatory medical care. The project is under the auspices of the Fortune Society and through a linkage with the Institute for Urban Family Health provides clients with medical care, discharge planning, intensive case management and a family focus. The model is designed with the goal of developing, evaluating, and disseminating a holistic model of care that reaches and retains one of the most difficult populations to reach through traditional medical models.</i>	

President's Advisory Council on HIV/AIDS

Recommendations

Progress (HUD)
7/31/97

(The following information was received in a letter from Secretary Cuomo to Sandy)
In 1994, HUD created the Office of HIV/AIDS Housing (OHH) within the Office of Community Planning and Development. A primary function of this office has been the management of the Housing Opportunities for Persons with AIDS (HOPWA).... The Department is also seeking to increase resources that address housing needs. For FY98 the Administration has requested \$204 million for HOPWA, an increase of \$8 million over current funding.... HUD anticipates that 10 new jurisdictions will qualify for formula allocations in 1998 and that all areas will experience increased needs.... An on-going dialogue with AIDS Housing providers and residents has provided this Department with up-to-date information about the epidemic and changes in care, to address challenges in meeting the housing needs of persons living with HIV/AIDS, and to seek ways that HUD could improve its responsiveness and programs.

Housing in Discharge Planning:

The OHH will develop HOPWA guidelines and technical assistance publications which highlight the need for transitional services and discharge planning for recently discharged prisoners/parolees with HIV/AIDS. Furthermore, the OHH will work in collaboration with national technical assistance providers, such as AIDS Housing of Washington (AHW), to address HIV/AIDS housing issues unique to recently incarcerated persons. Our collaboration will develop appropriate and replicable guidelines to better evaluate a community's current efforts, if any, and to expand or develop programs that would address these needs. The collaboration will also explore creative ways to coordinate efforts with other federal programs, such as resources available through HRSA's AIDS Educational Training Centers (AETC's), the Federal Bureau of Prisons, Ryan White Care Act Planning Councils, as well as HOPWA Planning Councils.

We can also learn from HOPWA projects that have been funded with Special Projects of National Significance (SPNS) competitive grants that address the needs of prison populations. One such project, the Tarzana Treatment Center in Tarzana, California, was funded in 1994 and focuses on emergency and transitional housing to State prison parolees with HIV/AIDS. Other projects funded through HOPWA formula grants have successfully integrated recently released prisoners into their client services programs. A review of HOPWA Annual Progress Reports identifies 1.5% of clients receiving housing assistance by HOPWA grantee's are clients who were recently incarcerated.... The Department will seek to use these projects as models to help other jurisdictions develop appropriate efforts in their communities.

**Follow-up Action
Recommended**
11/11/97

A more complete analysis of this issue is necessary.

VI.R.1

Passed on: 4/5/97
Resolved? No

The President should direct the Justice Department and the Director of the Federal Bureau of Prisons to revise administrative and judicial standards of compassionate release for use in all Federal and Federally-funded prisons. Prisons will do this in accordance with American Bar Association (ABA) Standards. Furthermore, equivalent compassionate release programs should be required in state and local prisons as a condition of these institutions receiving federal funds. The Federal Bureau of Prisons also should be directed to maintain statistical and evaluative records concerning the compassionate release policy and file an annual report to the President, Secretary of Health and Human Services and the Office of National AIDS Policy.

Assessment of Response

Of special concern is whether inmates or their representatives may "motion" for compassionate release. What are the plans for the Bureau to improve treatment protocols consistency to ensure continued health to inmates with AIDS? Suggesting that, "revision of the current process for a compassionate release is necessary," does not adequately address our concerns.

President's Advisory Council on HIV/AIDS

Recommendations

Administration Response (DOJ)

There are two models for compassionate release legislation:

ADMINISTRATIVE MODEL FOR COMPASSIONATE RELEASE LEGISLATION

Many of the concerns underlying the model legislation are already addressed pursuant to the above referenced statute and Bureau of Prisons regulations and policy. The model legislation would however, substantially alter the procedure followed by the Bureau of Prisons with respect to requests for a Compassionate Release. In addition, it is presumed that this legislation would not be restricted to inmates diagnosed with HIV/AIDS, but would apply to all serious medical conditions.

In section (a), Authorization, it appears that the proposed language would authorize either the United States Parole Commission or the Bureau of Prisons to directly grant parole or release for an inmate with a terminal medical condition. As such, there would be no need for the sentencing court to modify the inmate's sentence as currently required. We advise against changing this process. The sentencing court should have the final decision making authority. The Bureau of Prisons serves an advisory role, but should not be the sole decision maker.

In addition, section (b) replaces the discretion currently granted to the Director of the Federal Bureau of Prisons with mandatory release language. Under the proposed model, the Director would be required to release an inmate upon finding that the inmate is likely to die within one year, unless there is a finding that the prisoner poses a danger of committing additional crimes, that the prisoner will not receive adequate care upon release, or that the release would denigrate the seriousness of the offense*. This mandatory language could conceivably create an entitlement to a compassionate release. As drafted, there is a presumption in favor of releasing terminally ill inmates, thereby placing the burden on officials to preclude release. Furthermore, there is no explanation for the removal of discretion, such as an abuse of discretion. Therefore, the Bureau would strongly advise maintaining discretion with the Director, as opposed to mandating a release.

* These issues and others are currently taken into consideration by the Bureau of Prisons.

In section (c), Application Process, as drafted, only the inmate or a medical officer of the Department of Corrections may file an application of release. According to current Bureau of Prisons policy, anyone, including the inmate's family may request a compassionate release on behalf of an inmate. The model language may want to provide similar language. In addition, under current Bureau policy, the United States Attorney 5 Office is consulted throughout the process, but receives a formal request to file a motion on behalf of the Bureau of Prisons only upon final approval by the Director**. One reason for this is that a request may be denied prior to the Director's review. Thus, a copy of a request for release need not be served upon the prosecutor immediately upon receipt as required in section (c).

With the various levels of review required by the Bureau and the need to achieve a consensus with the United States Attorney's Office, the time lines listed in section (d) Medical Report and section (e), Summary Disposition of Unmeritorious Applications, may be unrealistic. The Bureau of Prisons appreciates the urgency of a request for compassionate release and all efforts are made to ensure expedient review. However, in addition to possibly being unrealistic, statutorily mandated time lines may create liability for the agency if not strictly adhered to.

The Bureau of Prisons would also advise against requiring a hearing, and thereby creating a due process interest, as indicated in section (f), Procedure for Hearing. The Bureau has operated the compassionate release program for years and based upon agency experience, there is no need for a hearing in this process. If the inmate's medical condition has deteriorated so severely and there are no policy concerns such as those listed in section (a) of the model language, the inmate's request will generally be granted. In addition, there are grievance procedures available to the inmate if he or she is denied a compassionate release.

In section (g), Decision, the Bureau would again advise against statutorily mandated time lines. In addition, under subsection (3), the Bureau proposes using the term parole officer or probation officer as inmates ineligible for parole would report to the United States Probation Office. Also, the provision for periodic re-examination of the inmate's medical condition is prudent. Current Bureau policy does not provide such a condition.

** According to current Bureau of Prisons policy, the request is first reviewed at the institutional level. If approved by the designated committee and Warden the request is then forwarded to the Regional Office. Upon approval, the Regional Office then forwards the request

President's Advisory Council on HIV/AIDS Recommendations

Administration Response

(DOJ)
10/15/97

The Federal Bureau of Prisons (BOP) has provided extensive comments to the Council in the past regarding the administrative and judicial standards for compassionate release proposed by the American Bar Association. A copy of these comments is enclosed for your reference.

In general, the BOP does not believe that revision of the current process for compassionate release is necessary. The BOP revised the compassionate release procedures in January, 1994, in accordance with 18 U.S.C. ** 3582 (c)(1)(A) and 4205 (g). Pursuant to these statutes, the Director of the BOP may make a motion for modification of sentence under "extraordinary and compelling circumstances." The BOP has chosen to restrict the application of this statute to those inmates suffering from a serious medical condition. Generally, the condition must be terminal, with a determinable life expectancy. However, an inmate with some other serious and debilitating medical condition may also be considered. Additionally, the severity of the illness must be of such nature that it could not reasonably have been foreseen by the court at the time of sentencing. Thus, where an inmate's physical health has deteriorated severely, and his or her current medical condition is critical, the BOP may make a motion for modification of sentence even if the court was aware that an inmate was seriously ill at the time of sentencing.

We believe that the Bureau's current procedure regarding compassionate release is sufficient to address all serious medical conditions, including HIV/AIDS. Furthermore, the BOP currently maintains statistical and evaluative records on compassionate release requests. From July, 1990 to the present, 90 compassionate release requests for HIV/AIDS inmates have been forwarded to the courts for disposition. Sixteen such compassionate release requests have been denied by the BOP.

Compassionate release does not apply to Immigration and Naturalization Service (INS) detainees due to the transient nature of their detention. All INS detainees are destined to be released in a very short period of time.

Progress (DOJ)

10/15/97

There are two models for compassionate release legislation which are being considered: The Administrative Model and the Judicial Model. (See DOJ memo to ONAP Director, Sandra Thurman; October 15, 1997)

Follow-up Action

Recommended
11/11/97

We request a copy of the Bureau's official procedures regarding Compassionate Release (January, 1994) and their statistical evaluative records regarding Inmates with AIDS (1990, on). We also request copies of appropriate statutory language for review.

VI.R.2

Passed on: 4/5/97
Resolved? No

The President should direct the Secretary of Health and Human Services to develop standards of care to ensure that, prior to release, ex-offenders with HIV/AIDS are provided timely, thorough, and appropriate case management/discharge planning. These standards should address behavioral and social service needs; continuity of care; and appropriate linkages to local community services, medical services, social service benefits, appropriate case management, and housing assistance programs to ensure against homelessness.

Progress

See IV.R.2 "Progress"

Assessment of Response

The Federal Bureau of Prisons maintains six medical referral centers with discharge planning. That this service is not available at general institutions where non-patient HIV/AIDS inmates reside is of great concern.

President's Advisory Council on HIV/AIDS

Recommendations

Administration Response (HUD)

In 1994, HUD created the Office of HIV/AIDS Housing (OHH) within the Office of Community Planning and Development. A primary function of this office has been the management of the Housing Opportunities for Persons with AIDS (HOPWA). The Department is also seeking to increase resources that address housing needs. For FY98 the Administration has requested \$204 million for HOPWA, an increase of \$8 million over current funding. HUD anticipates that 10 new jurisdictions will qualify for formula allocations in 1998 and that all areas will experience increased needs. An on-going dialogue with AIDS Housing providers and residents has provided this Department with up-to-date information about the epidemic and changes in care to address challenges in meeting the housing needs of persons living with HIV/AIDS and to seek ways that HUD could improve its responsiveness and programs.

Housing in Discharge Planning:

The OHH will develop HOPWA guidelines and technical assistance publications which highlight the need for transitional services and discharge planning for recently discharged prisoners/parolees with HIV/AIDS. Furthermore, the OHH will work in collaboration with national technical assistance providers, such as AIDS Housing of Washington (AHW), to address HIV/AIDS housing issues unique to recently incarcerated persons. Our collaboration will develop appropriate and replicable guidelines to better evaluate a community's current efforts, if any, and to expand or develop programs that would address these needs. The collaboration will also explore creative ways to coordinate efforts with other federal programs, such as resources available through HRSA's AIDS Educational Training Centers (AETC's), the Federal Bureau of Prisons, Ryan White Care Act Planning Councils, as well as HOPWA Planning Councils.

We can also learn from HOPWA projects that have been funded with Special Projects of National Significance (SPNS) competitive grants that address the needs of prison populations. One such project, the Tarzana Treatment Center in Tarzana, California, was funded in 1994 and focuses on emergency and transitional housing to State prison parolees with HIV/AIDS. Other projects funded through HOPWA formula grants have successfully integrated recently released prisoners into their client services programs. A review of HOPWA Annual Progress Reports identifies 1.5% of clients receiving housing assistance by HOPWA grantee's are clients who are recently incarcerated. The Department will seek to use these projects as models to help other jurisdictions develop appropriate efforts in their communities.

Administration Response (DOJ) 10/15/97

The BOP concurs with the recommendation to direct the Secretary of Health and Human Services to develop case management/discharge planning for appropriate linkages of medical and social services available in the local community. The BOP presently provides community discharge planning for all HIV/AIDS patients at all six Medical Referral Centers. Staff social workers contact the appropriate agencies and care providers in the community in which the inmate is to be discharged. This service is currently not available at the Bureau's general population institutions, where non-inpatient HIV/AIDS inmates are housed.

This recommendation does not apply to INS detainees due to the transient nature of their detention. However, INS provides counseling, which includes, but is not limited to, facts about the cause and progression of HIV infection, treatment techniques, and effective measures to prevent transmission of infection to others.

Follow-up Action Recommended 11/11/97

Statistical data on both types of facilities is requested. What are the plans for the Federal Bureau of Prisons to extend Discharge Planning to inmates in general (non-medical) facilities, specifically in conjunction with local parole boards and community-based agencies? How is the Bureau working with HHS to "go forward with" standards of care and compassionate release? What is the timeline? A mechanism for demonstrating effectiveness has yet to be devised.

President's Advisory Council on HIV/AIDS Recommendations

VI.R.3

Passed on: 4/5/97
Resolved? No

The President shall direct the Federal Bureau of Prisons to incorporate the upcoming Report from the HHS Panel on Clinical Practices for the Treatment of HIV Infections in all correctional medical facilities. It should be required that care providers be adequately trained to implement these standards and all appropriate therapeutic options associated with the management of HIV disease be available.

Administration Response (DOJ) 5/9/97

The BOP provides medical care for federal inmates through the medical staff assigned to BOP Health Services Units. Health Services staff clinically evaluates HIV-positive federal inmates at least once quarterly and monitors them closely. The BOP contracts for local medical services and transfers seriously ill inmates who are without families to Federal Medical Centers for advanced levels of care.

In providing medical care to inmates, the BOP follows the latest clinical care guidelines published by the Centers for Disease Control and Prevention. Pharmaceuticals approved by the Food and Drug Administration for use in the treatment of HIV/AIDS and associated illnesses, such as anti-viral medication, and protease inhibitors, are provided when needed. Furthermore, the BOP offers a compassionate release program, under which seriously ill inmates may be evaluated for release by the sentencing court. Inmates who are in the advanced states of AIDS may be released to their families under this program.

BOP realizes that substance abuse treatment and HIV/AIDS awareness among inmates are crucial to curtailing the education and prevention programs on HIV/AIDS, in addition to programs on tuberculosis, Hepatitis B and C, and sexually transmitted diseases. As part of the HIV/AIDS program, all newly committed federal inmates are required to view the Department's "AIDS Awareness and Prevention" video and to attend a question-and-answer session about HIV/AIDS. In addition, the BOP provides substance abuse treatment and drug education programs for inmates. Finally, BOP's new employees are provided HIV/AIDS and infectious disease training upon initial employment, and annually thereafter.

Additionally, BOP administers HIV testing to a number of categories of inmates. As part of a routine physical examination, BOP interviews newly admitted inmates to determine if they have an elevated risk for HIV infection. When warranted, HIV testing is administered in conjunction with an education and counseling program. Additionally, a ten percent sample of newly incarcerated inmates and another the percent sample of all inmates are tested for HIV annually. Inmates are authorized voluntary annual testing if they do not otherwise fall under a standardized testing category. Thus, BOP maintains that from a clinical and statistical viewpoint, it is not necessarily desirable to test all inmates. Finally, an inmate under consideration for full-term release, parole, good conduct time release, furlough, or placement in a community-based program is tested within one year before his or her new placement or release.

Administration Response (DOJ) 10/15/97

Current and future HHS guidelines for the medical management of HIV infections have been and will continue to define the community standard of care for BOP inmates. Ten anti-retroviral medications, including all four FDA-approved protease inhibitors, have been added to the BOP drug formulary and are being prescribed through combination therapy to inmates with HIV infections as medically indicated. Infectious disease subspecialty consultation is provided to inmates through community subspecialists, BOP Medical Referral Centers, and the BOP Chief of Infectious Diseases.

The INS Manual on Policies and Procedures contains detailed information on standards of care, which should conform with the upcoming report from the HHS Panel on Clinical Practices for the Treatment of HIV Infections in correctional medical facilities.

Assessment of Response 11/11/97

There is a growing concern regarding inmate reports of the noncompliance of prison officials/medical officials concerning AIDS Treatment Protocols -- especially with regard to Protease Therapies, with which compliance is crucial.

Follow-up Action Recommended 11/11/97

We would like to see a written memo to all appropriate prison officials addressing and remedying this issue.

President's Advisory Council on HIV/AIDS

Recommendations

VI.R.4	The President shall direct the Attorney General to direct the Federal Bureau of Prisons to ensure that condoms and dental dams are made readily available for all prisoners within correctional facilities to prevent transmission of HIV/AIDS.
Passed on: 4/5/97	
Resolved? No	

Administration Response

Administration Response
(DOJ)
10/19/97

This recommendation is inappropriate for inmates incarcerated in the Federal Bureau of Prisons. Sexual activity among inmates is prohibited and highly linked to a rise in inmate violence. Policy guidance is presented in P.S. 5270.07, Inmate Discipline in Special Housing Units. Condoms and dental dams are not medically necessary for use other than during sexual activity and therefore are not authorized. Inmates receive education on the dangers of HIV and other sexually transmitted diseases during admission and orientation at each institution and following any transfer. The Health Services Unit also provides inmates educational pamphlets and counseling. P.S. 6100.01 Health Promotion Disease Prevention, February 22, 1994, is designed to increase HIV/AIDS awareness and to decrease the number of seropositive conversions.

This recommendation is also inappropriate for INS detention facilities, given the transient nature of their detention.

Assessment of Response
(DOJ)
11/11/97

The statement that protective barriers "are not medically necessary and, therefore not authorized" is unacceptable in the context of AIDS prevention. This is underscored by several successful state models where Protective Barriers are available in prisons.

Follow-up Action
Recommended
11/11/97

We request copies of PS 5270.07 & PS 6100.01 and comment on how these statutes might be revised.

VI.R.5	The President shall direct the Attorney General to direct the Federal Bureau of Prisons to investigate and report within 90 days on the feasibility of and various options for providing comprehensive substance abuse treatment for incarcerated individuals with a dual diagnosis of chemical dependency and HIV disease.
Passed on: 4/5/97	
Resolved? No	

Administration Response
(DOJ)
5/9/97

See VI.R.3 "Administration Response (DOJ)"

President's Advisory Council on HIV/AIDS

Recommendations

Further Administration Response (DOJ)

10/15/97

The Violent Crime Control and Law Enforcement Act of 1994 requires the BOP, subject to the availability of appropriations, to provide residential drug abuse treatment to all eligible inmates. To be eligible, an inmate must be sentenced to BOP custody, determined by the BOP to have a substance use disorder, and volunteer for treatment. The BOP makes its determination of a drug abuse problem based on the American Psychiatric Association's standards as published in the Diagnostic and Statistical Manual, Fourth Edition (DSM IV). BOP staff encourage inmates with drug abuse problems to enter the residential drug abuse treatment program, and approximately two-thirds of all inmates with drug use disorders volunteer for residential treatment.

Since the BOP does not require HIV testing for all inmates, the HIV status of all inmates is not always known. Inmates with a substance abuse problem who volunteer for treatment are admitted into residential substance abuse programs in sequential order based upon release date. To deter the passing on of HIV, each BOP drug abuse treatment program provides education on HIV transmission and high risk behaviors associated with HIV. The BOP also offers specialized group and individual sessions for inmates who disclose a positive HIV status or have close ties with others who are HIV positive. The counseling is available to inmates in the drug program with "dual diagnoses" of drug use disorders and HIV.

While INS initiates primary health care measures, comprehensive treatment is neither appropriate nor feasible due to the transient nature of detention in INS facilities.

Assessment of Further Response

11/11/97

Greater surveillance data is needed in order to adequately assess seroprevalence as well as greater access to Treatment programs.

Follow-up Action Recommended

11/11/97

A request for investigation into the viability and effectiveness of improved substance abuse intervention programs, including needle exchange, is needed. How would the Federal Bureau of Prisons respond?

President's Advisory Council on HIV/AIDS

Recommendations

Research

I.D.1

Passed on: 7/28/95
Resolved? No

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 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.D.2

Passed on: 7/8/96
Resolved? No

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

Administration Response 11/26/97

No response given to date.

II.D.1

Passed on: 12/8/95
Resolved? No

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 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 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.

Follow-up 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.

President's Advisory Council on HIV/AIDS Recommendations

II.D.2

Passed on: 12/8/95

Resolved? No

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 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 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).

Follow-up 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.

II.D.3

Passed on: 12/8/95

Resolved? No

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 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 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.

Follow-up 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.

President's Advisory Council on HIV/AIDS

Recommendations

II.D.4

Passed on: 12/8/95

Resolved? No

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 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 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.

Follow-up 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.

President's Advisory Council on HIV/AIDS

Recommendations

II.D.5

Passed on: 12/8/95

Resolved? No

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

Administration 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, AIDSDRUGS, 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 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.

Follow-up Action Recommended

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

President's Advisory Council on HIV/AIDS

Recommendations

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.
Passed on:	12/8/95	
Resolved?	No	
<i>Administration Response</i>		<i>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.</i>
<i>Assessment of Response</i>		<i>The Council is concerned that this recommendation has not been carried out in the timeframe we suggested.</i>
<i>Follow-up Action Recommended</i>		<i>The urgency of this issue would mandate that our recommendation must be accomplished as soon as possible.</i>
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.
Passed on:	12/8/95	
Resolved?	No	
<i>Administration Response</i>		<i>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.</i>
<i>Assessment of Response</i>		<i>We acknowledge that the FDA has a working group on this issue.</i>
<i>Follow-up Action Recommended</i>		<i>A status report on this recommendation should be provided to the Council 30 days prior to the next Council meeting.</i>
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.
Passed on:	12/8/95	
Resolved?	No	
<i>Administration Response</i>		<i>The FDA received 13 comments on this proposed rule to the regulations. The FDA is currently evaluating the comments and drafting the final rule.</i>
<i>Assessment of Response</i>		<i>As of April 25, 1996, this had not been done.</i>
<i>Follow-up Action Recommended</i>		<i>A status report on this recommendation should be provided to the Council 30 days prior to the next Council meeting.</i>

President's Advisory Council on HIV/AIDS

Recommendations

II.D.9 Passed on: 12/8/95 Resolved? No	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.
<i>Administration Response</i>	<i>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.</i>
<i>Assessment of Response</i>	<i>Current policy (Code of Federal Regulations, Part 46.207) addresses this concern and does not preclude the inclusion of pregnant women in clinical trials.</i>
<i>Follow-up Action Recommended</i>	<i>This information should be widely disseminated.</i>
III.D.1 Passed on: 4/26/96 Resolved? No	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.
<i>Administration Response</i> (ONAP) 8/30/97	<i>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.</i>
III.D.2 Passed on: 4/26/96 Resolved? No	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.
<i>Administration Response</i> (ONAP) 8/30/97	<i>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.</i> <i>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.</i> <i>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.</i>

President's Advisory Council on HIV/AIDS

Recommendations

III.D.3

Passed on: 4/26/96

Resolved? No

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 (ONAP) 8/30/97

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.

III.D.4

Passed on: 4/26/96

Resolved? No

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

Administration Response (ONAP) 8/30/97

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.

VI.D.1

Passed on: 4/5/97

Resolved? No

The President must declare an urgent goal of developing a vaccine to prevent HIV/AIDS within a decade in order to mobilize public opinion, political will, and international collaboration, and to assign high priority to this effort within each of the governmental agencies involved in HIV/AIDS vaccine research and development. As the HIV/AIDS epidemic has no borders, and a successful vaccine will require international collaboration, the President should work with the leaders of other nations in a global effort to achieve an HIV/AIDS vaccine for all the world.

Administration Response 11/26/97

No response given to date.

President's Advisory Council on HIV/AIDS

Recommendations

VI.D.2

Passed on: 4/5/97

Resolved? No

A significant and sustained increase in funds must be made available for HIV/AIDS vaccine research and development. These funds must be derived from NEW sources from both government and industry, and must not be taken from existing programs aimed at prevention, research, care, services, and/or treatment for persons with HIV/AIDS. Innovative use of such funds is essential, as seed money to initiate new and creative hypotheses in vaccine research; to support product development; to expand the proportion of successfully funded grant applications; and to bring additional entities into the HIV/AIDS vaccine field.

Administration Response

11/26/97

No response given to date.

VI.D.3

Passed on: 4/5/97

Resolved? No

Development of an effective HIV/AIDS vaccine will require expertise in many areas, including basic science, applied research, public health policy, and legal, ethical, industrial, and international issues. Dr. David Baltimore has recently been chosen to provide advice and leadership for the NIH HIV/AIDS vaccine effort, and the Council is highly supportive of this appointment. Additionally:

Participation by non-governmental sectors and organizations is also essential to achieve the goal of expedited vaccine research, product development and use. The Vice President should convene a public-private HIV/AIDS vaccine

Administration Response

11/26/97

No response given to date.

President's Advisory Council on HIV/AIDS

Recommendations

Services

I.B.1

Passed on: 7/28/95
Resolved? No

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 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 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.

Follow-up 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.

I.B.2

Passed on: 7/28/95
Resolved? No

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 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 Response

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

Follow-up Action Recommended

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

President's Advisory Council on HIV/AIDS

Recommendations

I.B.3 Passed on: 7/28/95 Resolved? No	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 Response	<i>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.</i>
Assessment of Response	<i>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.</i>
Follow-up Action Recommended	<i>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>
II.B.1 Passed on: 12/8/95 Resolved? No	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 Response	<i>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.</i>
Assessment of Response	<i>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.</i>
Follow-up Action Recommended	<i>The Council should continue monitoring changes in Medicaid and Medicare as they are proposed in legislation.</i>

President's Advisory Council on HIV/AIDS

Recommendations

II.B.2	Passed on: 12/8/95 Resolved? No	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.
<i>Administration Response</i>	<i>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.</i>	
<i>Assessment of Response</i>	<i>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.</i>	
<i>Follow-up Action Recommended</i>	<i>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.</i>	
<i>Follow-up Action Recommended</i>	<i>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.</i>	
II.B.3	Passed on: 12/8/95 Resolved? No	Direct HCFA to ensure that State Medicaid programs cover HIV testing and counseling.
<i>Administration Response</i>	<i>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.</i>	
<i>Assessment of Response</i>	<i>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.</i>	
<i>Follow-up Action Recommended</i>	<i>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.</i>	

President's Advisory Council on HIV/AIDS

Recommendations

II.B.4	Passed on: 12/8/95 Resolved? No	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 Response	<i>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.</i>	
Assessment of Response	<i>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.</i>	
Follow-up Action Recommended	<i>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.</i>	
II.B.5	Passed on: 12/8/95 Resolved? No	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 Response	<i>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.</i>	
Assessment of Response	<i>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.</i>	
Assessment of Response	<i>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.</i>	
Follow-up Action Recommended	<i>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.</i>	
Administration Response (DOJ) 4/23/96	<i>The Bureau of Prisons (BOP) agrees with this recommendation. In addition to following the latest clinical care guidelines published by the CDC, BOP employs an Infectious Disease Specialist who advised its medical director in the design, implementation, and evaluation of disease prevention programs, including those relating to HIV/AIDS. BOP looks forward to discussing with the National AIDS Policy Office a strategy for adopting a "standard for HIV care" and other ways in which they might respond to the above-described concern.</i>	

President's Advisory Council on HIV/AIDS

Recommendations

Administration Response (VA) 10/16/97

We have reviewed the Advisory Council recommendations and the Prevention Subcommittee's assessments that you enclosed. None of these seem to be primarily within the purview of the VA. However, it should be noted that the VA provided medical care to over 16,000 veterans with HIV/AIDS during the past year. In order to assure that the latest advances in treatment were available in all facilities, an additional \$6.5 million was allocated for earlier and more aggressive therapy. VA also has an active drug treatment and rehabilitation program which incorporates AIDS prevention and voluntary HIV testing for its participants.

II.B.6

Passed on: 12/8/95
Resolved? No

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 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; and
- 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 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.

President's Advisory Council on HIV/AIDS

Recommendations

Follow-up 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.

II.B.7

Passed on: 12/8/95

Resolved? No

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 benefits should be reimbursed under Medicaid.

Administration 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 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.

Follow-up 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.

II.B.8

Passed on: 12/8/95

Resolved? No

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 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 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.

President's Advisory Council on HIV/AIDS

Recommendations

Follow-up 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.

Administration Response 11/25/97

The AETC program has been incorporated into the Ryan White CARE Act by the Ryan White CARE Act Amendments of 1996 (Pub. L. 104-146). FY '97 funding for the program was \$16.287 million, and FY '98 funding is \$17.3 million.

II.B.9

Passed on: 12/8/95
Resolved? No

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 Response

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

Assessment of 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.

Follow-up 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.

III.B.1

Passed on: 4/26/96
Resolved? No

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 (ONAP) 8/30/98

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."

President's Advisory Council on HIV/AIDS

Recommendations

III.B.2

Passed on: 4/26/96

Resolved? No

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 **(ONAP)** 8/30/97

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.

III.B.3

Passed on: 4/26/96

Resolved? No

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

Administration Response **(ONAP)** 8/30/96

In a memo to the Council (subject: Administrative Response to Report Three), Patsy Fleming, Director of the Office of National AIDS Policy, stated the following:

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 fall 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.

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Recommendations

III.B.4 Passed on: 4/26/96 Resolved? No	The Administration should recommend a substantial increase in the NIH Office of Alternative Medicine (OAM) budget for FY 1997.
<i>Administration Response</i> (ONAP) 8/30/97	<i>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.</i>
III.B.5 Passed on: 4/26/96 Resolved? No	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.
<i>Administration Response</i> (ONAP) 8/30/96	<i>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.</i> <i>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.</i> <i>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.</i>
III.B.6 Passed on: 4/26/96 Resolved? No	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.
<i>Administration Response</i> (ONAP) 8/30/97	<i>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.</i>

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Recommendations

III.B.7

Passed on: 4/26/96

Resolved? No

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
(ONAP)
8/30/97

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.

III.B.8

Passed on: 4/26/96

Resolved? No

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

Administration Response
(ONAP)
8/30/97

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.

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Recommendations

IV.B.1

Passed on: 12/15/96

Resolved? No

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

Administration Response (HHS) 4/5/97

During fiscal year (FY) 1996 and continuing into FY 1997, the Health Resources and Services Administration (HRSA) has taken a variety of steps to assist States in utilizing multiple cost-saving strategies in purchasing and distributing medications to people living with HIV/AIDS (PLWH). To do this, HRSA continues to work in partnership with grantees funded under the Comprehensive AIDS Resources Emergency (CARE) Act, State administered AIDS Drug Assistance Programs (ADAPs), State AIDS Directors and the National Alliance of State and Territorial AIDS Directors, and the Health Care Financing Administration (HCFA). These efforts to increase cost-savings are in response to the growing strain on ADAPs resulting from increased numbers of low-income, under and uninsured PLWH being brought into care through CARE Act funded programs; the availability of new treatments; rapidly changing clinical treatment standards (dual and triple combination therapy); and the high cost of newly approved medications for treatment (including protease inhibitors). Highlights follow:

- 1. Program Guidance: a) HRSA required States to identify all cost-saving strategies in use (e.g., the Office of Drug Pricing (ODP)/Section 340B program, voluntary manufacturers' price discounts or rebates, pharmacy discounts) as part of their FY '96 and FY '97 Title II and ADAP supplemental applications. To receive an advance of FY'97 ADAP funds for use in '96, States had to demonstrate use of at least one cost-saving mechanism and describe plans for obtaining further cost reductions. b) Issued a Dear Colleague letter to Title I/II grantees (10/96) stressing HRSA's expectations re: administration of ADAPs, including the use of cost-saving strategies to obtain the best price. HRSA also: (1) strongly encouraged States to consider operating their ADAPs under a central purchase/distribution system to achieve higher cost-savings; and (2) underscored the importance of administrative mechanisms/contractual requirements to assure that Title I/II funds are used as payer-of-last-resort.*
- 2. Grantee Work Groups and Workshops: A small work group of ADAPs was convened in April 1996, to assist HRSA in assessing the impact of newly available drugs on ADAPs and develop strategies for assisting States to respond. At the national Title I/II Grantee Meeting in July, three ADAP workshops included a focus on the ODP/Section 340B program and other purchasing/distribution cost-saving strategies.*
- 3. On-going program coordination between ODP and DHS to update staff regularly on their respective programs/current activities; explore options for increasing ADAP participation in ODP/602 and reducing barriers; facilitate the annual re-enrollment/recertification process of participating entities; and plan joint technical assistance (TA) efforts. The latter included an ADAP TA conference call on the ODP program and a primer on cost-saving strategies; plans are underway to conduct joint site visits to States requesting TA, starting with Missouri in April.*
- 4. Development of Federal Register Notice on Rebate Mechanism by ODP to expand access to ODP/Section 602 program cost-savings for States operating their ADAPs on a reimbursement model. (Currently, 27 States reimburse Medicaid participating and/or other pharmacies who fill prescriptions for ADAP eligible clients. In these States, most ADAPs reimburse at the State's Medicaid rate and a few at some other discounted rate; and, all but one of these States currently obtains voluntary manufacturers' rebates or the HCF Medicaid rebate. DHS anticipates that all 29 ADAPs using a reimbursement model to provide access to treatment, will benefit from the addition of this mechanism.)*
- 5. Development of Prime Vendor Contract by the ODP Program as required by the statute for the distribution of drugs to covered entities under the ODP program. Since the statute permits covered entities to negotiate prices lower than the statutory ceiling prices used to calculate the ODP price, HRSA is reviewing options that include price negotiation in the PHS Prime Vendor Program as well as drug sales and distribution.*
- 6. Condition-of-Awards: When the Prime Vendor program and rebate mechanisms are added to ODP/Section 602 program, HRSA plans to condition grant awards to require grantees to participate in ODP/Section 602 through the Prime Vendor or Rebate mechanism, or to demonstrate comparable program costs in purchasing and distributing medications.*
- 7. Individualized and on-site TA to Title II and State ADAPs provided by DHS' project officers and through the DHS TA contract with John Snow, Inc. on request. TA provided includes methods to improve the efficiency and effectiveness of ADAP drug purchasing/distribution*

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systems, e.g. California, Tennessee, Arkansas.

8. HRSA collaboration with the National Association of State and Territorial AIDS Directors (NASTAD) to expand TA resources to State ADAPs and Title I/II grantees:

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IV.B.2

Passed on: 12/15/96

Resolved? No

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

Administration Response (HHS) 4/5/97

The Special Projects of National Significance (SPNS) Program currently funds six demonstration projects examining the financing of care for people with HIV under managed care settings. These projects may yield results relating to the timing of access to care and the effect on health status. In addition, the Office of Science and Epidemiology has just completed a paper predicting the lifetime costs associated with HIV care and will hold a conference in May 1997 focusing on risk adjustment related to the financing of HIV care.

The Agency for Health Care Policy Research (AHCPR) is funding a major research effort to collect information on a nationally representative sample of people receiving care for HIV infection. The HIV Cost and Services Utilization Study -- HCSUS -- is the first major research activity of its kind. The information generated by this study will inform policy decisions on the allocation of limited health care resources for the treatment of persons with HIV infection and AIDS.

HCSUS is collecting data on 3000 HIV-positive persons in 180 clinics, hospitals, and private practices in 28 urban areas as well as six clusters of rural counties in the United States. The project is over-sampling HIV-positive women, and collecting supplemental data samples to 1) cover additional rural clusters; 2) include persons who are in the very early stages of HIV disease; and 3) gather detailed information on mental health and HIV/AIDS. Additional studies are being conducted on oral health and oral health care delivery, substance abuse, HIV-infected persons over 50 years of age, and the impact of organization of care on the delivery of health care.

Through a baseline interview, follow-up interviews, and abstraction of medical, pharmaceutical, and financial records, HCSUS will examine many health care issues for HIV-positive persons, including

- cost, use, and quality of care*
- access to care*
- unmet needs for care*
- quality of life*
- social support*
- knowledge of HIV*
- clinical outcomes*
- mental health*
- the relationship of these variables to provider type and patient characteristics.*

The first phase of interviews began in 1996. Data collection is scheduled for completion in 1998. The data then will be made available through public use tapes for any interested party to analyze.

The information collected in this study will assist in measuring health-related quality of life, employment and insurance status, income and receipt of income subsidies. A particular focus of the study will be to estimate both lifetime and annual costs-of-care. In addition, HCSUS is obtaining in-depth information concerning access to care and barriers to access. Because data collection for HCSUS is occurring during the revolution in care caused by the advent of new therapies for HIV infection, the data will be invaluable both for assessing the changes resulting from protease inhibitors, as well as for establishing a baseline against which the outcomes of demonstration programs can be compared.

HCSUS is funded through a cooperative agreement between AHCPR and RAND (a private, nonprofit research institution headquartered in Santa Monica, California) which is coordinating a consortium of private and governmental institutions conducting the study. Local and national advisory groups have been established to facilitate communication between the HIV community and the research consortium. Supplemental funding has been provided by the Health Resources and Services Administration (HRSA), the National Institute of Mental

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Health (NIMH), the National Institute of Dental Research (NIDR), the National Institute on Drug Abuse (NIDA), the National Institute on Aging (NIA), and the Robert Wood Johnson Foundation.