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Problems in carrying out NBP---Report to the Secretary of HEW

ABC

Role-Develop safe, fast, efficient blood collection and distribution system

- Non-profit corporation
- Develop and test standards, guidelines, and procedures pertaining to blood banking

Problems- disagreement between two largest blood suppliers

- lack of funds
- resistance to regionalization of blood collecting and distributing
- problems obtaining data from blood banks
- lack of knowledge of blood banking by lay members

Health Care Financing Administration- had not developed system to relate costs and charges for blood

services

Recommendations-Commission consider a legislative or regulatory approach

ABC Officials

(ABC was formed to represent many diverse organizations concerned with the NBP)

1. Commission must coordinate planning and develop consensus within all segments of the blood service community (regarding ways and means of achieving NBP goals)
2. Commission will increase its influence by formulating standards and guidelines through a broadly based and powerful membership
3. Establish task force composed of experienced individuals from all segments of society

Various Task Forces that came out of ABC

ADMIN:
N Drive
Documents

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Blood Inventory Control--developed blood bag labeling

Regional Association of blood service units--

- formulated guidelines for a more effective blood service delivery system
- developed criteria for types and quality of blood services

Acknowledgments

Many people infected and affected by HIV shared their expertise and experiences with us over the last year. We are very grateful for this insight and appreciate the time taken to draw out the many, complicated issues. The report reflects the issues and messages that they considered to be most critical for young people today.

The AIDS Policy Center for Children, Youth and Families connected us with many of the young people we met. They and the Institute for Family Centered Care, through funding by the Health Resources and Services Administration (HRSA), helped a group of young people form the National Alliance of Positive Youth. Thank you to all of the young people who took time away from the conferences they came to Washington for and who let us sit in on some very eye-opening groups. Many of these youth met with us repeatedly and helped make sure the concepts in this report reflected all youth.

Metro TeenAIDS sponsored a conference for youth who were part of peer education programs in their schools or communities. We appreciate the room given to us to hold small meetings of both young people and the adults who mentor them. Participants ranging from rural schools with no HIV+ students to urban schools with students who live in neighborhoods where one tenth of the residents are HIV+ all agreed that youth speaking with youth can change the attitudes and behaviors that put young people at risk.

The National School Board led a coalition of organizations who, through funding by the Centers for Disease Control and Prevention and HRSA, sponsored a National Youth Summit on the Prevention of AIDS Among Youth. These organizations included: Young people from every state and background attended this conference. The power of diversity and a commitment to their futures resulted in a five part resolution on actions to be taken to decrease the spread of HIV among youth.

The National Advocacy Coalition on Youth and Sexual Orientation (NACYSO) invited us to their annual strategic planning meeting. Participants shared experiences in their home towns that called for greater national awareness of the barriers young people face in accessing information and services related to HIV/AIDS.

The National Youth Network facilitated a discussion among the members of its Safe Choices program. They described trends among the young people in their neighborhoods that seemed to impact whether young people put themselves at risk for acquiring HIV.

The Latino/a Lesbian and Gay Organization arranged for a group of young people to share how they were impacted by HIV/AIDS. This group recommended ways of making resources available to young people and how to build on the strengths of youth helping each other.

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We visited local prevention and treatment programs to hear experiences of health care providers and young people currently trying to cope with the impact of HIV/AIDS in their lives and communities. We are grateful to the following organizations in Atlanta that welcomed us into their daily efforts to work with youth on HIV/AIDS issues: AID Atlanta, Grady Hospital and Ask Us. A recurrent theme among everyone working day-to-day with young people is that we cannot treat each problem in isolation. Local communities need to be able to mix funding streams and coordinate their programs among the health care, education, welfare and criminal justice systems in order to effectively help a young person.

The National AIDS Fund, with support from ?, arranged for site visits to CDC's Prevention Marketing Initiative demonstration grant sites that focused on youth. Each site explained how they assessed their community's HIV prevention needs and solicited the support of local organizations in developing a prevention program that reflected local values and strengths.

The Department of Health and Human Services has several agencies that collaborate with States and local organizations to develop sound policies and programs related to youth and HIV/AIDS. The key agencies are: Centers for Disease Control and Prevention, Health Resources and Services Administration, Substance Abuse and Mental Health Services Administration and National Institutes of Health. Individuals and groups of staff from each of these agencies met with us to discuss their initiatives and the needs they are hearing from people around the country. We also participated in meetings with grantees from their programs, including the following:

- CDC's Prevention Marketing Initiative demonstration grantees' meeting
- CDC's planning group for a grantees' meeting on HIV prevention in school-aged youth
- HRSA's Special Projects of National Significance, youth projects, grantees' meeting

We were unable to reach many of the youth involved to get permission to list their names and did not wish to break anyone's confidentiality. The young people we spoke with represented the youth of this country. They came from rural, urban and suburban communities in every region of the country. Some grew up in two-parent, safe, loving homes and others faced abuse, neglect and homelessness. Young women and men from different religious backgrounds, cultures, sexual orientations, races, and economic levels shared their experiences with us and each other. We learned a lot from them and hope that their concerns and recommendations can be seen in this report.

In addition to the organizations mentioned above, we spoke with the following national and local health care providers, researchers, parents, teachers, and policy makers:

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Greater Mount Calvary Holy Church AIDS Ministry
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Prevention Marketing Initiative
Sacramento, CA

Mildred Williamson
Cook County Hospital
Chicago, IL

Laurie Yosick
Columbia AIDS Task Force
Columbia, OH

Toni Young
National Women and HIV/AIDS Project
Washington, DC

The President asked for a report on youth and HIV when he appointed Patricia Fleming as National AIDS Policy Director. Since that time, staff in her office have gathered information and refined the report to reflect the best thinking and real experiences of youth and those who work with them on HIV/AIDS issues. Richard Sorian guided the process and incorporated comments from the field into the final draft. Brenda Kunkel reached out to youth, health care providers, prevention experts, policy makers and researchers from across the country to develop an outline of the key issues and best practices for youth infected and affected by HIV/AIDS. We also appreciate the assistance of the volunteers and interns at the White House Office of National AIDS Policy. Thanks to: Jesse Souweine, Julie Blessing, Lisa DaValle, Rachel Garfield, Brenda Hahn, Vanessa Potkin, Jessica Purdy, Katie Smeltz, and Rachel Smith.

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June 3, 1998

MEMORANDUM FOR PATSY

FROM: Richard Sorian

SUBJECT: HOW TO DEAL WITH A DEMONSTRATION

Steve Rabin has offered some good suggestions of how to deal with an ACT-UP demonstration or any other demonstration. They are:

1. **Stop speaking.** Never try to talk over them. It only infuriates them and makes you look insensitive.
2. **Build an alliance with panel members.** If you are on a panel (which you are on Wednesday), discuss the possibility of protests with other members before you go on. Ask them: "How do you want to handle a protest if it happens?" In this way the other panelists won't simply sit back and leave you to deal with it.
3. **Turn to the moderator.** This is not your show, it's the moderator's show. Step back and turn to the moderator and ask him/her how they would like to proceed. (In this case, the moderator is an HIV + woman so it makes it difficult for the protestors to continue.)
4. **Give them another outlet.** Mention the town hall meetings later in the conference that will give everyone a chance to offer their opinions. You can also offer to meet with these groups later (but that rarely works).

HEALTH CARE DELIVERY:

- 1. Veto any legislation that inadequately funds or eliminates federal entitlements to Medicaid, Medicare, or welfare. People living with HIV/AIDS depend on these benefits to survive.**

President Clinton has aggressively advocated for the need for health care coverage, that could not be taken away, for all Americans. President Clinton's Health Security Act would have provided private health insurance for all people with AIDS and prohibited insurance companies from discriminating against people with preexisting medical conditions, including HIV and AIDS.

Congress is currently working on a Budget Reconciliation Bill that contains dramatic cuts to Medicaid, Medicare and the welfare system. The President has made clear in public statements that he will veto this bill in its current format. We believe that the magnitude of these cuts in these programs is unprecedented and would have a devastating impact on millions of individuals who depend on the safety net Medicaid, Medicare, and welfare provide.

- 2. Veto any legislation that would coerce pregnant women or their newborn babies to be tested for HIV.**

The President does not support mandatory approaches to HIV testing, especially before voluntary approaches have been fully implemented. There is also the concern that mandatory testing programs could drive people away from the care they desperately need. This is a difficult public health issue and it would be premature to discuss vetoes before the final legislative language has been developed.

- 3. Direct the Centers for Disease Control (CDC) to publish a statement against mandatory HIV testing of any population and forced administration of AZT during pregnancy.**

CDC recently published *U.S. Public Health Service Recommendations for Human Immunodeficiency Virus Counseling and Voluntary Testing for Pregnant Women*, which does state: "HIV testing of pregnant women and their infants should be voluntary. Consent for testing should be obtained in accordance with prevailing legal requirements. Women who test positive for HIV or refuse testing should not be a) denied prenatal or other health-care service, b) reported to child protective service agencies because of refusal to be tested or because of their HIV status, or c) discriminated against in any other way."

The Recommendations also state that "HIV-infected pregnant women should not be coerced into making decisions about ZDV therapy...A women's decision not to accept treatment should not result in punitive action or denial of care." Other CDC publications and program announcements consistently stress that counseling and testing be a voluntary activity.

4. Direct the Health Care Finance Administration (HCFA) to establish quality standards specific to persons living with HIV/AIDS for approval of state Medicaid managed care waiver applications.

HCFA requires that Medicaid managed care programs to provide adequate access and quality of care tailored to the population to be enrolled. If a state proposed to enroll persons with HIV/AIDS, HCFA examines the adequacy of the provider network, the scope of services, and the quality assurance and monitoring systems specific to that population prior to waiver approval. HCFA has also begun to consider specific clinical outcome measures that would be relevant for HIV/AIDS populations enrolled in managed care.

5. Order HCFA to direct all state Medicaid Directors to cover clearly useful HIV-related off-label drugs and alternative treatments.

Outpatient prescription drugs is an optional service under the Medicaid program. Although all states cover outpatient prescription drugs, they are not required to under current law. Medicaid coverage of outpatient prescription drugs is as generous or more generous than most private insurance coverage. Under current law, states have broad authority to cover prescription drugs for off-label uses for AIDS, cancer, and other diseases/conditions if the off-label use is listed in one of the three major pharmaceutical compendia. States also have the authority to cover investigational new drugs. This authority allows Medicaid early access to promising new treatment while they are still in the FDA approval process.

6. Direct HCFA to mandate Medicaid coverage of (anonymous) HIV counseling and testing.

Under current law, states are required to provide HIV screening and counseling in situations where symptoms are present that may indicate an HIV diagnosis. In addition, although there is no specific requirement for HIV testing and counseling services under EPSDT, physicians and other health practitioners providing EPSDT services may use their clinical judgement in determining the extent of services

needed. To our knowledge, all state Medicaid programs are providing beneficiaries with HIV screening and counseling services. For example, HCFA conducted a survey of the state with highest rates of HIV/AIDS among women; of these 11 states, all covered HIV testing and counseling services for women of child bearing age.

7. Direct the Department of Health and Human Services (HHS) Office of Civil Rights to use the Americans with Disabilities Act to regulate managed care waiver applications. The Americans with Disabilities Act must be used to protect people living with HIV/AIDS.

The Justice Department and the Equal Employment Opportunity Commission have vigorously enforced provisions of the Americans with Disabilities Act (ADA) that prohibit discrimination against people with HIV/AIDS. 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.

The movement of the increased use of managed care systems can create uncertainties for all individuals needing health care services, and certainly none more so than for people living with HIV/AIDS. For that reason HHS, including the Office for Civil Rights (OCR), has been and continues to be sensitive to issues of discrimination or potential discrimination in evaluating managed care waiver applications. The ADA and Section 504 responsibilities of HHS are a critical part of the framework for evaluating managed care waiver applications.

The Department has committed to reviewing civil rights issues as an integrated part of the waiver application evaluation process. As in any situation where each state may be working separately to develop systems tailored to their needs, there are great variations in the waiver applications that HHS receives. Issues of clear concern are flagged, raised and dealt with. HHS is very aware that some waivers involve matters not apparent on the face of the proposal, but rather involve details of implementation. In those situations, HHS and OCR have worked with the states and interest groups in an effort to achieve a better understanding of the impact on individuals with disabilities, including people living with HIV/AIDS. It is important in those situations to maintain a continuing exchange with all concerned parties--states, providers, and consumers--to insure that civil rights issues arising during implementation are appropriately addressed. HHS encourages

this type of exchange and encourages interested groups to share their specific concerns about managed care waiver applications.

8. Allow inmate in Federal prisons to require all federal prisons to practice the NIH-defined standards of care for prisoners with AIDS.

9. Order the federal Bureau of Prisons to require all federal prisons to practice the NIH-defined standards of care for prisoners with AIDS.

10. Order the Food and Drug Administration (FDA) to revoke its requirement that AIDS drugs imported by buyers' clubs be accompanied by individual prescriptions.

The Food and Drug Administration (FDA) has developed several mechanisms to permit expanded access for promising, but as yet unapproved therapeutic agents to AIDS patients outside of clinical trials. Thousands of patients have been able to gain legal access to unapproved therapies through parallel track protocols, treatment INDs, and emergency INDs.

The agency has also articulated a personal use importation policy under which it may exercise enforcement discretion to permit individuals with life threatening diseases to bring small amounts of unapproved drugs into the United States for personal use.

Concerned about potential threats to the health of people with advanced HIV disease and AIDS, resulting from the lack of physician involvement in their medical care; the use of injectable products of unknown purity, sterility and strength; the use of unproven drug products from unknown sources of manufacture; the use of potentially dangerous products; and health fraud, FDA requires that documentary evidence be available for review demonstrating that any patient importing products for personal use has a licensed physician who is accepting responsibility for the patient's care, including administration of the product. The personal use importation policy does not require a doctor's prescription, per se, but rather the name and address of a licensed physician in the U.S. responsible for the patient's treatment, or evidence that the product is for the continuation of treatment started in a foreign country. FDA does not believe the best interests of any individuals are served by having access to drugs for serious conditions without adequate physician oversight.

FDA has intensified its communication with various interest

groups, including buyers clubs and patient advocacy organizations, to identify products reported to have the greatest medical promise for HIV-infected individuals, but not yet legally available in the United States. The agency has successfully worked with these groups, as well as with other government agencies, doctors, and individual patients, to find ways to make these products more widely available as scientific data are gathered.

11. Order the FDA to approve acupuncture needles as medical devices to facilitate insurance reimbursements.

HOUSING:

12. Veto any bill that eliminates or decreases funding for the Housing of People with AIDS (HOPWA) program at the Department of Housing and Urban Development.

In the early phases of the Congressional efforts to rescind a portion of FY 1995 funding for a number of programs, a proposal was put forth to totally zero out the HOPWA program. The Clinton Administration strongly opposed the Congressional proposal and was able to negotiate a final decision which preserved \$171 million of the \$186 million program.

In his FY 1996 budget, the President supported funding the HOPWA program at its full FY 1995 level, \$186 million. Secretary Cisneros has continued to make funding for the program a priority in his budget negotiations. It appears that the FY 1996 appropriation will be approximately \$171 million, the same as the post decision funding level for FY 1995.

While both the Secretary and the President support significant funding for HOPWA, promising a veto solely as the result of the failure to fund a \$186 million program in an appropriation bill that exceeds \$20 billion (in HUD funding alone) is unlikely.

13. Grant the National HIV/AIDS Office of Housing at HUD the authority to enforce the development of local housing for people living with HIV/AIDS.

HUD is very cognizant of the discrimination and neighborhood opposition problems which are often faced by those seeking to provide housing for persons living with HIV/AIDS. However, granting enforcement authority to the Office of HIV/AIDS Housing is not an appropriate response since HUD already has an enforcement arm, the Office of Fair Housing

and Equal Opportunity (OFHEO), under the direction of Assistant Secretary Elizabeth Julian. This office is charged with ensuring that existing fair housing statutes are enforced.

Unfortunately, an effort is being mounted in Congress to move OFHEO out of HUD and into the Department of Justice. It is the Secretary's position that such a move would severely weaken the office at a time when more enforcement is needed to ensure that vulnerable populations have access to the housing and support services they need.

The Administration endorses the need for a strong and visible enforcement presence through an adequately funded and viable Office of Fair Housing at HUD.

In addition to the enforcement work of the OFHEO, the Office of HIV/AIDS Housing has provided technical assistance to AIDS housing providers regarding the education efforts that are often needed to overcome the initial public opposition to the location of facilities that assist persons living with HIV/AIDS.

14. Direct all HUD employees to recognize HIV/AIDS eligibility for McKinney Act (housing) programs, and ensure that all local governments allocate towards AIDS housing the mandated percentage of McKinney Act funds.

There is no mandated percentage set-aside for AIDS housing in the HUD McKinney programs. However, housing for homeless persons living with HIV/AIDS is clearly an eligible activity under the HUD McKinney programs. HUD's Office of Special Needs Assistance Programs (SNAPS) and the Office of HIV/AIDS Housing work closely together to ensure that each other's constituents are aware of the resources administered by both offices. In addition, both offices have encouraged participation by persons living with HIV/AIDS and HIV/AIDS housing providers in local Continuum of Care planning efforts (where plans are made for addressing the communities needs for services and housing for homeless persons) and the Consolidated Planning process (where local priorities for HOPWA funding are determined and an assessment of housing needs of persons with HIV/AIDS is made.)

In the FY 1995 round of funding, it is estimated that the following percentages of each HUD McKinney program went to serve homeless persons with HIV/AIDS:

- Supportive Housing (10%)
- Shelter Plus Care (8%)
- Section 8 SRO Mod Rehab (5%)

15. Order a percentage of AIDS housing dollars to be set aside for housing for former prisoners.

HUD has made a concerted effort in recent years to move primary decision-making regarding program development to the local level, where we believe the greatest knowledge resides regarding the needs of persons living with HIV/AIDS in the community. Ninety percent of the HOPWA funds are distributed by formula to cities and states with the greatest need. These communities can target funds as needed within the very flexible HOPWA guidelines. For example, the New York City Comprehensive Plan provides an estimate of HIV prevalence among detainees in city jails and detention facilities and establishes formerly incarcerated persons with HIV/AIDS as a special population as part of their strategic planning efforts.

The remaining 10% of the HOPWA funds are distributed through a national competition, a portion of which is designed to demonstrate the models of service delivery for replication as needed across the nation. For example, HUD recently awarded a \$1 million HOPWA grant to Tarzana Treatment Center, Inc. to provide emergency and transitional housing for 150 California State Prison parolees who are living with HIV/AIDS.

While HUD has not specified a HOPWA set-aside for former prisoners living with HIV/AIDS, the Department will disseminate information from programs such as the Tarzana program, that address the special needs of formerly incarcerated persons, so that local planners and advocates can replicate the model with HOPWA formula dollars and other funds.

RESEARCH:

16. Veto any bill which weakens the budget authority of the Office of AIDS Research (OAR) at the National Institutes of Health (NIH) or which fails to set a fixed funding level for AIDS research.

The President strongly supports the Office of AIDS Research. In fact, one of the first pieces of legislation signed by the President was the NIH reauthorization bill that strengthened the authority of the OAR.

This is a difficult issue and it would be premature to discuss vetoes before the final legislative language and budget levels have been set forth.

The President has clearly expressed his support for the Office of AIDS Research and its important authorities set forth in the NIH Revitalization Act of 1993. The President's veto message to the House Appropriations Committee included this issue.

17. Direct the OAR to maintain the budget for AIDS clinical trials, and specifically for the Community Programs for Clinical Research on AIDS (CPCRA), the sole federal research program focused on people of color, women, and substance users.

As part of the evaluation process initiated by the Office of AIDS Research, the CPCRA and other NIH-funded AIDS clinical trials network are being reviewed and evaluated. The evaluation is assessing the effectiveness of the various clinical trials program from a cross-NIH perspective and will develop a series of recommendations in this regard. The future role and most effective and efficient format of these networks also must be determined in view of industry's efforts in this area.

The goal of the NIAID, the major sponsor of AIDS clinical trials at the NIH, is to maintain a level budget for its overall clinical trials program assuming that the Institute's appropriation permits it to do so without harming other high priority areas of research. Continued support for specific programs, including the CPCRA, must be funded contingent upon high levels of scientific productivity and plans to carry out high priority research in the future. The CPCRA is, above all, a research program. Its primary mission is to involve primary care providers and community-based organizations in scientifically-sound clinical research on HIV infection and its sequelae. We do not agree with its characterization as "the sole federal research program focused on people of color, women, and substance users". Furthermore, all of NIAID's clinical trials programs must reach out to and enroll a racially/ethnically and demographically diverse population of HIV-infected patients to help ensure that study results are maximally useful in the general HIV-infected population.

18. Direct the OAR to fund small trials to screen promising HIV/AIDS treatments for later full-fledged trials, and to fund clinical management trials which study treatment use in the real world.

The NIH, through its ACTG, CPCRA, and DATRI clinical trials networks currently supports a number of small phase I clinical trials of new agents and compounds against HIV infection and its associated opportunistic infections and

malignancies. The Strategic Program for Innovative Research on AIDS Therapies (SPIRATS) similarly supports small proof of concept (phase I) clinical trials of innovative therapies. The NIH also supports clinical management trials or post approval phase IV clinical studies of agents against HIV and HIV-associated opportunistic infections. An example of such a large scale study is ACTG 175 which is currently evaluating several licensed drugs, singly and in combination, and has enrolled over 2500 patients.

19. Order that all NIH-funded trials include women and gender-specific analysis, and halt any trials which would exclude women of child-bearing potential. Women must be included in clinical trials.

In response to the NIH Revitalization Act of 1993, the NIH has revised its guidelines for the inclusion of women and minorities in clinical research, as published in the Federal Register on March 28, 1994. Data are being collected for analysis and monitoring of the implementation of these guidelines and for tracking the inclusion of women and minorities in clinical trials. As part of this effort, data will be available to determine if, and under what circumstances, exclusions from this policy were allowed. Data for the FY 1995 year should be available by early 1996. In addition, a PHS Human Subject Regulation Drafting Committee was established through the Office of Protection from Research Risks (OPRR) to recommend changes in current policies related to the inclusion of pregnant women in clinical trials.

20. Order the removal of all geographical and economic barriers to participation in NIH-sponsored clinical trials or conferences by low-income and rural people with HIV/AIDS.

NIH-sponsored clinical trials are open to all eligible individuals regardless of their gender, race, socio-economic, or geographic status. As the AIDS epidemic has spread throughout all sub-populations and geographic regions, the NIH-funded clinical trial networks have and are continuing to implement mechanisms and infrastructures to enroll HIV-infected individuals from these communities. In order to enroll and retain participants in clinical trials, many clinical trial sites provide ancillary services such as transportation vouchers, obstetric-gynecology care, and child care. An exemplary program demonstrating successful enrollment of rural HIV-infected residents is the University of North Carolina AIDS Clinical Trials Unit (ACTU). This

ACTU has established a state-wide structure of clinics and hospitals to enroll and retain study participants. Similar programs and infrastructure are being developed by ACTUs especially in the Southern and Southeastern U.S.

21. Direct the OAR to hold a conference on AIDS pathogenesis theories and to fund large-scale studies of long-term survivors and non-progressors.

The OAR holds meetings and workshops on a regular basis involving the world's leading scientists in the area of AIDS pathogenesis. Most notably, the OAR has involved these experts in both its planning and evaluation processes. The OAR has undertaken a major evaluation initiative to review and assess each of the components of the NIH AIDS research endeavor to determine whether those components are appropriately designed and coordinated to answer the critical scientific questions to lead to better treatments, prevention, and a cure for AIDS. Non-government experts are meeting on a regular basis to draft recommendations regarding pathogenesis research. The study of long-term non-progressors and long-term survivors is a high priority for NIH and significant resources are devoted to this area of investigation.

22. Order the NIH to adopt their drafted policy on conflict-of-interest disclosure for members of NIH peer review committees.

On August 22, 1995 NIH released the final policy entitled "Procedures for Preventing Conflict of Interest for NIH Special Government Employee (SGE) Advisory Committee Members" (NIH Policy Manual Chapter 1810-1). This chapter sets forth policy and procedures to avoid the occurrence of conflicts of interest or the appearance of such conflicts, in the use of Special Government Employees appointed as members of NIH advisory committees and subject to the Federal Advisory Committee Act. This issuance describes procedures for 1) selecting prospective members; 2) processing "Confidential Financial Disclosure Report" SF 450 forms; 3) standardizing methods of review of this form among Institutes, Centers and Division; 4) ensuring that the "Confidential Financial Disclosure Report" SF 450 forms are update' 5) ensuring that waivers are executed, where appropriate 6) ensuring that SGE advisory committee members receive annual training on conflict of interest procedures; and 7) ensuring that the confidentiality of information from these forms is maintained. This chapter interprets, supplements, and is intended to be used on conjunction with Executive Branch-wide statutes, regulations and Executive orders; regulations published by the Department of Health and Human Services; guidelines published by the Office of

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the Special Counsel for Ethics, HHS; and NIH policies and guidelines, including the NIH Policy Manual chapter "Avoiding Conflicts of Interest."

23. Direct that NIH reinstitute "reasonable pricing" clauses for drugs developed through federally subsidized research.

The "reasonable pricing" clause in the PHS model Cooperative Research and Development Agreement (CRADA) and the PHS model Exclusive License Agreement (ELA) was implemented in 1989 as part of the PHS interpretation of the 1986 Federal Technology Transfer Act. In 1994, the NIH Director initiated an extensive year-long review of this issue which involved representatives from academia, industry, and patient advocacy groups. These experts concluded that the clause was a disincentive to potential collaborations between industry and PHS scientists. Based on this assessment, the NIH Director removed the "reasonable pricing" clause on April 11, 1995 from NIH CRADAs and ELAs.

The National Task Force on AIDS Drug Development, chartered in 1993 by the Secretary of HHS to identify and eliminate barriers to AIDS drug development, recently reviewed these issues and subsequently agreed with the NIH determination that the "reasonable pricing clause" was a disincentive to the development of potential AIDS drugs. Since there continues to be a need to maximize incentives for the development of innovative treatments for HIV and its associated illnesses, the NIH will continue to place a high priority on collaborations with industry and academic researchers for the discovery and development of the next generation of AIDS drugs. The reinstatement of the "fair pricing" clause would only serve to slow these critical endeavors.

24. Order the National Institute of Drug Abuse (NIDA) and the Drug Enforcement Administration (DEA) to stop blocking the proposed University of California clinical trial comparing smoked marijuana to marinol for relief of HIV-related pain and nausea.

ONDCP -- The Office of National Drug Control Policy (ONDCP) looks to NIDA and its clinical scientist and staff to lead the federal effort in drug research and for the development of medications for the pharmacological treatment of chemically dependent addicts. This office is well aware of the fact that NIDA has reviewed and declined to support Dr. Abrams' marijuana research. As this discussion by NIDA was based on scientific design and methodological concerns, ONDCP will not intervene.

Dr. Lee P. Brown, ONDCP Director and Fred W. Garcia, ONDCP Deputy Director, have discussed the matter with leading physicians around the country and have been informed that the prescribed drug Marinol provides many of the same benefits as the active ingredient (tetrahydrocannabinol) found in cannabis sativa plants, without the adverse effects of compounds found in smoked marijuana.

NIH --The University of California requested marijuana from the NIDA for use in a small clinical trial of its comparative efficacy in treatment AIDS wasting. Unfortunately, the scientific design of the study was inadequate to test the proposed hypothesis in a definitive way. Therefore, the request was denied. The investigator was encouraged to develop an improved study which could be submitted to the NIH for scientific review. If such a study is reviewed by a scientific review committee of NIH, found to be scientifically meritorious according to established criteria, and is funded by the relevant NIH institute, NIDA would provide the marijuana for the research.

IMMIGRATION:

25. Direct the Immigration and Naturalization Service (INS) to be liberal in suspending deportation proceedings where the immigrant is living with HIV/AIDS. Unless it can be shown that the quality of HIV treatment and social services in the country of origin is equal to those in the U.S., hardship should be presumed in deportation cases involving people living with HIV/AIDS.

26. Direct INS to recognize person with AIDS as a social category protected under the asylum law. The U.S. government cannot send persons living with HIV/AIDS to nations where they may be persecuted.

27. Order that Immigration and Naturalization Service (INS) waivers of HIV-related restrictions in family-based categories be liberally granted.

28. Direct INS to implement an AIDS training program for its employees. No federal employees should use rubber gloves when dealing with people living with AIDS.

29. Direct INS to exempt all immigrants with disabilities, including HIV/AIDS, from new welfare legislation restricting immigrant's ability for government benefits.

Pending legislation on welfare currently does not contain a

provision which exempts legal immigrants with disabilities from proposed benefit restriction. The Administration, however, believes that a disability exemption is an important part of equitable reform. In a letter dated October 18, 1995, for Alice Rivlin, director of the Office and Management and Budget, to Congressional leaders regarding welfare reform, she states that the Administration's position is that "immigrants who become disabled after entering the country should be eligible for SSI," and that "fairness dictates the adoption of the House provision that exempts those...too disabled to complete the naturalization process from benefit cutoffs."

EDUCATION AND PREVENTION:

30. Issue regulations removing non-legislated content restrictions on federally-supported HIV prevention programs. Vernacular language and descriptions of sexual practices and sexual orientations must be available to educators.

The current requirements that pertain to the content and review of CDC-supported HIV prevention and education materials are a condition of grant awards for CDC funding of HIV prevention and education materials. These are outlined in the *Interim Revision of Requirements for Content of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions in Centers for Disease Control Assistance Programs*, first issued in June 1992. These requirements include the following:

"Written materials....should use terms, descriptors, or displays necessary for the intended audience to understand dangerous behaviors and explain less risky practices concerning HIV transmission."

Section 2500 of this document also contains several additional requirements and prohibitions that are to be considered when HIV prevention materials are being developed, but stresses the provision of "accurate information about various means to reduce an individual's risk of exposure to, or the transmission of, the etiologic agent for acquired immune deficiency syndrome...."

31. Direct the Centers for Disease Control (CDC) to provide technical assistance for HIV prevention to all community groups that request it.

CDC currently provides technical assistance directly to

funded community organizations and supports the efforts of many national organizations, such as national and regional minority organizations, the U.S. Conference of Mayors, and the National Association of People with AIDS, to provide technical assistance to HIV Prevention Community Planning groups (see questions 33) through a special technical assistance network to support this initiative.

32. Order that the CDC certify the usefulness of needle exchange in order to remove existing restrictions on the use of federal funds for such programs. Recognize that needle exchange has been proven to prevent HIV transmission.

Federal restrictions on the use of funds to support needle exchange can be removed if the Surgeon General declares that there is sufficient reason to believe there is a public health benefit to removing the restriction. The U.S. Public Health Service is currently reviewing the data from a number of studies and will issue any recommendations that may be needed. CDC cannot act unilaterally on this matter.

33. Reallocate CDC prevention dollars to target underreached groups, including prisoners, substance abusers, and gay youth. The CDC should promote the distribution of condoms and dental dams as a means of preventing HIV transmission, especially in prisons and jails.

Nearly 2 years ago, CDC instituted HIV Prevention Community Planning, which refers to an ongoing process in which grantees share responsibilities for developing a comprehensive HIV prevention plan with other state/local agencies, nongovernmental organizations, and representatives of communities and groups at risk for, or infected with, HIV. This type of planning is evidence-based (i.e., based on HIV/AIDS epidemiologic surveillance and other data, ongoing program experience, program evaluation, and a comprehensive, objective needs assessment process) and incorporates the views and perspectives of the groups for whom the programs are intended, as well as the providers of the services.

The community planning process allows states and local grantees to determine areas where prevention programs are needed and to prioritize efforts to address these needs. If the planning groups determine that certain populations are not being reached, the community can direct shifts in prevention strategies.

The distribution of condoms and dental dams in prisons remains a locally-determined policy. Any official policy

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for federal corrections facilities would have to be set by the Department of Justice's Bureau of Prisons.

34. Direct the CDC to publish a statement summarizing evidence regarding the role of state laws requiring a prescription for the purchase of syringes in the transmission of HIV.

CDC is currently compiling a complete database of state laws pertaining to the purchase and possession of injection equipment. CDC is also participating in a meeting, hosted by the Association of State and Territorial Health Officials, on the subject of state prescription and possession laws for injection equipment. This meeting is being held December 4-5, 1995, in Alexandria, Virginia.

35. Direct that developing new drug abuse treatments, especially for crack addiction, becomes a priority. Drug abuse treatments other than methadone are vital to fighting HIV/AIDS.

36. Reallocate federal drug treatment dollars to improve substance abuse treatment programs for prisoners.

THE "BULLY PULPIT":

37. Speak against HIV-related discrimination and condemn prejudice based on race, ethnicity, or sexual orientation.

The President and members of his Administration have spoken out against discrimination and prejudice on many occasions. Not only has the Administration vigorously enforced anti-discrimination protection for persons with HIV and AIDS, placed AIDS programs among his investment priorities, and increased funding for AIDS research, prevention, and care by 40% (including a 108% increase for the Ryan White CARE Act programs), the President has a deep personal commitment to supporting people with HIV, their families, and their communities.

38. Appoint a surgeon general committed to frank AIDS prevention education, needle exchange, and a high profile on AIDS issues.

The President has appointed senior public health officials who are both knowledgeable of and sensitive to the need for a coordinated Federal response to HIV/AIDS. These officials continue to give serious and considered attention to developing innovative and effective approaches for slowing the spread of HIV. Since President Clinton took office, the federal government has established a community planning process that involves groups at the community level to help

tailor prevention interventions to local needs. There has also been an easing of rules guiding the content of prevention materials. With regard to needle exchange, the recent National Academy of Sciences report is a major contribution to the public debate on this issue. Some communities strongly support needle exchange programs while others do not. The Administration believes that the Federal role is to support research that gives communities the information they need to make this decision. [????]

39. Encourage national media to accurately report on the nature and extent of HIV disease in the United States.

Through its support of activities such as the CDC National AIDS Hotline and Clearinghouse, the AIDS Clinical Trial Information Service (ACTIS), the Prevention Marketing Initiative, and federally-sponsored state-of-art conferences, the federal government has made considerable effort to provide all persons easy access to accurate and up-to-date information on HIV and AIDS.

40. Commit to international leadership on HIV/AIDS, including holding and AIDS summit to last year's conference in France, and offer to share federally-developed treatments and trial methodology and data with developing nations.

The United States is the world's largest bilateral and multilateral donor for international HIV/AIDS activities. The U.S. Agency for International Development, the CDC and their non-governmental partners have provided unparalleled technical assistance to AIDS programs in developing countries since 1986. The U.S. contribution will likely be reduced given the budget cuts, however, the U.S. will continue to play a significant leadership and financial role in the shaping of UNAIDS, the new joint and cosponsored United Nations programme on HIV/AIDS.

The UNAIDS programme on HIV/AIDS and its six members organizations and programmes were given the mandate to implement the Paris Declaration in coordination with multilateral and bilateral aid programmes and intergovernmental and nongovernmental organizations. The United States has provided additional funds, outside of its core contribution to UNAIDS to support that effort.

U.S. researchers work collaboratively with researchers from developing countries on issues ranging from microbicide development to clinical trials. In addition to increasing capacity of researchers to design and implement their own clinical trials, researchers are also working in

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consultation with local health advocates to identify effective strategies for incorporating the community's perspectives in all aspects of research, developing and introduction of products.

HEALTH CARE DELIVERY:

- 1. Veto any legislation that inadequately funds or eliminates federal entitlements to Medicaid, Medicare, or welfare. People living with HIV/AIDS depend on these benefits to survive.**

President Clinton has aggressively advocated for the need for health care coverage, that could not be taken away, for all Americans. President Clinton's Health Security Act would have provided private health insurance for all people with AIDS and prohibited insurance companies from discriminating against people with preexisting medical conditions, including HIV and AIDS.

Congress is currently working on a Budget Reconciliation Bill that contains dramatic cuts to Medicaid, Medicare and the welfare system. The President has made clear in public statements that he will veto this bill in its current format. We believe that the magnitude of these costs in these programs is unprecedented and would have a devastating impact on millions of individuals who depend on the safety net Medicaid, Medicare, and welfare provide.

- 2. Veto any legislation that would coerce pregnant women or their newborn babies to be tested for HIV.**

The President does not support mandatory approaches to HIV testing, especially before voluntary approaches have been fully implemented. There is also the concern that mandatory testing programs could drive people away from the care they desperately need. This is a difficult public health issue and it would be premature to discuss vetoes before the final legislative language has been developed.

- 3. Direct the Centers for Disease Control (CDC) to publish a statement against mandatory HIV testing of any population and forced administration of AZT during pregnancy.**

CDC recently published *U.S. Public Health Service Recommendations for Human Immunodeficiency Virus Counseling and Voluntary Testing for Pregnant Women*, which does state: "HIV testing of pregnant women and their infants should be voluntary. Consent for testing should be obtained in accordance with prevailing legal requirements. Women who test positive for HIV or refuse testing should not be a) denied prenatal or other health-care service, b) reported to child protective service agencies because of refusal to be tested or because of their HIV status, or c) discriminated against in any other way."

The Recommendations also state that "HIV-infected pregnant women should not be coerced into making decisions about ZDV therapy...A women's decision not to accept treatment should not result in punitive action or denial of care." Other CDC publications and program announcements consistently stress that counseling and testing be a voluntary activity.

4. Direct the Health Care Finance Administration (HCFA) to establish quality standards specific to persons living with HIV/AIDS for approval of state Medicaid managed care waiver applications.

HCFA requires that Medicaid managed care programs to provide adequate access and quality of care tailored to the population to be enrolled. If a state proposed to enroll persons with HIV/AIDS, HCFA examines the adequacy of the provider network, the scope of services, and the quality assurance and monitoring systems specific to that population prior to waiver approval. HCFA has also begun to consider specific clinical outcome measures that would be relevant for HIV/AIDS populations enrolled in managed care.

5. Order HCFA to direct all state Medicaid Directors to cover clearly useful HIV-related off-label drugs and alternative treatments.

Outpatient prescription drugs is an optional service under the Medicaid program. Although all states cover outpatient prescription drugs, they are not required to under current law. Medicaid coverage of outpatient prescription drugs is as generous or more generous than most private insurance coverage. Under current law, states have broad authority to cover prescription drugs for off-label uses for AIDS, cancer, and other diseases/conditions if the off-label use is listed in one of the three major pharmaceutical compendia. States also have the authority to cover investigational new drugs. This authority allows Medicaid early access to promising new treatment while they are still in the FDA approval process.

6. Direct HCFA to mandate Medicaid coverage of (anonymous) HIV counseling and testing.

Under current law, states are required to provide HIV screening and counseling in situations where symptoms are present that may indicate an HIV diagnosis. In addition, although there is no specific requirement for HIV testing and counseling services under EPSDT, physicians and other health practitioners providing EPSDT services may use their clinical judgement in determining the extent of services

needed. To our knowledge, all state Medicaid programs are providing beneficiaries with HIV screening and counseling services. For example, HCFA conducted a survey of the state with highest rates of HIV/AIDS among women; of these 11 states, all covered HIV testing and counseling services for women of child bearing age.

7. Direct the Department of Health and Human Services (HHS) Office of Civil Rights to use the Americans with Disabilities Act to regulate managed care waiver applications. The Americans with Disabilities Act must be used to protect people living with HIV/AIDS.

The Justice Department and the Equal Employment Opportunity Commission have vigorously enforced provisions of the Americans with Disabilities Act (ADA) that prohibit discrimination against people with HIV/AIDS. 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.

The movement of the increased use of managed care systems can create uncertainties for all individuals needing health care services, and certainly none more so than for people living with HIV/AIDS. For that reason HHS, including the Office for Civil Rights (OCR), has been and continues to be sensitive to issues of discrimination or potential discrimination in evaluating managed care waiver applications. The ADA and Section 504 responsibilities of HHS are a critical part of the framework for evaluating managed care waiver applications.

The Department has committed to reviewing civil rights issues as an integrated part of the waiver application evaluation process. As in any situation where each state may be working separately to develop systems tailored to their needs, there are great variations in the waiver applications that HHS receives. Issues of clear concern are flagged, raised and dealt with. HHS is very aware that some waivers involve matters not apparent on the face of the proposal, but rather involve details of implementation. In those situations, HHS and OCR have worked with the states and interest groups in an effort to achieve a better understanding of the impact on individuals with disabilities, including people living with HIV/AIDS. It is important in those situations to maintain a continuing exchange with all concerned parties--states, providers, and consumers--to insure that civil rights issues arising during implementation are appropriately addressed. HHS encourages

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this type of exchange and encourages interested groups to share their specific concerns about managed care waiver applications.

8. Allow inmates in Federal prisons to apply for post-release Medicaid coverage while still incarcerated.

Prior to releasing any federal inmate, the Federal Bureau of Prisons' Unit Management staff completes a pre-release plan. The plan is tailored to the specific needs of the inmate and may include, as appropriate, working with the inmate to fill out and file a medicaid application. BOP also works with prisoners about to be released to ensure that they will have a place to live. This may include securing a bed in a state-run nursing facility for an inmate with advanced AIDS who has nowhere to go upon release.

9. Order the federal Bureau of Prisons to require all federal prisons to practice the NIH-defined standards of care for prisoners with AIDS.

By policy, the Federal Bureau of Prisons (BOP) provides extensive education on HIV, AIDS and other infectious diseases and does not provide condoms or needles to inmates. Currently, the BOP follows the CDC's *"USPHS/IDSA Guidelines for Prevention of Opportunistic Infections in Persons Infection with Human Immunodeficiency Virus."* The BOP does not use experimental medications without a request/recommendation from the institution Clinical Director or treating physician by the Medical Director.

10. Order the Food and Drug Administration (FDA) to revoke its requirement that AIDS drugs imported by buyers' clubs be accompanied by individual prescriptions.

The Food and Drug Administration (FDA) has developed several mechanisms to permit expanded access for promising, but as yet unapproved therapeutic agents to AIDS patients outside of clinical trials. Thousands of patients have been able to gain legal access to unapproved therapies through parallel track protocols, treatment INDs, and emergency INDs.

The agency has also articulated a personal use importation policy under which it may exercise enforcement discretion to permit individuals with life threatening diseases to bring small amounts of unapproved drugs into the United States for personal use.

Concerned about potential threats to the health of people with advanced HIV disease and AIDS, resulting from the lack of physician involvement in their medical care; the use of injectable products of unknown purity, sterility and strength; the use of unproven drug products from unknown sources of manufacture; the use of potentially dangerous products; and health fraud, FDA requires that documentary evidence be available for review demonstrating that any patient importing products for personal use has a licensed physician who is accepting responsibility for the patient's care, including administration of the product. The personal use importation policy does not require a doctor's prescription, per se, but rather the name and address of a licensed physician in the U.S. responsible for the patient's treatment, or evidence that the product is for the continuation of treatment started in a foreign country. FDA does not believe the best interests of any individuals are served by having access to drugs for serious conditions without adequate physician oversight.

FDA has intensified its communication with various interest groups, including buyers clubs and patient advocacy organizations, to identify products reported to have the greatest medical promise for HIV-infected individuals, but not yet legally available in the United States. The agency has successfully worked with these groups, as well as with other government agencies, doctors, and individual patients, to find ways to make these products more widely available as scientific data are gathered.

11. Order the FDA to approve acupuncture needles as medical devices to facilitate insurance reimbursements.

The FDA has recently reviewed information regarding acupuncture needles which may lead to expanded availability. In the course of the review it appeared that acupuncture needles may have been commercially available prior to a 1976 regulation which requires testing for efficacy. If this is determined to be the case, then acupuncture needles could be approved for market without "for investigational use" labelling. As some third-party payors do not cover investigational therapies, this change could lead the way for more patients to receive insurance reimbursements.

HOUSING:

12. Veto any bill that eliminates or decreases funding for the Housing of People with AIDS (HOPWA) program at the Department of Housing and Urban Development.

In the early phases of the Congressional efforts to rescind a portion of FY 1995 funding for a number of programs, a proposal was put forth to totally zero out the HOPWA program. The Clinton Administration strongly opposed the Congressional proposal and was able to negotiate a final decision which preserved \$171 million of the \$186 million program.

In his FY 1996 budget, the President supported funding the HOPWA program at its full FY 1995 level, \$186 million. Secretary Cisneros has continued to make funding for the program a priority in his budget negotiations. It appears that the FY 1996 appropriation will be approximately \$171 million, the same as the post decision funding level for FY 1995.

While both the Secretary and the President support significant funding for HOPWA, promising a veto solely as the result of the failure to fund a \$186 million program in an appropriation bill that exceeds \$20 billion (in HUD funding alone) is unlikely.

13. Grant the National HIV/AIDS Office of Housing at HUD the authority to enforce the development of local housing for people living with HIV/AIDS.

HUD is very cognizant of the discrimination and neighborhood

opposition problems which are often faced by those seeking to provide housing for persons living with HIV/AIDS. However, granting enforcement authority to the Office of HIV/AIDS Housing is not an appropriate response since HUD already has an enforcement arm, the Office of Fair Housing and Equal Opportunity (OFHEO), under the direction of Assistant Secretary Elizabeth Julian. This office is charged with ensuring that existing fair housing statutes are enforced.

Unfortunately, an effort is being mounted in Congress to move OFHEO out of HUD and into the Department of Justice. It is the Secretary's position that such a move would severely weaken the office at a time when more enforcement is needed to ensure that vulnerable populations have access to the housing and support services they need.

The Administration endorses the need for a strong and visible enforcement presence through an adequately funded and viable Office of Fair Housing at HUD.

In addition to the enforcement work of the OFHEO, the Office of HIV/AIDS Housing has provided technical assistance to AIDS housing providers regarding the education efforts that are often needed to overcome the initial public opposition to the location of facilities that assist persons living with HIV/AIDS.

14. Direct all HUD employees to recognize HIV/AIDS eligibility for McKinney Act (housing) programs, and ensure that all local governments allocate towards AIDS housing the mandated percentage of McKinney Act funds.

There is no mandated percentage set-aside for AIDS housing in the HUD McKinney programs. However, housing for homeless persons living with HIV/AIDS is clearly an eligible activity under the HUD McKinney programs. HUD's Office of Special Needs Assistance Programs (SNAPS) and the Office of HIV/AIDS Housing work closely together to ensure that each other's constituents are aware of the resources administered by both offices. In addition, both offices have encouraged participation by persons living with HIV/AIDS and HIV/AIDS housing providers in local Continuum of Care planning efforts (where plans are made for addressing the communities needs for services and housing for homeless persons) and the Consolidated Planning process (where local priorities for HOPWA funding are determined and an assessment of housing needs of persons with HIV/AIDS is made.)

In the FY 1995 round of funding, it is estimated that the following percentages of each HUD McKinney program went to

serve homeless persons with HIV/AIDS:

Supportive Housing (10%)
Shelter Plus Care (8%)
Section 8 SRO Mod Rehab (5%)

15. Order a percentage of AIDS housing dollars to be set aside for housing for former prisoners.

HUD has made a concerted effort in recent years to move primary decision-making regarding program development to the local level, where we believe the greatest knowledge resides regarding the needs of persons living with HIV/AIDS in the community. Ninety percent of the HOPWA funds are distributed by formula to cities and states with the greatest need. These communities can target funds as needed within the very flexible HOPWA guidelines. For example, the New York City Comprehensive Plan provides an estimate of HIV prevalence among detainees in city jails and detention facilities and establishes formerly incarcerated persons with HIV/AIDS as a special population as part of their strategic planning efforts.

The remaining 10% of the HOPWA funds are distributed through a national competition, a portion of which is designed to demonstrate the models of service delivery for replication as needed across the nation. For example, HUD recently awarded a \$1 million HOPWA grant to Tarzana Treatment Center, Inc. to provide emergency and transitional housing for 150 California State Prison parolees who are living with HIV/AIDS.

While HUD has not specified a HOPWA set-aside for former prisoners living with HIV/AIDS, the Department will disseminate information from programs such as the Tarzana program, that address the special needs of formerly incarcerated persons, so that local planners and advocates can replicate the model with HOPWA formula dollars and other funds.

RESEARCH:

16. Veto any bill which weakens the budget authority of the Office of AIDS Research (OAR) at the National Institutes of Health (NIH) or which fails to set a fixed funding level for AIDS research.

The President strongly supports the Office of AIDS Research. In fact one of the first pieces of legislation signed by the President was the NIH reauthorization bill that strengthened

the authority of the OAR.

This is a difficult issue and it would be premature to discuss vetoes before the final legislative language and budget levels have been set forth.

The President has clearly expressed his support for the Office of AIDS Research and its important authorities set forth in the NIH Revitalization Act of 1993. The President's veto message to the House Appropriations Committee included this issue.

17. Direct the OAR to maintain the budget for AIDS clinical trials, and specifically for the Community Programs for Clinical Research on AIDS (CPCRA), the sole federal research program focused on people of color, women, and substance users.

As part of the evaluation process initiated by the Office of AIDS Research, the CPCRA and other NIH-funded AIDS clinical trials network are being reviewed and evaluated. The evaluation is assessing the effectiveness of the various clinical trials program from a cross-NIH perspective and will develop a series of recommendations in this regard. The future role and most effective and efficient format of these networks also must be determined in view of industry's efforts in this area.

The goal of the NIAID, the major sponsor of AIDS clinical trials at the NIH, is to maintain a level budget for its overall clinical trials program assuming that the Institute's appropriation permits it to do so without harming other high priority areas of research. Continued support for specific programs, including the CPCRA, must be funded contingent upon high levels of scientific productivity and plans to carry out high priority research in the future. The CPCRA is, above all, a research program. Its primary mission is to involve primary care providers and community-based organizations in scientifically-sound clinical research on HIV infection and its sequelae. We do not agree with its characterization as "the sole federal research program focused on people of color, women, and substance users". Furthermore, all of NIAID's clinical trials programs must reach out to and enroll a racially/ethnically and demographically diverse population of HIV-infected patients to help ensure that study results are maximally useful in the general HIV-infected population.

18. Direct the OAR to fund small trials to screen promising

HIV/AIDS treatments for later full-fledged trials, and to fund clinical management trials which study treatment use in the real world.

The National Institutes of Health through its ACTG, CPCRA, and DATRI clinical trials networks currently supports a number of small phase I clinical trials of new agents and compounds against HIV infection and its associated opportunistic infections and malignancies. The Strategic Program for Innovative Research on AIDS Therapies (SPIRATS) similarly supports small proof of concept (phase I) clinical trials of innovative therapies. The NIH also supports clinical management trials or post approval phase IV clinical studies of agents against HIV and HIV-associated opportunistic infections. An example of such a large scale study is ACTG 175 which is currently evaluating several licensed drugs, singly and in combination, and has enrolled over 2500 patients.

19. Order that all NIH-funded trials include women and gender-specific analysis, and halt any trials which would exclude women of child-bearing potential. Women must be included in clinical trials.

In response to the NIH Revitalization Act of 1993, the NIH has revised its guidelines for the inclusion of women and minorities in clinical research, as published in the Federal Register on March 28, 1994. Data are being collected for analysis and monitoring of the implementation of these guidelines and for tracking the inclusion of women and minorities in clinical trials. As part of this effort, data will be available to determine if, and under what circumstances, exclusions from this policy were allowed. Data for the FY 1995 year should be available by early 1996. In addition, a PHS Human Subject Regulation Drafting Committee was established through the Office of Protection from Research Risks (OPRR) to recommend changes in current policies related to the inclusion of pregnant women in clinical trials.

20. Order the removal of all geographical and economic barriers to participation in NIH-sponsored clinical trials or conferences by low-income and rural people with HIV/AIDS.

NIH-sponsored clinical trials are open to all eligible individuals regardless of their gender, race, socio-economic, or geographic status. As the AIDS epidemic has spread throughout all sub-populations and geographic

regions, the NIH-funded clinical trial networks have and are continuing to implement mechanisms and infrastructures to enroll HIV-infected individuals from these communities. In order to enroll and retain participants in clinical trials, many clinical trial sites provide ancillary services such as transportation vouchers, obstetric-gynecology care, and child care. An exemplary program demonstrating successful enrollment of rural HIV-infected residents is the University of North Carolina AIDS Clinical Trials Unit (ACTU). This ACTU has established a state-wide structure of clinics and hospitals to enroll and retain study participants. Similar programs and infrastructure are being developed by ACTUs especially in the Southern and Southeastern U.S.

21. Direct the OAR to hold a conference on AIDS pathogenesis theories and to fund large-scale studies of long-term survivors and non-progressors.

The OAR holds meetings and workshops on a regular basis involving the world's leading scientists in the area of AIDS pathogenesis. Most notably, the OAR has involved these experts in both its planning and evaluation processes. The OAR has undertaken a major evaluation initiative to review and assess each of the components of the NIH AIDS research endeavor to determine whether those components are appropriately designed and coordinated to answer the critical scientific questions to lead to better treatments, prevention, and a cure for AIDS. Non-government experts are meeting on a regular basis to draft recommendations regarding pathogenesis research. The study of long-term non-progressors and long-term survivors is a high priority for NIH and significant resources are devoted to this area of investigation.

22. Order the NIH to adopt their drafted policy on conflict-of-interest disclosure for members of NIH peer review committees.

On August 22, 1995 NIH released the final policy entitled "Procedures for Preventing Conflict of Interest for NIH Special Government Employee (SGE) Advisory Committee Members" (NIH Policy Manual Chapter 1810-1). This chapter sets forth policy and procedures to avoid the occurrence of conflicts of interest or the appearance of such conflicts, in the use of Special Government Employees appointed as members of NIH advisory committees and subject to the Federal Advisory Committee Act. This issuance describes procedures for 1) selecting prospective members; 2) processing "Confidential Financial Disclosure Report" SF 450 forms; 3) standardizing methods of review of this form among Institutes, Centers and Division; 4) ensuring that the "Confidential Financial Disclosure Report" SF 450 forms are

update' 5) ensuring that waivers are executed, where appropriate 6) ensuring that SGE advisory committee members receive annual training on conflict of interest procedures; and 7) ensuring that the confidentiality of information from these forms is maintained. This chapter interprets, supplements, and is intended to be used on conjunction with Executive Branch-wide statutes, regulations and Executive orders; regulations published by the Department of Health and Human Services; guidelines published by the Office of the Special Counsel for Ethics, HHS; and NIH policies and guidelines, including the NIH Policy Manual chapter "Avoiding Conflicts of Interest."

23. Direct that NIH reinstitute "reasonable pricing" clauses for drugs developed through federally subsidized research.

The "reasonable pricing" clause in the PHS model Cooperative Research and Development Agreement (CRADA) and the PHS model Exclusive License Agreement (ELA) was implemented in 1989 as part of the PHS interpretation of the 1986 Federal Technology Transfer Act. In 1994, the NIH Director initiated an extensive year-long review of this issue which involved representatives from academia, industry, and patient advocacy groups. These experts concluded that the clause was a disincentive to potential collaborations between industry and PHS scientists. Based on this assessment, the NIH Director removed the "reasonable pricing" clause on April 11, 1995 from NIH CRADAs and ELAs.

The National Task Force on AIDS Drug Development, chartered in 1993 by the Secretary of HHS to identify and eliminate barriers to AIDS drug development, recently reviewed these issues and subsequently agreed with the NIH determination that the "reasonable pricing clause" was a disincentive to the development of potential AIDS drugs. Since there continues to be a need to maximize incentives for the development of innovative treatments for HIV and its associated illnesses, the NIH will continue to place a high priority on collaborations with industry and academic researchers for the discovery and development of the next generation of AIDS drugs. The reinstatement of the "fair pricing" clause would only serve to slow these critical endeavors.

24. Order the National Institute of Drug Abuse (NIDA) and the Drug Enforcement Administration (DEA) to stop blocking the proposed University of California clinical trial comparing smoked marijuana to marinol for relief of HIV-related pain and nausea.

ONDCP--The Office of National Drug Control Policy (ONDCP) looks to NIDA and its clinical scientist and staff to lead the federal effort in drug research and for the development of medications for the pharmacological treatment of chemically dependent addicts. This office is well aware of the fact that NIDA has reviewed and declined to support Dr. Abrams' marijuana research. As this discussion by NIDA was based on scientific design and methodological concerns, ONDCP will not intervene.

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IMMIGRATION:

25. Direct the Immigration and Naturalization Service (INS) to be liberal in suspending deportation proceedings where the immigrant is living with HIV/AIDS. Unless it can be shown that the quality of HIV treatment and social services in the country of origin is equal to those in the U.S., hardship should be presumed in deportation cases involving people living with HIV/AIDS.

The INS' current approach to the suspension of deportation is consistent with existing statutory and regulatory provisions. The Immigration and Nationality Act (INA) defines eligibility according to specific requirements, and calls for a case-by-case determination. Under the law, INS does not itself suspend deportation proceedings; it's role is solely prosecutorial. The authority to suspend deportation proceedings lies generally with the Executive Office for Immigration Review, and, in particular, with the

immigration judge before whom the deportation hearing is heard.

Additionally, an INS district director has the discretionary authority to deter initiation of deportation proceedings, or stay deportation, on a case-by-case basis. In each case, the district director weighs the humanitarian factors, the alien's equities, and the possible impact on the community. There is no precedent for a single factor being the sole reason to defer action in all similar instances.

26. Direct INS to recognize person with AIDS as a social category protected under the asylum law. The U.S. government cannot send persons living with HIV/AIDS to nations where they may be persecuted.

The INS cannot expand on or issue a direction inconsistent with the statutory definition of a refugee in section 101(a)(42) of the INA. This provision includes the term "particular social group," defining a refugee as "any person who is outside any country of such person's nationality," and who is "unable or unwilling to return to.....that country because of persecution or a well-founded fear of persecution on account of race, religion, nationality, membership in a particular social group, or political opinion.

Courts have interpreted the phrase "persecution on account of membership in a particular social group" to mean persecution directed at a person who is a member of a group of persons sharing a common, immutable characteristic that group members either cannot change or should not be required to change. Whether HIV/AIDS infection is a characteristic that may define a "particular social group" under asylum law depends on the practices of the government of the home country. Nothing in existing law or practice precludes recognition of "persons with AIDS" as a particular social group, if the proof in the individual case supports such a conclusion.

It must be recognized, however, that qualifying for asylum also requires applicants to prove that they satisfy other elements of the statutory definition. These elements include the requirement that a person has suffered or has a well-founded fear of suffering "persecution." Persecution denotes extreme harm and does not include every sort of treatment that U.S. society may regard as offensive or unjust. Further, it must be the government of the refugee's country or an entity the government cannot or will not control that persecutes the refugee. The persecutor's motive is also key to an asylum adjudication; the

persecutor must seek to harm the person specifically because of his membership in the social group.

Apart from the issue of eligibility for asylum, current law as enacted by Congress designates HIV/AIDS infection as a ground for exclusion for immigrant admission purposes. An asylee who seeks to adjust to legal permanent resident status is subject to this exclusion ground, as is a person applying abroad for resettlement as a refugee. However, the statute allows the INS to waive exclusion for humanitarian purposes, to assure family unity, or when it is in the public interest.

27. Order that Immigration and Naturalization Service (INS) waivers of HIV-related restrictions in family-based categories by liberally granted.

Statutory excludability provisions, such as those for HIV infection, recognize special circumstances of overriding humanitarian and family unity concern by incorporating waiver provisions. Such provisions enable the Attorney General to exercise discretionary authority to waive certain grounds of excludability (including medical-related grounds), provided the excludable person demonstrates that admission to the U.S. would not adversely affect the national safety, security and welfare of the U.S.

All requests for medical-related waivers of excludability, including those involving HIV infection and AIDS, are adjudicated on a discretionary basis after a careful review and weighing of all factors.

28. Direct INS to implement an AIDS training program for its employees. No federal employees should use rubber gloves when dealing with people living with AIDS.

Pursuant to the President's federal directive on HIV/AIDS, all INS employees received HIV/AIDS training. The INS will continue to provide followup training on an annual basis as needed.

29. Direct INS to exempt all immigrants with disabilities, including HIV/AIDS, from new welfare legislation restricting immigrant's ability for government benefits.

DOJ--INS cannot exempt immigrants from statutory requirements absent express waiver authority. There are a number of problems, however, under the various provisions of the welfare reform bill that the Administration feels should be remedied. Most notably, the bill would eliminate the

eligibility for thousands of legal immigrants currently receiving medical benefits. The Administration also opposes application of the new deeming and eligibility provisions to the disabled who are exempted under current law, particularly those who become disabled after entry. We have informed both the House and Senate Immigration Subcommittees of our interest in working with them to establish a reasonable deeming policy that addresses such concerns.

HHS--Pending legislation on welfare currently does not contain a provision which exempts legal immigrants with disabilities from proposed benefit restrictions. The Administration, however, believes that a disability exemption is an important part of equitable reform. In a letter dated October 18, 1995, from Alice Rivlin, Director of the Office of Management and Budget, to Congressional leaders regarding welfare reform, she states that the Administration's position is that "immigrants who become disabled after entering the country should be eligible for SSI," and that "fairness dictates the adoption of the House provision that exempts those...too disabled to complete the naturalization process from benefit cutoffs."

EDUCATION AND PREVENTION:

30. Issue regulations removing non-legislated content restrictions on federally-supported HIV prevention programs. Vernacular language and descriptions of sexual practices and sexual orientations must be available to educators.

The current requirements that pertain to the content and review of CDC-supported HIV prevention and education materials are a condition of grant awards for CDC funding of HIV prevention and education materials. These are outlined in the *Interim Revision of Requirements for Content of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions in Centers for Disease Control Assistance Programs*, first issued in June 1992. These requirements include the following:

"Written materials....should use terms, descriptors, or displays necessary for the intended audience to understand dangerous behaviors and explain less risky practices concerning HIV transmission."

Section 2500 of this document also contains several additional requirements and prohibitions that are to be considered when HIV prevention materials are being

developed, but stresses the provision of "accurate information about various means to reduce an individual's risk of exposure to, or the transmission of, the etiologic agent for acquired immune deficiency syndrome....

31. Direct the Centers for Disease Control (CDC) to provide technical assistance for HIV prevention to all community groups that request it.

CDC currently provides technical assistance directly to funded community organizations and supports the efforts of many national organizations, such as national and regional minority organizations, the U.S. Conference of Mayors, and the National Association of People with AIDS, to provide technical assistance to HIV Prevention Community Planning groups (see questions 33) through a special technical assistance network to support this initiative.

32. Order that the CDC certify the usefulness of needle exchange in order to remove existing restrictions on the use of federal funds for such programs. Recognize that needle exchange has been proven to prevent HIV transmission.

Federal restrictions on the use of funds to support needle exchange can be removed if the Surgeon General declares that there is sufficient reason to believe there is a public health benefit to removing the restriction. The U.S. Public Health Service is currently reviewing the data from a number of studies and will issue any recommendations that may be needed. CDC cannot act unilaterally on this matter.

33. Reallocate CDC prevention dollars to target underreached groups, including prisoners, substance abusers, and gay youth. The CDC should promote the distribution of condoms and dental dams as a means of preventing HIV transmission, especially in prisons and jails.

Nearly 2 years ago, CDC instituted HIV Prevention Community Planning, which refers to an ongoing process in which grantees share responsibilities for developing a comprehensive HIV prevention plan with other state/local agencies, nongovernmental organizations, and representatives of communities and groups at risk for, or infected with, HIV. This type of planning is evidence-based (i.e., based on HIV/AIDS epidemiologic surveillance and other data, ongoing program experience, program evaluation, and a comprehensive, objective needs assessment process) and incorporates the views and perspectives of the groups for whom the programs are intended, as well as the providers of

the services.

The community planning process allows states and local grantees to determine areas where prevention programs are needed and to prioritize efforts to address these needs. If the planning groups determine that certain populations are not being reached, the community can direct shifts in prevention strategies.

The distribution of condoms and dental dams in prisons remains a locally-determined policy. Any official policy for federal corrections facilities would have to be set by the Department of Justice's Bureau of Prisons.

34. Direct the CDC to publish a statement summarizing evidence regarding the role of state laws requiring a prescription for the purchase of syringes in the transmission of HIV.

CDC is currently compiling a complete database of state laws pertaining to the purchase and possession of injection equipment. CDC is also participating in a meeting, hosted by the Association of State and Territorial Health Officials, on the subject of state prescription and possession laws for injection equipment. This meeting is being held December 4-5, 1995, in Alexandria, Virginia.

35. Direct that developing new drug abuse treatments, especially for crack addiction, becomes a priority. Drug abuse treatments other than methadone are vital to fighting HIV/AIDS.

SAMSHA presently provides funding to states and community based organizations to support comprehensive treatment programs including treatment for crack and other drugs.

The Center for Substance Abuse Treatment (CSAT) funds demonstration programs and direct funding to states to provide support for: comprehensive substance abuse treatment in residential settings for alcohol and drug dependent women and their children, treatment campuses whose goals are to enhance and improve the quality of treatment, and substance abuse programs that target specific populations such as adolescents, women with dependent children, racial and ethnic minorities, residents of public housing, and the homeless.

All of these funded programs attempt to foster comprehensive services integration, linking primary health care, pediatric care, substance abuse, and mental health services. Other treatment services include education and counseling related to HIV/AIDS, sexually transmitted diseases, domestic violence, sexual abuse, and legal and

employment issues.

Although SAMSHA does not develop new medications for substance abuse treatments it does provide funding and support to treatment providers, and encourages new knowledge in the field.

36. Reallocate federal drug treatment dollars to improve substance abuse treatment programs for prisoners.

DOJ Federal substance abuse programs for prisoners are well documented and continue to improve and expand. In FY 1995, the Bureau of Prisons spent \$19.2 million for substance treatment programming. During the fiscal year, 11,681 inmates participated in drug education programming; 4,839 inmates participated in residential drug abuse treatment; 2,136 inmates participated in non-residential treatment; and the Bureau's community transitional program maintained an average daily population of 1,126.

SAMSHA -- SAMSHA strongly supports the need for increased services to prisoners and has made this population a priority for funding. CSAT supports the development of model treatment approaches for specific criminal offender populations and linked criminal justice-treatment systems in addressing the public health and public safety issues of these populations.

Since 1992, CSAT has devoted over 100 million to criminal justice treatment programs and related technical support to serve over 26,000 offenders per year. These programs have shown the importance of providing a comprehensive continuum of care as a key to prolonged treatment success for the substance abusing offender, especially the need for continuity of care during transition from confinement to the community. CSAT demonstration programs provide substance abuse treatment to individuals incarcerated in prisons, jails, or community correctional settings, and to those who are pre-trial releases, post-trial releases, probationers, parolees or on supervised release. Priority is given to programs which offer a continuum of services, reach juvenile and female offenders and offer outreach and treatment as an alternative to incarceration.

THE "BULLY PULPIT":

37. Speak against HIV-related discrimination and condemn prejudice based on race, ethnicity, or sexual orientation.

The President and members of his Administration have spoken out against discrimination and prejudice on many occasions. Not only has the Administration vigorously enforced anti-discrimination protections for persons with HIV and AIDS, placed AIDS programs among his investment priorities, and increased funding for AIDS research, prevention, and care by 40% (including a 108% increase for the Ryan White CARE Act programs), the President has a deep personal commitment to supporting people with HIV, their families, and their communities.

38. Appoint a surgeon general committed to frank AIDS prevention education, needle exchange, and a high profile on AIDS issues.

The President has appointed senior public health officials who are both knowledgeable of and sensitive to the need for a coordinated Federal response to HIV/AIDS. These officials continue to give serious and considered attention to developing innovative and effective approaches for slowing the spread of HIV. Since President Clinton took office, the federal government has established a community planning process that involves groups at the community level to help tailor prevention interventions to local needs. There has also been an easing of rules guiding the content of prevention materials. With regard to needle exchange, the recent National Academy of Sciences report is a major contribution to the public debate on this issue. Some communities strongly support needle exchange programs while others do not. The Administration believes that the Federal role is to support research that gives communities the information they need to make this decision. [????]

39. Encourage national media to accurately report on the nature and extent of HIV disease in the United States.

Through its support of activities such as the CDC National AIDS Hotline and Clearinghouse, the AIDS Clinical Trial Information Service (ACTIS), the Prevention Marketing Initiative, and federally-sponsored state-of-art conferences, the federal government has made considerable effort to provide all persons easy access to accurate and up-to-date information on HIV and AIDS.

40. Commit to international leadership on HIV/AIDS, including holding and AIDS summit to last year's conference in France, and offer to share federally-developed treatments and trial methodology and data with developing nations.

The U.S. is the world's largest bilateral and multilateral donor for international HIV/AIDS activities. The U.S. Agency for International Development, the Centers for Disease Control and

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Prevention and their non-governmental partners have provided unparalleled technical assistance to AIDS programs in developing countries since 1986. The US contribution will likely be reduced given the budget cuts, however, the US will continue to play a significant leadership and financial role in the shaping of UNAIDS, the new joint and cosponsored United Nations programme on HIV/AIDS.

The UNAIDS programme on HIV/AIDS and its six members organizations and programmes were given the mandate to implement the Paris Declaration in coordination with multilateral and bilateral aid programmes and intergovernmental and nongovernmental organizations. The US has provided additional funds, outside of its core contribution to UNAIDS to support that effort.

U.S. researchers work collaboratively with researchers from developing countries on issues ranging from microbicide development to clinical trials. In addition to increasing capacity of researchers to design and implement their own clinical trials, researchers are also working in consultation with local health advocates to identify effective strategies for incorporating the community's perspectives in all aspects of research, developing and introduction of products.

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

July 23, 1996

STATEMENT BY THE PRESS SECRETARY

President Clinton announced today that he will raise his 1997 budget request for State AIDS drug assistance programs (ADAP) by \$65 million to help Americans living with the human immunodeficiency virus (HIV) to get life-saving prescription drugs.

"New classes of drugs and new methods of treatment hold out the possibility that we can halt the progress of HIV and begin to repair the health of those who are living with this virus," the President said. "Therefore, it is important to take action to do so."

The President's announcement comes at a time of great hope and opportunity in the battle against HIV and AIDS, as illustrated by the scientific advances discussed earlier this month at the Eleventh International Conference on AIDS in Vancouver, Canada.

State ADAP programs help about 69,000 low-income people with HIV buy recently-discovered, life-extending drug therapies; these individuals do not get Medicaid, nor do they get prescription coverage through private health insurance. The ADAP programs are partially supported by grants under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act.

Earlier this year, after the Food and Drug Administration's rapid approval of the first three protease inhibitor drugs, the President asked Congress to increase the Federal commitment to ADAP by \$52 million. With strong bipartisan support, Congress agreed to the request, and the money is now being distributed to every state, the District of Columbia, and Puerto Rico.

Now, with the promising results reported in Vancouver, the President has increased his 1997 request specifically for ADAP to \$117 million, which more than doubles the amount the President is seeking specifically for these life-saving therapies. The President also asked States to maintain their strong commitments to providing additional resources for ADAP. Similarly, the President urged pharmaceutical manufacturers, who have made an admirable investment in the development of these drugs, to continue their commitment to helping make these products available for those who need them.

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"While new drug treatments offer enormous hope to people living with HIV, it is also clear that our work is far from complete," the President said. Indeed, further research is necessary to determine the long-term effect of protease inhibitors and other drugs, the proper dosages and combination of drugs, the optimal time to begin treatment, and the potential for drug resistance. The National Institutes of Health, working closely with scientists and clinicians from medical schools, hospitals, and the pharmaceutical industry, is committed to providing answers to these critical questions.

Without this budget amendment, thousands of Americans may lack access to the medications that hold promise for extending the lives of people with AIDS. The House has indicated an admirable bipartisan interest in boosting 1997 funding for these drugs.

The Administration looks forward to continuing to work with Congress to see that people who need these life-saving AIDS drugs can have greater access to them.

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THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

March 5, 1996

President Clinton today asked the Congress for \$914.3 million in emergency fiscal 1996 supplemental appropriations to provide relief to communities affected by recent natural disasters in the United States and the Virgin Islands, and \$52 million to help thousands of people with AIDS live longer and fuller lives.

The devastating disasters include the severe winter flooding in the Pacific Northwest, the blizzard and subsequent flooding in the Northeast, and damaging hurricanes. This request includes \$168.6 million for the Department of Agriculture; \$165 million for the Corps of Engineers; \$100 million for the Department of the Interior; \$267 million for the Department of Transportation; \$100 million for the Small Business Administration; \$103.7 million for the Federal Emergency Management Agency; and \$10 million for the Department of Commerce.

Included in today's transmittal to the Congress is a proposal that would increase by \$52 million the 1996 budget request for Ryan White AIDS Treatment grants. These funds will be targeted to State AIDS drug assistance activities authorized under title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990 and used to purchase medications, including a new class of AIDS therapies called "protease inhibitors," some of which are beginning to be approved by the Food and Drug Administration (FDA).

The State AIDS drug assistance programs funded through the Ryan White grants are a lifeline for an estimated 55,000 people with AIDS who do not have prescription drug coverage or who cannot themselves afford the full regimen of costly AIDS medications that can prolong their lives. Unfortunately, the current funding levels for these programs cannot meet the additional demand these and other new drugs may create. Without additional funding above the 1996 request, thousands of people with AIDS could be denied the medications they need.

This request reflects the success of the Administration's AIDS research effort. Through unprecedented collaboration between the National Institutes of Health and the pharmaceutical industry, new AIDS drugs are being developed -- and they are being approved

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by the FDA in record time. Additional promising new treatments may become available in the next few months.

While these medications hold promise for extending the lives of people with AIDS, many are costly. This amendment will help make them available to people who otherwise could not afford them. We hope the Congress will join the Administration in recognizing that we should make available the fruits of our research success to those living with HIV and AIDS.

In addition, other nonemergency requests for fiscal year 1996 were submitted for the Departments of Agriculture, Energy, Transportation, and Veterans Affairs; the Office of National Drug Control Policy; and the Panama Canal Commission.

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Add 1:

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/Ft. Worth, New York, and Newark NJ. Further meetings are planned for Miami/Ft. Lauderdale, Chicago, Cleveland, Los Angeles, San Diego, San Francisco, Durham NC, and Boston.

In addition, Administration officials are continuing their ongoing dialogue with national and community leaders. For example, HUD Secretary Cisneros. . .

add 2:

The President and the Administration strongly opposed enactment of the so-called "Dornan Amendment." The President cited that provision as one of the reasons that he vetoed the first version of the DoD reauthorization bill. However, Congressional Republicans insisted on keeping the Dornan Amendment in the final version of the bill and it was clear that there were not sufficient votes to maintain a Presidential veto. A veto override would have made it significantly more difficult to repeal the Dornan Amendment or to succeed in any legal challenges. The President decided, instead, to sign the bill and make clear his revulsion for the Dornan Amendment. In addition, the President took the courageous step of declaring the Dornan Amendment unconstitutional and directing the Department of Justice not to defend it in court. The Administration has lent its strong support to repeal of the Dornan Amendment and believes that can be accomplished before a single military service member is discharged. This Administration has a remarkable record of standing up for the rights of people living with HIV and AIDS, including very strong enforcement of the Americans with Disabilities Act.

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MEMORANDUM FOR CAROL H. RASCO

FROM: Patsy Fleming

SUBJECT: Update on Report on HIV/AIDS and Adolescents

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

Status

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

Rollout Strategy

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

Attachment

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Part I

A GENERATION AT RISK

"It is one of the joys of childhood that children think they will live forever. It is one of the curses of childhood in some of our meanest neighborhoods that children think they won't live to be much beyond 25 anyway. In a perverse way, both of those attitudes are contributing to the problem, because one group of our children think that they are at no risk because nothing can ever happen to them -- they're bulletproof. Another group believes that no matter what they do, they don't have much of a future anyway. And they are bound together in a death spiral when it comes to this. This is crazy. We have got to find some way to tell them you must stop this." -- President Clinton, December 6, 1995, to the White House Conference on HIV and AIDS.

Today's youth are tomorrow's future. Yet, every day in the United States, as many as 50 Americans under the age of 24 become infected with the Human Immunodeficiency Virus (HIV) and nearly 25 of them are teenagers. While the number of cases of AIDS among teenagers is relatively low, it is growing rapidly from one case in 1981 to 417 cases in 1994. But the rate of HIV infection among teenagers becomes more obvious when you look at the number of AIDS cases among people in their 20s. One in five AIDS cases in the U.S. is diagnosed in the 20-29 year age group. Since we know that infection generally occurs about 10 years before diagnosis, it is clear that virtually all of those cases resulted from teenage infections.

Among adolescents, HIV infection and AIDS diagnosis are more prevalent among those in their late teens, males, and racial and ethnic minorities. But recent trends also point to a rise in infection and diagnosis among adolescent females (increasing from 14 percent of diagnosed cases among adolescents in 1987 to 43 percent in 1994).

What is also clear is that American adolescents are increasingly engaging in behaviors that put them at risk for acquiring HIV infection as well as other sexually transmitted diseases and infections associated with drug injection. Approximately three-quarters of high school students have had sexual intercourse by the time they reach the twelfth grade. Only half of sexually-active high school seniors report consistent use of latex condoms and surveys indicate that condom use declines with age. In a recent survey, one in 62 high school students reported having injected an illegal drug.

Without forceful and focused action, these already troubling trends will increase. This is a particularly complex challenge. Adolescents are neither large children nor small adults. Yet they often are considered as one or the other. Adolescents (13 to 19 years of age) are in a unique developmental stage that can make them particularly vulnerable -- physiologically and emotionally -- to take actions that put them at risk of becoming infected with HIV. Young people also may

be particularly responsive to methods to safeguard them from infection. Yet they may also be resistant to prevention messages.

Like all Americans young people are at risk of becoming infected with HIV. They are at greatest risk if they have sex, use injection drugs, or use alcohol or other drugs that impair their decision-making abilities. That risk may increase when you recognize that adolescents often do not have the maturity, experience or range of options that adults usually bring to their decision-making processes. Adolescents are engaged in a developmental process that includes development of decision-making skills, sexual maturation and experimentation, emotional and cognitive changes, and the molding of identity and self-worth.

"I was infected with HIV by my first partner when I was 16-years-old. Now at 20 years I have this virus that's taking my life because everything I heard when I was younger was sugar coated. We need more complete information than what we are being given. You all think sex and masturbation are taboo. Even the pamphlets concerning HIV/AIDS prevention are too basic and bland. We need to know real stuff. Everybody does not live in a big house with a white picket fence." -- Ryan, age 20.

Adolescents live in a world in which their families, cultural institutions, religious institutions, media, and peers compete to instill values, dictate actions, and impart positive and negative messages to them. Often those messages conflict with each other, or battle to drown each other out.

Adolescents, particularly those in their early teens, tend to be short-term thinkers. To them, the present is all important, and the future is often perceived in very vague terms. Adolescents then, may feel invulnerable to harm. They often make decisions based on immediate desires rather than after consideration of the long-term consequences of such decisions. Young people also see around them a society that values their youth. Why live past the age of 35, or worry about a disease like HIV that may take more than 10 years to manifest itself?

At the same time, many young people suffer from a variety of stigmas that can confound their ability to successfully negotiate the significant issues and problems they confront. These stigmas can result from discrimination due to age, race, HIV status, sexual orientation, gender, and economic status.

Growing up has always been tough, but there are a host of reasons why it is tougher -- and particularly risky -- to grow up in this day and age. Taking risks and testing boundaries are important parts of adolescent development. Many of the experimental activities in which young people engage are not fundamentally different from those of their parents. But the repercussions of such actions have changed dramatically in the last 15 years due, in part, to HIV. A national poll of adults conducted by the Sexuality Information and Education Council of the United States

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found that 80 percent reported that they experienced their first sexual intercourse as a teenager. In a poll of today's teenage population, more than 50 percent of females between the ages of 15 and 19, reported having had sexual intercourse, while nearly 75 percent of males in the same age group reported having had sexual intercourse.

The world is increasingly fast-paced and sophisticated, and young people believe they must move at the same pace -- and with the same degree of sophistication -- in order to keep up. Society is also increasingly violent and sexual. Recreational drugs are more affordable, prevalent, and dangerous than ever before. Adolescents often feel bored, with nothing exciting to do. They may view alternative activities as either too safe or not any fun. It is, therefore, not surprising that young people take risks with their health. From a young person's perspective, a decision to engage in unprotected sex or inject drugs may seem to be a perfectly rational choice.

Set against this backdrop is the fact that young Americans are beginning the physiological and emotional phenomenon of puberty earlier in their lives than previously. Yet they are also postponing until they are older such traditional "adult" responsibilities as full-time employment, marriage, or a committed monogamous relationship.

It is clear that all young people need thoughtful guidance and loving care. The role of effective parents has never been more important in the successful development of adolescents. But it's a job that's also gotten much tougher. Parents, too, need assistance in learning how to best communicate with their children about such often difficult subjects as sex, drug use, and death. At the same time, many adolescents do not have adults in their lives who can effectively provide the nurturing and guidance that they need. They need alternative role models.

Adolescents live in a world of competing messages. The challenge lies in recognizing all the many influences that touch young people's lives and turning each of them into resources for HIV prevention messages, decision-making skills, and adult support. Media portrayals of relationships often don't distinguish bad judgment and promiscuity from traditional expressions of sexuality.

There also are categories of adolescents who have been pushed to the margins of society and for whom the risks of contracting HIV is particularly high. Gay, lesbian, and bisexual youth often are isolated from positive adult role models and peers. Personal and institutional homophobia can deny them access to opportunities to address their developing sexuality. Many turn to furtive sexual experimentation that puts them at higher risk for HIV infection.

"We grow up hating ourselves like society teaches us to. If someone had been 'out' about their sexuality. If the teachers hadn't been afraid to stop the 'fag' and 'dyke' jokes. If my human sexuality class had even mentioned homosexuality. If the school counselors would have been open to a discussion of gay and lesbian issues. If any of those possibilities had existed, perhaps I would not have grown up hating what I was. And, just perhaps, I wouldn't have attempted suicide." -- Kyallee, 19.

Another group of young people who are at high risk for HIV infection are those who have experienced sexual abuse. They are at increased risk for two reasons. Direct transmission of HIV by the abuser has been demonstrated in some cases. Research experts also believe that sexual

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abuse during childhood increases the likelihood of later high-risk behavior that can lead to HIV infection.

There are also those youth who have left or been kicked out of their homes or who have fled abusive family relationships. They are highly susceptible to risky behavior just to survive. Their self-worth is usually low or non-existent. They often trade sex for food, housing, drugs, and affection. Adolescents challenged with homelessness rarely view reducing their risk factors for HIV as a high priority in comparison with their daily struggle for survival.

Other groups of marginalized youth include: non-English speaking adolescents who sometimes view American youth as sexually active and desire to fit in; youth with physical or mental disabilities who often are assumed incapable of engaging in behaviors that would lead to infection and are, therefore, not given information or skills training; and heterosexual males who are at risk because no one -- including themselves -- think they could be at risk. Adolescent females also face a greater biological risk of infection because they do not have fully developed tissue linings of the cervix.

"I'm HIV positive. I'm a teenage mother. I'm affected by my community. How do you expect me to live? Where is my future leading? Where is the future leading for my 3-year-old daughter?" -- Haitien.

Adolescents who abuse drugs are at a very high risk for HIV infection. They use alcohol and other drugs that can impair decision-making abilities. And, of course, for the injecting drug user there is a high risk of HIV infection through the sharing of contaminated needles and syringes.

Adolescents need the tools to successfully navigate through an increasingly dangerous world. They need to hear from adults that they are loved, valued, and have worth as individuals so they will internalize those feelings and believe they are worth protecting. They must be shown the dangers they may encounter and taught negotiation and decision-making skills. They need to be engaged in activities that will involve them and their peers in decision-making activities.

Adolescent HIV prevention is a job too big for any one segment of society. All adults, all leaders, all policy-makers, all young people and all institutions must become cooperatively and constructively engaged in the important business of protecting our nation's most precious resource from HIV.

ADOLESCENT POPULATIONS AT RISK FOR HIV

POPULATION

RISK FACTORS

Lower Socioeconomic Adolescents	Adolescents in low-income families often may find they need to take greater risks to survive. A sense of fatality is more common among youth who see little hope of leaving a violent, oppressive neighborhood. Youth with few opportunities for success may not feel that protecting themselves from a disease they may get and that may kill them in 10 years is a high priority.
Youth who have lost parents to AIDS	AIDS orphans need support and access to services because they often feel stigmatized and trapped within their grief.
Adolescents born HIV positive	Some youth who were born HIV positive are moving into their teen years. As they develop sexually, they need access to prevention services. Those who progress to AIDS need access to a range of health and support services. They also need a school and community environment that permits free discussion of their disease and that is open about grief in losing friends.
Rural Adolescents	Rural youth are at risk because they often don't perceive any risk. However, HIV infection is increasing in rural communities and increased mobility leaves rural youth at greater risk.
Illiterate adolescents.	Illiterate adolescents often don't admit that they can't read. Services and prevention messages must be promoted in a variety of ways to ensure that these youth are reached.

PART II

Prevention Education

"People say HIV is this or that group's problem, not mine. But for HIV, it's a matter of risk behaviors, not risk groups. Because if you say it's a risk group thing, I don't identify with that group, so I'm not at risk. That makes people feel invincible to HIV." -- HIV-positive youth.

Until a vaccine is found, the only way to prevent new HIV infections is through education. Adolescents can protect themselves if they are given comprehensive information, tools, and skills, and the reasons to use them. Communities promoting the close cooperation of parents, teachers, coaches, clergy, physicians, and other adults interacting with youth can ensure that every young person has access to this information and every adult who touches a young person's life will be equipped to impart this knowledge in a clear, accurate, sensitive manner.

Parents are the best teachers for their children so HIV prevention programs must also reach parents. Ideally, parents should be key participants in HIV prevention programs. If parents aren't convinced of the risk to their children, they may fail to recognize their child's risk-taking behavior.

Most young people have or will become sexually active. Programs to encourage sexual abstinence should continue to be supported and more effective models should be explored. It is important that young people make healthy and safe choices about sex. To help them make those decisions, families and communities should foster growth in their young citizens and provide a safe environment to accomplish that growth through schools, role models, and other opportunities. Without community support and reinforcement, even the best AIDS prevention programs will falter or fail.

It is important to consider how youth may perceive HIV prevention programs. Many young people have an enhanced sense of invincibility and may be unprepared to respond to situations that place them at risk. They may not perceive a need to avoid the risk or aren't aware that certain behaviors can place them at risk for contracting HIV. Still others may welcome the risk as part of the "adventure" of growing up.

"We, the young people of this country, need a place where we can go to ask our questions, where we won't be teased or ridiculed. We need a place where we can ask about our mixed up feelings, about sex, and about AIDS." -- 15-year-old high school student from Concord NH.

It is artificial to separate HIV prevention from sexually transmitted disease prevention, pregnancy prevention, drug abuse prevention, sexuality education, self-esteem activities, and human development education. Effective HIV prevention is not a single program or a single

event; it must take place over the course of many years and be developmentally appropriate.

That's why smart and caring communities know that the job of HIV prevention is too important to be left to health educators alone. As mentioned before, all adults who work with young people should be armed to impart HIV prevention information effectively and sensitively to adolescents in their charge. This requires programs that work -- those tailored to work well in a given community -- and that can be employed to meet a variety of prevention needs.

"If you're going to educate kids about AIDS, you have to educate them about drugs as well. If you're a youth, you're going to experiment with drugs, especially if you live in a metropolitan area. Even though you get stupid with drugs, you still think about things you don't want to do, but you do it anyhow." 16-Year-old HIV-positive youth from San Francisco.

In 1994, the Centers for Disease Control and Prevention (CDC) launched the Prevention Marketing Initiative (PMI), a comprehensive HIV/AIDS education and prevention program involving community-based organizations throughout the U.S. The PMI specifically targets young adults between the ages of 18 and 25. In 1994 and again in 1995, CDC prepared and distributed public service announcements aimed at young adults that communicate two central messages. First, sexual abstinence or delaying sexual activity is the most effective way to prevent sexual transmission of HIV. Second, for those who are sexually active, the correct and consistent use of latex condoms is an effective method of preventing HIV transmission. The PMI is a forceful effort to empower young people to protect themselves and their peers from HIV.

Yet, teach young people something and ensuring that they will follow through with what they've been taught are two separate things. Lessons learned from programs to prevent smoking, alcohol, drug abuse, and teenage pregnancy demonstrate that such efforts can positively affect adolescents' behavior. Successful programs concentrate on providing access to accurate information, personalizing this information to motivate change, providing training in behavioral skills for implementing decisions, and reinforcing and rehearsing skills to build competence and enhance self-esteem. Reality-based programs recognize that people sometimes use bad judgment. Therefore these programs talk about how to recover from a mistake or relapse and start over with self-esteem intact.

Successful HIV prevention programs also have recognized that behavior isn't changed with knowledge alone. An analysis of programs that are successful in reducing high risk behavior among young people found that schools were at the focal point of these efforts and that community-wide, multi-agency efforts provided resources and reinforced messages. Successful prevention programs also have been tailored to meet the specific needs of a particular audience, and offer their services outside the traditional school-based setting.

Community-based organizations are a valuable and credible source of prevention messages that supplement, support, and reinforce messages from within families and schools. Outreach to youth where they gather -- i.e. shopping malls, arcades, sporting events, and local pharmacies and beauty supply stores -- further guarantees that prevention messages will be heard and reinforced.

Schools are a highly effective and appropriate site for AIDS education. An estimated 91 percent of young people between the ages of 5 and 19 are enrolled in schools, providing an effective way to reach young people. As of 1992, 34 states had developed and implemented comprehensive HIV/AIDS education programs. Schools, working closely with community leaders and parent advocates, will have unique opportunities to dispel myths about HIV and teach young people the skills to avoid infection.

Beginning at the earliest appropriate age, young people should be given HIV/AIDS education as part of a comprehensive curriculum of health education that includes accurate information, the opportunity to assess their personal risk of infections, and skills training. HIV prevention information can be tailored to be age-, language-, and culturally-relevant and comfortable if designed to accommodate the context of young people's lives.

There is a compelling need for comprehensive school-based HIV prevention education efforts, yet those school-based efforts are just the first step of a long journey to effectively protecting adolescents from HIV. School-based programs do not reach all youths at risk. Those adolescents not in school -- because they have graduated or dropped out -- will need to be reached with the same kind of basic information that schools provide to all others.

Misconceptions and misunderstandings about HIV transmission and high-risk behaviors often arise when relevant information is omitted. Yet in some school districts, education policies preclude discussion of subjects such as intercourse, homosexuality and bisexuality, and condom use. It is important to note that there is no evidence to suggest that age-appropriate sexuality education promotes sexual behavior. Studies suggest that this information has either no effect on the initiation of sexual activity or actually delays such activity.

In the end, successful HIV prevention programs are those that involve all the stakeholders in assessing needs, developing strategies, implementing programs, and evaluating progress. Youth and parents, plus major community and youth influences should be involved in this process.

Peer counselors -- young people trained in providing HIV/AIDS-specific information -- have proven to be particularly successful messengers. Peer educators have repeatedly demonstrated that they can present material in a way that addresses the relevance of HIV and HIV prevention to young people's lives. Adolescents find prevention messages more believable

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when they are delivered by their peers.

Peer-led prevention programs are currently being conducted at a variety of sites around the country but many more programs are needed in many more sites. The challenge lies in supporting the development and application of programs that are innovative and address the unique needs of adolescents.

PART III

TREATMENT AND CARE

While prevention efforts are central to protecting young people from HIV, there is also a great need for access to HIV counseling and voluntary testing. Those who are HIV positive need access to a continuum of care in order to lead productive and fulfilling lives. However, services that are routinely available to adults -- including counseling and testing -- are difficult for many adolescents to access. As a result, a variety of health care options for HIV-positive adults are not practical or accessible options for young people.

Adolescents' access to routine counseling and voluntary testing is often severely limited by a variety of factors. First, many adolescents don't know how to arrange for HIV testing and where to go. Second, adolescents are not independent; their activities are shaped and limited by school, finances, and transportation. Parental consent requirements for counseling and voluntary testing also may pose a barrier for many young people -- especially those who cannot communicate openly with their parents about this subject.

Taken singly, these barriers can make it difficult for an adolescent to get counseled and tested. Combined, they present a formidable barrier that only a truly determined adolescent can surmount.

Counseling and voluntary testing sites should be tailored to be accessible to adolescents. Ideally, business hours should complement school schedules and offer their services at low or no cost to adolescents. This would accommodate adolescents who don't own a car and must use public transportation, are in school, and/or have little money or no independent health insurance.

Of all the barriers to counseling, testing, and treatment for adolescents, however, perhaps the most challenging one is that of parental consent. Consent is usually necessary for medical care of adolescents under the age of 18. Some states have enacted laws that give minors a limited ability to access HIV testing in an effort to balance the public health need to treat infectious diseases and the desire for parents to have input into their children's medical care. In at least 14 states, minors can consent to their own HIV testing because AIDS is classified as a sexually transmitted disease and those states allow adolescents to consent to such diagnosis and subsequent treatment. In addition, other states allow minors to consent to their own medical care based on their living situation or legal status (i.e. emancipated minors, married minors, or minors who are parents).

"What can we do and who can we turn to if we are turned away from our families?"-- David, 21, Connecticut.

The justification for allowing minors to consent to testing and treatment varies greatly from state to state and there is an unmet need for trained and sensitive counselors and health care providers who can work with adolescents to engage parents and guardians in treatment and care decisions as often as possible. Making sure health providers work to ensure appropriate adult guidance and parental supervision is available, builds critically-needed support into the process.

Millions of young people who have engaged in risky behaviors do not know their HIV status, and thousands do not know if they are infected. Adolescents should be strongly encouraged to learn their HIV status voluntarily. A negative test provides the best opportunity to reinforce the importance and efficacy of risk-reduction behaviors. A positive test provides an opportunity to link young people to care and prolong their lives. That, too, is why HIV testing must include appropriate pre- and post-test counseling to ensure that both HIV-negative and HIV-positive youth understand their status and the responsibilities they have to themselves and others as a result of that status.

"I go to a free clinic that I feel really comfortable in. It's really family oriented. The people are really caring, and they all know me. When I was 19, I took the HIV test on a whim. I really didn't expect a positive result. But that's what it was. Everybody working at the clinic cried." Ayisa, 20, New York.

Pre- and post-test counseling are particularly important for adolescents around the issue of HIV testing. Effective counseling must be appropriate for the adolescents' social and emotional development, language, and culture, both prior to and after HIV testing.

Counselors must be sensitive to the great anxiety that adolescents feel about HIV testing because of fear of the disease itself as well as the stigma attached to the disease. The process of testing for HIV forces adolescents to evaluate their own behavior and think of their own mortality. As a result, there are tremendous emotional needs that must be dealt with by both adolescent and counselor if the effort is to be a success.

Whether the results are positive or negative, post-test counseling is equally important. For adolescents who test negative, post-test counseling provides an opportunity for risk reduction. For some, this may be the only opportunity for meaningful prevention education.

Positive results require immediate intervention. It is essential that adolescents talk to a knowledgeable person who can help them understand what their HIV status means and can help them deal with some issues that may seem overwhelming. That same knowledgeable person will also be able to immediately link the HIV-positive adolescent to the care he or she will need.

Currently only a fraction of HIV-infected adolescents are receiving medical and psychosocial care. An integrated care system, in which medical services are connected to mental health, substance abuse, education, juvenile justice, and social support will meet the needs of these adolescents. For runaway or homeless youth, such an integrated system includes adequate housing and nutrition.

Immediately linking HIV-positive adolescents to HIV treatment after a positive diagnosis is vital in order to prevent or delay the onset of HIV-related opportunistic infections, such as pneumocystis carinii pneumonia (PCP), and to prolong the healthy lives of HIV-positive individuals.

Currently, there are few programs that meet the full range of health-care needs for HIV-positive adolescents. Barriers to the full range of services include insufficient numbers of health care providers specifically trained to work with adolescents, lack of financial assistance, a fragmented treatment system, and geographically remote facilities.

Federal grants for program development such as the Health Resources and Service Administration's Special Programs of National Significance (SPNS), funded under the Ryan White CARE Act, have encouraged models that consider the special needs of the adolescent population and provide communities with the tools they need to conduct effective outreach programs.

Large numbers of young people are uninsured or underinsured, and the sources for funds to pay for the services they need are limited. Others are found ineligible for health insurance coverage as a result of their HIV-positive status.

Besides responding to an HIV-positive adolescent's physical and mental health needs, linkage with important social services must also be accomplished. Social service providers should be prepared to provide referrals for legal assistance, other treatment programs, information about housing, job-training assistance, and help in obtaining health insurance. They should also offer outreach services for adolescents who are homeless, pregnant, or engaging in survival sex.

Finally, the Federal Government and the states should examine opportunities to provide treatment and care through the Medicaid system for HIV-positive adolescents who live below the poverty line.

PART IV

RESEARCH

HIV/AIDS research, generally, has made great strides on many fronts: Physicians have an impressive array of medications with which to treat the variety of HIV-related opportunistic infections. As a result, HIV-positive people who have access to care usually aren't getting sick as often, their illnesses aren't as severe, and they are spending less time hospitalized than they did 10 years ago. But adolescents have not received the full benefit of recent research discoveries, and there is a significant unmet need for adolescent-specific treatment and behavioral research. We clearly do not know enough about adolescents in general, about how HIV affects them physiologically or behaviorally, and about the progress of HIV disease in young bodies.

The scientific community's HIV/AIDS research efforts have primarily focused on two specific populations: infants and adults. Adolescents generally fall into a research void. Funding for adolescent-related AIDS research has traditionally come from those pursuing pediatric research. But adolescents are biologically more like young adults than infants for the purpose of many HIV/AIDS clinical trials, and those same "young adults" often aren't physiologically the same as the adults they might be grouped with in adult clinical trials.

Adolescents are not considered central to the pediatric mission, and researchers who focus on adults usually are not funded to include adolescents in their research programs. The result has been that adolescents appear only peripherally on the radar screens of most AIDS researchers, and when they do, it's only to the extent that they share adults' physical or behavioral traits.

Additionally, a variety of developmental and behavioral factors challenge efforts to draw adolescents into the few adolescent-specific protocols that have been developed for their benefit. Adolescents sometimes can be particularly challenging subjects for research. Researchers have reported difficulty enrolling adolescents in protocols, keeping them enrolled and ensuring that they are following precisely the guidelines for protocol conduct.

Further, adolescents often don't enter clinical trials because many such trials require participants to have a primary-care physician. Many adolescents do not have such a physician due to limitations on or lack of coverage, so they keep their HIV status secret for as long as they are asymptomatic and stay away from trials and protocols that might help improve their health and prolong their lives.

Such neglect by current research efforts, understandably, has left significant gaps in the knowledge base about adolescents that need to be filled in. NIH scientists are quick to

acknowledge that a lot of catching up remains to be done. There are some areas of adolescent research -- both general and HIV-specific -- that are particularly needed. Basic research on adolescent reproductive system and immune system development is lacking. Data is just beginning to be gathered on how adolescent immune systems differ from those of adults, an important consideration in defining the path of the response of an adolescent's body to HIV. Some studies have found abnormalities in growth and puberty among HIV-positive adolescents. More research into the reproductive system of adolescents needs to be done.

There must also be increased support for studying the natural history of HIV in adolescents as well as expanded study of youth and their behaviors. There are things we need to know about HIV-positive adolescents that we don't know such as how they become infected or how they effectively resist infection; and how long they live or how quickly they die. We don't know enough about the factors that influence the behavior of young people, including why some choose to be sexually active and others do not, and why certain sexual behaviors are chosen over others.

The family of seroprevalence surveys should be expanded to target and teach us more about the epidemic as it affects young people. Surveillance of HIV infection among adolescents in the United States has not been comprehensive enough to accurately estimate the scope of the problem. Such studies would help us learn which communities are experiencing high infection rates, how the disease is being transmitted, how long HIV-infected adolescents are ill and the general scope of the epidemic among this age group. Accurate data helps to target HIV prevention efforts and to forecast the kinds of services needed.

Including adolescents in all relevant AIDS-related research designs and clinical trials will begin the process of targeting them with appropriate treatment. Things such as the optimum time to begin treatment, kinds and dosages of medication and care are still not well understood for adolescents.

There must also be a coordinated effort to disseminate this information in as thorough and timely a fashion a way as possible. Presently, the lack of a significant base of adolescents enrolled in trials has resulted in little dissemination of information. At this early period in the study of adolescent-related HIV issues, even anecdotal information is important to clinicians and researchers if they are to begin building a response to the epidemic among young people.

The National Institutes of Health (NIH) have recognized that current research efforts aimed at young people are few in number and much further behind than those for adults and children. A collaborative effort has been launched between the NIH and the Health Resources and Services Administration (HRSA) called the Adolescent HIV/AIDS Research Network. The purpose of the network is to plan and conduct research on the medical, biobehavioral, and psychosocial aspects of HIV and AIDS in young people.

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This network, combined with other youth-focused programs at NIH and CDC can reduce the barriers to young people participating in research and narrow the information gap.

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It must be the goal of the Federal Government to integrate HIV awareness into all programs that reach adolescents and craft Federal responses that address these related factors as well.

"If I could talk to the President, or a Senator, or anyone in the Federal Government who can make a difference, I'd tell them to take a look, learn a lesson from the youth that are currently dealing with the disease. Listen to them, hear their stories and then see that they have a future. If they don't have that future, then we won't have an America." -- Allan, San Francisco.

Part V

ACTION PLAN

"The great burden we have as Americans is that when we have to deal with something new, too often we can't deal with it from imagination and empathy, we have to actually experience it first. I do not want to wait until every single family has somebody die before we have a good policy on HIV and AIDS." -- President Clinton, December 6, 1995, to the White House Conference on HIV and AIDS.

This examination of youth and HIV revealed five common themes that require action at all levels of American society, including the Federal government. There is remarkable consensus among scientists, health care providers, community leaders, and young people themselves on these matters. They are:

- Innovative, creative prevention programs aimed at young people must be encouraged, adequately funded, and -- when found to be successful -- broadly distributed.
- Comprehensive HIV/AIDS education for all adolescents should be available to all young people in all 50 states and U.S. territories.
- Routine counseling and voluntary HIV testing must be made available to young people in a way that is easy to access.
- HIV-positive adolescents must be linked to a continuum of care and services that will extend their lifespan.
- Adolescent-specific treatment and behavioral research must be increased to enhance our knowledge of the progress of HIV disease in adolescents and of effective AIDS prevention approaches.

THE FEDERAL ROLE

The Federal Government has three central responsibilities in leading our country's battle against HIV infection among young people: (1) Seeking a cure for AIDS and a preventive vaccine to protect those who are uninfected; (2) Sharing with communities the financial costs of caring for those who are living with AIDS; and (3) Working with communities to foster behaviors that prevent the spread of HIV.

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During the past three years, the Federal government has sought to fulfill those obligations. Overall funding for AIDS-related programs has been increased by 40 percent. Funding for AIDS-related research has been increased by 26 percent and the Office of AIDS Research at the National Institutes of Health has been strengthened. Funding for AIDS prevention efforts has been increased by 33 percent and a new community planning process has directly involved local organizations in the design of prevention programs. Funding for AIDS-related care has increased by 90 percent, including a 108 percent increase in money going to the Ryan White CARE Act. New efforts have been made to involve young people in each of these areas including, in particular, the creation of the Prevention Marketing Initiative at the Centers for Disease Control and Prevention.

In conjunction with this report, the following new initiatives are being undertaken by the Clinton Administration:

Listening to the Voices of Youth. Young people must have a voice in the development and implementation of HIV/AIDS prevention, treatment, and research efforts. The Federal government will take the following steps to assure that voice is heard:

- The Secretary of Health and Human Services will create an advisory committee of young people who are infected or affected by HIV. The committee will report directly to the Secretary and be charged with identifying and articulating the unique needs of adolescents in fashioning Federal responses to the epidemic.
- The Centers for Disease Control and Prevention (CDC) will assure the participation of young people on HIV prevention community planning councils.
- The Health Resources and Services Administration (HRSA) will issue a directive that requires the inclusion of young people on Ryan White CARE Act planning councils. These councils will be charged with ensuring these young people are provided with the technical assistance and support necessary for them to be full participants in the decision-making process.

Examining the Impact of HIV on Youth. Sufficient scientific information exists to indicate that HIV behaves differently in infected adolescents and that there are adolescent-specific health-care needs and treatment protocols that must be identified in order to respond effectively. The following steps are being taken to assure that this occurs:

- The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) will formulate rules requiring the inclusion of young people, when appropriate, in HIV/AIDS clinical trials.

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- In releasing data from clinical trials, NIH and FDA will include specific data related to adolescents. In those cases when the number of adolescents participating in a trial is too small, anecdotal data will be released on a limited basis to allow clinicians an opportunity to begin building a base of information for their use in treatment.

Making Informed Decisions. HIV counseling and voluntary testing provide an important bridge between HIV prevention and care. To assure that young people have access to such services, the following steps are being taken:

- CDC's counseling and testing guidelines will be expanded to acknowledge and address the special needs of adolescents seeking testing and counseling. This guidance will address such issues as consent, confidentiality, and payment for services. The guidance will be integrated into the training of all personnel at CDC-funded counseling and testing sites.
- CDC will require that, as part of the state grant application, states demonstrate how young people will be able to access counseling and testing services.

SHARED RESPONSIBILITIES

Any effort to protect young Americans from the threat of HIV and AIDS cannot begin and end with the Federal government. Federal efforts must be a catalyst for action on all levels of society. Throughout the 15-year history of the epidemic, states, localities, communities, schools, churches, synagogues, private foundations, and voluntary charitable organizations have been actively committed to combatting the spread of HIV. These efforts must continue and they must be expanded. The Federal government seeks a partnership with communities involved in this effort and pledges its continuing support for the critical work being done.

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Talking points for Remarks at the 25th Anniversary of Family Health International

November 20, 1996

Theme: Improving Reproductive Health
Worldwide

PF's remarks should focus on the importance
of HIV/AIDS prevention and reproductive
health and the role of the United States around
the world -

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I. Interest of the US

■ While HIV/AIDS continues to be a serious problem in the US, in many developing countries the epidemic is much more advanced. At the global level, women and men are affected by HIV in almost equal numbers, usually in the prime of their economically productive years.

■ By the year 2000, experts estimate that as many as 40 million people around the world will be HIV positive. Ninety percent will live in developing countries. Close to five million children will have been orphaned in this decade alone with estimates that the numbers will increase to 15 million worldwide by the year 2000.

■ Let us be very clear: The US government is interested in what happens around the world.

■ The practical reason: Science is an international enterprise, and international scientific dialogue and research are essential in advancing knowledge about HIV infection and AIDS. International HIV-related research intersects with other foreign policy issues. Some of the most critical scientific information on HIV/AIDS has been derived from collaboration with colleagues in other countries, with implications for prevention and treatment of HIV infection and disease. These studies have provided information on the variation of strains of HIV from various geographical regions; risk factors for heterosexual and mother to child transmission of HIV; the role of sexually transmitted disease in HIV transmission; and the list could go on.

■ Another practical reason why the US government is interested in HIV/AIDS around the world is that unless we are able to successfully fight this pandemic, it threatens to undermine other key US policy goals, including democratization, economic development, conflict resolution and peacekeeping, and promotion of individual and political rights. The AIDS epidemic will overwhelm underfunded and inadequate health care systems in much of the developing world and could undo hard-won health, social and economic gains. Take as an example the fact that AIDS mainly affects adults in their most productive years. It will surely have a negative impact on the economies of some of the hardest hit countries.

■ Then there are the ethical and humanitarian reasons: We cannot and should not be satisfied with good news which impacts only those who live within our borders.

■ The World AIDS Day theme this year "One World - One Hope" embraces the idea that HIV recognizes no geographical borders. It is estimated that 21.8 million adults and children are living with HIV/AIDS and as many as three million people are expected to become infected with HIV in this year alone, including an estimated one thousand children a day.

■ One World - One Hope means just that. Our futures are all tied together and we must demonstrate global unity in facing and overcoming the challenges caused by HIV/AIDS. Every living person, regardless of their HIV status, wants to be treated with dignity and allowed to live their lives without discrimination. The US is committed to their ideals.

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■The U.S. has been a leader, providing initial funding and support for the creation of the Global Programme on AIDS and later by playing an instrumental role in establishing the new streamlined Joint United Nations Programme on HIV/AIDS (UNAIDS). The US continues to be the largest contributor to multilateral and bilateral HIV/AIDS efforts in the world.

We cannot afford to reduce our level of support and commitment at this critical stage of the pandemic. Prevention efforts must continue, despite the recent gains in new drugs, but the truth is that most of the world will not have access to these drugs for a very long time. Even in the US, it is not accessible to everyone.

■Although the foreign assistance budget has suffered under the most recent Congress, the US government does not intend to retreat from its commitment as a leader and a full partner in the global response to HIV and AIDS.

II. Access to Treatment

■We have made important strides toward our goal of finding drugs that will stop HIV. While we are still far from our ultimate goal, there is reason for hope. We are seeing progress in many areas, especially in the development of protease inhibitors.

■UNAIDS is trying to find a way to develop and expand some pilot projects for delivering care for persons with HIV in Africa and Latin America. US government should support that initiative.

■Domestic ASOs and International NGOs have been working to negotiate with drug companies over price reductions and concessions for bulk purchasing. It would be good if the US government could apply some leverage to the drug companies on behalf of people with HIV, regardless of where they lived. Then poor countries would be able to purchase the drugs at the same reduced prices as Americans or stipulate in their policies that whatever reduced prices are negotiated would also apply to international NGOS.

■Donations from pharmaceutical should not be left out in addition to asking companies to lower their prices. We must also work with international financial institutions such as the World Bank and the International Monetary Fund for more assistance in this area.

■The US Government should continue to support efforts for greater access to treatment in developing countries.

■PF spoke to a group of people in Vancouver during the XIth International Conference on AIDS about the problems of access to drugs in developing countries. PF talked about the need to identify the highest priority therapies including drugs to treat STDS, drugs to prevent and treat OIs, drugs to control pain and drugs to prevent mother to child transmission.

■Many of these drugs are inexpensive and can allow PWAs to live longer and if they are

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adults with children, to be with them to provide the nurturing that children need as long as possible. We could work to provide low-cost generic products for these purposes.

■ But the equation is not complete until we have trained our health care workers in the best ways to take care of PWAs and use the drugs appropriately. A study recently released in the US explained the correlation between the level of experience the physician had caring for AIDS patients and the quality of care and lifespan of the patient. This must surely be the case in developing countries as well.

III. Human rights

■ Human rights abuses are ever increasing - people are being imprisoned because of their HIV status. There is much evidence of organized prostitution rings and situations such as civil war that results in women and children being raped and suffering other abuses.

■ US should intervene to prevent persecution and abuses, especially as it relates to persons who are persecuted because of their HIV status.

■ In our diplomatic discussions, these issues should be raised, and urge countries to investigate and bring specific cases to justice.

IV. Research

■ The US should provide support and funding for persons with HIV living in developing countries to be included in clinical trials. This will enable them to have access to drugs and treatments that they ordinarily would not have.

■ A lot of research on anti-virals are on strains that are not the most prevalent in Africa and Latin America. We should be concerned about new strains being introduced into this country.

■ US Government should continue to encourage the exchange of information on research that could speed up the pursuit of treatments for other strains of the virus in developing countries.

■ US Government should continue to support studies for female controlled methods like microbicides which would be a critical tool in the fight against HIV in many countries where women may not be in a position to negotiate sex. Family Health International is doing a lot of work in this area of research on new products along with collaborators such as UNAIDS and the Contraceptive Research and Development Program (CONRAD).

V. Role of NGOs

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■US government should continue to support the work of NGOs working in AIDS. Not only here in the US through the American PVO and NGO communities, but at UNAIDS with adequate representation from NGOS and indigenous NGOs at the field level. This must continue to be a priority.

■There must continue to be public-private sector collaboration if we are to bring this disease to an end around the world

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Attendees:

Phil Lee, Assistant Secretary of Health, HHS
Patsy Fleming, Director, Office of National AIDS Policy
Fred Garcia, Acting Director, Office of National Drug Control Policy
Eric Goosby, Director, Division of HIV/AIDS Policy, HHS
Elaine Johnson, Director, Center for Substance Abuse Prevention, HHS
Helene Gayle, Director, HIV/STD/TB Prevention Center, CDC
Steve Jones, Assistant Director for Substance Abuse, Division of HIV/AIDS
Prevention, CDC
Ron Valdiserri, Acting Deputy Director for HIV/AIDS, CDC
Michele Applegate, Deputy Administrator, SAMHSA
Barbara Garcia, Assistant Administrator, SAMHSA
Alan Leshner, Director, NIDA
Harry Haverkos, Director, Office on AIDS, NIDA
Judy Auerbach, Behavioral and Social Science Coordinating Chair, OAR
David Mulligan, Commissioner, Massachusetts Dept. of Health
Don DesJarlais, Director of Research, Chemical Dependency Institute
Beth Israel Medical Center
Gerald Friedland, Director of AIDS Program, Professor of Medicine and
Epidemiology and Public Health, Yale University
Douglas Morgan, Assistant Commissioner for the Division of AIDS, New Jersey
Dept of Health