

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

Collection/Record Group: Clinton Presidential Records
Subgroup/Office of Origin: National AIDS Policy Office
Series/Staff Member: Kristine Gebbie
Subseries:

OA/ID Number: 8300
FolderID:

Folder Title:
[National HIV Action Agenda]

Stack:
S

Row:
66

Section:
5

Shelf:
1

Position:
3

— 1

Outline handed out at the first pre-plan meeting. It was used to guide the discussion.

Also handed out at the first meeting were the colations of Nat'l Comm. recommendations; also included in this package.

Following that meeting, status report I was created and shared with everyone in ONAPC via cc:Mail; included in this package with attachments

cc:Mail to which you have responded

|

(2)

—

Not included in this package because they are between paper and thought:

Work group guidelines

Meeting agenda

Meeting budget and tasks (i.e., scope of work for a conference planner contract)

Draft letter from you to Dept. Sec'y's

On going..

Gathering plans from PHS agencies outside groups

Determining if the President will participate, dates available

|

Please send written comments by April 29, 1994 to:
Andrew Barrer, Ph.D.
Office of the National AIDS Policy Coordinator
FAX: (202) 632-1096
Questions: (202) 632-1090

National HIV Action Agenda April 1994

DRAFT

INTRODUCTION From the National AIDS Policy Coordinator

The National HIV Action Agenda is a leadership statement.

It has been developed by the Office National AIDS Policy to give direction to our overall national effort to end the HIV/AIDS epidemic; the epidemic some have called the health crisis of our times. The action steps described within provide guidance and markers for the nation. The action steps are activities the nation can begin within a six-month horizon. Many are long-term or continuous, while others are short-term or immediate.

In the next iteration of the National HIV Action Agenda many of the action items will have been accomplished. New goals will be substituted for goals attained or goals no longer appropriate as the epidemic and our ability to respond to it continually change.

The commitment to provide the continuing national leadership necessary to end the epidemic is something this Administration takes very seriously. When President Clinton appointed me, he said "AIDS is terrifying. It inflicts tragedy on too many families. But ultimately, it is a disease; one we can defeat...with commitment and courage and constancy, and with vocal and responsible leadership from our nation's government."

The National HIV Action Agenda is organized into three areas for action: research, service, and prevention. In the day-to-day work of addressing the epidemic, however, the distinction between these areas is often blurred. It is only by coordinating efforts in all the areas and by focusing on common goals that we optimize our chances of ending this epidemic. It is incumbent upon everyone to understand that this epidemic is a national problem and it will take a national and unified effort to end it.

In 1993, 104,468 new cases of AIDS were reported nationally. In the United States, the virus has flourished in disenfranchised, disadvantaged, and marginalized populations. It is associated with some behaviors that are illegal and others which are

considered to be inappropriate by many. By doing so, the virus itself has managed to dilute the nation's ability to coalesce in common purpose. This document attempts to bring the nation's attention to the real issues: What should we do? What can we do? Where do we go from here?

Also, as a member of the world community, the United States has a responsibility to join other countries in the international effort. Therefore, in the Action Agenda, international HIV/AIDS issues are an important part of the three primary areas of research, service, and prevention.

The arrangement of three primary areas is not meant to give special emphasis to one over another. Research findings are the foundation for action. The National HIV Action Agenda attempts to drive the nation to resolve questions of cure and prevention, of drugs and behavior, by suggesting steps to enhance the organization of the effort and to improve communications among researchers engaged in the effort, between researchers and care givers, and between researchers and the prevention effort.

Service action steps aspire to better ensure that people and families affected by HIV can receive the care and support they need, that effective therapies are available, and that the length of life after infection is as long and healthy as possible.

In the prevention area the Action Agenda seeks to better focus efforts to interrupt transmission of the virus by improving the educational effort, improving the focus and enhancing efforts to reduce the risky behaviors associated with transmission, and by increasing the application of the science base in planning and program implementation.

The President and I are committed to the requirement that everyone affected be given "a seat at the table." Throughout the document, specific action steps to facilitate cooperation and leadership are stated.

With everyone's help, we can stop AIDS.

DRAFT

Kristine M. Gebbie, RN, MN, FAAN
National AIDS Policy Coordinator

Goal A: National HIV/AIDS research strengthened through coordination, planning, and evaluation.

Commentary: Billions of dollars are invested annually in the United States and abroad in an effort to further development of safe, effective therapeutics, prophylactic vaccines, and improved methodologies to reduce risky behaviors. Nevertheless, the challenges still to be faced by research into the Human Immunodeficiency Virus (HIV) disease and the Acquired Immune Deficiency Syndrome (AIDS) are profound. While progress has been made in many areas, there has been a recent lack of significant clinical advances in the treatment and prevention of the underlying disease. Given the scope of the scientific questions still unanswered, and the dimensions of the growing pandemic, there is a great need to search for creative ways to maximize public and private resources.

Action (A.1): Implement, as necessary, new formal planning linkages between federal agencies and departments engaged in HIV/AIDS biomedical or behavioral research, based on agencies' complementary research agenda and portfolios.

Commentary: Federal AIDS research programs have undergone continual evaluation and evolution since the beginning of the epidemic. The pace of evaluation and reform has accelerated significantly in the last year. Very likely, the next year will bring even closer scrutiny and intense public debate of the complex scientific, administrative, regulatory, legal, and ethical challenges and opportunities facing HIV/AIDS research today. Within the federal government, many agencies plan and budget HIV/AIDS research programs independently of one another, and current communications systems between researchers in the public and private sectors may not allow for sufficient timely coordination. Mechanisms for communications and planning must be fully evaluated and improved to maximize efficiency.

Action (A.2): Seek expeditious and full implementation of the National Institutes of Health (NIH) AIDS research program reforms provided in the NIH Revitalization Act of 1993.

Commentary: The Office of AIDS Research (OAR) of the NIH has been strengthened with centralized evaluation, planning, and budgeting authorities across all institutes of the NIH. While the intent of the legislation is clear, it is important that the interpretation of the provisions of the Act be carefully monitored.

Action (A.3): Develop strong linkages between federally chartered advisory committees to coordinate development of complementary national HIV/AIDS research policies.

DRAFT

Commentary: The Office of AIDS Research (OAR) Advisory Council, the National Task Force on AIDS Drug Development, the Presidential HIV/AIDS Advisory Council and other advisory bodies will be critical for providing recommendations and input into the evolving national AIDS agenda; their independent policy deliberations must be coordinated.

Action (A.4): Ensure strong support for the role of behavioral and social science research related to biomedical research, treatment regimens (e.g., substance abuse treatment), and as the scientific basis for sound prevention programs.

Commentary: Findings from behavioral and social science research are critical to the control of the epidemic through the successful administration of prevention, research and treatment programs. This research, which has often been overlooked, must receive strong support, and findings from this research must be fully integrated into programs.

Action (A.5): Work with HIV/AIDS-affected communities and federal agencies to assure that the unique social and physiological characteristics of all HIV-affected populations are taken into consideration in the design of clinical trials and other research programs.

Commentary: Women, children, adolescents, ethnic and racial minority groups, injecting drug users, gay and bisexual men, lesbians and bisexual women and others have unique needs that should be accommodated both through appropriate inclusion in clinical trials and the conduct of trials specifically designed to address their needs.

Goal B: Government, industry, academia, and community attention focused on promising, innovative proposals that could expedite the discovery of new therapeutics for HIV/AIDS and build consensus toward potential solutions.

Commentary: The National Task Force on AIDS Drug Development, recently chartered by the Secretary of Health and Human Services has been formed to identify obstacles and opportunities in HIV/AIDS drug discovery and development. The work of this task

force must be strongly supported, with prompt response to its requests for information and recommendations for action. Additionally, other federal and private agencies should continue to evaluate programs and policies affecting HIV/AIDS drug development.

Action (B.1): Identify regulatory and legal obstacles to research collaboration among federal agencies and non-governmental entities.

DRAFT

Commentary: Technology transfer, the Cooperative Research and Development Agreements (CRADA), liability, patent issues, and drug pricing have been identified as potential obstacles or disincentives to AIDS research collaboration and investment. Working with the National Task Force on AIDS Drug Development, appropriate governmental and private sector groups must develop reforms to address these and related issues.

Goal C: Obstacles to the development of an HIV/AIDS prophylactic vaccine identified and removed.

Action (C.1): Utilizing existing reports and ongoing discussions, develop consensus and, when appropriate, design and implement legislative or administrative solutions to address the obstacles to vaccine development.

Commentary: A number of governmental and non-governmental committees have published recommendations concerning scientific, legal, ethical, cultural, and administrative issues facing vaccine development. This is a continuing process with ongoing fora within NIH and the Department of Defense among others. Consensus among the recommendations must be formed and the recommendations must expeditiously become policy to pave the way for widespread development, clinical testing, and use of prophylactic vaccines in the United States and other countries.

Goal D: Domestic research planning and priority-setting integrated with international efforts.

Action (D.1): Explore mechanisms for increased international collaboration.

Commentary: Research activities cannot be viewed from a strictly national perspective. Working with U.S. and internationally-convened fora, public and private HIV/AIDS research programs should be evaluated to improve mechanisms for communication and collaboration to increase efficiency and productivity.

Goal E: Continued and expanded access to quality mental and physical health services for people living with HIV/AIDS.

Action (E.1): Develop and implement an affordable universal health insurance plan which will provide coverage for HIV-/AIDS related physical and mental health services, including substance abuse treatment.

Commentary: Populations who may traditionally have had little or no access to health care have been disproportionately impacted by the epidemic. This lack of access may be due to reasons of finance or to actual and perceived discrimination. By providing a universal health care plan, the nation will be better able to address the needs of people living with HIV/AIDS.

Action (E.2): Encourage individuals to ascertain their HIV status and ensure appropriate linkages to treatment and services are available for those who test positive.

Commentary: Many individuals living with HIV are not aware of their serostatus. Counseling and testing programs must include outreach to individuals who may engage in high risk behavior to encourage them to ascertain their HIV status. Counseling and testing activities must encourage individuals to obtain their test results, reinforce safer behavioral practices, and provide adequate referral mechanisms including treatment providers.

Action (E.3): Work with Congress, agencies of the Public Health Service, constituent groups, and members of affected communities to ensure continuation of the Ryan White Comprehensive AIDS Resources Emergency Act and other federal programs which provide HIV/-AIDS services to ensure that they continue to meet the care needs of the HIV/AIDS community.

Action (E.4): Expand the availability of quality mental and physical health services for people living with HIV/AIDS.

Commentary: People living with HIV/AIDS are often unable to obtain services in many communities, particularly in some rural areas where they may be required to travel many miles. Much of the care needed by people living with HIV/AIDS infection is basic care which could be provided by family physicians, home health

care aides, family members, or other community-based service providers. However, treatment guidelines, adequate information, and training must be provided to those practitioners if they are to provide those services.

Action (E.5): Identify barriers to the availability of mental and physical health services, coordinate with appropriate agencies, community service organizations, constituent groups, people living with HIV/AIDS, and providers to remove those barriers.

DRAFT

Commentary: Because of limited access to care, many individuals only obtain acute care services in emergency situations. It is critical that HIV/AIDS-related services provide outreach to individuals and populations that may be difficult to reach, such as the homeless, through the traditional public health model. It is critical that in the creation of service delivery models, people living with HIV participate in program design and implementation.

Action (E.6): Stimulate development and implementation of effective evaluation methodologies for service delivery programs and for comprehensive networks of service delivery.

Commentary: In developing service delivery models, the planners must include evaluation methodologies that are capable of determining whether the programs are providing adequate access and care. Federal agencies coordinating service delivery nationally must encourage system-wide evaluation of service delivery networks and individual programs.

Action (E.7): Develop appropriate information dissemination mechanisms which facilitate rapid transfer of research findings, new clinical information, and appropriate educational material to public and private providers of care services.

Action (E.8): Ensure that care guidelines and other such materials are kept current and incorporate, at the earliest possible time, changes in the state of the art.

Action (E.9): Encourage all appropriate agencies, organizations, and institutions to provide HIV/AIDS training to providers both public and private.

Commentary: Because people living with HIV/AIDS and their families experience the disease and its effects in an almost infinite variety of ways, service needs are multiple and diverse. In many communities, dramatic and innovative ideas have emerged which, if disseminated and supported, could make an enormous difference.

Goal F: Early intervention information is provided to all those living with HIV.

Action (F.1): Encourage coordination and collaboration among federal agencies, state and local governments, non-governmental organizations, and service providers to provide people living with HIV accurate and timely information about early intervention and preventing opportunistic infections.

DRAFT

Commentary: Requires increasing linkages from the counseling and testing facilities to service providers as well as greater coordination between prevention and other services at the local level.

Action (F.2): Develop and implement programs to inform HIV service providers on ways to prevent opportunistic infections and coordinate efforts with tuberculosis elimination programs at all levels.

Commentary: Primary among the opportunistic infection concerns is the prevention of tuberculosis, which is posing greater threats to the HIV-affected community.

More than a third of the current cases of AIDS are a product of the ongoing, companion epidemic of drug dependency and abuse. There is a shortage of effective treatment services and many barriers keep substance abusers from accessing the services which do exist. Of great concern are injecting drug users. While there is universal agreement an ideal solution lies in finding ways to interrupt injection--and that remains the long term commitment. However, minimizing transmission is the immediate problem.

Goal G: People living with HIV/AIDS as well as people and families affected by HIV have access to a wide array of community and supportive (or enabling) services.

Action (G.1): At national, state, and local levels, promote coordination of community groups, acute care facilities, state and local governments, private funders, and others that are provid-

ing HIV/AIDS-related services to ensure that a comprehensive continuum of care and services are available and accessible.

DRAFT

Action (G.2): Stimulate and encourage appropriate agencies to develop helpful materials describing available services so families and individuals affected by HIV/AIDS will be empowered to access them.

Action (G.3): Encourage enforcement of prohibitions against discrimination in health care settings and encourage the creation of new protections to ensure access to care for people living with HIV/AIDS.

Action (G.4): Encourage appropriate agencies and governments to coordinate and link health care and supportive services (e.g., primary care, substance abuse, clinical trials, and HIV-related care).

Goal H: That treatment protocols and supportive service needs unique to minorities, women, adolescents, and children receive appropriate consideration in the planning, development, and implementation of all service-related activities.

Action (H.1): Identify the components of programs to address the unique health care and supportive service needs of minorities, women, adolescents, and children living with or affected by HIV/AIDS, and work with appropriate agencies to incorporate these elements into relevant programs.

Commentary: Lack of access, common to all populations disproportionately impacted by HIV/AIDS, is more critical among populations that have either lacked resources or been subjected to discrimination. In developing and implementing service delivery programs, the needs of these populations must be addressed, and, where necessary, additional resources must be applied.

Goal I: Updated information on HIV/AIDS management is communicated internationally.

Commentary: In many countries, current treatments are unfamiliar to local providers. Using information dissemination techniques, information on diagnosis, treatment, and prevention can be communicated around the globe rapidly and in a cost effective manner.

Action (I.1): Working in coordination with the United Nations-sponsored HIV/AIDS program, identify a mechanism to provide ongoing updated training in HIV management.

DRAFT

Action (I.2): Establish an advisory group of U.S. entities involved in international HIV activities for the purpose of global HIV issues and policy development.

Commentary: Many U.S. organizations represent ongoing projects relating to all aspects of HIV/AIDS throughout the world. Their insights into the practical aspects of the epidemic can provide crucial information for policy development.

PREVENTION

Goal J: Educational programs, activities, and campaigns that provide accurate and timely information to all Americans on how to prevent HIV transmission.

Commentary: National prevention campaigns and local community programs must deliver a consistent prevention message overall if they are to be effective. The prevention program design model shall include active participation of the target populations in all components of the program design and implementation. Wherever possible, members of the target population must participate in accessing people at high risk, especially for hard-to-reach populations.

Action (J.1): Develop and implement an affordable health insurance plan that would provide coverage for HIV prevention and would support a health system which promotes public health infrastructure re-building.

Action (J.2): Develop a continuum of HIV prevention services that are culturally diverse and linguistically specific and contain input from the diverse populations effected by AIDS.

Commentary: Prevention programs must provide both individual and community-level interventions. Although more individuals are being tested today than were a few years ago, counseling and testing programs alone are not reaching those most at risk and are not bringing about the behavior changes necessary to stop transmission. To this end, programs and messages must be aimed at the individuals at high risk for infection. Counseling and testing activities can continue to be used as a diagnostic tool with continued counseling on prevention intervention and any necessary treatment.

Action (J.3): Develop consistent prevention education messages to be used in HIV prevention programs at the national, regional, state, and local levels.

DRAFT

Commentary: Where research findings are available regarding risky behavior, they should be used in the development of linguistically specific, developmentally appropriate, and culturally-based prevention messages that speak of abstinence or sexual activity within a long term mutually monogamous, committed relationship as the surest way of preventing transmission, but also encourage safer sexual and substance-use practices for individuals.

Action (J.4): Sustain the federal agencies ongoing prevention campaigns to sponsor targeted national media campaigns that will specifically address HIV prevention.

Commentary: National media campaigns demonstrate the leadership of the federal government in delivering targeted prevention messages to persons at risk for HIV infection.

Action (J.5): Encourage communities throughout the country to follow the federal government's lead and carry the message of prevention to local populations at risk.

Action (J.6): Increase technical assistance from federal agencies to assist state and local governments and non-governmental organizations to develop targeted campaigns through community interventions and the media.

Commentary: To increase effectiveness, prevention messages must be population-specific. Therefore, they should be delivered through appropriate media and use language and imagery that most effectively communicates the message. Federal agencies engaging in HIV prevention activities should encourage state and local

governments and private agencies to provide targeted media campaigns and implement well-chosen community interventions.

Action (J.7): Encourage businesses and media to participate in national and local efforts for HIV prevention by sponsoring campaigns and activities in local media and in places of business.

DRAFT

Goal K: Community consultation routinely sought in the development and implementation of educational programs and campaigns.

Action (K.1): Develop and deliver prevention messages in an effective and appropriate manner for the intended audience.

Action (K.2): Target efforts to the needs of populations that may be particularly susceptible to HIV transmission: gay and bisexual men (including gay men of color), substance users, sexual and needle-sharing partners of substance users, and youth in high-risk situations (especially out-of-school and gay youth).

Commentary: Primary in this effort is prevention education for youth, both in and out of school. Messages stress building self-esteem and self-sufficiency. To obtain the most effective community consultation, collaboration between governmental and non-governmental organizations will be encouraged at all levels. Federal funding agencies should increase technical assistance to encourage partnerships.

Action (K.3): Continue the implementation of the community planning process and encourage state and local governments to expand the use of this representative process to set priorities at the state and local levels.

Goal L: An array of HIV preventive services available and accessible to substance abusers in treatment on the streets.

Action (L.1): Coordinate activities and policies within the federal government such that the elements of the Public Health Service, the Office of National Drug Control Policy, and oth-

er involved entities work together toward a common goal of a drug-abuse-free and an AIDS-free society.

DRAFT

Action (L.2): Identify and develop methods to encourage the entry of all psychoactive drug dependent people, with particular attention to injecting drug users, into public or private treatment programs.

Action (L.3): Encourage utilization of new or sterile needles and syringes among injecting drug users who are unwilling or unable to utilize treatment or abstain from injecting practices.

Action (L.4): Initiate policy discussions and encourage study of the concept of "harm reduction" to broaden the policy alternatives available as the nation confronts the double and interrelated epidemics of drug dependency and HIV/AIDS.

Goal M: A safe blood supply worldwide.

Commentary: This issue cuts across international boundaries and is amenable to increased blood screening, the use of deferral criteria for blood donors, and other efforts.

Action (M.1): In cooperation with the World Health Organization, Global Program on AIDS promote the "Blood Safety Initiative."

Action (M.2): Include blood safety standards in all U.S. sponsored international service programs.

Goal N: Comprehensive, continuing HIV prevention programs for international use through existing host country infrastructure.

Action (N.1): Develop a comprehensive HIV/AIDS educational exchange among national AIDS coordinators world-wide using electronic media.

Action (N.2): Work with foreign governments to develop a training program to educate members of their military orga-

Commentary: After developing and successfully implementing HIV/AIDS training for U.S. military personnel, the concept can be translated to foreign militaries world-wide, some of which have extremely high infection rates.

CROSS-CUTTING

INFORMATION DISSEMINATION

Goal O: A national HIV/AIDS information dissemination system.

Commentary: All possible users of HIV/AIDS information should have access to the information they need and obtaining it should be easy. Implementation of an all-inclusive, easy access system can be developed with existing technologies and expertise. All AIDS information should be available to the public via a single telephone access number. Transfer among databases to the appropriate information system should be transparent to the user.

- Action (O.1):** Develop a technological, inter-departmental portal through which AIDS information can be disseminated.
- Action (O.2):** Establish a interdepartmental group to identify and discuss the issues and to establish a coordinated national HIV information dissemination policy.
- Action (O.3):** Develop an HIV information plan to be followed by all relevant agencies.
- Action (O.4):** Provide a forum for community-based HIV organizations and people affected by HIV/AIDS to express their informational needs and the problems they encounter in obtaining the needed information.
- Action (O.5):** Develop a training and technical assistance program for users of the national HIV information system.
-

Bibliography

DRAFT

- "1993 Survey of AIDS Medicines: Drugs and Vaccines in Development"; Pharmaceutical Manufacturers Association; 1993.
- "AIDS An Expanding Tragedy"; National Commission on AIDS; June 1993.
- "AIDS in Foreign Policy"; Kimberly Hamilton, The Washington Quarterly; Winter, 1994.
- "AIDS and the Global Military"; Normal Miller, editor; AIDS and Society: International Research and Policy Bulletin 4; July/August 1993.
- "AIDS Research at the NIH: A Critical Review"; Gonsalves, Gregg and Harrington, Mark, Treatment Action Group; July 1992.
- "The AIDS Research Program of the National Institutes of Health"; Institute of Medicine, National Academy Press; 1991.
- "AIDS in the World"; Jonathan Mann, J.M. Tarantola, and Thomas W. Netter, editors; Harvard University Press; 1992.
- "America Living With AIDS"; National Commission on AIDS; September 1991.
- "The Barbara McClintock Project to Cure AIDS"; McClintock Project Working Group; June 1993.
- "Basic Research on HIV Infection: A Report From the Front"; Gonsalves, Gregg, Treatment Action Group; June 1993.
- "Behavioral and Social Sciences and HIV/AIDS Epidemic"; National Commission on AIDS; July 1993.
- "Bridging the Gap: A Workshop on HIV Treatment Information Dissemination"; Office of AIDS Research (OAR), National Institutes of Health (NIH), and the Health Resources and Services Administration (HRSA); February 1993.
- "Briefing Paper, Clinton-Gore Transition Team"; Black Leadership Commission on AIDS; January 1993.
- "The Challenge of HIV/AIDS in Communities of Color"; National Commission on AIDS; December 1992.
- "The Crisis in Clinical AIDS Research"; Harrington, Mark, Treatment Action Group; December 1993.
- "Emerging Infections: Microbial Threats to Health in the United States"; Institute of Medicine, National Academy Press; 1992.

"FDAR: The Madison Project (draft)"; The Harvard AIDS Institute, University of Wisconsin at Madison Medical Center and Project Inform; February 1994.

"The FY 1995 National Institutes of Health Plan for HIV-Related Research"; OAR/NIH; 1993.

"Federal AIDS Agenda '93"; Federal AIDS Agenda '93 Delegates; May 1993.

"Federal, State, and Local Responsibilities"; National Commission on AIDS; March 1990.

"The Global AIDS Disaster: Implications for the 1990s"; U.S. Department of State; July 1990.

"The HIV/AIDS Epidemic in Puerto Rico"; National Commission on AIDS; June 1992.

"The HIV/AIDS Pandemic: 1993 Overview"; World Health Organization, Global Programme on AIDS; 1993.

"Housing and the HIV Epidemic"; National Commission on AIDS; July 1992.

"How Foundations, Corporate America, and Government Can Work Together in the Fight Against AIDS/HIV"; Funders Concerned About AIDS; March 1993.

"The Human Immunodeficiency Virus Vaccine Challenge: Issues in Development and International Trials"; Committee on Life Sciences and Health, Federal Coordinating Council on Science, Engineering and Technology (FCCSET); July 1993.

"Investing in Health: World Development Report 1993"; World Bank; Oxford University Press; 1993.

"Leadership, Legislation, and Regulation"; National Commission on AIDS; April 1990.

"Mobilizing America's Response to AIDS: Recommendations to President Clinton"; National Commission on AIDS; January 1993.

"NIH Databook 1993"; NIH; September 1993.

"National Hispanic/Latino AIDS Agenda"; National Hispanic/Latino AIDS Coalition; June 1993.

"The NIH Revitalization Act of 1993"; Enacted June 10, 1993.

"Preventing HIV/AIDS in Adolescents"; National Commission on AIDS; June 1993.

"Proposal Preparation Kit"; Advanced Technology Program, National Institute of Standards and Technology, Technology Administration, U.S. Department of Commerce; February 1994.

"Putting People First: How We Can All Change America"; Governor Bill Clinton and Senator Al Gore; Random House, 1992.

"Social and Human Issues"; National Commission on AIDS; April 1991.

"Strategic Plan to Combat HIV & AIDS in the United States"; U.S. Public Health Service, Department of Health and Human Services; October 1992.

"The Twin Epidemics of Substance Abuse and HIV"; National Commission on AIDS; July 1991.

"Women and Health Research, Ethical and Legal Issues of Including Women in Clinical Studies"; Institute of Medicine, National Academy of Sciences; March 1994.

THE WHITE HOUSE
WASHINGTON

April 12, 1994

MEMORANDUM FOR ARTHUR JONES
DEPUTY PRESS SECRETARY

FROM JOHN PAUL GURROLA
DIRECTOR OF COMMUNICATIONS
OFFICE OF THE NATIONAL AIDS POLICY COORDINATOR

SUBJECT National HIV Action Agenda

Here is the talking points we spoke about and a rough run-down of the purpose of the purpose of the Action Agenda.

The HIV/AIDS Community has been asking for a "Action Agenda" of some sort for quite a while. The National Commission on AIDS recommended that a "national plan" of some sort be developed. We are responding to these recommendations with this Agenda. The Agenda will list about 15 goals, some of them short term, some of them long term. The various goals involve many different agencies and Departments within the Federal government.

Today, Kristine Gebbie distributed an **outline** of the **draft** document to about 12 different representatives of the AIDS Community for suggestions and comments. With this in mind, please keep the following notes in mind:

- This document is in **draft** form right now and all we are doing is requesting community input in order to make it a much more useful and saleable document to the American people.
- This is the first round of discussions we are holding. We have are already talking with other Departments/Agencies about the Agenda and have shared the document with some of them.
- There are virtually no new ideas in this Agenda. Most of the ideas have been extracted from other reports or documents, such as the National Commission on AIDS final report.

Thanks for everything Art, if you need to reach me you can SKY-PAGE me with pin# 2379161.

On White House Letterhead

National HIV Action Agenda

April 1994

INTRODUCTION

From the National AIDS Policy Coordinator

The National HIV Action Agenda is a leadership statement.

It has been developed by ~~my staff in an attempt~~ ^{the AIDS Policy office} to give direction to ~~the overall~~ ^{our national} effort to end the HIV/AIDS epidemic; the epidemic some have called the health crisis of our times. This document is not all inclusive, and it is intended to be dynamic. The goals, the action steps described within provide guidance and markers for the nation. The action steps are activities the nation can begin ^{now} within a six-month horizon. Many are long-term or continuous, while others are short-term or immediate.

As the nation's work progresses, the goals and the action steps will evolve. In the next iteration of the National HIV Action Agenda many of the immediate actions will have been replaced. Over time, new goals will be substituted for goals attained or goals no longer appropriate as the epidemic and our ability to respond to it continually change.

An implicit, unstated commitment underpins all the goals that are delineated in these pages. That is the commitment to provide the continuing national leadership necessary to end the epidemic. When President Clinton appointed me, he noted "AIDS is terrifying. It inflicts tragedy on too many families. But ultimately, it is a disease; one we can defeat...with commitment and courage and constancy, and with vocal and responsible leadership from our nation's government."¹

The National HIV Action Agenda is organized into three areas for action: research, service, and prevention. In the day-to-day work of addressing the epidemic, however, the distinction between the areas is often blurred. It is by only coordinating efforts in all the areas and by focusing on common goals that we optimize our chances of ending this epidemic. It is incumbent upon everyone to understand that this epidemic is a common problem and it will take a common effort to end it.

¹ Clinton, WJ. Remarks by the President in Announcement of Kristine M. Gebbie as AIDS Policy Coordinator. June 25, 1993.

- Carol
- Drug Policy Office
- P. J.
- Phil
- Focus Group outside
- TO DCC on 1/14
- E Bush turnaround -

In 1993, 103,500 ^{new} cases of AIDS were reported nationally. It is estimated there are 40,000 to 60,000 new infections every year. In the United States, the virus has flourished in disenfranchised, disadvantaged, and marginalized populations. It has associated itself with behaviors that are illegal and behaviors that many consider provocative. By doing so, the virus itself has managed to dilute the nation's ability to coalesce in common purpose. This document attempts to bring the nation's attention to the real issues: What should we do? What can we do? Where do we go from here?

Also, as a member of the world community, the United States has a responsibility to join other countries in the international effort. Therefore, in the Action Agenda, international HIV/AIDS issues are an important part of the three primary areas of research, service, and prevention.

The arrangement of three primary areas is not meant to give special emphasis to one over another. Research findings are the foundation for action. The National HIV Action Agenda attempts to drive the nation to resolve questions of cure and prevention, of drugs and behavior, by suggesting steps to enhance the organization of the effort and to improve communications among researchers engaged in the effort, between researchers and care givers, and between researchers and the prevention effort.

Service action steps aspire to better ensure that people and families affected by HIV can receive the care and support they need, that effective therapies are available, and that the period ^{length} between infection and disease manifestation is maximized.

^{of life after} ^{is as long and healthy as possible}
In the prevention area the Action Agenda seeks to better focus efforts to interrupt transmission of the virus by improving the educational effort, improving the focus and enhancing efforts to reduce the risky behaviors associated with transmission, and by increasing the application of the science base in planning and program implementation.

Common purpose and collaboration require that everyone affected be given "a seat at the table." Throughout the document, specific action steps to facilitate cooperation and leadership are stated. ~~That is, in the final analysis, the reason I have this job and why there is now a National Action Agenda.~~

with everyone's help, we can stop AIDS.

Kristine M. Gebbie, RN, MN, FAAN
National AIDS Policy Coordinator

RESEARCH

Goal: National HIV/AIDS research strengthened through coordination, planning, and evaluation.

Commentary: Billions of dollars are invested annually in the United States and abroad in an effort to further development of safe, effective therapeutics, prophylactic vaccines, and improved methodologies to reduce risky behaviors. Nevertheless, the challenges still to be faced by research into the Human Immunodeficiency Virus (HIV) disease and the Acquired Immune Deficiency Syndrome (AIDS) are profound. While progress has been made in many areas, there has been a recent lack of significant clinical advances in the treatment and prevention of the underlying disease. Given the scope of the scientific questions still unanswered, and the dimensions of the growing pandemic, there is a great need to search for creative ways to maximize public and private resources.

Action: Implement, as necessary, new formal planning linkages between federal agencies and departments engaged in HIV/AIDS biomedical or behavioral research, based on agencies' complementary research agenda and portfolios.

Commentary: Federal AIDS research programs have undergone continual evaluation and evolution since the beginning of the epidemic. The pace of evaluation and reform has accelerated significantly in the last year. Very likely, the next year will bring even closer scrutiny and intense public debate of the complex scientific, administrative, regulatory, legal, and ethical challenges and opportunities facing HIV/AIDS research today. Within the federal government, many agencies plan and budget HIV/AIDS research programs independently of one another, and current communications systems between researchers in the public and private sectors may not allow for sufficient timely coordination. Mechanisms for communications and planning must be fully evaluated and improved to maximize efficiency.

Action: Seek expeditious and full implementation of the National Institutes of Health (NIH) AIDS research program reforms provided in the NIH Revitalization Act of 1993.

Commentary: The Office of AIDS Research (OAR) of the NIH has been strengthened with centralized evaluation, planning, and budgeting authorities across all institutes of the NIH. While the intent of the legislation is clear, it is important that the

interpretation of the provisions of the Act be carefully monitored.

Action: Develop strong linkages between federally chartered advisory committees to coordinate development of complementary national HIV/AIDS research policies.

Commentary: The Office of AIDS Research (OAR) Advisory Council, the National Task Force on AIDS Drug Development, the Presidential HIV/AIDS Advisory Council and other advisory bodies will be critical for providing recommendations and input into the evolving national AIDS agenda; their independent policy deliberations must be coordinated.

Action: Ensure strong support for the role of behavioral and social science research related to biomedical research, treatment regimens (e.g., substance abuse treatment), and as the scientific basis for sound prevention programs.

Commentary: Findings from behavioral and social science research are critical to the control of the epidemic through the successful administration of prevention, research and treatment programs. This research, which has often been overlooked, must receive strong support, and findings from this research must be fully integrated into programs.

Action: Work with HIV/AIDS-affected communities and federal agencies to assure that the unique social and physiological characteristics of ~~each~~ *each* all HIV-affected populations ~~are~~ taken into consideration in the design of clinical trials and other research programs.

Commentary: Women, children, adolescents, ethnic and racial minority groups, injecting drug users, gay and bisexual men, *rural communities, the homeless* and others have unique needs that should be accommodated both through appropriate inclusion in clinical trials and the conduct of trials specifically designed to address their needs.

Goal: Government, industry, academia, and community attention focused on promising, innovative proposals that could expedite the discovery of new therapeutics for HIV/AIDS and build consensus toward potential solutions.

Commentary: The National Task Force on AIDS Drug Development, recently chartered by the Secretary of Health and Human Services ~~and the National AIDS Policy Coordinator~~, has been formed to

identify obstacles and opportunities in HIV/AIDS drug discovery. The work of this task force must be strongly supported, with prompt response to its requests for information and recommendations for action. Additionally, other federal and private agencies should continue to evaluate programs and policies affecting HIV/AIDS drug development.

Action: Identify regulatory and legal obstacles to research collaboration among federal agencies and non-governmental entities.

Commentary: Technology transfer, the Cooperative Research and Development Agreement (CRADA), liability, and patent issues have been identified as potential obstacles or disincentives to AIDS research collaboration and investment. Working with the National Task Force on AIDS Drug Development, appropriate governmental and private sector groups must develop reforms to address these and related issues.

and
drug
pricing

Goal: Domestic research planning and priority-setting integrated with international efforts.

Action: Explore mechanisms for increased international collaboration.

Commentary: Research activities cannot be viewed from a strictly national perspective. Working with U.S. and internationally-convened fora, public and private HIV/AIDS research programs should be evaluated to improve mechanisms for communication and collaboration to increase efficiency and productivity.

Goal: Obstacles to the development of an HIV/AIDS prophylactic vaccine identified and removed.

Action: Utilizing existing reports and ongoing discussions, develop consensus and, when appropriate, design and implement legislative or administrative solutions to address the obstacles to vaccine development.

Commentary: A number of governmental and non-governmental committees have published recommendations concerning scientific, legal, ethical, cultural, and administrative issues facing vaccine development. This is a continuing process with ongoing fora within NIH and the Department of Defense among others. Consensus among the recommendations must be formed and the recommendations must expeditiously become policy to pave the way

Put at
end of
Residual

for widespread development, clinical testing, and use of prophylactic vaccines in the United States and other countries.

SERVICE

Goal: Continued and expanded access to quality mental and physical health services for people living with HIV/AIDS.

Action: ~~Encourage~~ the development and implementation of an affordable universal health insurance plan which will provide coverage for HIV/AIDS related physical and mental health services, including substance abuse treatment.

Commentary: Populations that traditionally have had little or no access to health care have been disproportionately impacted by the epidemic. This lack of access may be due to reasons of finance or to actual and perceived discrimination. By providing a universal health care plan, the nation will be better able to address the needs of people living with HIV/AIDS.

Action: Encourage individuals to ascertain their HIV status and ensure appropriate linkages to treatment and services are available for those who test positive.

Commentary: Many individuals living with HIV are not aware of their serostatus. Counseling and testing programs must include outreach to individuals ~~that~~ may engage in high risk behavior to encourage them to ascertain their HIV status. Counseling and testing activities must encourage individuals to obtain their test results, reinforce safer behavioral practices, and provide adequate referral mechanisms including treatment providers.

Action: Work with Congress, agencies of the Public Health Service, constituent groups, and members of affected communities to ensure continuation of the Ryan White Comprehensive AIDS Resources Emergency Act and other federal programs which provide HIV/AIDS services to ensure that they continue to meet the care needs of the HIV/AIDS community.

Action: Expand the availability of quality mental and physical health services for people living with HIV/AIDS.

Commentary: People living with HIV/AIDS are often unable to obtain services in many communities, particularly in some rural

areas where they may be required to travel many miles. Much of the care needed by people living with HIV/AIDS infection is basic care which could be provided by family physicians, home health care aides, family members, or other community-based service providers. However, treatment guidelines, adequate information, and training must be provided to those practitioners if they are to provide those services.

Action: Identify barriers to the availability of mental and physical health services, coordinate with appropriate agencies, community service organizations, constituent groups, people living with HIV/AIDS, and providers to remove those barriers.

Commentary: Because of limited access to care, many individuals only obtain acute care services in emergency situations. It is critical that HIV/AIDS-related services provide outreach to individuals and populations that may be difficult to reach through the traditional public health model. It is critical that in the creation of service delivery models, people living with HIV participate in program design and implementation.

Action: Encourage development and implementation of effective evaluation methodologies for service delivery programs and for comprehensive networks of service delivery.

Commentary: In developing service delivery models, the planners must include evaluation methodologies that are capable of determining whether the programs are providing adequate access and care. Federal agencies coordinating service delivery nationally must encourage system-wide evaluation of service delivery networks and individual programs.

Action: Encourage development of appropriate information dissemination mechanisms which facilitate rapid transfer of research findings, new clinical information, and appropriate educational material to public and private providers of care services.

Action: Ensure that care guidelines and other such materials are kept current and incorporate, at the earliest possible time, changes in the state of the art.

Action: ^{all} Encourage appropriate agencies, organizations, and institutions to provide HIV/AIDS training to providers both public and private.

Commentary: Because people living with HIV/AIDS and their families experience the disease and its effects in an almost infinite variety of ways, service needs are multiple and diverse. In many communities, dramatic and innovative ideas have emerged which, if disseminated and supported, could make an enormous difference.

Goal: People living with HIV/AIDS as well as people and families affected by HIV have access to a wide array of community and supportive (or enabling) services.

Action: At national, state, and local levels, promote coordination of community groups, acute care facilities, state and local governments, private funders, and others that are providing HIV/AIDS-related services to ensure that a comprehensive continuum of care and services are available and accessible.

Action: Stimulate and encourage appropriate agencies to develop helpful materials describing available services so families and individuals affected by HIV/AIDS will be empowered to access them.

Action: Encourage enforcement of prohibitions against discrimination in health care settings and encourage the creation of new protections to ensure access to care for people living with HIV/AIDS.

Action: Encourage appropriate agencies and governments to coordinate and link health care and supportive services (e.g., primary care, substance abuse, clinical trials, and HIV-related care).

Goal: That treatment protocols and supportive service needs unique to minorities, women, adolescents, and children receive appropriate consideration in the planning, development, and implementation of all service-related activities.

Action: Identify the components of programs to address the unique health care and supportive service needs of minorities, women, adolescents, and

children living with or affected by HIV/AIDS, and work with appropriate agencies to incorporate these elements into relevant programs.

Commentary: Lack of access, common to all populations disproportionately impacted by HIV/AIDS, is more critical among populations that have either lacked resources or been subjected to discrimination. In developing and implementing service delivery programs, the needs of these populations must be addressed, and, where necessary, additional resources must be applied.

Goal: Updated information on HIV/AIDS management is communicated internationally.

Commentary: In many countries, current treatments are unfamiliar to local providers. Using information dissemination techniques, information on diagnosis, treatment, and prevention can be communicated around the globe rapidly and in a cost effective manner.

Action: Working through the United Nations-sponsored HIV/AIDS program, disseminate the AIDS Education and Training Center program as a model for updated training in HIV management.

Action: Expand the state-of-the-art clinical conference call to include all aspects of HIV/AIDS management.

Action: Develop a mechanism for the continuous involvement of international private voluntary organizations (PVOs) and AIDS service organizations (ASOs) with policy processes.

Commentary: The PVOs and ASOs represent ongoing projects relating to all aspects of HIV/AIDS throughout the world. Their insights into the practical aspects of the epidemic can provide crucial information for policy development.

Action: Initiate a global issues and policy advisory board *representing all which includes govt & private US orgs. involved in global AIDS science*

PREVENTION

Goal: Educational programs, activities, and campaigns that provide accurate and timely information to all Americans on how to prevent HIV transmission.

Commentary: National prevention campaigns and local community programs must deliver a consistent prevention message overall if they are to be effective.

Action: Encourage development and implementation of an affordable health insurance plan that would provide coverage for HIV prevention counseling for disenfranchised populations.

PH infrastructure

Action: Develop a continuum of HIV prevention services.

Commentary: Prevention programs must provide ^{both} individual-level interventions and large scale community-level interventions. Although more individuals are being tested today than were a few years ago, counseling and testing programs alone are not reaching those most at risk and are not bringing about the behavior changes necessary to stop transmission. To this end, programs and messages must be aimed at the individuals at high risk for infection. Counseling and testing activities can continue to be used as a diagnostic tool with continued counseling on prevention intervention and any necessary treatment.

Action: Develop consistent prevention education messages to be used in HIV prevention programs at the national, regional, state, and local levels.

Commentary: Where research findings are available regarding risky behavior, they should be used in the development of linguistically specific, developmentally appropriate, and culturally-based prevention messages that speak of abstinence or sexual activity within a long term ^{monogamous} relationship as the surest way of preventing transmission, but also encourage safer sexual and substance-use practices for individuals ~~who are sexually active or who continue to use substances.~~ *who continues risky behavior.*

Action: Work with the federal agencies ^{Continue} conducting prevention campaigns to sponsor targeted national media campaigns that will specifically address HIV prevention.

Commentary: National media campaigns demonstrate the leadership of the federal government in delivering targeted prevention messages to persons at risk for HIV infection.

Action: Encourage communities throughout the country to follow the federal government's lead and

carry the message of prevention to local populations at risk.

Action: Increase technical assistance from federal agencies to assist state and local governments and non-governmental organizations to develop targeted campaigns through community interventions and the media.

Commentary: To increase effectiveness, prevention messages must be population-specific. Therefore, they should be delivered through appropriate media and use language and imagery that most effectively communicates the message. Federal agencies engaging in HIV prevention activities should encourage state and local governments to provide targeted media campaigns and implement well-chosen community interventions.

Action: *and private resources*
Encourage businesses and media to participate in national and local efforts for HIV prevention by sponsoring campaigns and activities in local media and in places of business.

Goal: Community consultation routinely sought in the development and implementation of educational programs and campaigns.

Action: Develop and deliver prevention messages in an effective and appropriate manner for the intended audience.

Action: Target efforts to the needs of populations that may be particularly susceptible to HIV transmission: gay and bisexual men (including gay men of color), substance users, sexual and needle-sharing partners of substance users, and youth in high-risk situations (especially out-of-school and gay youth).

Commentary: *must*
Primary in this effort is prevention education for youth, both in and out of school. Messages/stress building self-esteem and self-sufficiency. To obtain the most effective community consultation, collaboration between governmental and non-governmental organizations will be encouraged at all levels. Federal funding agencies should increase technical assistance to encourage partnerships.

Action: Encourage the use of a representative process to determine the appropriate allocation of prevention resources at the local level.

Action: Continue the implementation of the community planning process and encourage state and local governments to expand the use of this representative process to set priorities at the state and local levels.

Goal: Early intervention information is provided to all those living with HIV.

Goes with Service

Action: Encourage coordination and collaboration among federal agencies, state and local governments, non-governmental organizations, and service providers to provide people living with HIV accurate and timely information about early intervention and preventing opportunistic infections.

Commentary: Requires increasing linkages from the counseling and testing facilities to service providers as well as greater coordination between prevention and other services at the local level.

Action: Provide service providers at all levels with the most current information on the prevention of opportunistic infections.

Commentary: Primary among the opportunistic infection concerns is the prevention of tuberculosis, which is posing greater threats to the HIV-affected community as well as the general population.

Action: Work with service providers to coordinate effort to prevent opportunistic infections, including tuberculosis.

Action: Develop and implement programs to train HIV service providers on ways to prevent opportunistic infections and coordinate efforts with tuberculosis elimination programs at all levels.

Commentary: More than a third of the current cases of AIDS are a product of the ongoing, companion epidemic of drug dependency and abuse. There is a shortage of effective treatment services and many barriers keep substance abusers from accessing the services which do exist. Of great concern are injecting drug users. While there is universal agreement an ideal solution lies in finding ways to interrupt injection--and that remains the long term commitment. However, minimizing transmission is the immediate problem.

Goal: An array of HIV preventive services available and accessible to substance abusers in treatment ^{or} on the streets.

Action: Coordinate activities and policies within the federal government such that the elements of the Public Health Service, the Office of National Drug Control Policy, and other involved entities work together toward a common goal of a drug-abuse-free and an AIDS-free society.

Action: Identify and develop methods to encourage the entry of all psychoactive drug dependent people, with particular attention to injecting drug users, into public or private treatment programs.

Action: Encourage utilization of new or sterile needles and syringes among injecting drug users who are unwilling or unable to utilize treatment or abstain from injecting practices.

Action: Initiate policy discussions and encourage study of the concept of "harm reduction" to broaden the policy alternatives available as the nation confronts the double and interrelated epidemics of drug dependency and HIV/AIDS.

Goal: A safe blood supply worldwide.

Commentary: This issue cuts across international boundaries and is amenable to increased blood screening, the use of deferral criteria for blood donors, and other efforts.

Action: Encourage implementation of the World Health Organization, Global Program on AIDS "Blood Safety Initiative."

Action: Include blood safety standards in all international service programs.

Goal: Comprehensive, continuing HIV prevention programs in military organizations around the world.

Action: Work closely with the Department of Defense to develop a comprehensive workplace HIV/AIDS education program for active duty service members, their dependents, and civilian employees.

Action: Expand prevention and education activities to reach all segments of the military communities on a regular basis.

Commentary: After developing and successfully integrating HIV/AIDS training for U.S. military personnel, the concept can be translated to foreign militaries, some of which have extremely high infection rates.

Action: Work with military organizations worldwide to implement HIV/AIDS education programs.

CROSS-CUTTING

INFORMATION DISSEMINATION

Goal: A national HIV/AIDS information dissemination system.

Commentary: All possible users of HIV/AIDS information should have access to the information they need and obtaining it should be easy. Implementation of an all-inclusive, easy access system can be developed with existing technologies and expertise. All AIDS information should be available to the public via a single telephone access number. Transfer among databases to the appropriate information system should be transparent to the user.

Action: Develop a technological, interdepartmental portal through which AIDS information can be disseminated.

Action: Establish a interdepartmental group to identify and discuss the issues and to establish a coordinated national HIV/AIDS information dissemination policy.

Action: Develop an AIDS information plan to be ^{followed} implemented by all agencies with HIV/AIDS information to disseminate.

Action: Provide a ^{federal} forum for community-based AIDS organizations and people affect by HIV/AIDS to express their informational needs and the problems they encounter in obtaining the needed information.

Action: Develop a training and technical assistance program for users of the national AIDS information system.

Bibliography

"1993 Survey of AIDS Medicines: Drugs and Vaccines in Development"; Pharmaceutical Manufacturers Association; 1993.

"AIDS An Expanding Tragedy"; National Commission on AIDS; June 1993.

"AIDS in Foreign Policy"; Kimberly Hamilton, The Washington Quarterly; Winter, 1994.

"AIDS and the Global Military"; Normal Miller, editor; AIDS and Society: International Research and Policy Bulletin 4; July/August 1993.

"AIDS Research at the NIH: A Critical Review"; Gonsalves, Gregg and Harrington, Mark, Treatment Action Group; July 1992.

"The AIDS Research Program of the National Institutes of Health"; Institute of Medicine, National Academy Press; 1991.

"AIDS in the World"; Jonathan Mann, J.M. Tarantola, and Thomas W. Netter, editors; Harvard University Press; 1992.

"America Living With AIDS"; National Commission on AIDS; September 1991.

"The Barbara McClintock Project to Cure AIDS"; McClintock Project Working Group; June 1993.

"Basic Research on HIV Infection: A Report From the Front"; Gonsalves, Gregg, Treatment Action Group; June 1993.

"Behavioral and Social Sciences and HIV/AIDS Epidemic"; National Commission on AIDS; July 1993.

"Bridging the Gap: A Workshop on HIV Treatment Information Dissemination"; Office of AIDS Research (OAR), National Institutes of Health (NIH), and the Health Resources and Services Administration (HRSA); February 1993.

"Briefing Paper, Clinton-Gore Transition Team"; Black Leadership Commission on AIDS; January 1993.

"The Challenge of HIV/AIDS in Communities of Color"; National Commission on AIDS; December 1992.

"The Crisis in Clinical AIDS Research"; Harrington, Mark, Treatment Action Group; December 1993.

"Emerging Infections: Microbial Threats to Health in the United States"; Institute of Medicine, National Academy Press; 1992.

"FDAR: The Madison Project (draft)"; The Harvard AIDS Institute, University of Wisconsin at Madison Medical Center and Project Inform; February 1994.

"The FY 1995 National Institutes of Health Plan for HIV-Related Research"; OAR/NIH; 1993.

"Federal AIDS Agenda '93"; Federal AIDS Agenda '93 Delegates; May 1993.

"Federal, State, and Local Responsibilities"; National Commission on AIDS; March 1990.

"The Global AIDS Disaster: Implications for the 1990s"; U.S. Department of State; July 1990.

"The HIV/AIDS Epidemic in Puerto Rico"; National Commission on AIDS; June 1992.

"The HIV/AIDS Pandemic: 1993 Overview"; World Health Organization, Global Programme on AIDS; 1993.

"Housing and the HIV Epidemic"; National Commission on AIDS; July 1992.

"How Foundations, Corporate America, and Government Can Work Together in the Fight Against AIDS/HIV"; Funders Concerned About AIDS; March 1993.

"The Human Immunodeficiency Virus Vaccine Challenge: Issues in Development and International Trials"; Committee on Life Sciences and Health, Federal Coordinating Council on Science, Engineering and Technology (FCCSET); July 1993.

"Investing in Health: World Development Report 1993"; World Bank; Oxford University Press; 1993.

"Leadership, Legislation, and Regulation"; National Commission on AIDS; April 1990.

"Mobilizing America's Response to AIDS: Recommendations to President Clinton"; National Commission on AIDS; January 1993.

"NIH Databook 1993"; NIH; September 1993.

"National Hispanic/Latino AIDS Agenda"; National Hispanic/Latino AIDS Coalition; June 1993.

"The NIH Revitalization Act of 1993"; Enacted June 10, 1993.

"Preventing HIV/AIDS in Adolescents"; National Commission on AIDS; June 1993.

"Proposal Preparation Kit"; Advanced Technology Program, National Institute of Standards and Technology, Technology Administration, U.S. Department of Commerce; February 1994.

"Putting People First: How We Can All Change America"; Governor Bill Clinton and Senator Al Gore; Random House, 1992.

"Social and Human Issues"; National Commission on AIDS; April 1991.

"Strategic Plan to Combat HIV & AIDS in the United States"; U.S. Public Health Service, Department of Health and Human Services; October 1992.

"The Twin Epidemics of Substance Abuse and HIV"; National Commission on AIDS; July 1991.

"Women and Health Research, Ethical and Legal Issues of Including Women in Clinical Studies"; Institute of Medicine, National Academy of Sciences; March 1994.

3-30- Version

On White House Letterhead

National HIV Action Agenda

April 1994

*See
highlights
Andrew*

INTRODUCTION

From the National AIDS Policy Coordinator

The National HIV Action Agenda is a leadership statement.

It has been developed by my staff in an attempt to give direction to the overall effort to end the HIV/AIDS epidemic; the epidemic some have called the health crisis of our times. This document is not all inclusive, and it is intended to be dynamic. The goals, the action steps described within provide guidance and markers for the nation. The action steps are activities the nation can begin within a six-month horizon. Many are long-term or continuous, while others are short-term or immediate.

As the nation's work progresses, the goals and the action steps will evolve. In the next iteration of the National HIV Action Agenda many of the immediate actions will have been replaced. Over time, new goals will be substituted for goals attained or goals no longer appropriate as the epidemic and our ability to respond to it continually change.

An implicit, unstated commitment underpins all the goals that are delineated in these pages. That is the commitment to provide the continuing national leadership necessary to end the epidemic. When President Clinton appointed me, he noted "AIDS is terrifying. It inflicts tragedy on too many families. But ultimately, it is a disease; one we can defeat...with commitment and courage and constancy, and with vocal and responsible leadership from our nation's government."¹

The National HIV Action Agenda is organized into three areas for action: research, service, and prevention. In the day-to-day work of addressing the epidemic, however, the distinction between the areas is often blurred. It is only by coordinating efforts in all the areas and by focusing on common goals that we optimize our chances of ending this epidemic. It is incumbent upon everyone to understand that this epidemic is a common problem and it will take a common effort to end it.

¹ Clinton, WJ. Remarks by the President in Announcement of Kristine M. Gebbie as AIDS Policy Coordinator. June 25, 1993.

In 1993, 103,500 cases of AIDS were reported nationally. It is estimated there are 40,000 to 60,000 new infections every year. In the United States, the virus has flourished in disenfranchised, disadvantaged, and marginalized populations. It has associated itself with behaviors that are illegal and behaviors that many consider provocative. By doing so, the virus itself has managed to dilute the nation's ability to coalesce in common purpose. This document attempts to bring the nation's attention to the real issues: What should we do? What can we do? Where do we go from here?

Also, as a member of the world community, the United States has a responsibility to join other countries in the international effort. Therefore, in the Action Agenda, international HIV/AIDS issues are an important part of the three primary areas of research, service, and prevention.

The arrangement of three primary areas is not meant to give special emphasis to one over another. Research findings are the foundation for action. The National HIV Action Agenda attempts to drive the nation to resolve questions of cure and prevention, of drugs and behavior, by suggesting steps to enhance the organization of the effort and to improve communications among researchers engaged in the effort, between researchers and care givers, and between researchers and the prevention effort.

Service action steps aspire to better ensure that people and families affected by HIV can receive the care and support they need, that effective therapies are available, and that the period between infection and disease manifestation is maximized.

In the prevention area the Action Agenda seeks to better focus efforts to interrupt transmission of the virus by improving the educational effort, improving the focus and enhancing efforts to reduce the risky behaviors associated with transmission, and by increasing the application of the science base in planning and program implementation.

Common purpose and collaboration require that everyone affected be given "a seat at the table." Throughout the document, specific action steps to facilitate cooperation and leadership are stated. That is, in the final analysis, the reason I have this job and why there is now a National Action Agenda.

Kristine M. Gebbie, RN, MN, FAAN
National AIDS Policy Coordinator

RESEARCH

Goal: National HIV/AIDS research strengthened through coordination, planning, and evaluation.

Commentary: Billions of dollars are invested annually in the United States and abroad in an effort to further development of safe, effective therapeutics, prophylactic vaccines, and improved methodologies to reduce risky behaviors. Nevertheless, the challenges still to be faced by research into the Human Immunodeficiency Virus (HIV) disease and the Acquired Immune Deficiency Syndrome (AIDS) are profound. While progress has been made in many areas, there has been a recent lack of significant clinical advances in the treatment and prevention of the underlying disease. Given the scope of the scientific questions still unanswered, and the dimensions of the growing pandemic, there is a great need to search for creative ways to maximize public and private resources.

Action: Implement, as necessary, new formal planning linkages between federal agencies and departments engaged in HIV/AIDS biomedical or behavioral research, based on agencies' complementary research agenda and portfolios.

Commentary: Federal AIDS research programs have undergone continual evaluation and evolution since the beginning of the epidemic. The pace of evaluation and reform has accelerated significantly in the last year. Very likely, the next year will bring even closer scrutiny and intense public debate of the complex scientific, administrative, regulatory, legal, and ethical challenges and opportunities facing HIV/AIDS research today. Within the federal government, many agencies plan and budget HIV/AIDS research programs independently of one another, and current communications systems between researchers in the public and private sectors may not allow for sufficient timely coordination. Mechanisms for communications and planning must be fully evaluated and improved to maximize efficiency.

Action: Seek expeditious and full implementation of the National Institutes of Health (NIH) AIDS research program reforms provided in the NIH Revitalization Act of 1993.

Commentary: The Office of AIDS Research (OAR) of the NIH has been strengthened with centralized evaluation, planning, and budgeting authorities across all institutes of the NIH. While the intent of the legislation is clear, it is important that the

interpretation of the provisions of the Act be carefully monitored.

Action: Develop strong linkages between federally chartered advisory committees to coordinate development of complementary national HIV/AIDS research policies.

Commentary: The Office of AIDS Research (OAR) Advisory Council, the National Task Force on AIDS Drug Development, the Presidential HIV/AIDS Advisory Council and other advisory bodies will be critical for providing recommendations and input into the evolving national AIDS agenda; their independent policy deliberations must be coordinated.

Action: Ensure strong support for the role of behavioral and social science research related to biomedical research, treatment regimens (e.g., substance abuse treatment), and as the scientific basis for sound prevention programs.

Commentary: Findings from behavioral and social science research are critical to the control of the epidemic through the successful administration of prevention, research and treatment programs. This research, which has often been overlooked, must receive strong support, and findings from this research must be fully integrated into programs.

Action: Work with HIV/AIDS-affected communities and federal agencies to assure that the unique social and physiological characteristics of all HIV-affected populations are taken into consideration in the design of clinical trials and other research programs.

Commentary: Women, children, adolescents, ethnic and racial minority groups, injecting drug users, gay and bisexual men, lesbians and bisexual women and others have unique needs that should be accommodated both through appropriate inclusion in clinical trials and the conduct of trials specifically designed to address their needs.

Goal: Government, industry, academia, and community attention focused on promising, innovative proposals that could expedite the discovery of new therapeutics for HIV/AIDS and build consensus toward potential solutions.

Commentary: The National Task Force on AIDS Drug Development, recently chartered by the Secretary of Health and Human Services

and the National AIDS Policy Coordinator, has been formed to identify obstacles and opportunities in HIV/AIDS drug discovery. The work of this task force must be strongly supported, with prompt response to its requests for information and recommendations for action. Additionally, other federal and private agencies should continue to evaluate programs and policies affecting HIV/AIDS drug development.

Action: Identify regulatory and legal obstacles to research collaboration among federal agencies and non-governmental entities.

Commentary: Technology transfer, the Cooperative Research and Development Agreement (CRADA), liability, patent issues, and drug pricing have been identified as potential obstacles or disincentives to AIDS research collaboration and investment. Working with the National Task Force on AIDS Drug Development, appropriate governmental and private sector groups must develop reforms to address these and related issues.

Goal: Domestic research planning and priority-setting integrated with international efforts.

Action: Explore mechanisms for increased international collaboration.

Commentary: Research activities cannot be viewed from a strictly national perspective. Working with U.S. and internationally-convened fora, public and private HIV/AIDS research programs should be evaluated to improve mechanisms for communication and collaboration to increase efficiency and productivity.

Goal: Obstacles to the development of an HIV/AIDS prophylactic vaccine identified and removed.

Action: Utilizing existing reports and ongoing discussions, develop consensus and, when appropriate, design and implement legislative or administrative solutions to address the obstacles to vaccine development.

Commentary: A number of governmental and non-governmental committees have published recommendations concerning scientific, legal, ethical, cultural, and administrative issues facing vaccine development. This is a continuing process with ongoing fora within NIH and the Department of Defense among others. Consensus among the recommendations must be formed and the recommendations must expeditiously become policy to pave the way

for widespread development, clinical testing, and use of prophylactic vaccines in the United States and other countries.

SERVICE

Goal: Continued and expanded access to quality mental and physical health services for people living with HIV/AIDS.

Action: Encourage the development and implementation of an affordable universal health insurance plan which will provide coverage for HIV/AIDS related physical and mental health services, including substance abuse treatment.

Commentary: Populations that traditionally have had little or no access to health care have been disproportionately impacted by the epidemic. This lack of access may be due to reasons of finance or to actual and perceived discrimination. By providing a universal health care plan, the nation will be better able to address the needs of people living with HIV/AIDS.

Action: Encourage individuals to ascertain their HIV status and ensure appropriate linkages to treatment and services are available for those who test positive.

Commentary: Many individuals living with HIV are not aware of their serostatus. Counseling and testing programs must include outreach to individuals that may engage in high risk behavior to encourage them to ascertain their HIV status. Counseling and testing activities must encourage individuals to obtain their test results, reinforce safer behavioral practices, and provide adequate referral mechanisms including treatment providers.

Action: Work with Congress, agencies of the Public Health Service, constituent groups, and members of affected communities to ensure continuation of the Ryan White Comprehensive AIDS Resources Emergency Act and other federal programs which provide HIV/AIDS services to ensure that they continue to meet the care needs of the HIV/AIDS community.

Action: Expand the availability of quality mental and physical health services for people living with HIV/AIDS.

Commentary: People living with HIV/AIDS are often unable to obtain services in many communities, particularly in some rural

areas where they may be required to travel many miles. Much of the care needed by people living with HIV/AIDS infection is basic care which could be provided by family physicians, home health care aides, family members, or other community-based service providers. However, treatment guidelines, adequate information, and training must be provided to those practitioners if they are to provide those services.

Action: Identify barriers to the availability of mental and physical health services, coordinate with appropriate agencies, community service organizations, constituent groups, people living with HIV/AIDS, and providers to remove those barriers.

Commentary: Because of limited access to care, many individuals only obtain acute care services in emergency situations. It is critical that HIV/AIDS-related services provide outreach to individuals and populations that may be difficult to reach, such as the homeless, through the traditional public health model. It is critical that in the creation of service delivery models, people living with HIV participate in program design and implementation.

Action: Encourage development and implementation of effective evaluation methodologies for service delivery programs and for comprehensive networks of service delivery.

Commentary: In developing service delivery models, the planners must include evaluation methodologies that are capable of determining whether the programs are providing adequate access and care. Federal agencies coordinating service delivery nationally must encourage system-wide evaluation of service delivery networks and individual programs.

Action: Encourage development of appropriate information dissemination mechanisms which facilitate rapid transfer of research findings, new clinical information, and appropriate educational material to public and private providers of care services.

Action: Ensure that care guidelines and other such materials are kept current and incorporate, at the earliest possible time, changes in the state of the art.

Action: Encourage appropriate agencies, organizations, and institutions to provide HIV/AIDS training to providers both public and private.

Commentary: Because people living with HIV/AIDS and their families experience the disease and its effects in an almost infinite variety of ways, service needs are multiple and diverse. In many communities, dramatic and innovative ideas have emerged which, if disseminated and supported, could make an enormous difference.

Goal: People living with HIV/AIDS as well as people and families affected by HIV have access to a wide array of community and supportive (or enabling) services.

Action: At national, state, and local levels, promote coordination of community groups, acute care facilities, state and local governments, private funders, and others that are providing HIV/AIDS-related services to ensure that a comprehensive continuum of care and services are available and accessible.

Action: Stimulate and encourage appropriate agencies to develop helpful materials describing available services so families and individuals affected by HIV/AIDS will be empowered to access them.

Action: Encourage enforcement of prohibitions against discrimination in health care settings and encourage the creation of new protections to ensure access to care for people living with HIV/AIDS.

Action: Encourage appropriate agencies and governments to coordinate and link health care and supportive services (e.g., primary care, substance abuse, clinical trials, and HIV-related care).

Goal: That treatment protocols and supportive service needs unique to minorities, women, adolescents, and children receive appropriate consideration in the planning, development, and implementation of all service-related activities.

Action: Identify the components of programs to address the unique health care and supportive service needs of minorities, women, adolescents, and

children living with or affected by HIV/AIDS, and work with appropriate agencies to incorporate these elements into relevant programs.

Commentary: Lack of access, common to all populations disproportionately impacted by HIV/AIDS, is more critical among populations that have either lacked resources or been subjected to discrimination. In developing and implementing service delivery programs, the needs of these populations must be addressed, and, where necessary, additional resources must be applied.

Goal: Updated information on HIV/AIDS management is communicated internationally.

Commentary: In many countries, current treatments are unfamiliar to local providers. Using information dissemination techniques, information on diagnosis, treatment, and prevention can be communicated around the globe rapidly and in a cost effective manner.

Action: Working through the United Nations-sponsored HIV/AIDS program, disseminate the AIDS Education and Training Center program as a model for updated training in HIV management.

Action: Expand the state-of-the-art clinical conference call to include all aspects of HIV/AIDS management.

Action: Develop a mechanism for the continuous involvement of international private voluntary organizations (PVOs) and AIDS service organizations (ASOs) with policy processes.

Commentary: The PVOs and ASOs represent ongoing projects relating to all aspects of HIV/AIDS throughout the world. Their insights into the practical aspects of the epidemic can provide crucial information for policy development.

Action: Initiate a global issues and policy advisory board.

PREVENTION

Goal: Educational programs, activities, and campaigns that provide accurate and timely information to all Americans on how to prevent HIV transmission.

Commentary: National prevention campaigns and local community programs must deliver a consistent prevention message overall if they are to be effective.

Action: Encourage development and implementation of an affordable health insurance plan that would provide coverage for HIV prevention counseling for disenfranchised populations.

Action: Develop a continuum of HIV prevention services.

Commentary: Prevention programs must provide individual-level interventions and large scale community-level interventions. Although more individuals are being tested today than were a few years ago, counseling and testing programs alone are not reaching those most at risk and are not bringing about the behavior changes necessary to stop transmission. To this end, programs and messages must be aimed at the individuals at high risk for infection. Counseling and testing activities can continue to be used as a diagnostic tool with continued counseling on prevention intervention and any necessary treatment.

Action: Develop consistent prevention education messages to be used in HIV prevention programs at the national, regional, state, and local levels.

Commentary: Where research findings are available regarding risky behavior, they should be used in the development of linguistically specific, developmentally appropriate, and culturally-based prevention messages that speak of abstinence or sexual activity within a long term monogamous, committed relationship as the surest way of preventing transmission, but also encourage safer sexual and substance-use practices for individuals who are sexually active or who continue to use substances.

Action: Work with the federal agencies conducting prevention campaigns to sponsor targeted national media campaigns that will specifically address HIV prevention.

Commentary: National media campaigns demonstrate the leadership of the federal government in delivering targeted prevention messages to persons at risk for HIV infection.

Action: Encourage communities throughout the country to follow the federal government's lead and

carry the message of prevention to local populations at risk.

Action: Increase technical assistance from federal agencies to assist state and local governments and non-governmental organizations to develop targeted campaigns through community interventions and the media.

Commentary: To increase effectiveness, prevention messages must be population-specific. Therefore, they should be delivered through appropriate media and use language and imagery that most effectively communicates the message. Federal agencies engaging in HIV prevention activities should encourage state and local governments to provide targeted media campaigns and implement well-chosen community interventions.

Action: Encourage businesses and media to participate in national and local efforts for HIV prevention by sponsoring campaigns and activities in local media and in places of business.

Goal: Community consultation routinely sought in the development and implementation of educational programs and campaigns.

Action: Develop and deliver prevention messages in an effective and appropriate manner for the intended audience.

Action: Target efforts to the needs of populations that may be particularly susceptible to HIV transmission: gay and bisexual men (including gay men of color), substance users, sexual and needle-sharing partners of substance users, and youth in high-risk situations (especially out-of-school and gay youth).

Commentary: Primary in this effort is prevention education for youth, both in and out of school. Messages stress building self-esteem and self-sufficiency. To obtain the most effective community consultation, collaboration between governmental and non-governmental organizations will be encouraged at all levels. Federal funding agencies should increase technical assistance to encourage partnerships.

Action: Encourage the use of a representative process to determine the appropriate allocation of prevention resources at the local level.

Action: Continue the implementation of the community planning process and encourage state and local governments to expand the use of this representative process to set priorities at the state and local levels.

Goal: Early intervention information is provided to all those living with HIV.

Action: Encourage coordination and collaboration among federal agencies, state and local governments, non-governmental organizations, and service providers to provide people living with HIV accurate and timely information about early intervention and preventing opportunistic infections.

Commentary: Requires increasing linkages from the counseling and testing facilities to service providers as well as greater coordination between prevention and other services at the local level.

Action: Provide service providers at all levels with the most current information on the prevention of opportunistic infections.

Commentary: Primary among the opportunistic infection concerns is the prevention of tuberculosis, which is posing greater threats to the HIV-affected community.

Action: Work with service providers to coordinate effort to prevent opportunistic infections, including tuberculosis.

Action: Develop and implement programs to train HIV service providers on ways to prevent opportunistic infections and coordinate efforts with tuberculosis elimination programs at all levels.

Commentary: More than a third of the current cases of AIDS are a product of the ongoing, companion epidemic of drug dependency and abuse. There is a shortage of effective treatment services and many barriers keep substance abusers from accessing the services which do exist. Of great concern are injecting drug users. While there is universal agreement an ideal solution lies in finding ways to interrupt injection--and that remains the long term commitment. However, minimizing transmission is the immediate problem.

Goal: An array of HIV preventive services available and accessible to substance abusers in treatment on the streets.

Action: Coordinate activities and policies within the federal government such that the elements of the Public Health Service, the Office of National Drug Control Policy, and other involved entities work together toward a common goal of a drug-abuse-free and an AIDS-free society.

Action: Identify and develop methods to encourage the entry of all psychoactive drug dependent people, with particular attention to injecting drug users, into public or private treatment programs.

Action: Encourage utilization of new or sterile needles and syringes among injecting drug users who are unwilling or unable to utilize treatment or abstain from injecting practices.

Action: Initiate policy discussions and encourage study of the concept of "harm reduction" to broaden the policy alternatives available as the nation confronts the double and interrelated epidemics of drug dependency and HIV/AIDS.

Goal: A safe blood supply worldwide.

Commentary: This issue cuts across international boundaries and is amenable to increased blood screening, the use of deferral criteria for blood donors, and other efforts.

Action: Encourage implementation of the World Health Organization, Global Program on AIDS "Blood Safety Initiative."

Action: Include blood safety standards in all international service programs.

Goal: Comprehensive, continuing HIV prevention programs in military organizations around the world.

Action: Work closely with the Department of Defense to develop a comprehensive workplace HIV/AIDS education program for active duty service members, their dependents, and civilian employees.

Action: Expand prevention and education activities to reach all segments of the military communities on a regular basis.

Commentary: After developing and successfully integrating HIV/AIDS training for U.S. military personnel, the concept can be translated to foreign militaries, some of which have extremely high infection rates.

Action: Work with military organizations worldwide to implement HIV/AIDS education programs.

CROSS-CUTTING

INFORMATION DISSEMINATION

Goal: A national HIV/AIDS information dissemination system.

Commentary: All possible users of HIV/AIDS information should have access to the information they need and obtaining it should be easy. Implementation of an all-inclusive, easy access system can be developed with existing technologies and expertise. All AIDS information should be available to the public via a single telephone access number. Transfer among databases to the appropriate information system should be transparent to the user.

Action: Develop a technological, interdepartmental portal through which AIDS information can be disseminated.

Action: Establish a interdepartmental group to identify and discuss the issues and to establish a coordinated national HIV/AIDS information dissemination policy.

Action: Develop an AIDS information plan to be implemented by all agencies with HIV/AIDS information to disseminate.

Action: Provide a forum for community-based AIDS organizations and people affect by HIV/AIDS to express their informational needs and the problems they encounter in obtaining the needed information.

Action: Develop a training and technical assistance program for users of the national AIDS information system.

Bibliography

"1993 Survey of AIDS Medicines: Drugs and Vaccines in Development"; Pharmaceutical Manufacturers Association; 1993.

"AIDS An Expanding Tragedy"; National Commission on AIDS; June 1993.

"AIDS in Foreign Policy"; Kimberly Hamilton, The Washington Quarterly; Winter, 1994.

"AIDS and the Global Military"; Normal Miller, editor; AIDS and Society: International Research and Policy Bulletin 4; July/August 1993.

"AIDS Research at the NIH: A Critical Review"; Gonsalves, Gregg and Harrington, Mark, Treatment Action Group; July 1992.

"The AIDS Research Program of the National Institutes of Health"; Institute of Medicine, National Academy Press; 1991.

"AIDS in the World"; Jonathan Mann, J.M. Tarantola, and Thomas W. Netter, editors; Harvard University Press; 1992.

"America Living With AIDS"; National Commission on AIDS; September 1991.

"The Barbara McClintock Project to Cure AIDS"; McClintock Project Working Group; June 1993.

"Basic Research on HIV Infection: A Report From the Front"; Gonsalves, Gregg, Treatment Action Group; June 1993.

"Behavioral and Social Sciences and HIV/AIDS Epidemic"; National Commission on AIDS; July 1993.

"Bridging the Gap: A Workshop on HIV Treatment Information Dissemination"; Office of AIDS Research (OAR), National Institutes of Health (NIH), and the Health Resources and Services Administration (HRSA); February 1993.

"Briefing Paper, Clinton-Gore Transition Team"; Black Leadership Commission on AIDS; January 1993.

"The Challenge of HIV/AIDS in Communities of Color"; National Commission on AIDS; December 1992.

"The Crisis in Clinical AIDS Research"; Harrington, Mark, Treatment Action Group; December 1993.

"Emerging Infections: Microbial Threats to Health in the United States"; Institute of Medicine, National Academy Press; 1992.

"FDAR: The Madison Project (draft)"; The Harvard AIDS Institute, University of Wisconsin at Madison Medical Center and Project Inform; February 1994.

"The FY 1995 National Institutes of Health Plan for HIV-Related Research"; OAR/NIH; 1993.

"Federal AIDS Agenda '93"; Federal AIDS Agenda '93 Delegates; May 1993.

"Federal, State, and Local Responsibilities"; National Commission on AIDS; March 1990.

"The Global AIDS Disaster: Implications for the 1990s"; U.S. Department of State; July 1990.

"The HIV/AIDS Epidemic in Puerto Rico"; National Commission on AIDS; June 1992.

"The HIV/AIDS Pandemic: 1993 Overview"; World Health Organization, Global Programme on AIDS; 1993.

"Housing and the HIV Epidemic"; National Commission on AIDS; July 1992.

"How Foundations, Corporate America, and Government Can Work Together in the Fight Against AIDS/HIV"; Funders Concerned About AIDS; March 1993.

"The Human Immunodeficiency Virus Vaccine Challenge: Issues in Development and International Trials"; Committee on Life Sciences and Health, Federal Coordinating Council on Science, Engineering and Technology (FCCSET); July 1993.

"Investing in Health: World Development Report 1993"; World Bank; Oxford University Press; 1993.

"Leadership, Legislation, and Regulation"; National Commission on AIDS; April 1990.

"Mobilizing America's Response to AIDS: Recommendations to President Clinton"; National Commission on AIDS; January 1993.

"NIH Databook 1993"; NIH; September 1993.

"National Hispanic/Latino AIDS Agenda"; National Hispanic/Latino AIDS Coalition; June 1993.

"The NIH Revitalization Act of 1993"; Enacted June 10, 1993.

"Preventing HIV/AIDS in Adolescents"; National Commission on AIDS; June 1993.

"Proposal Preparation Kit"; Advanced Technology Program, National Institute of Standards and Technology, Technology Administration, U.S. Department of Commerce; February 1994.

"Putting People First: How We Can All Change America"; Governor Bill Clinton and Senator Al Gore; Random House, 1992.

"Social and Human Issues"; National Commission on AIDS; April 1991.

"Strategic Plan to Combat HIV & AIDS in the United States"; U.S. Public Health Service, Department of Health and Human Services; October 1992.

"The Twin Epidemics of Substance Abuse and HIV"; National Commission on AIDS; July 1991.

"Women and Health Research, Ethical and Legal Issues of Including Women in Clinical Studies"; Institute of Medicine, National Academy of Sciences; March 1994.

Plan to Develop
NATIONAL PLAN TO COMBAT HIV AND AIDS

- I. Basic tenets (extracted from prior recommendations)
 - A. Commission recommendations to be beginning
 - 1. Collate by subject
 - a. Use "America Living with AIDS" as template
 - b. Add major topics, as needed
 - B. Add recommendations from other plans into the template
 - 1. NMAC, Minority concerns
 - 2. ACT UP "Manhattan plan"
- II. Establish a small planning group
- III. Assemble a Task Force
 - A. Include federal departments, PHS agencies
 - B. Include ONAC Policy Group team leaders
 - C. Include
 - 1. State and local government (NASTAD, ASTHO?, USCM?)
 - 2. Non-governmental organizations
 - a. CBOs
 - b. National Commission
 - 3. Germane working advisory groups
- IV. Kick off meeting
 - A. Presidential charge
 - 1. Optimal, realistic
 - 2. Date report expected
 - 3. Weekly reports required
 - B. Where we are
 - C. Where we are going
 - D. Elements of the plan
 - E. Create work groups (subcommittees)
- V. Work groups, task force process
 - A. Biweekly meetings of task force (use telephone "conferencing")
 - B. Work groups develop documents
 - 1. First draft--TB did it in 3 months
 - a. Use Bulletin Board, "ForComment"
 - (1) Allows everyone in workgroup to see all comments
 - (2) Allow ONAP planners to see comments and monitor progress
 - b. An 800 number
 - 2. Review by task force and revise (probably multiple times)
 - C. Weekly updates to National Policy Coordinator
 - 1. Every second "Update" will include task force summary--minutes--we will need someone to take notes
 - 2. Purposes
 - a. To keep Coordinator informed
 - b. To keep task force and work groups motivated, and on track
- VI. National closure meeting
 - A. Distribute draft for public comment
 - B. "The Challenge"
 - 1. Presentations by work groups
 - 2. Celebration
- VII. Time lines to consider
 - A. Kick off meeting, before Thanksgiving
 - B. First Draft, mid-February
 - C. Public comment period, 60 days
 - D. Final, end of June

Status Report 1--DRAFT

PRESIDENT'S ACTION PLAN
For HIV and AIDS

Note: throughout this report names in bracket indicate an assignment, commitment, or request of someone. If your name is associated with something, please let me know if that is a problem. More importantly, if you see something that you can do, please say something. I need all the help I can get.

1. The name of the project is above, but it is not yet chiseled in stone. Comments and suggestions are welcome, but please note a couple of characteristics of the name that we think are important. "President's plan," puts it a certain perspective. It specifically addresses HIV **and** AIDS. "Action plan" is meant to convey this is implementation. The purpose of the exercise is to set the national priorities and state how and by whom the priority will be addressed (dispatched?). A possible format for the final report is attached for comment. If anyone has a better idea, we would like to hear it as soon as possible. (Please note that it is a WordPerfect Document. Because it contains graphics, it would not reproduce true in the cc:Mail environment. If you need a hard copy, please see me.)

2. Currently all the recommendations issued by the National Commission on AIDS have been collated into four subject areas: prevention and education, caring for people with HIV disease, research, and government responsibilities. (These documents are attached, and, because of their length, are also WordPerfect documents. Again, if you need a hard copy, please let me know.)

As you review these documents, questions you might want to consider are: are the Commission's individual recommendations in the right subject area? Should there be additional subject areas? Bear in mind that the Commission's comprehensive report, "America Living with AIDS" had only five subject areas. We eliminated one subject area, "health care financing," and have included the relevant recommendations under "government responsibilities."

Current thought is that these subjects areas will be the areas around which work groups (see below) will form. The need to keep the number of workgroups manageable is an important consideration, but the need to have the right subjects addressed adequately is more important.

Referring to the subject area documents, recommendations from other groups will be added to these documents. The following will be abstracted (the name in brackets is the person who will obtain a copy of the report):

National Hispanic/Latino AIDS Agenda [Bob]

The Barbara M'Clintock Project to Cure AIDS [Bob]

SAMHSA [Buck]
HRSA [Does anyone have a copy?]
CDC [Bob]
Lambda Defense [Art]
NORA [Buck]
Funders Concerned About AIDS [Buck]
AIDS Action Council [Carlos]
Office of AIDS Research [Jo]

Unless someone feels strongly otherwise, this should be pretty representative. In the letters we will draft to the other Departments (see below), we will also request written plans they may have. [Sandy, we will need some typing support include those recommendations into the existing documents. Because we have some of those plans in hand, we need support right away. Can you assign some one to work with Bob?]

4. We will prepare [Bob] a letter to the Department Secretaries. The content will be something like, the President has asked us to move ahead in preparing his national plan to address the HIV/AIDS epidemic.... we will be asking you for input and support in the development of the plan.... please designate a person who reports to you to represent you in this undertaking.... [and] do you have a written plan....

This letter will also describe the process and announce the date for a "kick off" meeting (see below).

5. With our meeting of October 6 we have established a "planning staff." This is basically an in-house group that will address process issues, not the content of the plan. This "planning staff" is not exclusive. Future meetings will be announced. We appreciate that other commitments may preclude someone's attendance. We will continually try to provide enough information to ensure that you are current.

Also, we will be producing a diagram of the relationships and links to the various entities (see below) that will be involved with the plan. [Bob, Carlos, Art]

6. To take overall responsibility for monitoring the content and progress in developing the plan, we will form a task force. On this task force, there will be representatives from the federal departments and PHS agencies, ONAPC policy groups, state and local governments, non-governmental organizations, germane working or advisory groups, the National Commission, and (if there are not prohibitions) Congress. [Who is determining if Congressional staff involvement is appropriate?]

The task force, as you can see, will be quite large. We intend to use "teleconferencing" technology to convene it every two weeks. The "real work" of developing the plan will be done in work groups (see below).

7. Sometime before Thanksgiving, there will be a "kick off" meeting. **[Sandy M., Bob, Contractor]** This will as all inclusive as possible. There will be about 150 in attendance. Highlights of this meeting will include a Presidential charge. **[Buck? Ben? John?]** Elements of the charge we would like to see would be, that the plan be optimal, but realistic, a deadline, and a request for progress reports--every two weeks.

Another highlight will be the inclusion of high government officials. Of particular interest are the Secretaries of Education and HHS, the Attorney General, and the Coordinator. **[Ben?? John??]**

Another highlight will be an announcement **[Kristine]** that the Coordinator and ONAPC will not be standing still while the planning process unfolds. An action agenda will be announced during the Coordinator's presentation (see below): "During the period we are developing the President plan, my office will be doing the following X-number of things...." **[All]**

Still another highlight will be our attempt to have the first session of this meeting--the President charge, presentations by top government officials--at the White House. **[Buck will check White House calendar: availability of space, participation of the President--we need this information ASAP, as other arrangements will be made around this.]** Preferred dates are (best) November 30, December 1, and 2--the week after Thanksgiving, (2nd best) December 7, 8, and 9--second week after Thanksgiving, and (3rd best) November 16, 17, and 18--that is the week before Thanksgiving. The meeting will be two and a half days, ending around noon.

The opening session will also include a presentation by the Coordinator describing where we are and where we are going. Also another presentation--which could be folder into the Coordinator's presentation--about the elements of the plan, where each work group will meet, the co-chairpersons of the work groups (one government, one non-government), and an agenda for the work groups.

After the opening session, the participants will break out into their respective work groups (as of this moment, 4 groups). The details of the logistics for these meeting **[Sandy M., Bob]** will follow in a separate communication. An agenda for these meetings **[Bob]** will also follow in a separate communication.

8. The work groups will develop the documents. We will be ask for a first draft in three months (i.e., end of February).

To facilitate the drafting, we will make our technology--particularly our ability to provide a "virtual office"--available **[Vesta]**. There will be an 800 number **[Vesta, Sandy B.]** We envision a one, two, or three people from each work group to do the drafting, to make it available to entire work groups via our

(ONAPC) technology for comment. What we expect to receive from the work groups are consensus documents.

The use of ONAPC technology by the work groups, will also allow ONAPC [Bob] to monitor the process and progress.

The drafts will be presented to the entire task force for review, and revised. We anticipate several revisions at this point. Again, the objective is a national consensus.

9. Products: The task force is intended to be a more or less permanent body. As noted above, it will meet every two weeks. After overseeing the development of the plan, it will monitor the implementation and lead the revisions (see below). ONAPC will chair the meetings of the task force. [Bob? Art? George? Other?]. [Sandy B., we will need someone to take notes, produce minutes, get a draft out to the membership quickly, revise per the comments, and get a final out to participants--ideally, we would have a final minutes out in less than two weeks.]

Status reports will be produced every two weeks. Minutes from the task force meetings will be the heart of these reports. They will be augmented with additional information relevant to the plan or the process of developing the plan, to be determined as the situation evolves.

The purpose of the status report is two fold. First, it will serve to keep the work groups and task force focused and motivated. Second, it will serve to keep the Coordinator informed. The latter, is nuanced to the hilt. The Coordinator (or her office) can use this "product" to demonstrate to the community, the Administration, whomever, that the process is on track, or, if it is off track, what the situation is.

The plan itself is not be a "be-all, end-all" document. We envision it to be a "rolling" plan. As implementation unfolds and progress in attainment is made, it will be revised; priorities may change, implementation steps may drop off or be added, new ventures may be initiated. This nature of the plan necessitates that the task force be perpetuated and that periodic status reports continue. The frequency of the meetings and status reports, however, may change as the situation changes.

10. When the plan is ready for public comment, we will have a "closure" or "cloture" meeting. The agenda will allow each work group to present its plan. The nature of the meeting will be a celebration for having developed a national plan and formed a national consensus.

11. After this meeting the plan will be subjected to public comment for 60 days (90?) and revised.

Attachments (all WordPerfect documents:

1. Suggested format for final report

2. National Commission recommendations for education and prevention
3. National Commission recommendations for caring for people with HIV disease
4. National Commission recommendations for research
5. National Commission recommendations for government responsibilities.
6. A copy of this draft status report

Format for Final Product
Demonstrates Format ONLY

Priority Level for this implementation step is: 1

Prevention and Education

Goal Statement: Federal, state, and local governments should join forces with the private sector in providing long-term support to community-based organizations serving communities of color. As part of this effort, the U.S. Public Health Service should expand and promote comprehensive and integrated programs for technical assistance and capacity building in these communities. (National Commission on AIDS, Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--June 1993)

Problem 1: Strategies for training and delivering HIV/AIDS information and education to health professionals and others has have been inadequate.

Objective A: Develop an integrated system for professional information and communication on HIV and AIDS.

Implement Step 1: Educate policy makers, community-based organizations, and the public about HIV and AIDS.

Lead Organization	Government Contributors	Non Government Contributors	Projected Start Date	Projection Completion Date
CDC	State and local health depts	Community-based organizations	1/94	Ongoing
Significant Milestones				
Develop a list of national, state, and local organizations that serve high-risk populations			1/94	Ongoing
Conduct in-service training for national organizations and services that can serve to reach CBOs and high-risk populations			6/94	8/94
Compile samples of education and training materials for high-risk populations and evaluate for accuracy, appropriateness, and effectiveness			7/94	11/94
Based on a review of existing materials, identify gaps and develop new materials			12/94	Ongoing
Develop directories of existing materials for high-risk populations and distribute to organizations that serve high-risk populations.			4/95	10/95

Format for Final Product
Demonstrates Format ONLY

Priority Level for this implementation step is: 1

Prevention and Education

Goal Statement: Federal, state, and local governments should join forces with the private sector in providing long-term support to community-based organizations serving communities of color. As part of this effort, the U.S. Public Health Service should expand and promote comprehensive and integrated programs for technical assistance and capacity building in these communities. (National Commission on AIDS, Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--June 1993)

Problem 1: Strategies for training and delivering HIV/AIDS information and education to health professionals and others has have been inadequate.

Objective A: Develop an integrated system for professional information and communication on HIV and AIDS.

Implement Step 5: [Note: there are no implementation steps 2, 3, or 4 in this demonstration] Evaluate the effectiveness of the training and educational efforts.

Lead Organization	Government Contributors	Non Government Contributors	Projected Start Date	Projection Completion Date
CDC	Dept. Education AHCPR HRSA State, Dept of Education	Community-based organizations	4/94	Ongoing
Significant Milestones				
Clarify the relationship between education and epidemic control			4/94	Ongoing
Clarify the information, education, and training problems: analyze the problems and their determinants			4/94	Ongoing
Link interventions to the problems identified			4/94	Ongoing
Design measures--prior to implementation of interventions and collect baseline data			4/94	Ongoing
Evaluate			4/94	Ongoing
Develop and implement an evaluation system to assess knowledge, attitudes, and skills of the people trained			1/95	Ongoing

Format for Final Product
Demonstrates Format ONLY

Priority Level for this implementation step is: 1

Prevention and education

Goal Statement: Federal, state, and local governments should join forces with the private sector in providing long-term support to community-based organizations serving communities of color. As part of this effort, the U.S. Public Health Service should expand and promote comprehensive and integrated programs for technical assistance and capacity building in these communities. (National Commission on AIDS, Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--June 1993)

Problem 1: Strategies for training and delivering HIV/AIDS information and education to health professionals and others has have been inadequate

Objective B: Train and build the capacity of teachers, other school staff, and other professionals providing services to youth, including health care providers who are charged with providing HIV education, treatment, and services.

Implement Step 1: Provide adequate, ongoing staff development, including pre-service, in-service, and continuing education.

[illegible]

PREVENTION AND EDUCATION

AIDS education and outreach services in rural communities should be expanded and designed to provide clear and direct messages about how HIV is and is not transmitted and the kinds of behaviors that may place an individual at risk for HIV and other sexually transmitted diseases. Expansion of programs, resources, and health care providers is also needed to respond to rural America's need for prevention and treatment programs that address the three epidemics of HIV infection, drug addiction, and sexually transmitted diseases. (Nat'l Comm.: Interim Report Number Three: "Research, the Workforce and the HIV Epidemic in Rural America"--August 1990)

Meaningful drug treatment must be made available on demand inside and outside correctional facilities. Access to family social services and nondirective reproductive counseling should also be made available with special emphasis on the populations of incarcerated women, youth, and children born in custody. (Nat'l Comm.: Interim Report Number Four: "HIV Disease in Correctional Facilities"--March 1991)

There is a need for a consistent commitment to provision and expansion of drug treatment. Attention must be given to the development of care relevant to HIV disease. High-quality HIV education needs to be an integral part of all drug treatment programs. States should consider making this an explicit requirement of licensure for drug treatment programs. (Nat'l Comm.: Working Group Report: "Social and Human Issues"--April 1991)

Despite the potential therapeutic benefit of HIV antibody testing, there exists an array of educational and counseling interventions that can proceed independent of testing. Much more needs to be done about education and prevention for women and people of color. (Nat'l Comm.: Working Group Report: "Social and Human Issues"--April 1991)

Those who design and implement education and prevention programs must have the freedom to use explicit communication acceptable to the particular culture or group being addressed. Sound principles of health education demand that messages which encourage behavior change be in language people understand and consistent with values they accept. (Nat'l Comm.: Working Group Report: "Social and Human Issues"--April 1991)

Expand drug abuse treatment so that all who apply for treatment can be accepted into treatment programs. Continually work to improve the quality and effectiveness of drug abuse treatment. (Nat'l Comm.: Interim Report Number Five: "The Twin Epidemics of Substance Use and HIV"--July 1991)

Remove legal barriers to the purchase and possession of injection equipment. Such legal barriers do not reduce illicit drug injection. They do, however, limit the availability of new,

clean injection equipment, thereby encouraging the sharing of injection equipment, and the increase in HIV transmission. (Nat'l Comm.: Interim Report Number Five: "The Twin Epidemics of Substance Use and HIV"--July 1991)

All levels of government and the private sector need to mount a serious and sustained attack on the social problems that promote licit and illicit drug use in American society. (Nat'l Comm.: Interim Report Number Five: "The Twin Epidemics of Substance Use and HIV"--July 1991)

The U.S. Public Health Service should expand and promote comprehensive programs for technical assistance and capacity building for effective long-term prevention efforts. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

Federal, state, and local governments should join forces with the private sector in providing long-term support to community-based organizations. Community-based efforts are now and will continue to be an integral part of any HIV prevention strategy. The role of people with HIV disease must be recognized, encouraged, and supported. In designing services, community-based organizations and their programs must be accountable, yet they must be afforded sufficient flexibility to implement programs that will best serve communities in need. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

Policies should be developed now to address future plans for the distribution of AIDS vaccines and the ethical and liability issues that will arise when vaccines become available. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

The federal government should expand drug abuse treatment so that all who apply for treatment can be accepted into treatment programs. The federal government should also continually work to improve the quality and effectiveness of drug abuse treatment. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

That the Department of Anti-Addiction Services, the Puerto Rico Department of Health, nongovernmental organizations, and the federal government work together to create a strong, coordinated response to the twin epidemics of substance use and HIV. This response should include the expansion of treatment programs and establishment of bleach and clean needle/syringe programs. (Nat'l Comm.: Interim Report Number Six: "The HIV/AIDS Epidemic in Puerto Rico"--June 1992)

That the Public Health Service, the Commonwealth of Puerto Rico, and community-based organizations continue, coordinate, and intensify existing prevention efforts. Additionally, these entities should develop ways to establish and expand prevention initiatives specifically targeted at adolescents; incarcerated

populations; men who have sex with men; substance users; and women. (Nat'l Comm.: Interim Report Number Six: "The HIV/AIDS Epidemic in Puerto Rico"--June 1992)

The Centers for Disease Control and Prevention should review the adequacy of demographic information regarding HIV/AIDS currently available by race, ethnicity, and nationality, particularly with regard to Asian Americans/Pacific Islanders and Native Americans. Additionally, the National Center for Health Statistics should make information available regarding HIV/AIDS knowledge, attitudes, beliefs, and behaviors among Asian Americans/Pacific Islanders and Native Americans. (Nat'l Comm.: Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--December 1992)

The Centers for Disease Control and Prevention should ensure that the prevention and education needs of persons of color who engage in high-risk behaviors are appropriately addressed by current and future prevention initiatives and funding efforts. Programs specifically targeted toward men of color who have sex with other men, toward injection drug users, and toward women are needed. (Nat'l Comm.: Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--December 1992)

Federal, state, and local governments should join forces with the private sector in providing long-term support to community-based organizations serving communities of color. As part of this effort, the U.S. Public Health Service should expand and promote comprehensive and integrated programs for technical assistance to and capacity building in these communities. (Nat'l Comm.: Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--December 1992)

The Centers for Disease Control and Prevention should expand its support for the Business Responds to AIDS initiative by including efforts to obtain greater collaboration from existing mainstream organizations serving the business and labor sectors, such as the U.S. Chamber of Commerce, the Business Roundtable, the Conference Board, and others, to promote the availability of this program to their members and to make AIDS far more visible as a business concern.

CDC should more actively strive to establish links between businesses and local or regional sources of technical assistance on workplace issues and education. The need for targeted support in particular industries should be assessed. (Nat'l Comm.: Interim Report Number Eleven: "HIV/AIDS: A Challenge for the Workplace"--June 1993)

The Centers for Disease Control and Prevention should undertake a comprehensive program of research and development for infection control technologies and strategies to prevent occupational transmission of HIV and other bloodborne pathogens, specifically

including the safety performance evaluation of needle-bearing devices and other causes of percutaneous injuries to health care workers and sterilization and disinfection of reusable medical devices (as discussed in the Commission's previous report, *Preventing HIV Transmission in the Health Care Setting*.)

The foregoing discussions and recommendations focus on HIV/AIDS, as that is the Commission's specific mandate. However, much of what has been discussed in regard to the appropriate responses to employees with health problems and the opportunities for health promotion in the workplace are pertinent to other health problems. Opportunities to include initiatives on other health problems should be considered as the above recommendations are urgently implemented, with the ultimate goal of a comprehensive approach to health promotion in the workplace. (Nat'l Comm.: Interim Report Number Eleven: "HIV/AIDS: A Challenge for the Workplace" - June 1993)

One component to the national prevention initiative should address the prevention of HIV infection in adolescents, particularly youth in high-risk situations. Comprehensive HIV prevention should include information, exploration of values and attitudes, skill building, and access to health care and social services, including condom availability. School-based prevention should be presented in an integrated, comprehensive health curriculum that includes discussion of sexuality and that teaches general prevention skills, while still providing HIV-specific information. Schools and other youth-serving institutions should select curricula and teaching strategies that have been tested for efficacy through research and/or evaluation. Programs should be developed with the involvement of parents and young people. (Nat'l Comm.: Interim Report Number Twelve: "Preventing HIV/AIDS in Adolescents" - June 1993)

HIV prevention programs should be nonjudgmental in approach and structured from a public health perspective to help young people learn how to make healthy choices about sexuality. Such programs will be the most effective. The information provided to young people about sexuality and HIV should vary according to their age. Exhortations that adolescents perceive as unhelpful may only serve to distance youth, who may already be alienated, even further from the advice, care, and services they need and deserve. Prevention efforts limited to instilling fear or that omit important information will not be effective in facilitating healthy choices or sustained risk reduction. (Nat'l Comm.: Interim Report Number Twelve: "Preventing HIV/AIDS in Adolescents" - June 1993)

Abstinence messages—such as the message to postpone sexual activity—should be included because this can be an effective way of reducing the risk of HIV. Those who choose abstinence require

support. Information and skills building about other means of reducing the risk of HIV and other STDs, such as use of condoms, should be included. This potentially life-saving information is needed immediately by those who are sexually active and by all who may become so at some point later in their lives. Withholding such information leaves individuals vulnerable to HIV/STDs through ignorance. (Nat'l Comm.: Interim Report Number Twelve: "Preventing HIV/AIDS in Adolescents"--June 1993

Congress should increase the level of federal resources for teacher training and other educational staff development in the sensitive areas raised in HIV education. Preparation must address not only knowledge about HIV, but also help providers explore their own attitudes, which affect what and how they teach. It should also offer opportunities to practice and develop new teaching methods.

There is a lack of training and capacity building for both teachers, other school staff, and other youth-serving professionals, including health care providers who are charged with providing HIV education treatment and services. While it is expensive to provide adequate, ongoing staff development, it is essential for the provision of adequate HIV prevention education. Pre- and inservice training and continuing education are all necessary.

The issues raised by HIV—including sexuality, alcohol and other drug use, sickness, and death—are emotionally charged topics that cannot be effectively addressed by unprepared instructors. (Nat'l Comm.: Interim Report Number Twelve: "Preventing HIV/AIDS in Adolescents"--June 1993

"School health" should be made a priority in the education sector. Within education reform, competency-based performance standards for health education, sexuality education, and HIV education should be set that will ask students to demonstrate mastery of a variety of health and prevention-related topics and tasks. (Nat'l Comm.: Interim Report Number Twelve: "Preventing HIV/AIDS in Adolescents"--June 1993

Health care and education reform should merge to create "healthy schools" that provide students with respect, adult mentoring, and critical thinking skills and that also work in partnership with the community to ensure students' access to health and other social services. (Nat'l Comm.: Interim Report Number Twelve: "Preventing HIV/AIDS in Adolescents"--June 1993

As the nation moves forward with both health care and education reform, important opportunities to address adolescent health needs emerge. Adequately providing for the health needs of young people presents special challenges

because of the developmental, behavioral, and psychosocial aspects of adolescence. Providing appropriate care for this population presents a unique opportunity for prevention of disease and for the resulting future cost savings.

The federal government should work with the entertainment industry and other media (for example, the advertising industry) to develop strategies for conveying positive messages on HIV/STD and drug-use risk reduction to adolescents. (Nat'l Comm.: Interim Report Number Twelve: "Preventing HIV/AIDS in Adolescents"--June 1993)

Messages conveyed by the entertainment and advertising media that glamorize sexuality or drug and alcohol use and ignore the consequences of unprotected intercourse or substance abuse feed adolescent denial of the threat of HIV/AIDS and other potential consequences.

The National Commission on AIDS believes It is critically Important to immediately make effective use of behavioral and social science knowledge in the national response to the HIV/AIDS epidemic. It is also necessary that this knowledge base be expanded. The Commission calls for the behavioral and social sciences to be properly integrated into the mainstream of the HIV/AIDS response in the United States. (Nat'l Comm.: Interim Report Number Thirteen: "Behavioral and Social Sciences and the HIV/AIDS Epidemic"--July 1993)

To highlight neglected fields and to emphasize the breadth of relevant information, this report identifies some priority areas within behavioral and social science research on AIDS. The central concern of the Commission, however, is not establishing research priorities. Rather the objective is that from this point onward, behavioral and social sciences play an appropriate and central role in the overall battle against AIDS through expanded research and its application. In many cases, only multidisciplinary efforts will produce the comprehensive information required by HIV prevention workers and care providers. Greater inclusion of behavioral and social scientists at policy formulation, and research and program management levels of PHS is required.

We must employ all available tools to thwart the AIDS epidemic. As the Ninth international Conference on AIDS held in Berlin, in June 1993, made clear, equivocating about such action in the hope of near-term 'magic bullets' would be foolhardy.

CDC's HIV/AIDS prevention efforts, including public health education, epidemiological training, and service programs, need to more fully take into account knowledge from behavioral and

social science research. While CDC has made strides to recruit more behavioral scientists over the past several years, it still must do more to infuse its programs with those trained in the behavioral sciences, who should be vested with significant policy-making responsibility and authority. Moreover, CDC should endeavor to promote a more behaviorally-oriented methodology and theoretical framework in the prevention efforts it supports. Collaboration with NIH agencies supporting basic and applied behavioral and social science research should be strengthened. (Nat'l Comm.: Interim Report Number Thirteen: "Behavioral and Social Sciences and the HIV/AIDS Epidemic"--July 1993)

A plan for a National Prevention Initiative should be formulated. It should embrace the following (Nat'l Comm.: Interim Report Number Thirteen: "Behavioral and Social Sciences and the HIV/AIDS Epidemic"--July 1993:

- Improved prevention planning must be a central element of a restructured national HIV prevention effort. Federal, state, and local government agencies and community-based organizations involved in AIDS prevention efforts must join together to develop comprehensive plans for the delivery of HIV prevention services to individuals, communities and the population in general.
- Prevention resources should follow the epidemiology of HIV transmission and risk behavior. Where it is impossible to determine current rates of new HIV infection, surrogate markers for risk behavior (such as sexually transmitted diseases, like hepatitis B, unintended pregnancy, and injection drug use) should be used for the allocation of resources. All groups in which risk behavior occurs should be targeted by prevention programs.
- Prevention programs should reflect the best and most current knowledge generated from behavioral and social science research about AIDS-related **behavior change**.
- A key element of any kind of prevention reform must be greater involvement in the allocation of resources to prevention programs by those who are intended to benefit from them. Only by allowing local communities to assess their own local needs will such resources be appropriately targeted.

Local community groups and agencies representing populations at risk for HIV disease and persons with HIV who have been disenfranchised from funding allocations in the past, such as those

serving women and racial/ethnic populations, must be included in the planning and decision-making process around HIV/AIDS prevention.

- Prevention materials must include frank and explicit messages about how to stem the transmission of HIV, including culturally-sensitive and specific language and/or vernacular directed at targeted population groups.
- Technical assistance to local communities designing and delivering AIDS prevention programs must be provided by behavioral and social scientists experienced in preventive interventions.
- Careful consideration of the findings of the external review to which CDC is presently subjecting five of its HIV/AIDS program areas.

The Commission recognizes that much of the necessary reorganization and expansion of AIDS prevention efforts can be accomplished through administrative and regulatory actions. The newly-appointed National AIDS Policy Coordinator should give high priority to rapidly formulating a plan for a National Prevention Initiative and making any administrative changes it requires. A vigorous national prevention effort will require increased resources; the AIDS Policy Coordinator should consult with Congress in its formulation to ensure that its implementation is properly funded.

If presentation of a plan for a National Prevention Initiative is unreasonably delayed, Congress should exercise a leadership role and enact a suitable framework for this effort. Any such legislation should reflect the fact that (1) such an initiative is, by nature, long-term; (2) flexibility will be needed to modify approaches and targets in the light of the evolving epidemic and knowledge base; (3) integrated planning at the local level should be emphasized; and (4) adequate resources must be appropriated for implementation.

There must be a greater emphasis on improving methods of evaluation and on obtaining high quality evaluation of prevention efforts through CDC-supported HIV/AIDS prevention programs, such as demonstration projects. A realistic plan should be developed that matches the intensity of evaluation needed with the purpose of the activity to be evaluated. In this regard, a need identified to the Commission by recipients of small awards is for the recommendation of some indicators and methods of measuring them, whereby the effects of prevention efforts can be roughly

estimated simply and cheaply. Appropriations should take into account the need for more attention to evaluation, which should not be at the expense of prevention programs *per se*. (Nat'l Comm.: Interim Report Number Thirteen: "Behavioral and Social Sciences and the HIV/AIDS Epidemic"--July 1993

CARING FOR PEOPLE WITH HIV DISEASE

Frank recognition is needed that a crisis situation exists in many cities that will require extraordinary measures to overcome. Significant changes must be made not only in our health care system but in how we think about the system and the people it is designed to serve. As one witness told the Commission, it can no longer be "business as usual." (Nat'l Comm.: Interim Report Number One: "Failure of U.S. Health Care System to Deal with HIV Epidemic"--December 1989)

The creation of a flexible, patient-oriented, comprehensive system of care, closely linking hospital, ambulatory, residential, and home care is needed. Primary care physicians must be central to such a system. But if primary care doctors are to care for patients with HIV infection and AIDS, they need the financial, social, and institutional support to assist them in managing complicated patients. (Nat'l Comm.: Interim Report Number One: "Failure of U.S. Health Care System to Deal with HIV Epidemic"--December 1989)

Consideration of the creation of regional centers of networks of care, perhaps using the already existing regionalized hemophilia treatment program as a model is needed. These centers would not serve as a replacement for the care provided by primary care physicians but would provide backup and consultation to help strengthen community-based primary care. (Nat'l Comm.: Interim Report Number One: "Failure of U.S. Health Care System to Deal with HIV Epidemic"--December 1989)

It is essential that everyone be afforded early intervention and access to care. In addition, the availability of backup and consultation from appropriate specialists is required to provide the assistance and encouragement primary care doctors need to see more people with HIV infection and AIDS. Regional centers should also provide the appropriate link with the hospital when hospital services are needed.

Units which can treat patients who have both HIV infection and drug addiction are needed. The availability of drug treatment on request is essential for responding to the combined HIV and drug epidemic that imperils not only drug users but also their sexual partners and children. (Nat'l Comm.: Interim Report Number One: "Failure of U.S. Health Care System to Deal with HIV Epidemic"--December 1989)

Given the massive link between drug use and HIV infection, and the fact that there is an alarming increase in the number of new infections among intravenous drug users, the Commission wishes to go on record in expressing its surprise and disappointment that the White House National Drug Control Strategy mentions AIDS only four times in its ninety pages of text and not at all in its recommendations or discussions of how to allocate resources. The President's

drug strategy simply must acknowledge and include HIV infection and AIDS.

Provision of comprehensive health care services under one roof is needed. Fragmented services create additional barriers to needed health care. Often mothers will seek health care services needed for their babies but are not able to then gain access to care for themselves. Health care services for women and children need to be provided in one place. For the homeless, housing and health care need to go hand in hand. This is true not only for those who are homeless today but for those who will become homeless tomorrow because of the HIV epidemic. (Nat'l Comm.: Interim Report Number One: "Failure of U.S. Health Care System to Deal with HIV Epidemic"--December 1989

A comprehensive community-based primary health care system, supported by adequate funding and reimbursement rates, is essential for the care and treatment of all people, including people living with HIV infection and AIDS. The Commission highlighted this need in its first report and continues to believe that lack of access to primary care services provided by adequately trained primary care providers is undermining current efforts in HIV/AIDS research, prevention and treatment. The development of a comprehensive system with linkages to research protocols, existing community-based services, hospitals, drug treatment programs, local health departments, and long-term care facilities, based on a foundation of adequate support, is long overdue and should be a top priority for the federal government. (Nat'l Comm.: Interim Report Number Three: "Research, the Workforce, and the HIV Epidemic in Rural America"--August 1990

There is a shortage of crisis proportions of health care providers capable and willing to care for people living with HIV infection and AIDS. This crisis will only get worse as the HIV epidemic continues into the 1990s. Action must be taken now to increase and improve the effectiveness of all programs designed to educate and retain practicing health care professionals, and to create incentives for providers to care for people in underserved areas. Existing programs such as the National Health Service Corps should be expanded. New programs such as those outlined in the Disadvantaged Minority Health Improvement Act (H.R. 3240) should be created. And, specific HIV/AIDS fellowships and training programs should be established and supported to prevent a crisis of greater magnitude. (Nat'l Comm.: Interim Report Number Three: "Research, the Workforce, and the HIV Epidemic in Rural America"--August 1990

The U.S. Public Health Service should develop guidelines for the prevention and treatment of HIV disease in all federal, state, and local correctional facilities. Immediate steps should be taken to control the subsidiary epidemics of tuberculosis and

sexually transmitted diseases. Particular attention should be given to the specific needs of women and youth within all policies. (Nat'l Comm.: Interim Report Number Four: "HIV Disease in Correctional Facilities"--March 1991

Given the dearth of anecdotal and research information on incarcerated women, incarcerated youth, and children born in custody, federal and state correctional officials should immediately assess and address conditions of confinement, adequacy of health care delivery systems, HIV education programs, and the availability of HIV testing and counseling for these populations. (Nat'l Comm.: Interim Report Number Four: "HIV Disease in Correctional Facilities"--March 1991

Prison officials should ensure that both inmates and correctional staff have access to comprehensive HIV education and prevention programs. Particular attention should be paid to staff training on confidentiality and educating inmates about the resources available in the prison setting that may be employed to reduce the risk of infection. (Nat'l Comm.: Interim Report Number Four: "HIV Disease in Correctional Facilities"--March 1991

Increased efforts must be made to reach those who have historically been denied access to health care. These efforts must include the development and enhancement of health care and social service providers within and by minority communities. (Nat'l Comm.: Work Group Report: "Social and Human Issues"--April 1991

Meaningful early intervention is more than the provision of AZT or other drugs to those with HIV disease before they develop symptoms. Early intervention also entails psychological support, education and counseling, substance use treatment, and social services. (Nat'l Comm.: Work Group Report: "Social and Human Issues"--April 1991

People living with HIV disease should be provided a continuum of care so that at every stage of illness they are cared for in the least restrictive setting possible, preserving the greatest degree of independence. A responsive continuum of care will depend upon complex and intricate relationships among public health agencies, community-based and voluntary organizations, hospitals, nursing homes, and hospices. (Nat'l Comm.: Work Group Report: "Social and Human Issues"--April 1991

Comprehensive models of medical and psychosocial care for asymptomatic and mildly symptomatic individuals must be developed to ensure prevention and appropriate treatment. Stronger links are needed among the HIV testing enterprise, the public health system, health care delivery systems, and social services. In particular, case management programs should be supported, and evaluated on an ongoing basis. (Nat'l Comm.: Work Group Report: "Social and Human Issues"--April 1991

Spiritual counseling can be a critical component of care. Spiritual counseling should be encouraged, not only in the hospital setting, but also in the outpatient and home care environment. Professional pastoral training programs, whether based in hospitals or graduate schools, should include curricula designed to prepare trainees to care for people living with HIV disease. (Nat'l Comm.: Work Group Report: "Social and Human Issues"--April 1991

It is inappropriate to create HIV antibody testing programs to identify asymptomatic individuals for therapeutic interventions unless they include plans to deliver and pay for appropriate follow-up services for a substantial majority of those screened. (Nat'l Comm.: Work Group Report: "Social and Human Issues"--April 1991

Presently available or foreseeable therapeutic benefits cannot justify mandatory testing programs. The prospect of therapeutic benefits is not a sufficient reason for abandoning long-standing principles of informed consent. (Nat'l Comm.: Work Group Report: "Social and Human Issues"--April 1991

Long-standing principles of confidentiality of medical information should not be abandoned, especially in light of the history of discrimination against persons with HIV disease. (Nat'l Comm.: Work Group Report: "Social and Human Issues"--April 1991

HIV antibody testing must be accompanied by pre- and post-test counseling. People with both positive and negative results should receive counseling. For those engaging in high-risk behaviors, whether infected or not, counseling must be viewed as a sustained process. More comprehensive standards are necessary to ensure consistently high-quality counseling in a wide range of settings. More trained counselors are needed. (Nat'l Comm.: Work Group Report: "Social and Human Issues"--April 1991

Legal protections against discrimination and unwarranted disclosures of HIV status are even more critical as more at-risk individuals are encouraged to undergo HIV antibody testing for early intervention. Mechanisms for the enforcement of the Americans with Disabilities Act and other anti-discrimination provisions must be put into place. In particular, state and local laws against discrimination must be rigorously enforced. Where such laws do not exist, or where they are weak, they need to be established and strengthened. (Nat'l Comm.: Work Group Report: "Social and Human Issues"--April 1991

Government should assure access to a system of health care for all people with HIV disease. At a minimum, a system of care for all people with HIV disease should include a package of continuous and comprehensive medical and social services designed to enhance quality of life and minimize hospital-based care.

States, counties, and municipalities should assure that such services are available for individuals with HIV disease. Case management programs should be available to coordinate such care. These services must include (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991:

HIV antibody testing that is voluntary and must be accompanied by counseling—both anonymous and confidential testing contribute in different ways and both options should be available;

Education and counseling to help foster and maintain behavioral changes to reduce transmission of the virus;

Medical care, including drug therapy and frequent diagnostic monitoring, ongoing primary care, coordination of inpatient and outpatient care, access to investigational new therapies, and adequate options for long-term care;

Psychological care, including mental health counseling and spiritual support, that is helpful in coping with a frightening and sometimes overwhelming condition;

Drug treatment to help individuals stop using or injecting drugs or adopt safer drug use practices; and

Social services, including a range of housing options and income maintenance, without which medical advances may be beyond the grasp of those who could most benefit from them.

HIV-related services should be expanded to facilities where underserved populations receive health care and human services, in part to ensure their increased participation in trials of investigational new therapies. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991

HIV education and training programs for health care providers should be improved and expanded, and better methods should be developed to disseminate state-of-the-art clinical information about HIV disease, as well as drug and alcohol use, to the full range of health care providers. The Commission believes all health care providers have an ethical responsibility to care for people with HIV disease. In order to equip providers to better counsel and care for people with HIV disease, government at all levels and local agencies and institutions must develop more effective education programs and methods for getting the information to all providers, particularly primary care providers. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991

Programs to train health care providers to recognize and manage drug and alcohol use must be expanded, and programs that integrate treatment of drug use with primary care must be created and supported. The Commission believes more federal funds are needed for these efforts.

Federal, state, and local entities should provide support for training, technical assistance, supervisory staff, and program coordination to acknowledge and support the family members, friends, and volunteers who are an integral part of the care system of a person with HIV disease. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

That special efforts be undertaken in Puerto Rico to educate the community and advocates for persons infected with HIV about the provisions of and rationale for anti-discrimination laws, such as the Americans with Disabilities Act, and to build adequate mechanisms to facilitate the enforcement of these laws. These efforts should be undertaken jointly by the federal government and the government of the Commonwealth of Puerto Rico. The Commonwealth government may wish to consider the possibility of establishing an HIV/AIDS anti-discrimination office similar to those found in cities such as Los Angeles and San Francisco. (Nat'l Comm.: Interim Report Number Six: "The HIV/AIDS Epidemic in Puerto Rico"--June 1992)

At the local level a continuum of housing options should be made available for people living with HIV disease that includes a range of alternatives, from hospice care and intermediate or supportive housing to rental subsidies that could allow people to reside independently until such time as they need additional care. (Nat'l Comm.: Interim Report Number Seven: "Housing and the HIV Epidemic"--July 1992)

The federal government should work with the states to establish and support foster care programs for children with HIV infection and noninfected youth orphaned by the loss of parents to HIV/AIDS. Federal and state government should also support programs designed to assist family members in caring for children whose lives have been affected by HIV/AIDS. (Nat'l Comm.: Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--December 1992)

In addition to the recommendations offered above, many of the recommendations set forth in previous reports and statements issued by the Commission are relevant to efforts to address the HIV/AIDS epidemic in communities of color. In particular, the Commission directs attention to the following reports and statements: *America Living with AIDS*, *HIV Disease in Correctional Facilities*, *The Twin Epidemics of Substance Use and HIV*, *The HIV/AIDS Epidemic in Puerto*

*Rico, Housing and the HIV/AIDS Epidemic, and Resolution on
U.S. Visa and Immigration Policy.*

TO: Kristine Gebbie
National AIDS Policy Coordinator

10/18/93

FROM: Claudia Bingham
Organizational Development Consultant.

RE: **ORGANIZATIONAL DEVELOPMENT AND TEAM BUILDING
PROPOSAL FOR THE OFFICE OF NATIONAL AIDS POLICY**

PURPOSE: To facilitate the transition and development of the organization by providing direction and support in the areas of staff training and team building, systems and procedures development, information and communication flow, and space planning and staff relocation as needed for the Office of National AIDS Policy.

PHASE 1: Three Month Period

STAFF TRAINING AND TEAM BUILDING

- o Establish self-directed work teams and facilitate a series of team meetings with support and professional staff to assist with role definition and clarification, goal setting, information sharing, team building, and developing cohesive relationships with staff in both locations.
- o Work with all staff to negotiate a consensus between the goals of the office (where we are going) and the demands of daily operations (how we will get there). Both of these areas needs to be synchronized.
- o Provide or ensure training of support staff and interns in providing professional office support, including consistent and effective phone coverage, organizing mail flow, scheduling trips and meetings, preparing meeting briefing materials, and following new procedures.
- o Develop guidelines and clarify roles for interns based upon education, experience, and interest and establish a process for training new interns on an ongoing basis.
- o Review and modify position descriptions of support staff according to roles defined and agreed upon at team meetings.
- o Ensure that all staff receive necessary training on electronic schedulers, cc:mail, tracking systems, etc.

SYSTEMS AND PROCEDURES DEVELOPMENT

- o Develop basic operating procedures and internal message control guidelines with support staff at both locations. Revise policies and procedures manual into easy-to-use format which includes specific instructions on how to use telephone, computer, tracking, routing, and filing systems, and mechanism for adding new procedures as they develop.
- o Evaluate and modify as necessary electronic correspondence tracking system to reduce number of times each piece of correspondence is handled and establish a separate tracking system for correspondence generated at 750 location.
- o Develop standard for White House correspondence which includes return address for Office of National AIDS Policy printed on letterhead. Ensure that all mail addressed to staff at 750 location is delivered there.
- o Establish records management system at 750 location which includes central filing system for all correspondence and issues generated from that location; relocate appropriate files.
- o Evaluate and modify filing systems as necessary at 200 location to meet staff needs; ensure that retention guidelines are established and followed, systems are organized, and staff is trained to use filing systems at both locations.
- o Establish a publications system which includes a process for renewing subscriptions, receiving, circulating, and filing publications or creating a central library; identify student or staff to coordinate the process and train backup.
- o Establish a centralized rolodex and/or quick index listing of common HIV programs/questions which is posted by all reception/secretarial phones, giving the appropriate referral information (names, addresses, phone numbers, organizations, and contact persons by issue and expertise).
- o Ensure that computer systems at 700 location are connected with OASIS (White House LANS) and that off-site electronic scheduler is fixed to work efficiently.

INFORMATION AND COMMUNICATION FLOW

- o Modify internal routing procedures to facilitate dissemination of information efficiently to staff (e.g. route information copies at each of the three current locations -- eliminate blue folder process).
- o Assist staff with identifying a variety of groups to establish an electronic mail system to facilitate communication between those who need the information and reduce overload of information by those who do not need to see everything.
- o Devise system to encourage and facilitate information sharing and two-way communication between staff based upon informal survey of internal staff and ideas generated at team building meetings.
- o Evaluate new telephone voice mail system to ensure that it meets the communication needs of staff and train staff as needed in using voice mail effectively.

SPACE PLANNING AND RELOCATION

- o Plan and organize office space at 750 location to create work stations for additional staff.
- o Negotiate to obtain space on the 6th Floor of 750 location (if needed) and oversee relocation of some or all staff from the 9th to the 6th Floor.
- o Assist with consolidation and relocation of two offices at 200 location. Negotiate to provide staff space for a quiet reading/thinking area as requested by staff.

PHASE 2: Six Month Period

STAFF TRAINING AND TEAM BUILDING

- o Facilitate team meetings regularly with various staff teams in order to further develop internal communications, team building, and staff cohesiveness.
- o Establish system to provide ongoing training of support staff and interns as staff turnover occurs in the areas of office procedures and new software and automated procedures.

SYSTEMS AND PROCEDURES DEVELOPMENT

- o Ensure further development and completion of all systems and procedures identified in Phase 1.

INFORMATION AND COMMUNICATION FLOW

- o Conduct a comprehensive operational assessment survey of staff (see sample attached) related to information systems and linkages; compile and evaluate survey responses; and modify information processes where possible according to survey results.

SPACE PLANNING AND RELOCATION

- o Ensure that all staff have been relocated and plan for any future space needs.

PHASE 3: Nine Month Period

STAFF TRAINING AND TEAM BUILDING

- o After completing all items in Phases 1 and 2, train specified staff in team building facilitation in order to ensure that teams continue to become a part of the office culture.

SYSTEMS AND PROCEDURES DEVELOPMENT

- o Ensure completion of all items identified in Phases 1 and 2 and develop an ongoing process for review and modification of office systems and procedures on a regular basis.

INFORMATION AND COMMUNICATION FLOW

- o Make recommendations for further changes to improve information linkages based upon the results of the survey; analyze cost vs. benefit of making such changes.

SPACE PLANNING AND RELOCATION

- o Assist with planning for any future space needs.

Operational Assessment Questions

1. Describe your position (duties, function, responsibilities, goals).
What are your most important duties and why?
2. What decisions do you usually make in your job?
3. What information do you need to make those decisions? When is it obtained (e.g., daily, weekly)? How do you receive the information? (e.g., voice, manual, automated)? How much time does the process take? What is the quality (e.g. clear, useable, concise, accurate) level (low 1 - high 10) of the information?
4. What information linkages, processes and activities currently work well?
What information linkages, processes and activities do not work well?
What would you change? Why? How?
5. Do you get all the information you need?
What is missing and why?
6. What unnecessary, low value information do you receive? From whom? How do you receive it? Why do you receive it? What do you do with it?
7. What other kind of information (e.g., organizational, MCH systems, programs, regulations) do you usually receive? When do you usually receive it? How do you receive it? What is the quality level? What do you do with it? What would you change? Why? How?
8. What are the major strengths, weaknesses, opportunities, and risks within your area of responsibility and/or participation?
What would you like to change? Why? How?
9. What are the major strengths, weaknesses, opportunities, and risks within CCFH?
What would you like to change? Why? How?
10. What are the major strengths, weaknesses, opportunities, and risks within OHD?
What would you like to change? Why? How?

11. What are the most significant issues (political, economic, technical, social) currently facing your area of responsibility?
How will (should) these issues be addressed/resolved?
12. What are the most significant issues (political, economic, technical, social) currently facing CCFH?
How will (should) these issues be addressed/resolved?
13. What are the most significant issues currently facing the OHD?
How will (should) these issues be addressed/resolved?
14. What changes (e.g., target service groups, processes, materials, methods, people, structure, policies, financial expenditures and revenues, information needs) do you anticipate in your area within the next three years?
How will (should) these changes be addressed?
15. What changes (e.g., target groups, processes, materials, methods, people, structure, policies, financial expenditures and revenues, information needs) do you anticipate in the CCFH within the next three years?
16. What changes (e.g., target groups, processes, materials, methods, people, structure, policies, financial expenditures and revenues, information needs) do you anticipate in the OHD within the next three years?
17. What are the driving and restraining forces to achieving goals and desired outcomes in your area?
18. What are the driving and restraining forces to achieving goals and desired outcomes in the CCFH?
19. What are the driving and restraining forces to achieving goals and desired outcomes in the OHD?
20. How do you measure your success?
How do your coworkers measure your success?
21. How do you measure your coworkers (peers, superiors, subordinates) success?
22. Is there anything else you would like to talk to me about?



Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

July 19, 1993

NOTE TO SEE BELOW:

SUBJECT: HIV Counseling and Testing in Health-Care Settings

Enclosed is a final draft of a memorandum to Art Lawrence articulating principles of providing HIV counseling and testing services in health-care settings. NAPO has suggested that another envision conference be convened, and they will be in touch with you shortly.

Thank you for providing your comments on the earlier version of this draft. We have incorporated many of them into this version where appropriate.

Wanda K. Jones, Dr.P.H.
Assistant Director for Science
Office of the Associate Director
for HIV/AIDS

Enclosure

Addressees:

Dr. Eric Goosby, HRSA
Ms. Shelley Gordon, HRSA
Ms. Beth Roy, HRSA
Ms. Lauren Deigh, HRSA
Dr. David Henderson, NIH
Ms. Susan Beekmann, NIH
Dr. Melvyn Haas, SAMHSA
Dr. Myron Belfer, SAMHSA
Dr. Saul Levin, SAMHSA
Mr. Robert Moran, NAPO
Dr. Enrique Fernandez, HRSA
Ms. Joan Holloway, HRSA
Dr. Steve Bowen, HRSA
Ms. Johanne Messoré, NAPO
Mr. Tim Fox, NAPO
Dr. Robert Eisinger, NIH
Dr. Don Schneider, AHCPR
Ms. Alice Litwinowicz, NAPO
Ms. Sandra Massenburg, NAPO
Dr. Marilyn Gaston, HRSA
Ms. Sandy Bart, NAPO

DRAFT

FROM: Wanda K. Jones, Dr.P.H., Assistant Director for Science
Office of HIV/AIDS, CDC

TO: Art Lawrence, Acting Director
National AIDS Program Office

SUBJECT: Principles of Providing HIV Counseling and Testing
Services in Health-Care Settings

DATE: July , 1993

As originally requested by Dr. Audrey Manley, we include below the principles and considerations for the provision of HIV counseling and testing. We have worked with HRSA, NIH, SAMHSA, and NAPO to develop this information. We solicited their comments on an earlier draft of this document, and have incorporated those comments where appropriate. Many of the comments we received were client-, site-, or population-specific, beyond the intended scope of this document. For example, we retain the use of the term "client" although we recognize that in some settings an entire family may be the client.

We have not attempted to describe specific aspects of a counseling and testing program for individual sites or types of sites that might be funded by PHS agencies. Instead, we articulate a framework under which a site (or an agency) can plan for the provision of these services to best fit its particular needs.

Recommendations were published by the U.S. Public Health Service in 1993 for human immunodeficiency virus (HIV) counseling and testing of inpatients and outpatients in acute-care hospital

settings (1). These recommendations were prompted by information regarding both the rates at which patients admitted to some acute-care hospitals have unrecognized HIV infection and the potential medical and public health benefits of recognizing HIV infection in persons who have not been diagnosed as having HIV-related disease. Similar epidemiologic and public health principles apply to a variety of health-care settings and constitute a standard of prevention services and clinical care for routinely offering HIV counseling and testing. The information which follows can be used by service providers to assess whether they can or should offer HIV counseling and testing services.

PURPOSE: Diagnosis of HIV infection in asymptomatic persons is useful for early medical management and for counseling regarding behaviors to prevent further HIV transmission. Counseling may also benefit uninfected persons who are at risk for infection.

NON-HOSPITAL SETTINGS: Persons who may be at risk for HIV infection seek health care in a variety of settings. Broadly defined, these settings include public health departments (e.g., sexually transmitted disease or TB clinics and free-standing HIV counseling and testing sites), women's clinics (including those delivering family planning services), community and migrant health centers, community mental health centers, drug abuse

treatment centers, community-based health organizations, private health-care providers, and correctional facilities.

PRIORITIES FOR SERVICE PROVIDERS: Priority for providing routine HIV counseling and testing services should be given to sites serving the residents of areas that have high rates of HIV seroprevalence and AIDS case incidence, and to sites with clientele known to have high prevalence rates of HIV seropositivity or risk behaviors.

In any given site, six factors should be considered in the decision to provide HIV counseling and testing services: (1) the estimated prevalence of undetected HIV infection in the patient population; (2) the prevalence of risk behaviors among the clientele; (3) the ability to perform, or refer clients to, high quality counseling and testing; (4) the relevance of HIV test results to the services provided, e.g., prevention or treatment of tuberculosis; (5) the ability to protect the confidentiality of test results; and (6) the ability to provide, on site or through referral, for ongoing care, including availability of coordinated community followup and support service.

Programs that can reach large numbers of persons at high risk for HIV, obtain tests results promptly, yield a high return rate of clients for posttest counseling, and provide ongoing care directly or refer clients for such services should consider

offering HIV counseling and testing. Facilities should assess their ability to offer the services in a cost-effective manner that does not duplicate the efforts of other facilities serving the same individuals. If counseling and testing is not provided directly on site, providers should have established mechanisms for referring individuals to these services in the same locale.

PRINCIPLES FOR THE PROVISION OF COUNSELING AND TESTING SERVICES:

Facilities that routinely offer HIV counseling and testing must also be able to provide (directly or through referral) preventive, medical, laboratory, therapeutic, psychological, and other support services to individuals who are HIV-infected or at increased risk of infection. Essential elements of counseling and testing services include:

- All health-care providers should routinely ask patients about their risks for HIV infection (including history of STDs) and offer HIV counseling and voluntary testing services to patients with risks (2).
- Health-care providers should consider identifying a direct or indirect indicator of undiagnosed HIV infection in the population to be offered testing. Each location or type of facility, even within a geographic area, may differ. For example, some sites may find it useful to offer HIV counseling and testing to all clients, whereas others may

opt to offer tests routinely only to clients in a particular age group.

- Patients must give informed consent for HIV testing. HIV counseling procedures should be structured to facilitate voluntary patient participation in a confidential or anonymous setting and include pretest information on the institution or physician's testing policies (including reporting mandated by law) as well as basic information about the medical implications of the test, the option to receive more information, and the documentation of informed consent. For persons who are impaired or too severely ill to understand the pretest information or give informed consent, HIV counseling and testing for purposes other than immediate medical care should be deferred until a later time.
- Persons who decline HIV testing or who consent to testing and are found to be HIV-antibody positive must not be denied needed medical care or provided suboptimal care. People with HIV infection should receive medical evaluation for their HIV infection and specific therapies and prevention services as needed. If therapeutic and prevention services are not available, the acute-care facility or provider must establish an effective system of referral to other sites where these services will be provided.

- Test results should be provided to the patient in a confidential manner. Posttest counseling for infected patients and those at increased risk should be performed by trained health-care providers in accordance with CDC recommendations (2,3). In states whose laws require HIV infection reporting, positive results should be reported to the local health department promptly and confidentially.
- Facilities offering HIV testing and counseling must take necessary steps to protect the confidentiality of test results at all stages of the counseling and testing process. All personal identifying information obtained in connection with the delivery of services provided to any person cannot be disclosed unless required by the law of a state or political subdivision or unless such a person voluntarily provides, in writing, informed consent. Facilities must maintain the physical security of records with personal identifying information at all times; have procedures in place and staff trained to prevent unauthorized disclosure of client-identifying information; obtain informed client consent by explaining the risks of disclosure and the recipient's policies and procedures for preventing unauthorized disclosure; and obtain assurances of confidentiality by agencies to which referrals are made.

- The type of services to which clients are referred will vary both with the scope of services available from the original provider and with the clients' needs. For example, clients who have received HIV counseling and testing may be referred for substance abuse treatment, primary care, social services or any combination of these and other services. The provider should have established linkages with a broad range of services available to clients who need them.
- HIV testing programs should not be used as a substitute for practicing universal precautions and other infection control techniques.
- Providers should routinely assess the performance and training needs of counselors and other staff providing HIV prevention counseling and referrals. Comprehensive quality assurance procedures and standards for staff performance should be developed and staff training provided as needed. Providers also should assess the adequacy of their services and/or referrals in meeting clients' needs.

PROVIDER CAPACITIES: Facilities should be able to obtain blood samples, test or ship them to a laboratory, and then provide the results to patients in a timely fashion. Personnel in the facility should be trained to elicit a medical and sexual history from clients in a setting that affords confidential

counselor-client interactions. Furthermore, counselors should deliver disease or prevention counseling that is client-centered by providing information, assisting clients in identifying their HIV prevention needs, and developing a strategy to address those needs (2). Facilities also should have a written policy for contacting clients who are infected with HIV but do not return for their results, and for carrying out partner notification.

Community collaboration and planning can enhance the success of counseling and testing services and follow-up care. Outpatient health-care facilities should work with other agencies, community groups, and organizations to facilitate planning, minimize duplication, and assure availability of preventive, medical, and social services.

THE ROLE OF HEALTH DEPARTMENTS: State and local health departments can provide technical assistance in identifying indicators of undiagnosed HIV infection. They may also be able to provide training to facility staff who will be responsible for HIV-related counseling and testing services in outpatient health-care settings. In addition, health departments can help facilities provide partner notification services for HIV-infected patients as well as other prevention services for uninfected patients who are at high risk for HIV infection. Effective and ongoing collaboration between outpatient health-care providers and health departments will improve both prevention and treatment

HIV SCREENING In Health Care Facilities

BACKGROUND

March 2: CDC presented its Recommendations for HIV Testing Services for Inpatients and Outpatients in Acute-Care Hospital Settings and Technical Guidance on HIV Counseling to the PHS HIV Leadership. In that meeting, other PHS agencies stated there was a need for parallel guidelines applicable to other health care settings.

April 6: The Acting ASH (Dr. Manley) asked that CDC "...take the lead in working with the appropriate PHS agencies to develop a consensus document which can be used to either modify the recently published recommendations or publish additional recommendations in the MMWR that will go beyond HIV testing for inpatient and outpatients in acute-care hospital settings. I have asked [NAPO to work with CDC] staff to arrange a presentation at a future HIV Leadership meeting."

April 30: A workgroup convened. The CDC, HRSA, NAPO, NIH, and SAMHSA were represented. The group agreed that CDC would draft general principles that could be applied by anyone considering HIV testing as a standard of care. The group considered the articulation of these general principles to be an important first step in the process of developing site-specific recommendations for HIV testing.

May 21: The CDC stated, it would "...summarize these principles for PHS and NAPO review during the next few weeks. We will continue to work with other agencies to determine under which circumstances non-hospital health services delivery sites should offer HIV counseling, testing, referral, and partner notification services to clients."

Date uncertain, late May: The CDC circulated a first draft for comment.

June 2: Deadline for comments. The NAPO made suggestions for wording changes and additional phrases, but was, on the whole, satisfied with the product. However, the office noted that the format, a memorandum, would not get broad dissemination. We asked CDC to consider publication.

July 6: The NAPO was informed that CDC had "worked through the agencies' comments...." The office was provided with a copy of the revised draft and asked, "what next?"

July 16: The NAPO suggested that the document be shared with everyone on the workgroup and that the workgroup be reconvened. The workgroup would, NAPO suggested, review "the content of the

document as well as the plan for its presentation to HIV Leadership, final format, and dissemination."

STATUS

July 19: The CDC agreed to send the draft to the workgroup and it was sent that day. The agency also noted, "it is not clear to us that another meeting is necessary." The onus to convene the workgroup was put upon NAPO. Reasons CDC does not want another meeting include the following: Comments from agencies included suggestions for site-specific text that CDC did not want to include; Given its current work load, this project has very low priority; CDC feels the product is not worthy of publication, it will not be well received because it is another recommendation that will siphon resources, and it would have minimal impact; and Given its "druthers," CDC would just as soon finalize the memorandum as it is and send it to the agencies. The agencies could implement and evaluate the document.

OPTIONS

The document could be allowed to die. We could expect little outcry from CDC. However, other agencies raised the issue in the first place and we should expect that this option would not be well received.

The document as it exists could be finalized for Dr. Lee's signature and disseminated to the PHS agencies. This would be the option preferred by CDC.

The AIDS Policy Office could reconvene the workgroup or cause it to be reconvened. The objective would be to discuss the content and dissemination issues. It should be noted, however, this could be the beginning of a process to build a broader consensus.

RECOMMENDATIONS

As this is a PHS document, the issues are PHS issues, and the participants are PHS agencies, whatever action is taken, decisions should include the concurrence and participation of the ASH.

This writer believes the principles articulated in this document have utility beyond the PHS. I recommend the workgroup be reconvened. The CDC should be offered the chance to be the convener.

DRAFT

White House Head

September 3, 1993

NOTE TO JAMES W. CURRAN, M.D., M.P.H.

FROM: National AIDS Policy Coordinator

SUBJECT: Principles of Providing HIV Counseling and Testing
Services in Health-Care Settings--ACTION

I have read the draft memorandum prepared by CDC on the above referenced subject. It is an excellent piece of work. It describes a clear set of epidemiologic and public health principles to which service providers can turn when they consider whether they can or should offer HIV counseling and testing services. I particularly appreciate that the document provides clear guidance that can be applied in a broad variety of individual circumstances and settings. Please express my kudos to the individuals who did this work.

The recommendations on HIV counseling and testing that CDC published in January [MMWR 1993;42 (RR-2)] address the issues in acute care hospitals. However, there are a variety of other provider facilities which may serve the same or similar elevated-risk communities or populations. The opportunity to enlist their support in controlling the epidemic in their communities is not only good public health, it is the essence of "reinvented" government on several planes. It empowers communities and puts the mission to the fore and into the driver's seat; it is an investment in prevention in the community; it decentralizes decision making; and it makes an attempt to solve a problem by leveraging the marketplace, rather than simply creating public programs. Therefore, I believe guidance such as this, with its universal utility and high potential to stimulate health care facilities not currently addressing the epidemic to become involved should be widely publicized. The opportunity to bring needed HIV counseling and testing services to people in need who are not currently receiving those services is very appealing.

Page 2-- NOTE TO JAMES W. CURRAN, M.D., M.P.H.

describe specific aspects of counseling and testing programs for individual sites or types of sites. Such detail would damage the pervasive utility of the work. Nonetheless, I would suggest you reconvene the workgroup that has been overseeing this project to discuss a process for making these principles widely known and widely accepted.

I have asked Mr. Robert Moran to represent my office in this process and to assist you as necessary to facilitate it. Please do not hesitate to call him at 202-690-5560. If I can be of any assistance, please do not hesitate to call me at 202-632-1090.

Kristine M. Gebbie, RN, MN

CC:

Dr. Arthur J. Lawrence
Mr. Robert D. Moran

AGENDA

Assessment of the situation: do we proceed?

If no, what then do we do about a national plan?

If yes...

Do we do this at the White House? Do we invite the President or the First Lady to make keynote, presidential charge address?

Review of the overall agenda? Is this a reasonable structure? What needs to be changed?

What needs to be done in preparation:

Collect recommendations? (This activity is in progress.)

Do a "white paper" on the collected recommendations?

What should the white paper look like?

How do we get it done?

What other hand outs will be necessary?

Contracting for conference planning services? What should they do?

An invitation list--please see the attached document? Is the number 150 still valid?

What do we want the work groups to accomplish? Please see the attached--it is first thoughts only.

What about a date?

AGENDA
NATIONAL PLANNING MEETING

Monday		
Time	Description	Person
1:30-4:00	Meeting of Work Group Leaders	Contractor
4:00-6:00	No host cocktail hour	Hotel

Tuesday		
Time	Description	Person
9:00-10:00	Welcomes	Lawrence
	Attorney General	Reno
	Secretary of Education	Reilly
	Secretary of HHS	Shalala
10:00-10:30	Presidential Charge	Clinton (designate)
10:30-10:45	Break	
10:45-11:30	Purpose: a national consensus for action	Gebbie
	Immediate action	
	Action to be taken while the action plan is in development	
	Establish priorities	
	Implementation in the next 12 months	
	Implementation in the period beyond 12 months	
11:30-1:30	Lunch and travel to hotel	
1:30-5:00	Work groups convene	Everyone

Wednesday		
Time	Description	Person
8:30-5:00	Work groups meet	Everyone

Thursday		
Time	Description	Person
8:30-8:45	Convene final session	Lawrence
8:45-10:00	Workgroup reports	Work group leaders
10:00-10:15	Break	
10:15-11:15	Work group reports continue	Work group leaders
11:15-11:30	Thank you, adjourn	Gebbie

WORK GROUP GUIDANCE
Work Plan

Given the various recommendations, which ones should be discarded (eg, accomplished, no longer relevant, not appropriate)?--White paper?

Which of the remaining recommendations can be combined in a single recommendation?--White paper?

Can the remaining recommendations be combined into major areas of consideration or somehow grouped? What are the areas or groups?

Using the priority scale below, what is the priority designation for each of the areas, groups, or recommendations?

Priority 1: Urgent. In time of limited resources, this must be addressed.

Priority 2: Important. However, not as important as priority one or cannot be initiated immediately.

Choices between 1 and 2 should be hard choices. If everything cannot be done at once, what should be done first.

Priority 3: In time of limited resources, this may have to be put aside.

For expediency and efficiency, can the work group be broken into smaller groups? Perhaps, a smaller group to work on a major area or group of related recommendations? Should there be a different writer or team of writers for each major area or group of recommendations?

A final work group draft--in the format specified--must be submitted to the ONAPC by [date] .

Who will be the individuals on the writing team or teams? Alternatively, are there better options for developing the plan?

How will the writers and the co-chairs ensure that everyone in the group has an opportunity to comment?

When will a draft be submitted to the entire work group?

How long will the work group have to comment?

For priority 1 items, identify in general terms, the action steps that can be implemented in 12 months or less? Who is responsible? Who needs to be involved?

For priority 1, identify in general terms, the action steps that should be implemented, but will require more than 12 months? Who is responsible? Who needs to be involved?

If time allows, continue the process for priority 2.

Format for Final Product
Demonstrates Format ONLY

Priority Level for this implementation step is: 1

Prevention and Education

Goal Statement: Federal, state, and local governments should join forces with the private sector in providing long-term support to community-based organizations serving communities of color. As part of this effort, the U.S. Public Health Service should expand and promote comprehensive and integrated programs for technical assistance and capacity building in these communities. (National Commission on AIDS, Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--June 1993)

Problem 1: Strategies for training and delivering HIV/AIDS information and education to health professionals and others has have been inadequate.

Objective A: Develop an integrated system for professional information and communication on HIV and AIDS.

Implement Step 1: Educate policy makers, community-based organizations, and the public about HIV and AIDS.

Lead Organization	Government Contributors	Non Government Contributors	Projected Start Date	Projection Completion Date
CDC	State and local health depts	Community-based organizations	1/94	Ongoing
Significant Milestones				
Develop a list of national, state, and local organizations that serve high-risk populations			1/94	Ongoing
Conduct in-service training for national organizations and services that can serve to reach CBOs and high-risk populations			6/94	8/94
Compile samples of education and training materials for high-risk populations and evaluate for accuracy, appropriateness, and effectiveness			7/94	11/94
Based on a review of existing materials, identify gaps and develop new materials			12/94	Ongoing
Develop directories of existing materials for high-risk populations and distribute to organizations that serve high-risk populations.			4/95	10/95

Format for Final Product
Demonstrates Format ONLY

Priority Level for this implementation step is: 1

Prevention and Education

Goal Statement: Federal, state, and local governments should join forces with the private sector in providing long-term support to community-based organizations serving communities of color. As part of this effort, the U.S. Public Health Service should expand and promote comprehensive and integrated programs for technical assistance and capacity building in these communities. (National Commission on AIDS, Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--June 1993)

Problem 1: Strategies for training and delivering HIV/AIDS information and education to health professionals and others has have been inadequate.

Objective A: Develop an integrated system for professional information and communication on HIV and AIDS.

Implement Step 5: [Note: there are no implementation steps 2, 3, or 4 in this demonstration] Evaluate the effectiveness of the training and educational efforts.

Lead Organization	Government Contributors	Non Government Contributors	Projected Start Date	Projection Completion Date
CDC	Dept. Education AHCPR HRSA State, Dept of Education	Community-based organizations	4/94	Ongoing
Significant Milestones				
Clarify the relationship between education and epidemic control			4/94	Ongoing
Clarify the information, education, and training problems: analyze the problems and their determinants			4/94	Ongoing
Link interventions to the problems identified			4/94	Ongoing
Design measures--prior to implementation of interventions and collect baseline data			4/94	Ongoing
Evaluate			4/94	Ongoing
Develop and implement an evaluation system to assess knowledge, attitudes, and skills of the people trained			1/95	Ongoing

Format for Final Product
Demonstrates Format ONLY

Priority Level for this implementation step is: 1

Prevention and education

Goal Statement: Federal, state, and local governments should join forces with the private sector in providing long-term support to community-based organizations serving communities of color. As part of this effort, the U.S. Public Health Service should expand and promote comprehensive and integrated programs for technical assistance and capacity building in these communities. (National Commission on AIDS, Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--June 1993)

Problem 1: Strategies for training and delivering HIV/AIDS information and education to health professionals and others has have been inadequate

Objective B: Train and build the capacity of teachers, other school staff, and other professionals providing services to youth, including health care providers who are charged with providing HIV education, treatment, and services.

Implement Step 1: Provide adequate, ongoing staff development, including pre-service, in-service, and continuing education.

[illegible]

RESEARCH

Clinical Trials, Treatment-Related
Behavioral

The NIH clinical trials program is in serious trouble. The limited number of enrollees in trials and the lack of demographic and geographic diversity of the participants threatens the success of the program and denies many people living with HIV infection and AIDS the opportunity to participate in experimental drug therapies. The academic health centers involved have not been as vigorous as one would hope in advancing these trials, nor has the NIH been vigorous in monitoring their performance. Aggressive efforts must be made to overcome the obstacles to participation of many who are underrepresented. Success in this area can only be measured by increased participation in trials. (Nat'l Comm.: Interim Report Number Three: "Research, the Workforce and the HIV Epidemic in Rural America"--August 1990)

There is a desperate need for more research on the management of opportunistic infections, usually the cause of death for people with AIDS. The NIH simply must expand the level of research in this area. This expansion must not come at the expense of other research efforts and should be an integral part of a comprehensive AIDS research plan. This plan should outline the AIDS research priorities and goals for the entire NIH and the resources needed to achieve them. The plan should be widely disseminated and should incorporate the views of persons living with HIV infection and AIDS. (Nat'l Comm.: Interim Report Number Three: "Research, the Workforce and the HIV Epidemic in Rural America"--August 1990)

Greater priority and funding should be given to behavioral, social science, and health services research. Behavioral, social science, and health services research are currently grossly underfunded. The Commission believes there must be a more appropriate balance of funding between these areas of study and biomedical research. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

Current efforts at the National Institutes of Health (NIH) to expand the recruitment of underrepresented populations in the AIDS Clinical Trials Group should be continued and increased. While the Commission recognizes that lack of access to health care seriously hampers efforts to recruit underrepresented people into clinical trials, this does not mean it is impossible to do so. NIH has begun to increase participation and should aggressively pursue the participation of women and people of color in their clinical trials. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

The Secretary of Health and Human Services should direct the National Institutes of Health, the Health Care Financing Administration, and the Health Resources and Services Administration to work together to develop a series of recommendations to address the obstacles that keep many people from participating in HIV-related clinical trials, as well as the

variables that force some people to seek participation in trials because they have no other health care options. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

The Food and Drug Administration should aggressively pursue all options for permitting the early use of promising new therapies for conditions for which there is no standard therapy or for patients who have failed or are intolerant of standard therapy. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

The National Institutes of Health should develop a formal mechanism for disseminating state-of-the-art treatment information in an expeditious and far-reaching manner. While the Commission is aware of the efforts at NIH to disseminate information about state-of-the-art HIV treatment, the Commission is also aware that many health care providers are still not getting the information they need to responsibly care for their patients with HIV disease. The Commission believes NIH needs to develop a more formalized mechanism for disseminating information in a timely and ongoing fashion and should work with the federally funded AIDS Education and Training Centers, as well as professional medical societies, to reach as many people as possible. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

That approaches to expanding clinical research, as well as increasing access to experimental therapies (through clinical trials or expanded access programs) be explored by all involved in the HIV epidemic in Puerto Rico, including the federal, commonwealth, and municipal governments, as well as the private sector. (Nat'l Comm.: Interim Report Number Six: "The HIV/AIDS Epidemic in Puerto Rico"--June 1992)

Federal health and education agencies should increase cooperation in order to facilitate "technology transfer" between the research and public health worlds and the education sector and to involve the education community in health promotion. Collaboration between state and local health agencies and education agencies should also be encouraged. (Nat'l Comm.: Interim Report Number Twelve: "Preventing HIV/AIDS in Adolescents"--June 1993)

The education community does not have ready access to much of the cutting-edge research on strategies for HIV prevention. The "transfer of technology" between the research community and schools needs strengthening. Teachers, school administrators, and school boards do not often read the technical journals in which research results are published, and, even if they do, researchers' language is often difficult for nonexperts to understand.

Organizations that sponsor research and pilot projects should undertake and publish meta-analyses that identify the program design and implementation characteristics for prevention efforts that are predictors of effectiveness. Guidance for local action should be developed through collaboration between federal health and education agencies.

More research is needed to refine the knowledge base about adolescent sexual and other risk-taking behavior and to point the way toward effective HIV prevention strategies. Research, however, should not be funded at the expense of primary prevention programs. A coordinated research agenda should be instituted that includes (Nat'l Comm.: Interim Report Number Twelve: "Preventing HIV/AIDS in Adolescents"--June 1993):

- a. A national survey on adolescent sexual behavior that will provide data not only on prevalence and demographics of sexual activities, but also on who and what has an impact on adolescent risk-taking behavior.
- b. Research on effective behavior change strategies and programs, including those that focus on youth in high-risk situations, and an assessment of how well the comprehensive approach to risk reduction works.
- c. New research that builds upon previously implemented comprehensive HIV programs for adolescents. Examples of such programs include the HIV Center for Clinical and Behavioral Studies (Rotherman-Borus, 1991), the Center for AIDS Prevention Studies at the University of San Francisco, programs for gay and bisexual youth (Remafedi, Farrow, and Deisher, 1991), and those programs implemented by the National Network of Hemophilia Treatment Centers and The National Hemophilia Foundation.

Additionally, a greater commitment of resources is needed for research including evaluation of interventions and for the dissemination of results from successful programs.

Research should be expanded in the following behavioral and social science categories (Nat'l Comm.: Interim Report Number Thirteen: "Behavioral and Social Sciences and the HIV/AIDS Epidemic"--July 1993):

- A. Behavioral epidemiology which seeks to establish the prevalence and determinants of risk behaviors. For example, it remains to be determined to what extent, nationally, young gay men are failing to adhere to the norms of safer sex that some older gay populations have established.

- B. Cognitive science, which employs field studies and laboratory investigations to understand cognitive processes and social psychology, and their relationship to behavior. We need to know more about the antecedents and determinants of sexual intercourse and drug use behavior. We need to get to the specifics of such behaviors, i.e, which factors (such as peer pressure, etc.) carry the most weight in determining values, attitudes, and actual behavior, so that we can design interventions to target the critical variables.
- C. Cultural and ethnographic studies, which investigate determinants of behavior within varying cultural groups. For example, we need to conduct the research needed to clarify the meaning of concepts such as risk, health, and personal responsibility to those who have an elevated risk of HIV infection. Cultural and ethnographic studies will not only help tell us what to target in interventions for different groups but can also help in ensuring that interventions are culturally sensitive and delivered through appropriate channels. For example, designing the most attention-grabbing and memorable stimuli possible for social marketing of condoms, or countering stigmatization and discrimination, in different populations.
- D. Intervention research, which employs controlled designs to judge the relative effectiveness of various theory-based intervention strategies. For example, we have not, as yet, pinpointed the elements in prevention programs for young adolescents that are necessary and sufficient to delay the age of first sexual intercourse, and to foster early and consistent use of barrier methods of contraception/disease prevention when intercourse is initiated. Research into the most effective risk reduction strategies among sexual partners of at-risk drug users is also a significant unmet need.
- E. Mental Health Research, which strives to understand and intervene in stress, coping, substance abuse, and other psychopathologies in order to preserve the well-being of those with, or at risk of, HIV infection.
- F. Behavioral aspects of technological interventions, an area which seeks to determine the non-medical factors influencing utilization of 'technological' medical intervention. It is critically important to assess the ways we can get the maximum benefit out of existing and future agents (such as drugs, vaccines, or condoms) by ensuring they are used properly. Clinical trials of

vaccines and other therapeutics would be greatly improved by research on the inclusion and retention of people of color and women into these trials. In addition, we need interdisciplinary studies on the development and use of female-controlled prevention methods. Such studies should recognize that insistence by some women on condom use for HIV and STD protection may be extremely difficult if not impossible, due to such factors as the threat of violence or sexual abuse. Behavioral utilization studies should be an early part of product research and development.

- G. Organizational studies, which seek to understand the dynamics of organizational life and the interaction between individuals and organizations. For example, a major unmet need is identifying effective means of volunteer recruitment, staff retention and burnout prevention among health care providers and workers in AIDS organizations.

Technology transfer and feedback between behavioral and social science research and prevention efforts must be improved, increased, and accelerated. There must be greater collaboration and cooperation between researchers and their nonresearcher counterparts working in AIDS prevention. To achieve this, strong linkages should be established so that researchers and prevention workers (e.g., NIH, CDC, HRSA, and SAMHSA grantees) come together to facilitate both prevention and treatment effectiveness and the conduct of research. (Nat'l Comm.: Interim Report Number Thirteen: "Behavioral and Social Sciences and the HIV/AIDS Epidemic"--July 1993)

A variety of mechanisms can promote such linkages, and should include joint grants, workshops and the development of an interagency infrastructure that fosters collaboration; a national conference should be considered. Ethnic minority and women's health organizations should be included in formulating the research agenda. Agencies supporting prevention research and prevention programs have a responsibility to synthesize and disseminate the conclusions that can be drawn from work they support more systematically than has been done to date.

Intervention research should be outcome-oriented, but should also investigate motivations, intentions, and barriers in addition to behavior change itself. Studies must be conducted on the effectiveness of prevention strategies with groups of various ages, from various ethnic/cultural backgrounds, and in a wide variety of socio-economic and environmental settings. (Nat'l Comm.: Interim Report Number Thirteen: "Behavioral and Social Sciences and the HIV/AIDS Epidemic"--July 1993)

Because behavioral and social science research on AIDS is currently conducted at various federal agencies and applied by others, including the states, it is critically important that, at a sufficiently high governmental level (e.g., in the office of the AIDS Policy Coordinator), staff resources are devoted to ensuring that the potential contributions of behavioral and social science are fully utilized and coordinated. This has particular relevance in the prevention arena where a comprehensive HIV prevention plan, which must fully integrate behavioral and social science research, is urgently needed. Steps to achieve the goal of increased collaboration among agencies should include a monitoring/advisory mechanism, a comprehensive prevention plan, joint grantmaking programs between agencies such as CDC, NIH, SAMHSA, HRSA, and AHCPR, and a mechanism to facilitate collaboration. (Nat'l Comm.: Interim Report Number Thirteen: "Behavioral and Social Sciences and the HIV/AIDS Epidemic"--July 1993)

Such coordination would be best achieved by a centralized office that should also coordinate and monitor programs of the Department of Defense, the Agency for International Development, and other agencies of government that are involved in behavioral, social science, and health research on AIDS. As an ongoing part of this coordination, progress in implementing recommendations made in reports by entities such as the Presidential Commission on the HIV Epidemic, the National Commission on AIDS, the NAS/NRC, and the Institute of Medicine should be assessed.

Behavioral and social sciences should receive appropriate attention and support within the newly reorganized NIH Office of AIDS Research. To ensure continued emphasis, one or more senior positions with budgeting and planning responsibility and authority for behavioral and social science should be established in OAR. In addition, at least one third of those appointed to the OAR Advisory Council should be behavioral or social scientists. Representatives of NIAID, NIMH, NIDA, NIAAA, NICHD, and other interested institutes should be included on this Advisory Council in an ex officio capacity. The categories similar to those identified in the research priorities section of this document should be used for budgeting, planning and structuring NIH/OAR behavioral and social science activities. (Nat'l Comm.: Interim Report Number Thirteen: "Behavioral and Social Sciences and the HIV/AIDS Epidemic"--July 1993)

Research and services in AIDS must be permitted to be culturally and linguistically relevant to the needs of their Intended audiences. Scientists and prevention workers must be free to conduct research or prevention efforts, using the tools, the language, and the methods which are the most appropriate for

their purposes. (Nat'l Comm.: Interim Report Number Thirteen: "Behavioral and Social Sciences and the HIV/AIDS Epidemic"--July 1993)

NIH support for interdisciplinary research should also be increased. It is imperative that behavioral and social science become more fully integrated into the biomedical AIDS research conducted and supported throughout the agency. (Nat'l Comm.: Interim Report Number Thirteen: "Behavioral and Social Sciences and the HIV/AIDS Epidemic"--July 1993)

GOVERNMENT RESPONSIBILITIES

Efforts in the public sector at all levels of government should be guided by broad policy goals. (Nat'l Comm.: Working Group Summary Report: "Federal, State, and Local Responsibilities"--March 1990)

The Working Group suggested that the policy goals identified by the National Association of Counties Task Force on HIV Infection and AIDS could serve as a model for all levels of government. These goals are:

- To end the HIV epidemic through prevention, education, and research;

- To assure access to treatment, care, and support services for all persons with HIV infection;

- To protect the civil rights of all citizens; and

- To assure adequate funding for a continuum of HIV prevention, treatment, care, and support services and HIV research through effective public sector (federal, state, and local government) and private sector leadership and partnership.

Federal, state, and local governments should develop comprehensive plans for implementing identified goals. These plans should be developed in response to the policy recommendations of the National Commission on AIDS with interagency government representation and private sector involvement, including community-based organizations and persons with HIV disease. (Nat'l Comm.: Working Group Summary Report: "Federal, State, and Local Responsibilities"--March 1990)

The Working Group strongly recommended that the federal government should immediately develop a forceful comprehensive national HIV plan addressing prevention, education, treatment, care, support services, civil rights, research, and funding for these activities. The President should designate the Secretary of Health and Human Services to chair a cabinet-level Task Force to develop the national implementation plan. While the National Commission on AIDS fully intends to recommend policy goals for a national plan, the Commission believes it is essential that a Task Force be in place to enhance government-wide implementation of such a plan. In this way, those who are ultimately responsible for the implementation will have had an active role in its development, thus enhancing the likelihood of implementation. The Task Force should include each Department in the federal government and should solicit input from state and local governments and the private sector, including community-based organizations and persons with HIV disease.

The U.S. House of Representatives should, like the United States Senate, pass the Americans with Disabilities Act and state and local governments should pass laws forbidding discrimination in areas not covered by the Americans with Disabilities Act or other federal statutes. (Nat'l Comm.: Working Group Summary Report: "Federal, State, and Local Responsibilities"--March 1990)

Immediate action is necessary at the federal level to assist states, counties, and cities disproportionately impacted by the HIV epidemic. "Impact Aid" disaster relief or direct emergency relief is needed to assist states and localities in developing a continuum of HIV prevention, treatment, care, and support services. (Nat'l Comm.: Working Group Summary Report: "Federal, State, and Local Responsibilities"--March 1990)

The issues of health care financing and health care and social service organization and delivery require a level of expertise and commitment of time that was not provided for in this working group session. The Working Group believes these issues would be best addressed by the full Commission. (Nat'l Comm.: Working Group Summary Report: "Federal, State, and Local Responsibilities"--March 1990)

Incentives at the federal, state, and local level need to be created to recruit, retain, and train human services personnel. The Working Group recommends that the federal government should support a National Health Service Corps approach to involving more primary care providers in the care of persons with HIV. Medicaid reimbursement rates for outpatient care should be augmented and all universities (public and private) should include HIV education in health professional education and training. (Nat'l Comm.: Working Group Summary Report: "Federal, State, and Local Responsibilities"--March 1990)

Federal, state, and local government should have in place policies to encourage the development of housing programs that meet emergency, short-term and long-term needs of persons with HIV. Congress should support legislation to establish housing programs that provide short-term and long-term housing with necessary support services. State legislation should encourage flexibility in developing alternative housing and residential settings. Localities need to address the "not-in-my-backyard" syndrome related to shelters and residencies, and work closely with neighborhood groups. (Nat'l Comm.: Working Group Summary Report: "Federal, State, and Local Responsibilities"--March 1990)

Federal, state, and local governments and community-based agencies need to develop more effective partnerships in HIV prevention, education, and information. The Working Group believes that federal restrictions on the use of education and prevention funds is counterproductive and prolongs the HIV epidemic. Restrictive legislative language appears to hinder

states and localities and community-based agencies in providing the prevention message in ways that would reduce individual risk and limit the spread of HIV infection. Therefore, while states and localities should be accountable for the federal funds they receive, the use of these dollars for education and prevention programs should be flexible. Evaluation of these programs to determine what approaches work best is essential and these programs should be innovative, creative, and culturally respectful. Finally, since community-based organizations are at the heart of HIV education efforts, these agencies should be supported by all levels of government, including the provision of support for education and training of agency staff and organizational development assistance. (Nat'l Comm.: Working Group Summary Report: "Federal, State, and Local Responsibilities"--March 1990)

The National Commission on AIDS will continue to recommend policy goals for a national plan. However, the Commission believes it is essential that a federal interagency mechanism be in place to coordinate a national plan. In this way, those who are ultimately responsible for the implementation will have an active role in its development. (Nat'l Comm.: Interim Report Number Two: "Leadership, Legislation, and Regulation"--April 1990)

Federal disaster relief or direct emergency relief is urgently needed to help states and localities most seriously impacted to provide the HIV prevention, treatment, care, and support services now in short supply. The Commission strongly supports the efforts in Congress, now embodied in S.2240, to address this need. The resources simply must be provided now or we will pay dearly later. (Nat'l Comm.: Interim Report Number Two: "Leadership, Legislation, and Regulation"--April 1990)

Housing is an absolutely vital component of any comprehensive effort to address the multiple problems posed by HIV infection and AIDS. While the Commission recognizes that coordination between the state and local government, with input from community-based organizations, is essential to effectively respond to the homeless crisis, we also believe the federal government must take the lead in providing the dollars needed to respond to this overwhelming, indeed catastrophic, problem. (Nat'l Comm.: Interim Report Number Two: "Leadership, Legislation, and Regulation"--April 1990)

Government restrictions imposed on the use of education and prevention funds are seriously impeding HIV control. They are clearly serving to prolong the HIV epidemic and should be removed. (Nat'l Comm.: Interim Report Number Two: "Leadership, Legislation, and Regulation"--April 1990)

Because the Americans with Disabilities Act (ADA) guarantees protection against discrimination for people with HIV infections

and AIDS, the National Commission on AIDS strongly urges the U.S. House of Representatives to pass the ADA in a swift and timely manner. State and local governments should pass laws forbidding discrimination in areas not covered by the ADA or other federal statutes. (Nat'l Comm.: Interim Report Number Two: "Leadership, Legislation, and Regulation"--April 1990)

Volunteers should be publicly recognized not only for the invaluable contribution they have made to people living with HIV infection and AIDS, but also for the way in which they fight fear and bigotry by fostering compassion and caring. The cost-effective dollars needed to recruit, train, support, and manage volunteers must be provided by the government and the private sector, and recognized as essential to our national response to the HIV epidemic. (Nat'l Comm.: Interim Report Number Three: "Research, the Workforce, and the HIV Epidemic in Rural America"--August 1990)

3. To combat the overwhelming effects which drug addiction, overcrowding, and HIV disease are having on the already severely inadequate health care services of correctional systems nationwide, a program such as the National Health Service Corps should be created to attract health care providers to work in correctional systems. (Nat'l Comm.: Interim Report Number Four: "HIV Disease in Correctional Facilities"--March 1991)
4. The Department of Health and Human Services should issue a statement clarifying the federal policies on prisoners' access to clinical trials and investigational new drugs. In addition, the Food and Drug Administration, in conjunction with the Health Resources and Services Administration and the National Institutes of Health, should initiate an educational program directed toward informing inmates and health care professionals working in correctional facilities of the availability of investigational new drugs, expanded access programs, and applicable criteria for eligibility of prisoners in prophylactic and therapeutic research protocols. (Nat'l Comm.: Interim Report Number Four: "HIV Disease in Correctional Facilities"--March 1991)
7. The burden of determining and assuring standards of care has largely fallen to the courts, due, in part, to the failure of the public health authorities to take a leadership role in assuring appropriate standards of health care and disease prevention for our incarcerated populations. Bar associations and entities such as the Federal Judicial Center must, therefore, establish programs to educate judges, judicial clerks, and court officers about HIV disease. (Nat'l Comm.: Interim Report Number Four: "HIV Disease in Correctional Facilities"--March 1991)

Housing tailored to a range of medical and social needs is a critical part of the continuum of care for persons living with HIV disease. Congress should fund fully the AIDS Housing Opportunity Act of 1990. (Nat'l Comm.: Working Group Report: "Social and Human Issues"--April 1991)

Planning is key to developing a coordinated and effective response to HIV disease, and people living with HIV disease must be included in planning activities. The planning process should be vigorously directed by the governmental agencies responsible for planning the communities' HIV response. Such planning should include the private sector and members of affected communities. The receipt of government funding should be conditional upon the establishment of relationships between service providers and affected communities. (Nat'l Comm.: Working Group Report: "Social and Human Issues"--April 1991)

Leadership is essential. Leadership entails developing a vision of the response needed to meet the challenge of the HIV epidemic in a community, developing a plan to realize it, and accepting responsibility for its fulfillment. (Nat'l Comm.: Working Group Report: "Social and Human Issues"--April 1991)

Continued and increased government and private support of voluntary and community-based organizations is critical. Fledgling organizations established more recently to meet the needs of minority communities may require special technical assistance and financial support. (Nat'l Comm.: Working Group Report: "Social and Human Issues"--April 1991)

Where the appropriate governmental entity is unable or unwilling to assume responsibility for planning and coordination, voluntary and community-based organizations should coordinate local efforts to avoid needless duplication and support the creation of mechanisms to provide national volunteer leadership, technical assistance, and resource sharing. Volunteer efforts are too important to be fragmentary and competitive. (Nat'l Comm.: Working Group Report: "Social and Human Issues"--April 1991)

Cooperation and accountability is necessary in coordinating the resources of a panoply of service providers and interest groups. Government leaders, elected and appointed, must vigorously support the coordination effort. (Nat'l Comm.: Working Group Report: "Social and Human Issues"--April 1991)

The HIV disease caseload will continue to skyrocket, even if HIV disease loses its salience as a matter of public attention. Because of the disproportionate impact of HIV and its enormous impact on already suffering communities, the federal government has the ultimate responsibility of assuring that a continuum of medical, psychological, and social services are available to

people living with HIV disease. (Nat'l Comm.: Working Group Report: "Social and Human Issues"--April 1991)

The federal government must take the lead in developing and maintaining programs to prevent HIV transmission related to licit and illicit drug use. (Nat'l comm.: Interim Report Number Five: "The Twin Epidemics of Substance Use and HIV"--July 1991)

Research and epidemiologic studies on the relationships between licit and illicit drug use and HIV transmission should be greatly expanded and funding should be increased, not reduced or merely held constant. (Nat'l comm.: Interim Report Number Five: "The Twin Epidemics of Substance Use and HIV"--July 1991)

The federal government should establish a comprehensive national HIV prevention initiative. This initiative should be authorized by Congress and developed by the Department of Health and Human Services. It should provide flexible resources to state and local government and other public or private nonprofit entities for community-wide HIV prevention efforts. It must also include input from individuals who have expertise through experience, education, or training. The prevention initiative is an essential component of a national HIV plan. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

Congress should remove the government restrictions that have been imposed on the use of funds for certain kinds of HIV education, services, and research. Government restrictions on certain HIV programs and on behavior-oriented research studies impede the fight against HIV disease. HIV prevention programs and research into sexual and drug-using behaviors must be conducted and evaluated. Results from these and other health promotion and disease prevention efforts must be shared and rapidly incorporated into HIV prevention and education strategies. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

Legal barriers to the purchase and possession of injection equipment should be removed. Legal barriers do not reduce illicit drug injection. They do, however, limit the availability of new, clean injection equipment, thereby encouraging the sharing of injection equipment, and the increase in HIV transmission. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

Universal health care coverage should be provided for all persons living in the United States to ensure access to quality health care services. The Commission believes universal health care coverage is a necessary step to ensuring access to quality health care. This coverage should be comprehensive and should include prescription drugs. In the interim, the Commission recommends a series of immediate short-term steps to address the urgent

problem of inadequate coverage for people with HIV disease.
(Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

Medicaid should cover all low-income people with HIV disease. The Commission recommends eliminating the disability requirement and raising the income level for Medicaid eligibility for people with HIV disease. By eliminating the disability requirement, low-income people with HIV infection who have not had a clinical diagnosis of AIDS could be covered by Medicaid and receive the early intervention treatments and services they need. Increasing the income eligibility requirement would prevent many people with HIV infection from having to impoverish themselves in order to qualify for basic health care services. At the same time it would relieve some of the reliance on public hospitals by the uninsured. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

The Commission strongly believes these changes should be mandated; however, at the very least, states should be given the option of making these changes. In addition, the Commission believes these changes can and should lead to further changes that will include people with serious chronic conditions other than HIV disease.

Medicaid payment rates for providers should be increased sufficiently to ensure adequate participation in the Medicaid program. Unrealistically low reimbursement rates under the Medicaid program serve as a serious disincentive for health care providers to care for people who rely on Medicaid. Medicaid rates should be raised to Medicare levels. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

Congress and the Administration should work together to adequately raise the Medicaid cap on funds directed to the Commonwealth of Puerto Rico to ensure equal access to care and treatment. Because of the existing cap on Medicaid funds allocated to the Commonwealth of Puerto Rico, none of the Medicaid recommendations the Commission has put forward to expand benefits for people with HIV disease would include individuals living in this part of the United States. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

States and/or the federal government should pay the COBRA premiums for low-income people with HIV disease who have left their jobs and cannot afford to pay the health insurance premium. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

Social Security Disability Insurance (SSDI) beneficiaries who are disabled and have HIV disease or another serious chronic health condition should have the option of purchasing Medicare during

the current two-year waiting period. Medicaid should be required to purchase Medicare coverage for low-income SSDI beneficiaries. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

The federal government should fund the Ryan White CARE Act at the fully authorized level. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

The following interim steps to improve access to expensive HIV-related drugs should be taken. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991):

- (a) Adequately reimburse for the purchase of drugs required in the prevention and treatment of HIV disease, including clotting factor for hemophilia;
- (b) Undertake, through the Department of Health and Human Services, a consolidated purchase and distribution of drugs used in the prevention and treatment of HIV disease; and
- (c) Amend the Orphan Drug Act to set a maximum sales cap for covered drugs.

The Department of Health and Human Services should conduct a study to determine the policies of third-party payers regarding the payments of certain health service costs that are provided as part of an individual's participation in clinical trials conducted in the development of HIV-related drugs. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

A comprehensive national HIV plan should be developed with the full participation of involved federal agencies and with input from national organizations representing various levels of government to identify priorities and resources necessary for preventing and treating HIV disease. To develop the comprehensive national HIV plan, the Commission calls upon the President of the United States to designate an individual or lead agency with the authority and responsibility for instituting a cabinet-level process to articulate the federal component of an HIV plan, develop a mechanism for interagency as well as state and local participation and coordination, and establish a timeline for completion of key tasks. (Nat'l Comm.: Second Annual Report: "America Living With AIDS"--September 1991)

All levels of government should develop comprehensive HIV plans that establish priorities, ensure consistent and comprehensive policies, and allocate resources. These plans should build on the national HIV plan and be developed at the state level with clear direction and support from each governor and at the

appropriate local level (city or county) with clear direction and support from the appropriate locally elected official body. Each level of government should have an HIV Advisory Committee that is composed of representatives of diverse community-based organizations; the private sector; religious organizations; public safety officials; people living with AIDS; housing, health, and social service agencies; and other appropriate representatives. (Nat'l Comm.: Second Annual Report: "America Living With AIDS" -- September 1991)

The Commission recognizes that most states and many local governments may have an HIV plan. However, these existing plans should be carefully reviewed to ensure that they are up to date and comprehensive, and that they coordinate the entire spectrum of prevention and treatment services.

Implementation of the Americans with Disabilities Act should be carefully monitored, and states and localities should evaluate the adequacy of existing state and local antidiscrimination laws and ordinances for people with disabilities, including people living with HIV disease. (Nat'l Comm.: Second Annual Report: "America Living With AIDS" -- September 1991)

Elected officials at all levels of government have the responsibility to be leaders in this time of health care crisis and should exercise leadership in the HIV epidemic based on sound science and informed public health practices. The Commission recognizes that many issues raised by the HIV epidemic place pressures on elected officials to pass laws intended to respond to constituent fears and concerns. The Commission, however, is very concerned that policies may be enacted into law that are better left to scientists and public health experts. Legislative focus should be on full funding of HIV-related research, prevention, and treatment programs and on protecting those with HIV disease from discrimination. (Nat'l Comm.: Second Annual Report: "America Living With AIDS" -- September 1991)

The federal government should develop an evaluation and technical assistance component for all federally funded HIV-related programs. Understanding what works and why is essential to the development of effective prevention and care services for people living with HIV disease. It is essential that all HIV-related prevention and treatment efforts be evaluated and that the information be integrated into all planning, prevention, and health care delivery programs. (Nat'l Comm.: Second Annual Report: "America Living With AIDS" -- September 1991)

That the issues confronted by the people of the Commonwealth of Puerto Rico be fully taken into consideration when establishing national policy and programs related to HIV infection and AIDS.

(Nat'l Comm.: Interim Report Number Six: "The HIV/AIDS Epidemic in Puerto Rico"--June 1992)

That the federal government and the Commonwealth of Puerto Rico urgently explore innovative approaches to partnerships, so that appropriate programs to respond to the HIV epidemic can be put in place with and for Puerto Ricans. (Nat'l Comm.: Interim Report Number Six: "The HIV/AIDS Epidemic in Puerto Rico"--June 1992)

That Congress authorize the U.S. Department of Health and Human Services to conduct, in collaboration with the Commonwealth of Puerto Rico, a comprehensive study of the overall health status and services of people living in Puerto Rico. This study should also review the organization and delivery of health care in Puerto Rico and assess the federal role in assisting the people of Puerto Rico in addressing their most pressing health issues, particularly HIV disease. Consideration should also be given to including Puerto Rico in health surveys that cover the rest of the United States, such as NHANES, NMES, and NHIS, in such a manner that data on island residents can also be analyzed independently. (Nat'l Comm.: Interim Report Number Six: "The HIV/AIDS Epidemic in Puerto Rico"--June 1992)

That Congress and the Administration work together to raise the Medicaid cap on funds directed to the Commonwealth of Puerto Rico to ensure equal and adequate access to care and treatment. (Nat'l Comm.: Interim Report Number Six: "The HIV/AIDS Epidemic in Puerto Rico"--June 1992)

That the U.S. Department of Health and Human Services, in collaboration with the government of the Commonwealth of Puerto Rico, seek ways to strengthen the technical, administrative, and coordinating capabilities of the Puerto Rico Department of Health. Similar support should also be provided directly to other health, social service, and housing agencies and community-based organizations in Puerto Rico. Technical assistance provided in these areas should be on-site and ongoing. (Nat'l Comm.: Interim Report Number Six: "The HIV/AIDS Epidemic in Puerto Rico"--June 1992)

The HUD should make HIV/AIDS a top priority. The federal government must help support AIDS housing. The failure to do so contributes significantly to unnecessary human suffering and is costing the nation millions of dollars. (Nat'l comm.: Interim Report Number Seven: "Housing and the HIV Epidemic"--July 1992)

Congress should mandate that HUD recognize HIV/AIDS as a disability and not continue to deny people with HIV/AIDS access to housing funds targeted toward the disabled. (Nat'l comm.: Interim Report Number Seven: "Housing and the HIV Epidemic"--July 1992)

People with HIV/AIDS should be granted access to traditional housing programs. By the same token, Congress and HUD must adapt

program requirements to meet the specific housing needs of people with HIV/AIDS. (Nat'l comm.: Interim Report Number Seven: "Housing and the HIV Epidemic"--July 1992)

Congress should make clear that HIV/AIDS-specific housing, under Shelter Plus Care and other federal programs, is both permitted and essential. (Nat'l comm.: Interim Report Number Seven: "Housing and the HIV Epidemic"--July 1992)

Congress should continue to play a leadership role in developing new funds to address the HIV/AIDS housing crisis. (Nat'l comm.: Interim Report Number Seven: "Housing and the HIV Epidemic"--July 1992)

The President of the United States should name a lead official or agency to be responsible for a national plan to combat HIV/AIDS with cabinet-level, interagency coordination. (Nat'l comm.: Interim Report Number Seven: "Housing and the HIV Epidemic"--July 1992)

Federal, state, and local governments should squarely confront problems associated with racial inequality and its effect on the public health. Public health officials should ensure that effective and equitable HIV policy, programs, and funding efforts are brought to bear in communities of color. (Nat'l Comm.: Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--December 1992)

Public health officials should work with researchers, health professionals, and community-based service providers to gain a better understanding of the role of cultural and socioeconomic factors in the transmission of HIV, the disease process, and access to care. Information gleaned from these efforts should be taken into account in designing HIV prevention messages, services, and programs, and in providing expanded treatment opportunities. (Nat'l Comm.: Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--December 1992)

The President and the Congress should increase support for community-based primary care, including community health centers, migrant health centers, and clinics funded by the Indian Health Service to ensure delivery of prevention and care services, including those for HIV/AIDS. (Nat'l Comm.: Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--December 1992)

The President and the Congress should fully fund the Ryan White CARE Act and ensure that communities of color are adequately represented in the planning process and appropriately served by the resources available. (Nat'l Comm.: Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--December 1992)

The President and the Congress should provide additional incentives for health care professionals to work in underserved areas by increasing support for programs such as the National

Health Service Corps and programs such as the Disadvantaged Minority Health Improvement Act of 1990 targeted specifically at increasing the number of minority health care professionals. (Nat'l Comm.: Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--December 1992)

Likewise, state and local jurisdictions should increase support for public hospitals and other locally supported components of comprehensive primary care systems that deliver HIV prevention and care services. (Nat'l Comm.: Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--December 1992)

Additionally, the Health Resources and Services Administration should assess the capacity of special initiatives, such as the Ryan White CARE Act and the Health Care for the Homeless Program, to develop and support a strong primary care infrastructure in communities of color. (Nat'l Comm.: Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--December 1992)

The federal government should provide adequate resources to community programs designed to improve access to health care and support services and to prevent the spread of HIV among adolescents. Passage of legislation similar to the proposed Comprehensive Services for Youth Act of 1992 would foster coordination and collaboration among educators, health care providers, and community-based organizations through the development and operation of citywide and statewide youth service center systems. (Nat'l Comm.: Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--December 1992)

The Agency for Health Care Policy and Research, the Health Resources and Services Administration, and the National Institute of Allergy and Infectious Diseases should conduct a review of current efforts to educate physicians on developments in HIV/AIDS care and aggressively pursue methods to improve the quality of HIV/AIDS care. In order to assure that people of color living with HIV receive the benefit of current developments in HIV/AIDS care these agencies should strive to coordinate better the dissemination of information, target physicians who practice in communities of color, and work intensively with schools and professional associations that have traditionally trained minority health professionals. (Nat'l Comm.: Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--December 1992)

The National Institutes of Health, in conjunction with other appropriate agencies within the Department of Health and Human Services, should intensify efforts to assure access to HIV/AIDS clinical trial information, with regard to trial opportunities, the results of research efforts, and their significance for clinical management. Emphasis should be placed on reaching populations that have had poor or underrepresentative access to

clinical trial opportunities. Efforts should include the collection and dissemination of trial-related research and information on new developments in treatment. Dissemination should be carried out in a manner that ensures that information is current, accurate, and comprehensible to target populations and the health professionals who serve them. (Nat'l Comm.: Interim Report Number Nine: "The Challenge of HIV/AIDS in Communities of Color"--December 1992)

The President should discuss the AIDS crisis with the American people. (Nat'l Comm.: Interim Report Number Ten: "Mobilizing America's Response to AIDS: Recommendations to President Clinton"--January 1993)

The President should establish an AIDS Coordinator's Office reporting to the President. (Nat'l Comm.: Interim Report Number Ten: "Mobilizing America's Response to AIDS: Recommendations to President Clinton"--January 1993)

The President should instruct the Secretary of HHS, in cooperation with the AIDS Coordinator and other Cabinet Secretaries as necessary, to immediately develop a National Strategic Plan to confront the epidemic. The plan should include (Nat'l Comm.: Interim Report Number Ten: "Mobilizing America's Response to AIDS: Recommendations to President Clinton"--January 1993):

- a. Steps to implement a comprehensive, effective initiative for prevention of HIV infection that build on the knowledge already developed in many communities.
- b. Steps to ensure access to health care and supportive services for those who are HIV infected.
- c. Steps for education and legal action that will diminish unwarranted fears, stigmatization and discrimination against people with HIV infection.
- d. Steps to ensure a broadly based, better directed research approach to HIV/AIDS problems.
- e. Steps to enhance U.S. involvement in the international response to HIV.

The President should request full funding for the Ryan White CARE Act. (Nat'l Comm.: Interim Report Number Ten: "Mobilizing America's Response to AIDS: Recommendations to President Clinton"--January 1993)

The President should remove unwarranted restrictions relating to HIV infection. (Nat'l Comm.: Interim Report Number Ten: "Mobilizing America's Response to AIDS: Recommendations to President Clinton"--January 1993)

The President should request a plan to make immediate treatment a reality for all drug users who seek it. (Nat'l Comm.: Interim Report Number Ten: "Mobilizing America's Response to AIDS: Recommendations to President Clinton"--January 1993)

The President should emphasize the importance of addressing AIDS as a workplace issue by requesting initiation of an ongoing federal workplace AIDS program, which should include, with a timetable, the following (Nat'l Comm.: Interim Report Number Eleven: "HIV/AIDS: A Challenge for the Workplace"--June 1993):

- a. Leadership, within their respective domains, by cabinet members and other senior administration officials.
- b. New mechanisms for using the commitment of prominent business sector leaders to help guide the Administration's response to the challenges of AIDS in the workplace.
- c. Convening of a national business and labor conference to focus on the impact of HIV/AIDS on the business sector.
- d. Agency-specific workplace policies. As part of this effort, federal agencies should mandate the Office of Personnel Management guidelines, as originally suggested by the Presidential Commission in 1988. This recommendation has still not been implemented. Training of federal managers in workplace issues, notifying federal employees of their rights, and ensuring ongoing employee access to information and services should be priorities.
- e. Ongoing employee education for the entire federal work force, at all levels, beginning with the White House staff.
- f. Endorsement of CDC's Business Responds to AIDS program and utilization of its resources by federal and all other work sites throughout the nation.
- g. Consideration of mechanisms for federal government contracts that assure that all contracted employers conduct HIV/AIDS education for their work force, and that these employers be alerted to the requirements of other federal, state, and local laws and regulations that address and protect the rights of HIV-infected employees in the workplace (similar to the requirements regarding "drug-free workplaces.")

- h. Attention to ensuring that during the health care reform debate, all workplace health and education issues are given proper attention.

Federal agencies, particularly the Centers for Disease Control and Prevention, the Department of Justice, the Equal Employment Opportunity Commission, and the Department of Health and Human Services' Office of Civil Rights, should collaborate to provide increased support for continuing and strengthening the role played by AIDS service organizations and other community resources in providing assistance to businesses addressing AIDS workplace policies and education. (Nat'l Comm.: Interim Report Number Eleven: "HIV/AIDS: A Challenge for the Workplace"--June 1993)

The Small Business Administration (SBA) should formalize and strengthen its preliminary investments in AIDS education efforts by designating an AIDS Coordinator for the agency. This individual would design and manage workplace AIDS education programs for all SBA employees and make these programs available to small businesses as part of SBA-sponsored conferences and seminars. (Nat'l Comm.: Interim Report Number Eleven: "HIV/AIDS: A Challenge for the Workplace"--June 1993)

The Attorney General should underscore the commitment of the administration to enforcing the Americans with Disabilities Act and call upon states and employers to ensure full compliance with all aspects of the ADA dealing with HIV-infected employees, those perceived as having HIV, and those employees caring for people with HIV. (Nat'l Comm.: Interim Report Number Eleven: "HIV/AIDS: A Challenge for the Workplace"--June 1993)

The Departments of Justice, Health and Human Services, and Labor, and the Equal Employment Opportunity Commission should intensify their efforts to educate employers on the requirements of the ADA, and provide technical assistance and training to employers on how to meet those requirements, especially as they pertain to reasonable accommodation for HIV-infected employees. The Department of Labor, as part of its role in administering unemployment insurance to state employment agencies and commissions, should also alert employers in the states to the requirements of federal, state, and local laws and regulations that address and protect the rights of HIV-infected employees in the workplace.

The Department of Labor should intensify its efforts to ensure that employers are knowledgeable about and comply with the provisions of the OSHA Bloodborne Pathogen Standard. (Nat'l Comm.: Interim Report Number Eleven: "HIV/AIDS: A Challenge for the Workplace"--June 1993)

Employers should meet the standard's engineering controls, work practices, and personal protective equipment, employee education, and record keeping requirements, and rigorously monitor employee compliance with the requirements.

Congress, the Food and Drug Administration, and the Occupational Safety and Health Administration, after consultation with the Centers for Disease Control and Prevention, should take the steps necessary to reduce the risk of HIV transmission 1) for patients and workers in health care settings, and 2) for other employees in occupations or situations where there is a risk of HIV transmission including (Nat'l Comm.: Interim Report Number Eleven: "HIV/AIDS: A Challenge for the Workplace"--June 1993):

- a. Congressional passage of legislation ensuring the application of the Occupational Safety and Health Act and OSHA regulations to all employees, irrespective of state of residence; and
- b. FDA regulations designed to enhance the safety of devices used in health care settings.

The Commission reiterates its previous recommendations that the President should lead the American people to a new response to the HIV/AIDS epidemic, should appoint a National AIDS coordinator, and should call for the development of a national strategic plan to confront the epidemic. The national strategic plan should contain plans for a national prevention initiative (National Commission on AIDS, 1991 and 1993) that includes steps for educating the public more thoroughly about AIDS and building community recognition of the need for more effective prevention efforts, including those directed at youth. Congress should place high priority on legislation directed towards comprehensive services for youth. (Nat'l Comm.: Interim Report Number Twelve: "Preventing HIV/AIDS in Adolescents"--June 1993)

Congress and Agencies should act to break down barriers to collaboration and co-location of services established by categorical funding constraints. This would allow schools and other youth-serving organizations to provide comprehensive disease prevention and health promotion programs to young people. (Nat'l Comm.: Interim Report Number Twelve: "Preventing HIV/AIDS in Adolescents"--June 1993)

Categorical funding constraints make it difficult to best serve young people. Schools and many other youth-serving institutions receive a mix of funds for a variety of programs designed to improve healthy growth and development (Wilhoit and Fraser, 1993). The difficulties presented by the inflexibility of categorical funding streams make it difficult for programs to provide comprehensive prevention

programs. The inability to merge those funds to provide a comprehensive prevention program limits their effectiveness. The sheer number of sources from which an individual school or agency might receive funds can lead to overwhelming, time-consuming, duplicative paperwork. For example, the Klein Bottle Youth Programs, a community-based youth serving agency with an annual budget in excess of \$2.5 million, draws on over 65 federal, state, county, and city funding sources to provide comprehensive services to youth in Santa Barbara, California (Coburn, 1993). Another example of the problems created by categorical funding is the current regulatory restriction on discussion of risky sexual behavior in Drug Free School programs, the largest federally supported prevention initiative, even though this is a hazardous potential consequence of drug use (Select Committee on Children, Youth and Families, 1992).

Federal health and education agencies should increase cooperation in order to facilitate "technology transfer" between the research and public health worlds and the education sector and to involve the education community in health promotion. Collaboration between state and local health agencies and education agencies should also be encouraged. (Nat'l Comm.: Interim Report Number Twelve: "Preventing HIV/AIDS in Adolescents"--June 1993)

The education community does not have ready access to much of the cutting-edge research on strategies for HIV prevention. The "transfer of technology" between the research community and schools needs strengthening. Teachers, school administrators, and school boards do not often read the technical journals in which research results are published, and, even if they do, researchers' language is often difficult for nonexperts to understand (Wilhoit and Fraser, 1993).

Organizations that sponsor research and pilot projects should undertake and publish meta-analyses that identify the program design and implementation characteristics for prevention efforts that are predictors of effectiveness. Guidance for local action should be developed through collaboration between federal health and education agencies.

Within health care reform, adolescent health issues must be addressed. Incentives to encourage providers to make a commitment to adolescent health care should be considered. The Commission reiterates the importance of its previous recommendations in this regard, particularly those made in *America Living with AIDS* and *The Challenge of HIV/AIDS in Communities of Color*. Longer-term recommendations for universal health coverage and immediate needs, during the transition to a new system, should both be

addressed. (Nat'l Comm.: Interim Report Number Twelve: "Preventing HIV/AIDS in Adolescents"--June 1993)

For the critical task of reducing HIV transmission, substantial increases in resources for prevention, specifically for behavior change interventions and behavioral and social science research, must be requested by the Administration and/or appropriated by Congress. (Nat'l Comm.: Interim Report Number Thirteen: "Behavioral and Social Sciences and the HIV Epidemic"--June 1993)

The level appropriations for prevention and prevention research in recent years have--in the face of an expanding epidemic--left a prevention gap and substantial increases in resources for prevention will be needed over the next few year's to catch up. Increases for prevention must not be to the detriment of research or services that will benefit persons with HIV infection.

While Congress has the right and responsibility to address research policy issues and priority setting broadly, it must take steps to ensure the integrity of the scientific peer review processes for the future, and to protect reviewed and approved grants from politically motivated interference. (Nat'l Comm.: Interim Report Number Thirteen: "Behavioral and Social Sciences and the HIV Epidemic"--June 1993)

NIH, CDC, and other federal agencies conducting AIDS behavioral and social science research and supporting prevention programs must be allowed to conduct their activities in a climate in which they are unhindered by inappropriate political intrusion, censorship or threats.

The current levels of support for behavioral and social science activities on AIDS in each PHS agency should be accurately assessed, and detailed plans should be made to integrate behavioral and social science research into each component of the federal AIDS prevention and treatment effort. (Nat'l Comm.: Interim Report Number Thirteen: "Behavioral and Social Sciences and the HIV Epidemic"--June 1993)

Financial support for behavioral and social science research on AIDS at NIH should be increased overall by approximately 10 percent annually above the inflationary index over the next five fiscal years. (Nat'l Comm.: Interim Report Number Thirteen: "Behavioral and Social Sciences and the HIV Epidemic"--June 1993)

The Commission recognizes the need for increased behavioral and social science research efforts at NIH and suggests an overall specific funding target in order to determine whether real progress is being made. The target should be set in terms of absolute funding because funds should not be withdrawn from other critical areas in order to increase the

percentage applied to behavioral and social sciences. The new OAR Director should assess where increases should be applied, after responsibilities are assigned for an integrated research plan.

Leaders at all levels must speak out about AIDS to their constituencies. (Nat'l Comm.: Final Report: "AIDS: An Expanding Tragedy"-June 1993)

Our President must speak out clearly and forcibly about the nature, extent, and needs of the AIDS disaster. This has been our foremost recommendation since 1991. One AIDS activist group has as its symbol a pink triangle with the phrase, "silence=death." There is much to suggest that they are right. The appalling lack of frank discussion about the epidemic at all levels of national leadership fostered a woefully inadequate response, yielding death and suffering well in excess of what might have been. Silence has existed at too many levels of responsibility. Few governors, mayors, members of Congress, corporate executives, community or religious leaders, have stepped forward—perhaps taking their cue from previous Presidents. Consequently, the scale of the problem is seriously underestimated, and fear, prejudice, and misinformation abound. Leaders have both the capacity and the responsibility to coalesce their communities to find solutions.

We are vividly aware of the fact that addressing AIDS—and particularly issues that require discussing sexuality or drug use—is difficult for many to deal with comfortably. Further, some of the steps that will be required to address the epidemic better will be unpleasant or unpopular in the minds of many. But to confront difficult and sensitive issues is what true leadership means and requires. It would, in our judgment, make a profound difference in our national response to HIV disease if full and frank discussion of all its implications was initiated and encouraged by those in positions of responsibility at all levels.

We must develop a clear, well-articulated national plan for confronting AIDS. (Nat'l Comm.: Final Report: "AIDS: An Expanding Tragedy"--June 1993)

Again, high on our list of recommendations, and that of the Presidential Commission preceding us, has been the development of a carefully crafted national strategic plan to address the issues of prevention, care, and research, required to deal with the HIV epidemic. To this end, we have suggested such a plan directly to the President in our report, *Mobilizing America's Response to AIDS*. We have spelled out the authority and resources necessary for the

coordinating office required to deal with the numerous cabinet departments that must be involved in such planning. Along similar lines, we have pointed to the singular absence of a national prevention strategy worthy of the name. We have also indicated the need for more overall planning for HIV-related research, housed appropriately within the National Institutes of Health, and the desperate need for a compassionate continuum of care for those infected. The obvious reasons for having such overarching plans, still absent in the twelfth year of the epidemic, need little further comment, except perhaps that the underlying theme of the plans should be to address sexual and drug-use behavior from a public health perspective.

All of our other recommendations, past or present, follow logically from the above. There is a compelling need for a functioning public health system with the ability to conduct appropriate prevention programs, free from censorship, that would serve the special needs of gay men, of lesbians, of communities of color, of those who use drugs, of women, of children, and of adolescents. The need for better therapeutic agents, long-term care, housing, social support services, and their financing—all must be embodied in those plans. Our reports to date, and most particularly *America Living with AIDS*, spell out the particulars. Clearly our work is unfinished. Although the Commission has listened diligently, considered carefully, and kept the problem of AIDS before the public, most of our recommendations remain to be implemented. But it is time for AIDS to be swept into the mainstream of America's national agenda. To continue to treat HIV/AIDS as a marginal problem gravely threatens our nation's future. Without action on our nation's unfinished business on AIDS, we will have a continually expanding tragedy. We call on America to get on with the job. What should be done is not complicated. But it requires leadership, a plan, and the national resolve to implement it.

On Tuesday, October 19, immediately following the ONAPC all-hands meeting, the planning staff for the national plan will meet in the same room. The room is reserved until 12:30.

More background information will be provided before the meeting. The purpose of this cc:Mail is simply to request that you block out your calendar. The most pressing issues that needs to be discussed at this time is meeting logistics. This includes:

Setting a date certain for the meeting. There is considerable planning and preparation that will be necessary. Much of it is dependent on having a date and knowing the level of involvement from the White House;

Contracting for conference planning services--before the meeting, Sandy M. and I will work up a budget and a mock statement of work that can be used as a basis for this discussion;

An invitation list--we need to decide whom we will invite. Currently the estimated number is 150; and

The number of working groups--right now we have identified four working groups (prevention and education, caring for people with HIV disease, research, and government responsibilities. Are these the groups we will go with? The subject of sub working groups, if any, should we provide meeting space?

Thank you for your help. It is appreciated.



OFFICE OF NATIONAL DRUG CONTROL POLICY
EXECUTIVE OFFICE OF THE PRESIDENT
Washington, D.C. 20500

April 4, 1994

file
RG -
Please comment.
Andrew

MEMORANDUM FOR ANDREW BARRER

FROM: RICIA MCMAHON *RM*

SUBJECT: 1994 National HIV Action Agenda - ~~CONFIDENTIAL~~
DRAFT

Thank you for the opportunity to review and comment on the draft plan. ONAPC is to be commended for developing a statement that is both comprehensive and targeted.

ONDCP has nine specific comments: two addressing shared interests on which we might work together; one caveat regarding references to health care reform; and six recommended edits to ensure language that is most consistent with drug use research and with the President's National Drug Control Strategy.

Page 2., second listed "action"

ONDCP shares this support for behavioral research, which is critically important to interventions regarding drug use as well as other high risk behaviors.

Page 3., first listed "action"

ONDCP is also concerned regarding the extent to which Federal regulations might impede the development of medications for addiction treatment. IOM has recently concluded a study of medications development for NIDA, which might be of interest to ONAPC.

Page 4., first listed "action"

Page 8., first listed "action"

Since this is to be an Administration policy document, you should consider addressing needed health services by supporting the President's Health Security Plan. As worded, the statements connote that the Administration is seeking something different or in addition.

Page 8., third listed "commentary"

Please substitute the term "drug injecting practices" for the term "substance-use practices", and please substitute the term "inject drugs" for the term "use substances." The statement's

DETERMINED TO BE AN ADMINISTRATIVE
MARKING Per E.O. 13526

Sec. 3.2(C) Initials: *RM* Date: *6/18/94*

general wording implies that there are safe ways to smoke crack or use other drugs.

Page 9., fourth listed "action"

As above, please substitute the term "drug users" for "substance users" at both places in the sentence.

Page 10., third listed "commentary"

Please substitute "their ceasing drug use" for "finding ways to interrupt injection." The former expresses something closer to an ideal solution and is a more accurate expression of AIDS and drug control policy.

Page 11., second listed "action"

Please substitute "Expand and improve upon identified" for "Identify and develop." NIDA has demonstrated three outreach models, which appear rather effective in getting out-of-treatment users to enter treatment. ONDCP favors wider application of these efforts.

Page 11., third listed "action"

Please substitute the following language.

"For those drug users who are unwilling or unable to participate in treatment or abstain from injecting drugs, strongly discourage the sharing of needles, syringes, works, and rinse water as well as encourage and provide specific information and training to reduce high risk behaviors."

It is imperative that we not create a false sense of security by focusing either on one instrument of use (i.e., the needle), or one mode of use (i.e., injecting). Stemming the transmission of HIV is going to require changes in a number of the behaviors associated with drug seeking and drug using.

Page 11., fourth listed "action"

ONDCP strongly recommends that the term "harm reduction," be used only if it is specifically defined (i.e., exactly what is it, what does it include, and what does it not include). Without a specific definition, "harm reduction" can easily become a euphemism, a semantic shield for any number of interventions that can not be justified by credible evidence.

This statement diffuses the focus of an otherwise targeted document. ONDCP recommends that it be dropped.

DRAFT

4/4/94 DRAFT-----DRAFT-----DRAFT

~~CONFIDENTIAL~~

FOR INTERNAL USE ONLY-----CONFIDENTIAL-----

National HIV Action Agenda

April 1994

INTRODUCTION

From the National AIDS Policy Coordinator

The National HIV Action Agenda is a leadership statement.

It has been developed by the Office National AIDS Policy to give direction to our overall national effort to end the HIV/AIDS epidemic; the epidemic some have called the health crisis of our times. The action steps described within provide guidance and markers for the nation. The action steps are activities the nation can begin within a six-month horizon. Many are long-term or continuous, while others are short-term or immediate.

In the next iteration of the National HIV Action Agenda many of the action items will have been accomplished. New goals will be substituted for goals attained or goals no longer appropriate as the epidemic and our ability to respond to it continually change.

The commitment to provide the continuing national leadership necessary to end the epidemic is something this Administration takes very seriously. When President Clinton appointed me, he said "AIDS is terrifying. It inflicts tragedy on too many families. But ultimately, it is a disease; one we can defeat...with commitment and courage and constancy, and with vocal and responsible leadership from our nation's government."

The National HIV Action Agenda is organized into three areas for action: research, service, and prevention. In the day-to-day work of addressing the epidemic, however, the distinction between these areas is often blurred. It is only by coordinating efforts in all the areas and by focusing on common goals that we optimize our chances of ending this epidemic. It is incumbent upon everyone to understand that this epidemic is a national problem and it will take a national and unified effort to end it.

In 1993, 104,468 new cases of AIDS were reported nationally. In the United States, the virus has flourished in disenfranchised, disadvantaged, and marginalized populations. It is associated with some behaviors that are illegal and others which are considered to be inappropriate by many. By doing so, the virus itself has managed to dilute the nation's ability to coalesce in common purpose. This document attempts to bring the nation's

DETERMINED TO BE AN ADMINISTRATIVE

MARKING INITIALS: AB DATE: 6/18/94

*This copy sent to Patagon, Jo Boufford
+ Carol Raseo
AB.*

Action (A.3): Develop strong linkages between federally chartered advisory committees to coordinate development of complementary national HIV/AIDS research policies.

Commentary: The Office of AIDS Research (OAR) Advisory Council, the National Task Force on AIDS Drug Development, the Presidential HIV/AIDS Advisory Council and other advisory bodies will be critical for providing recommendations and input into the evolving national AIDS agenda; their independent policy deliberations must be coordinated.

Action (A.4): Ensure strong support for the role of behavioral and social science research related to biomedical research, treatment regimens (e.g., substance abuse treatment), and as the scientific basis for sound prevention programs.

Commentary: Findings from behavioral and social science research are critical to the control of the epidemic through the successful administration of prevention, research and treatment programs. This research, which has often been overlooked, must receive strong support, and findings from this research must be fully integrated into programs.

Action (A.5): Work with HIV/AIDS-affected communities and federal agencies to assure that the unique social and physiological characteristics of all HIV-affected populations are taken into consideration in the design of clinical trials and other research programs.

Commentary: Women, children, adolescents, ethnic and racial minority groups, injecting drug users, gay and bisexual men, lesbians and bisexual women and others have unique needs that should be accommodated both through appropriate inclusion in clinical trials and the conduct of trials specifically designed to address their needs.

Goal B: Government, industry, academia, and community attention focused on promising, innovative proposals that could expedite the discovery of new therapeutics for HIV/AIDS and build consensus toward potential solutions.

Commentary: The National Task Force on AIDS Drug Development, recently chartered by the Secretary of Health and Human Services has been formed to identify obstacles and opportunities in HIV/AIDS drug discovery and development. The work of this task

force must be strongly supported, with prompt response to its requests for information and recommendations for action. Additionally, other federal and private agencies should continue to evaluate programs and policies affecting HIV/AIDS drug development.

Action (B.1): Identify regulatory and legal obstacles to research collaboration among federal agencies and non-governmental entities.

Commentary: Technology transfer, the Cooperative Research and Development Agreements (CRADA), liability, patent issues, and drug pricing have been identified as potential obstacles or disincentives to AIDS research collaboration and investment. Working with the National Task Force on AIDS Drug Development, appropriate governmental and private sector groups must develop reforms to address these and related issues.

Goal C: Obstacles to the development of an HIV/AIDS prophylactic vaccine identified and removed.

Action (C.1): Utilizing existing reports and ongoing discussions, develop consensus and, when appropriate, design and implement legislative or administrative solutions to address the obstacles to vaccine development.

Commentary: A number of governmental and non-governmental committees have published recommendations concerning scientific, legal, ethical, cultural, and administrative issues facing vaccine development. This is a continuing process with ongoing fora within NIH and the Department of Defense among others. Consensus among the recommendations must be formed and the recommendations must expeditiously become policy to pave the way for widespread development, clinical testing, and use of prophylactic vaccines in the United States and other countries.

Goal D: Domestic research planning and priority-setting integrated with international efforts.

Action (D.1): Explore mechanisms for increased international collaboration.

Commentary: Research activities cannot be viewed from a strictly national perspective. Working with U.S. and internationally-convened fora, public and private HIV/AIDS research programs should be evaluated to improve mechanisms for communication and collaboration to increase efficiency and productivity.

SERVICE

Goal E: Continued and expanded access to quality mental and physical health services for people living with HIV/AIDS.

Action (E.1): Develop and implement an affordable universal health insurance plan which will provide coverage for HIV-/AIDS related physical and mental health services, including substance abuse treatment.

Commentary: Populations who may traditionally have had little or no access to health care have been disproportionately impacted by the epidemic. This lack of access may be due to reasons of finance or to actual and perceived discrimination. By providing a universal health care plan, the nation will be better able to address the needs of people living with HIV/AIDS.

Action (E.2): Encourage individuals to ascertain their HIV status and ensure appropriate linkages to treatment and services are available for those who test positive.

Commentary: Many individuals living with HIV are not aware of their serostatus. Counseling and testing programs must include outreach to individuals who may engage in high risk behavior to encourage them to ascertain their HIV status. Counseling and testing activities must encourage individuals to obtain their test results, reinforce safer behavioral practices, and provide adequate referral mechanisms including treatment providers.

Action (E.3): Work with Congress, agencies of the Public Health Service, constituent groups, and members of affected communities to ensure continuation of the Ryan White Comprehensive AIDS Resources Emergency Act and other federal programs which provide HIV-/AIDS services to ensure that they continue to meet the care needs of the HIV/AIDS community.

Action (E.4): Expand the availability of quality mental and physical health services for people living with HIV/AIDS.

Commentary: People living with HIV/AIDS are often unable to obtain services in many communities, particularly in some rural areas where they may be required to travel many miles. Much of the care needed by people living with HIV/AIDS infection is basic care which could be provided by family physicians, home health

care aides, family members, or other community-based service providers. However, treatment guidelines, adequate information, and training must be provided to those practitioners if they are to provide those services.

Action (E.5): Identify barriers to the availability of mental and physical health services, coordinate with appropriate agencies, community service organizations, constituent groups, people living with HIV/AIDS, and providers to remove those barriers.

Commentary: Because of limited access to care, many individuals only obtain acute care services in emergency situations. It is critical that HIV/AIDS-related services provide outreach to individuals and populations that may be difficult to reach, such as the homeless, through the traditional public health model. It is critical that in the creation of service delivery models, people living with HIV participate in program design and implementation.

Action (E.6): Stimulate development and implementation of effective evaluation methodologies for service delivery programs and for comprehensive networks of service delivery.

Commentary: In developing service delivery models, the planners must include evaluation methodologies that are capable of determining whether the programs are providing adequate access and care. Federal agencies coordinating service delivery nationally must encourage system-wide evaluation of service delivery networks and individual programs.

Action (E.7): Develop appropriate information dissemination mechanisms which facilitate rapid transfer of research findings, new clinical information, and appropriate educational material to public and private providers of care services.

Action (E.8): Ensure that care guidelines and other such materials are kept current and incorporate, at the earliest possible time, changes in the state of the art.

Action (E.9): Encourage all appropriate agencies, organizations, and institutions to provide HIV/AIDS training to providers both public and private.

Commentary: Because people living with HIV/AIDS and their families experience the disease and its effects in an almost infinite variety of ways, service needs are multiple and diverse. In many communities, dramatic and innovative ideas have emerged which, if disseminated and supported, could make an enormous difference.

Goal F: Early intervention information is provided to all those living with HIV.

Action (F.1): Encourage coordination and collaboration among federal agencies, state and local governments, non-governmental organizations, and service providers to provide people living with HIV accurate and timely information about early intervention and preventing opportunistic infections.

Commentary: Requires increasing linkages from the counseling and testing facilities to service providers as well as greater coordination between prevention and other services at the local level.

Action (F.2): Develop and implement programs to inform HIV service providers on ways to prevent opportunistic infections and coordinate efforts with tuberculosis elimination programs at all levels.

Commentary: Primary among the opportunistic infection concerns is the prevention of tuberculosis, which is posing greater threats to the HIV-affected community.

More than a third of the current cases of AIDS are a product of the ongoing, companion epidemic of drug dependency and abuse. There is a shortage of effective treatment services and many barriers keep substance abusers from accessing the services which do exist. Of great concern are injecting drug users. While there is universal agreement an ideal solution lies in finding ways to interrupt injection--and that remains the long term commitment. However, minimizing transmission is the immediate problem.

Goal G: People living with HIV/AIDS as well as people and families affected by HIV have access to a wide array of community and supportive (or enabling) services.

Action (G.1): At national, state, and local levels, promote coordination of community groups, acute care facilities, state and local governments, private funders, and others that are provid-

ing HIV/AIDS-related services to ensure that a comprehensive continuum of care and services are available and accessible.

Action (G.2): Stimulate and encourage appropriate agencies to develop helpful materials describing available services so families and individuals affected by HIV/AIDS will be empowered to access them.

Action (G.3): Encourage enforcement of prohibitions against discrimination in health care settings and encourage the creation of new protections to ensure access to care for people living with HIV/AIDS.

Action (G.4): Encourage appropriate agencies and governments to coordinate and link health care and supportive services (e.g., primary care, substance abuse, clinical trials, and HIV-related care).

Goal H: That treatment protocols and supportive service needs unique to minorities, women, adolescents, and children receive appropriate consideration in the planning, development, and implementation of all service-related activities.

Action (H.1): Identify the components of programs to address the unique health care and supportive service needs of minorities, women, adolescents, and children living with or affected by HIV/AIDS, and work with appropriate agencies to incorporate these elements into relevant programs.

Commentary: Lack of access, common to all populations disproportionately impacted by HIV/AIDS, is more critical among populations that have either lacked resources or been subjected to discrimination. In developing and implementing service delivery programs, the needs of these populations must be addressed, and, where necessary, additional resources must be applied.

Goal I: Updated information on HIV/AIDS management is communicated internationally.

Commentary: In many countries, current treatments are unfamiliar to local providers. Using information dissemination techniques, information on diagnosis, treatment, and prevention can be communicated around the globe rapidly and in a cost effective manner.

Action (I.1): Working in coordination with the United Nations-sponsored HIV/AIDS program, identify a mechanism to provide ongoing updated training in HIV management.

Action (I.2): Establish an advisory group of U.S. entities involved in international HIV activities for the purpose of global HIV issues and policy development.

Commentary: Many U.S. organizations represent ongoing projects relating to all aspects of HIV/AIDS throughout the world. Their insights into the practical aspects of the epidemic can provide crucial information for policy development.

PREVENTION

Goal J: Educational programs, activities, and campaigns that provide accurate and timely information to all Americans on how to prevent HIV transmission.

Commentary: National prevention campaigns and local community programs must deliver a consistent prevention message overall if they are to be effective. The prevention program design model shall include active participation of the target populations in all components of the program design and implementation. Wherever possible, members of the target population must participate in accessing people at high risk, especially for hard-to-reach populations.

Action (J.1): Develop and implement an affordable health insurance plan that would provide coverage for HIV prevention and would support a health system which promotes public health infrastructure re-building.

Action (J.2): Develop a continuum of HIV prevention services that are culturally diverse and linguistically specific and contain input from the diverse populations effected by AIDS.

CONFIDENTIAL

governments and private agencies to provide targeted media campaigns and implement well-chosen community interventions.

Action (J.7): Encourage businesses and media to participate in national and local efforts for HIV prevention by sponsoring campaigns and activities in local media and in places of business.

Goal K: Community consultation routinely sought in the development and implementation of educational programs and campaigns.

Action (K.1): Develop and deliver prevention messages in an effective and appropriate manner for the intended audience.

Action (K.2): Target efforts to the needs of populations that may be particularly susceptible to HIV transmission: gay and bisexual men (including gay men of color), substance users, sexual and needle-sharing partners of substance users, and youth in high-risk situations (especially out-of-school and gay youth).

Commentary: Primary in this effort is prevention education for youth, both in and out of school. Messages stress building self-esteem and self-sufficiency. To obtain the most effective community consultation, collaboration between governmental and non-governmental organizations will be encouraged at all levels. Federal funding agencies should increase technical assistance to encourage partnerships.

Action (K.3): Continue the implementation of the community planning process and encourage state and local governments to expand the use of this representative process to set priorities at the state and local levels.

Goal L: An array of HIV preventive services available and accessible to substance abusers in treatment on the streets.

Action (L.1): Coordinate activities and policies within the federal government such that the elements of the Public Health Service, the Office of National Drug Control Policy, and oth-

er involved entities work together toward a common goal of a drug-abuse-free and an AIDS-free society.

Action (L.2): Identify and develop methods to encourage the entry of all psychoactive drug dependent people, with particular attention to injecting drug users, into public or private treatment programs.

Action (L.3): Encourage utilization of new or sterile needles and syringes among injecting drug users who are unwilling or unable to utilize treatment or abstain from injecting practices.

Action (L.4): Initiate policy discussions and encourage study of the concept of "harm reduction" to broaden the policy alternatives available as the nation confronts the double and interrelated epidemics of drug dependency and HIV/AIDS.

Goal M: A safe blood supply worldwide.

Commentary: This issue cuts across international boundaries and is amenable to increased blood screening, the use of deferral criteria for blood donors, and other efforts.

Action (M.1): In cooperation with the World Health Organization, Global Program on AIDS promote the "Blood Safety Initiative."

Action (M.2): Include blood safety standards in all U.S. sponsored international service programs.

Goal N: Comprehensive, continuing HIV prevention programs for international use through existing host country infrastructure.

Action (N.1): Develop a comprehensive HIV/AIDS educational exchange among national AIDS coordinators world-wide using electronic media.

Action (N.2): Work with foreign governments to develop a training program to educate members of their military orga-

nizations so that they can teach civilian communities HIV prevention.

Commentary: After developing and successfully implementing HIV/AIDS training for U.S. military personnel, the concept can be translated to foreign militaries world-wide, some of which have extremely high infection rates.

CROSS-CUTTING

INFORMATION DISSEMINATION

Goal O: A national HIV/AIDS information dissemination system.

Commentary: All possible users of HIV/AIDS information should have access to the information they need and obtaining it should be easy. Implementation of an all-inclusive, easy access system can be developed with existing technologies and expertise. All AIDS information should be available to the public via a single telephone access number. Transfer among databases to the appropriate information system should be transparent to the user.

Action (O.1): Develop a technological, inter-departmental portal through which AIDS information can be disseminated.

Action (O.2): Establish a interdepartmental group to identify and discuss the issues and to establish a coordinated national HIV information dissemination policy.

Action (O.3): Develop an HIV information plan to be followed by all relevant agencies.

Action (O.4): Provide a forum for community-based HIV organizations and people affect by HIV/AIDS to express their informational needs and the problems they encounter in obtaining the needed information.

Action (O.5): Develop a training and technical assistance program for users of the national HIV information system.

Bibliography

- "1993 Survey of AIDS Medicines: Drugs and Vaccines in Development"; Pharmaceutical Manufacturers Association; 1993.
- "AIDS An Expanding Tragedy"; National Commission on AIDS; June 1993.
- "AIDS in Foreign Policy"; Kimberly Hamilton, The Washington Quarterly; Winter, 1994.
- "AIDS and the Global Military"; Normal Miller, editor; AIDS and Society: International Research and Policy Bulletin 4; July/August 1993.
- "AIDS Research at the NIH: A Critical Review"; Gonsalves, Gregg and Harrington, Mark, Treatment Action Group; July 1992.
- "The AIDS Research Program of the National Institutes of Health"; Institute of Medicine, National Academy Press; 1991.
- "AIDS in the World"; Jonathan Mann, J.M. Tarantola, and Thomas W. Netter, editors; Harvard University Press; 1992.
- "America Living With AIDS"; National Commission on AIDS; September 1991.
- "The Barbara McClintock Project to Cure AIDS"; McClintock Project Working Group; June 1993.
- "Basic Research on HIV Infection: A Report From the Front"; Gonsalves, Gregg, Treatment Action Group; June 1993.
- "Behavioral and Social Sciences and HIV/AIDS Epidemic"; National Commission on AIDS; July 1993.
- "Bridging the Gap: A Workshop on HIV Treatment Information Dissemination"; Office of AIDS Research (OAR), National Institutes of Health (NIH), and the Health Resources and Services Administration (HRSA); February 1993.
- "Briefing Paper, Clinton-Gore Transition Team"; Black Leadership Commission on AIDS; January 1993.
- "The Challenge of HIV/AIDS in Communities of Color"; National Commission on AIDS; December 1992.
- "The Crisis in Clinical AIDS Research"; Harrington, Mark, Treatment Action Group; December 1993.
- "Emerging Infections: Microbial Threats to Health in the United States"; Institute of Medicine, National Academy Press; 1992.

- "FDAR: The Madison Project (draft)"; The Harvard AIDS Institute, University of Wisconsin at Madison Medical Center and Project Inform; February 1994.
- "The FY 1995 National Institutes of Health Plan for HIV-Related Research"; OAR/NIH; 1993.
- "Federal AIDS Agenda '93"; Federal AIDS Agenda '93 Delegates; May 1993.
- "Federal, State, and Local Responsibilities"; National Commission on AIDS; March 1990.
- "The Global AIDS Disaster: Implications for the 1990s"; U.S. Department of State; July 1990.
- "The HIV/AIDS Epidemic in Puerto Rico"; National Commission on AIDS; June 1992.
- "The HIV/AIDS Pandemic: 1993 Overview"; World Health Organization, Global Programme on AIDS; 1993.
- "Housing and the HIV Epidemic"; National Commission on AIDS; July 1992.
- "How Foundations, Corporate America, and Government Can Work Together in the Fight Against AIDS/HIV"; Funders Concerned About AIDS; March 1993.
- "The Human Immunodeficiency Virus Vaccine Challenge: Issues in Development and International Trials"; Committee on Life Sciences and Health, Federal Coordinating Council on Science, Engineering and Technology (FCCSET); July 1993.
- "Investing in Health: World Development Report 1993"; World Bank; Oxford University Press; 1993.
- "Leadership, Legislation, and Regulation"; National Commission on AIDS; April 1990.
- "Mobilizing America's Response to AIDS: Recommendations to President Clinton"; National Commission on AIDS; January 1993.
- "NIH Databook 1993"; NIH; September 1993.
- "National Hispanic/Latino AIDS Agenda"; National Hispanic/Latino AIDS Coalition; June 1993.
- "The NIH Revitalization Act of 1993"; Enacted June 10, 1993.
- "Preventing HIV/AIDS in Adolescents"; National Commission on AIDS; June 1993.

"Proposal Preparation Kit"; Advanced Technology Program, National Institute of Standards and Technology, Technology Administration, U.S. Department of Commerce; February 1994.

"Putting People First: How We Can All Change America"; Governor Bill Clinton and Senator Al Gore; Random House, 1992.

"Social and Human Issues"; National Commission on AIDS; April 1991.

"Strategic Plan to Combat HIV & AIDS in the United States"; U.S. Public Health Service, Department of Health and Human Services; October 1992.

"The Twin Epidemics of Substance Abuse and HIV"; National Commission on AIDS; July 1991.

"Women and Health Research, Ethical and Legal Issues of Including Women in Clinical Studies"; Institute of Medicine, National Academy of Sciences; March 1994.

