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Presidential Advisory Council on HIV/AIDS

June 15–18, 1998

Madison Hotel
Washington, D.C.

DRAFT AGENDA
(MEMBERS ONLY)

Monday, June 15, 1998

9:00 a.m.	Interim Council Activities/Long-Range Strategic Planning R. Scott Hitt, M.D., Chair	*Dolley Madison Room*
9:30 a.m.	Office of National AIDS Policy (ONAP) Update Sandra L. Thurman, Director Todd Summers, Deputy Director	
10:45 a.m.	Break	
11:00 a.m.	Introductions and Strategic Planning Sessions Focus Long-Range Strategic Planning Overview • Introduction from the Chair R. Scott Hitt, M.D.	*Dolley Madison Room*
	Facilitation Process Facilitators: Myriam Figueroa, Mosaica Emily Gantz McKay, Mosaica Kayla Jackson, Mosaica Cristina Lopez, Mosaica	
	• Presentation/Discussion of Agenda and Process • Agreement on Ground Rules • Timeline: Key Dates Affecting Council Plans and Activities • Brief Presentation of Proposed Session Outcomes {See attached list} - Plan for June 1998 - July 1999: what we can do that will make a difference - Plan for August 1999 - January 2001: what we leave behind	
11:45 a.m.	Taking the Pulse of the Council • Focus for Discussion - How Members Feel as Individuals as a Council - Three Questions on Issues and Concerns to Address Before Moving Ahead	

12:00 p.m. **LUNCH** (on your own)
- Seating in Small Groups in the Restaurant
- Preliminary Discussion of Responses to the Three Questions

1:00 p.m. Taking the Pulse of the Council (Continued) *Dolley Madison Room*
- Discussion of Responses to the Four Questions
- Implications for Strategic Planning Process

2:30 p.m. Agreement on Desired Session Outcomes
- Discussion of Proposed Outcomes
  - Plan for June 1998 - July 1999 (Actionable Issues and Report, with Emphasis on Planned Strategies and Structure; Other Key Issues and Strategies for Keeping Them in Public View)
  - Plan for August 1999- January 2001 (Platform or Other Activities)
  - Other desired outcomes (in addition to or instead of the short-term and longer-term plans suggested above)
- Agreement on Desired Outcomes

3:00 p.m. Break

3:15 p.m. Subcommittee Meetings:
- What are the key issues on which the Council needs a briefing from each subcommittee to prepare it for making appropriate strategic planning decisions?
- What are the important time-sensitive or "actionable" issues in terms of policy or funding decisions or other" windows of opportunity" for action?
- Other Strategic Planning Issues
- Other Subcommittee Business

Prevention Subcommittee *Drawing Room I*
- Long-Range Planning Discussion

Research Subcommittee *Mt. Vernon C*
- Long-Range Planning Discussion
- Microbicide Development Update
  Ann Marie Corner, BIOSYN
  Polly Harrison, Ph.D., Alliance for Microbicide Development
  Penelope Hitchcock, D.V.M., M.S., National Institute of Allergy and Infectious Diseases, NIH

Monday, June 15, 1998 *(continued)*

3:15 p.m. Subcommittee Meetings (continued):

Services Subcommittee — *Drawing Room II*
- Long-Range Planning Discussion
- Ryan White Care Act Reauthorization Update
  John Palenicek, Ph.D., Health Resources Services Administration
- Review Recommendations and Assessments
- Native American Health Care Worker Guidelines Update
  Todd Weber, ONAP

5:45 p.m. Full Council Meeting — *Dolley Madison Room*
- Questions or Issues
- Review of Agenda for Tuesday

6:00 p.m. **ADJOURN**

Tuesday, June 16, 1998

{During meetings of the smaller subcommittees in the morning, members are asked to address the same questions the larger subcommittees addressed on Monday.}

9:00 a.m. Subcommittee Meetings

Discrimination Subcommittee Meeting — *Dolley Madison Room*
- Long-Range Planning Discussion

International Issues Subcommittee Meeting — *Drawing Room I*
- Long-Range Planning Discussion
- U.S. Department of State HIV/AIDS Strategic Plan Update/Discussion
  Nancy Carter-Foster, David Wagner, U.S. Department of State

Communities of African and Latino Descent Subcommittee Meeting — *Mt. Vernon C*
- Long-Range Planning Discussion
- Racial and Ethnic Minority Population Discussion
  - African American Update
  - National Minority HIV Plan Update and President's Initiative on Race/HHS Race and Health Initiative, Matthew Murguia, ONAP
  - Harvard AIDS Institute; Unidos Para La Vida
- Subcommittee Structure Discussion

9:00 a.m. Subcommittee Meetings (continued):

Prison Issues Subcommittee Meeting — *Drawing Room II*
- Long-Range Planning Discussion
- HIV Surveillance in Federal Correctional Institutions Recommendation
- National Summit Meeting on Prisons Discussion
- Update on Federal Interagency Meeting on Compassionate Release
- Review Recommendations and Assessments
- Update on Prison Site Visit

11:00 a.m. Subcommittee Meetings:

Prevention Subcommittee — *Drawing Room I*
- Long-Range Planning Discussion

Research Subcommittee Meeting — *Mt. Vernon C*
- Long-Range Planning Discussion

Services Subcommittee Meeting — *Drawing Room II*
- Long-Range Planning Discussion
- HIV Cost and Service Utilization Study Update
  Samuel Bozzette, M.D., Ph.D., University of California at San Diego
  Martin F. Shapiro, M.D., Ph.D., University of California at Los Angeles

12:00 noon **LUNCH** (on your own)

1:00 p.m. Panel Presentation to Full Council — *Dolley Madison Room*
Addressing HIV and AIDS Among Youth
Sean Sasser, Moderator
Margaret Campbell, The Multicultural AIDS Coalition
Donna C. Futterman, M.D., Montefiore Medical Center
David C. Harvey, AIDS Policy Center for Children, Youth & Families
Audrey Smith Rogers, Ph.D., M.P.H., National Institute for Child Health and Human Development, NIH
Bret Rudy, M.D., Children's Hospital
Robert Soliz, ONAP

3:00 p.m. Long-Range Strategic Planning — *Dolley Madison Room*
- Briefings from the Subcommittees
- Questions/Discussion

5:00 p.m. Break

Tuesday, June 16, 1998 *(continued)*

5:15 p.m. — Other Information for Council Consideration — *Dolley Madison Room*

- Discussion of Factors that May Affect the Council's Ability to Meet Objectives
- Other Information for Strategic Planning

6:00 p.m. — **ADJOURN**

Wednesday, June 17, 1998

9:00 a.m. — Long-Range Strategic Planning — *Dolley Madison Room*

Framework for the Strategic Plan

- Discussion of Key Questions Affecting Strategic Planning
  - Should the Council be rechartered, and if so, why is its existence important?
  - To whom should the Council be directing its recommendations and reports? What are its primary and secondary audiences?
  - How should the changes in the face of the epidemic be effected in the Council's strategic planning?
  - Other Key Questions
- Discussion and Agreement: What Should be the Framework and Scope of the Strategic Plan?
  - Possible components: actionable issues, criteria for selecting issues, strategies, structures and processes, responsibilities, time line
  - What decisions should be made by the end of the day?

10:30 a.m. — Break

10:45 a.m. — Long-Range Strategic Planning

A Strategic Plan for the Next 13 Months

- Discussion and Decisions
  - Does the Council want to focus on "short-term achievable" action items?
  - If no, what will be its focus?
  - If yes, what criteria should be used to set action priorities? How should these criteria be applied?
  - Should the Council prepare a report at the end of its current period of operations?
  - Other decisions

12:00 noon — **LUNCH** (on your own)

1:00 p.m. — Long-Range Strategic Planning — *Dolley Madison Room*

- A Strategic Plan for the Next 13 Months (continued)
  - Process to Obtain Agreement on Action Items
  - Strategies for Achieving Action Items

3:15 p.m. — Break

Wednesday, June 17, 1998

3:30 p.m.	A Strategic Plan for August 1999-January 2001 • Discussion and Agreement • Key Objectives and Desired Accomplishments • Strategies	*Dolley Madison Room*
5:30 p.m.	Review of Decisions and Plans • Review of Decisions and Plans • Identification of Any Unfinished Business • Implications of Decisions and Plans for Council Operations	
6:00 p.m.	**ADJOURN**	

Thursday, June 18, 1998

9:00 a.m.	General Council Business/Subcommittee Reports R. Scott Hitt, M.D.	*Dolley Madison Room*
9:30 a.m.	Services Subcommittee Report	
9:45 a.m.	Research Subcommittee Report	
10:00 a.m.	Prevention Subcommittee Report	
10:15 a.m.	Prison Issues Subcommittee Report	
10:30 a.m.	International Issues Subcommittee Report	
10:45 a.m.	Discrimination Subcommittee Report	
11:00 a.m.	Communities of African and Latino Descent Subcommittee Report	
11:15 a.m.	Presentation and Review of Strategic Planning Results	
11:45 a.m.	Agreement on Responsibilities for Next Steps and Follow-Through	
12:30 p.m.	Agreement on Content/Format of the Strategic Planning Session Report	
1:00 p.m.	**ADJOURN**	

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NEWS
FROM SFGH/UC-SAN FRANCISCO

UCSF

San Francisco General Hospital Medical Center...1001 Potrero Avenue, San Francisco, CA 94110

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1 in 4 PEOPLE STARTING TREATMENT FOR HIV ARE NOT TREATED ACCORDING TO US HHS HIV TREATMENT GUIDELINES

Louis Harris & Assoc. Survey Shows High Proportion of Women and Minorities Receive Care Inconsistent with HHS Guidelines

Washington, DC, June 3, 1998 – Results from the first National HIV/AIDS Treatment Survey showed that about 25 percent of people starting treatment for HIV are prescribed therapy that is inconsistent with the US Department of Health and Human Services Guidelines (HHS Guidelines) for the Use of Antiretroviral Agents in HIV Infected Adults and Adolescents issued in November 1997. These recommendations are similar to the HIV treatment guidelines issued by the International AIDS Society (IAS) of the USA in June 1997. The results were jointly announced today at a press conference by John G. Bartlett, MD, Chief, Division of Infectious Diseases, Johns Hopkins University and Co-Chair, US HHS Committee to Establish HIV/AIDS Treatment Guidelines and by Paul Volberding, MD, Professor of Medicine, AIDS Research Institute, University of California at San Francisco, Director, UCSF AIDS Program and Medical Oncology at San Francisco General Hospital and a board member of the IAS-USA. The survey was conducted by Louis Harris & Associates and funded with a grant from Merck & Co., Inc.

"Not suppressing viral replication to the greatest extent possible means that patients are more likely to experience symptoms of HIV, and their risk of developing an AIDS-related infection may be increased," said Dr. Bartlett. The survey evaluated HIV-treating physicians' current use of antiretrovirals, their general awareness and acceptance of the HHS Guidelines, and how closely they followed them.

The survey results specifically showed that physicians with the least experience treating HIV waited longer to begin treatment and prescribed fewer medications then recommended in the HHS Guidelines. "The disparity in the treatment of HIV - especially for particular populations - signals an urgent need to educate physicians and patients more aggressively on the HHS Guidelines for people with HIV," said Dr. Volberding, "and supports recent plans to create an HIV professional society."

In 1997, HHS convened a panel of scientific and medical experts and treatment advocates to design recommendations that would advise physicians on how to use antiretroviral medications most effectively in order to ensure the best possible outcomes for their patients with HIV. The HHS Guidelines recommend initiating treatment for HIV with triple therapy, including a protease inhibitor and two nucleoside analog reverse transcriptase inhibitors (RTIs). The decision to begin therapy is based on a patient's clinical state, viral load, and CD4 cell count (immune cell) level.

HIV-Treatment Experienced Physicians Provide The Most Progressive Care

"It's clear that physicians who receive new information and education on an ongoing basis are more likely to adopt and apply these treatment guidelines," said Dr. Volberding. "Likewise, patients who are familiar with the health benefits related to new treatments will more likely seek and receive the most aggressive care."

Physicians with the most experience in treating HIV more consistently prescribed according to the HHS Guidelines. Eighty-eight (88) percent of physicians with the most experience were most likely to prescribe a therapeutic regimen containing at least one protease inhibitor, compared to 60 percent of those with the least HIV-treatment experience. A number of physicians with more experience prescribed more than three medications for their treatment-inexperienced patients at the initial visit, compared to those physicians with the least experience who prescribed an average of two medications.

Smaller Proportion of Women and Minorities Treated By More-Experienced Physicians as Compared to White Men

A smaller proportion of women, African-Americans and Hispanics receive care from the most experienced physicians than do white men, according to the survey "The study has revealed some troubling information about the obstacles to treatment that women and minorities face which may, in part, contribute to the increased rate of mortality seen among this patient population, " said Dr. Volberding. "For example, many of the more experienced physicians are not always easily accessible to this growing segment of the population most affected by HIV."

The US Centers for Disease Control and Prevention (CDC) in June 1996 and again in January 1997 reported the first declines in the rates of AIDS-related deaths since the beginning of the HIV epidemic. The declines have been largely attributed to the use of protease inhibitors in triple therapy with reverse transcriptase inhibitors. The estimated number of deaths among women with AIDS decreased by 13 percent in 1996; similarly, the death rate among people of color decreased by 19 percent in 1996. The most significant decline, however, was found in the number of deaths among white patients - 33 percent in 1996.

Physicians with less treatment experience tend to treat the greatest proportion of women and people of color with HIV and start antiretroviral therapy later for their treatment-inexperienced patient. The survey results show that more women and minorities are HIV-symptomatic when beginning antiretroviral therapy (36% of women, 42% of African-Americans, 43% of Hispanics) and have higher viral load measures with lower CD4 cell (immune cell) counts at the start of therapy compared to 27% of white men who are symptomatic when starting therapy.

More Physician and Patient Education Needed On HHS Guidelines

These findings as well as those of prior research including that of the Community Consortium, affiliated with UCSF, support and are consistent with the new Louis Harris & Associates Survey "We now have even more evidence that further education is required," said Dr. Volberding. The Community Consortium is a San Francisco Bay Area association of healthcare providers who care for people living with HIV and AIDS.

"Several organizations are actively involved in addressing the concerns raised by the findings of this survey," according to Dr. Volberding. "The IAS-USA sponsors numerous HIV educational programs nationally and the Infectious Disease Society of America (IDSA) is creating the *HIV Medicine Association*."

The *HIV Medicine Association* of the IDSA is being created to help define the level of experience and commitment needed for high quality HIV care. The *HIV Medicine Association* will be chaired jointly by Dr. Volberding and Constance Benson, MD, University of Colorado.

Methodology

The first National HIV/AIDS Treatment Survey was conducted to evaluate current treatment practice and trends, assess them against the current HHS Guidelines, and identify gaps where additional treatment educational efforts might be appropriate. A follow-up survey will be conducted later this year to track physician treatment practices over time and gauge changes from previous treating habits.

The telephone survey of 476 physicians who prescribe treatment for patients with HIV was conducted by Louis Harris & Associates, Inc., between January 14 and March 3, 1998. The survey covered a number of practice settings, including solo and partnership private practices, hospital, non-hospital and university-affiliated clinics, and managed care organizations. Physicians who are employed by the military, a pharmaceutical company, the Veterans Administration, or any Federal health agency are not included in the survey.

Physicians were divided into five tiers, with each tier representing a group of physicians who write 20% of the total number of HIV prescriptions. Most survey questions ask the physician to describe his or her prescribing practices during the most recent visit of an antiretroviral-naïve patient.

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Community Spokespersons List

The following is a list of community leaders from leading AIDS service organizations who are available to discuss the results of the National HIV/AIDS Treatment Survey with interested media.

LOS ANGELES
Scott Hitt, MD
Chair
Presidential Advisory Council on HIV/AIDS
310-652-2562 (please ask to have Dr. Hitt paged regarding the Treatment Survey)

Charles Farthing, MD
Medical Director
AIDS Healthcare Foundation
213-654-8038

NEW YORK CITY
Pablo Colon
Director, Treatment Education & Advocacy
Gay Mens' Health Crisis
212-367-1450

Odell Mays
Executive Director
Treatment Action Group
212-924-3935

Julia Walker
Communications Director
The Balm In Gilead
212-730-7381

SAN FRANCISCO
Martin Delaney
Director
Project Inform
415-558-8669

WASHINGTON, DC
Daniel Zingale
Executive Director
AIDS Action Council
202-986-1300 ext. 3065

Jim Graham
Executive Director
Whitman-Walker Clinic
202-797-3500

MIAMI
Rick Siclari
Executive Director
CRI-South Florida
305-667-9296

PHLADELPHIA
Jane Shull
Executive Director
Philadelphia FIGHT
215-985-4448. Ext. 21

CHICAGO
Philip Matthews
Executive Director
Test Positive Aware Network
773-404-8726

NEW JERSEY
Asia Russell
Hyacinth AIDS Foundation
732-246-0204

Paul A. Volberding, MD
Professor of Medicine
University of California, San Francisco
Director, Center for AIDS Research
Director, AIDS Program and Medical Oncology
San Francisco General Hospital

Dr. Paul Volberding is a Professor of Medicine and the Director of the Center for AIDS Research at the University of California, San Francisco, and Director of the AIDS Program and Medical Oncology at San Francisco General Hospital. He received his undergraduate and medical degrees at the University of Chicago and the University of Minnesota, respectively, and finished training at the University of Utah and the University of California, San Francisco, where he studied for two years as a research fellow in the virology laboratory of Dr. Jay Levy, later a co-discoverer of HIV. Dr. Volberding's professional activities have centered at San Francisco General Hospital where he established a model program of AIDS patient care, research, and professional education. His research career began with investigations of HIV - related malignancies, especially Kaposis Sarcoma. His primary research focus, however, shifted to clinical trials of antiretroviral drugs. He has been instrumental in testing many compounds, but is best known for groundbreaking trials establishing standards of care for the use of zidovudine in asymptomatic HIV infection. Dr. Volberding has written many research and review articles. He is the co-editor in chief of the *Journal of Acquired Immune Deficiency Syndrome*, and is the founder and Chair of the Board of the International AIDS Society - USA. He is also the co-editor of *The Medical Management of AIDS*, the most widely used textbook of HIV medicine, now in its fifth edition.

"Compelling evidence that race and ethnicity correlate with persistent, and often increasing, health disparities among U.S. populations demands national attention."
The White House, 1998

African American Health and HIV and AIDS
A National State of Emergency

Introduction

By the year 2010 President William Jefferson Clinton has committed this nation to the goal of eliminating all racial and ethnic disparities in public health, while continuing his progress to improve the health of all Americans. Political experts believe that the President's call for the elimination of racial and ethnic disparities will be the cornerstone of his Health and Human Services Administration, and the affirming legacy of his Initiative on Race.

At the historic White House conference on HIV and AIDS, President Clinton also declared that he would, "End new infections from HIV and AIDS by the year 2000, until there are none." During this declaration the president committed to releasing **Healthy People 2010,** a report outlining the nations objectives for reaching this and other health goals for the nation, by the year 2000.

Despite the will and tenacity of the "leader of the free world" and his administration, the current status of the nation's public health crisis in African American communities, fueled by record rates of HIV and AIDS, drug abuse, sexually transmitted diseases and their accompanying co-factors, a national state of emergency in public health and AIDS has not been declared. One that will require radical emergency public health interventions, and the allocation and redistribution of new and existing health resources to begin to meet these goals.

African Americans, the nations oldest ethnic minority population, have long suffered the ramifications of a less than adequate system of policies and actions in their fight for acceptable public health initiatives. Historically this has community has faced decades of racial targeting by tobacco and alcohol industries, and the influx of illegal drugs. These factors, coupled with underfunded health systems and the unprecedented spread of diseases once believed to have been eradicated or controlled, have created an environment of public health indicators rivaling those of third world nations.

If present trends continue, when the history of HIV and AIDS in the African American community is written, AIDS will be documented as a modern day epidemic with multi-generational reach, posing grave detriment to all Americans in the new millennium.

A White House report concurs that, "The demographic changes that are anticipated over the next decade magnify the importance of addressing disparities in health status. Groups currently experiencing poorer health status are expected to grow as a portion of the U.S. population; therefore, the future health of America as a whole will be influenced substantially by our success in improving the health of these racial and ethnic minorities."

A Move to Action

The process for this emergency intervention began with 33 African American leaders in the field of HIV and AIDS who were called to a meeting by the Centers for Disease Control and Prevention to collaborate on a new African American prevention initiative. The new epidemiological data were alarming: **" Every hour in this country, seven (7) people are newly infected with HIV, the virus that causes AIDS, and three (3) of those seven are African American"**

When viewed in context with all other health related issues facing African Americans at all stages of life, such as high infant mortality rates, the growing proliferation of prostrate and breast cancers, unprecedented cardiovascular disease, hypertension, diabetes and the recurrence of childhood diseases, these concerns when co-factored with the affects of drug abuse, lack of treatment, and the new proliferation of sexually transmitted diseases moved the group of 33 to develop a list of demands and a national strategy for crisis intervention.

Our vast and unprecedented national investment in HIV and AIDS research, care, services and prevention have improved the quality of life and expectancy of many populations at risk of infection or infected by the disease. In the first wave of this eighteen year old epidemic, effectiveness in combating HIV and AIDS in other communities was clearly demonstrated through combined financial and human resources, local and nation government intervention and fair share funding for prevention programs and community development. Tragically, racial disparities in the AIDS crisis continues unabated as a multi-generational epidemic of magnificent proportions for the African American community, a community that has never benefitted fully from the nation's unprecedented investment.

Of all U.S. citizens, including other racial minorities, African Americans have the highest death rate from most diseases. For every 100,000 Americans, African American's diabetic death rate accounts for a whopping 76 percent of the nation's overall tally of 40 percent. Death from cancer accounts for 182 per 100,000, compared to the nations 135 per 100,000. Heart disease accounts for 158 per 100,000, compared to the national count of 122 per 100,000. Tuberculosis among African Americans is listed at 33 per 100,000. This number is triple the national rate of 10.3. Infant mortality among African American babies is 18 percent per 1,000 births. This is quite alarming when compared to the national average of 9.2 per 1,000 births. Coupled with these horrific numbers is the fact that African American women are dying during childbirth. These women account for a staggering 22.1 percent. This number is quite high when compared to the national average of 8.2 percent. Since

1960, death from cancer among Black men has risen steadily by 62 percent, compared to 19 percent for all men. Prostrate cancer is 30 percent higher among Black males who show a 66 percent survival rate for five years compared to an 81 percent survival rate for White men.

The facts are:

- AIDS is still the number one killer of African American females of child bearing age.
- African Americans account for 36 percent of the nation's cases of full-blown AIDS, yet remain only 12 percent of the national population; all racial and ethnic minorities account for 25 percent of the U.S. population yet account for nearly 54 percent of all AIDS cases.
- African American children account for half of all children with AIDS in the nation; combined with Latino children they make up 90 percent of the nations infected babies under 13 years of age.
- The number of new AIDS cases among Blacks is now far greater than the number of new AIDS cases among Whites.
- 125,000 children are expected to be orphaned as a result of losing one or both parents to HIV and AIDS by the year 2000. Ninety percent of these children will be Black and Latino.
- Every hour, seven Americans are infected with HIV, the virus that causes AIDS, and three of the seven are African American. That's 72 African Americans every day.
- One in fifty African American males are infected with HIV. Approximately 62 percent of all adults and adolescents reported with AIDS in the United States have already died from the disease.
- From 1995-1996, AIDS-related deaths declined 23 percent for the total U.S. population and 20 percent for Hispanics. African Americans experienced the lowest decline, a decline of only 13 percent. These numbers can be attributed to poor base line health, late identification of disease, and the lack of health insurance to pay for life prolonging drug therapies costing $10,000 to $12,000 per year, per patient.
- Fifty-six percent of the nations AIDS cases and new infections related to injection drug use are concentrated among African Americans

- Nearly 700,000 people who take the standard AIDS test each year, do not return to learn whether they are infected.

- An estimated 10 to 12 million new cases of sexually transmitted infections, 80 times the new cases of tuberculosis, are reported to the CDC each year.

- National rates of syphilis and gonorrhea particularly in rural and inner city areas, far exceed those of many industrialized nations.

- Last year four percent of African American girls ages 15 to 19 were infected with gonorrhea, according to CDC.

- A 1997 CDC study found that one in five Americans older than 12 was infected with a genital herpes virus.

- Annually, New York City teenagers account for 40 percent of the 2,500 cases of chlamydia infection.

- In Baltimore, where syphilis rates are 18 times the national average; 115 infants were born infected with syphilis in the past two years, the cure for syphilis was discovered more than 50 years ago.

- Intravenous drug users make up the vast majority of people with hepatitis C, which has no cure, shows no symptoms for up to 20 years and can be fatal.

- Seventy-nine percent of people with AIDS in Washington DC are African American.

- Over 100,000 African Americans have died from AIDS. In the next seven (7) years it is estimated that African Americans will account for up to 65 percent of all HIV infections in the nation

- In 1998, UNICEF released its new report on AIDS orphans world wide, while earlier estimates indicated that some 10 million children would be orphaned as a result of losing one or both parents to AIDS by 2005, the agency apologizes for under counting. The study surveyed 23 nations, 19 of which are on the continent of Africa. Should current trends continue, more than 40.7 million children will have been orphaned by the year 2010.

Note:

"AIDS is killing an entire race of Black people simultaneously, across two continents"

A Clarion Call from The Congressional Black Caucus (CBC)

On Monday, May 11th, following the nations celebration of motherhood, the Congressional Black Caucus met with more than 320 African American leaders in medicine, public health, religion, social policy, civil rights and elected officials, representing cities across the nation - including New York, San Francisco, Baltimore, Los Angeles, Durham, Miami, and Atlanta; to outline the emergency intervention needs for a community in crisis, in an attempt to save its men, women and children.

The meeting was hosted by CBC Chairwoman The Honorable Maxine Waters and attended by representatives from every division of the Health and Human Services Administration, and the Public health leadership of the CBC. Those attending the meeting included Representatives Louis Stokes, (D-OH), Donna Christian-Green (D-VI) and Eleanor Holmes Norton (D-DC). The collective represented the entire 46 member delegation.

At the meetings conclusion, the Caucus called on the U.S. Secretary of the Department of Health and Human Services, Donna Shalala, to declare a national "State of Public Health Emergency in HIV and AIDS" and to marshal the necessary resources, take leadership, develop comprehensive solutions and target funding to attack the disease in African American and minority comminutes where the HIV and AIDS epidemic is growing at an alarming rate.

During the collective call for government officials to aide and support community and capacity development of those comminutes in greatest need to respond to their public health crisis the Caucus declared, "Enough is enough." and continued, "This nation has shown most brightly in its fight against threats to its national security. We took on the fight of tuberculosis and smallpox in this country and won. We must exert the political will necessary to take on HIV and AIDS, drug abuse and sexually transmitted diseases and their accompanying co-factors in those comminutes reaching epidemic proportions with the same commitment and concerted effort. This is a national crisis, and we will not rest until it is considered one!"

Needling Clinton

ON APRIL 23 PRESIDENT CLINTON ALLOWED BAD POLITICS to override good science in our battle against AIDS. On the same day that his secretary of Health and Human Services declared, finally, that science had proved that needle-exchange programs reduce HIV infections without encouraging drug use, our president ordered that federal funds could not be used for this purpose. It was the kind of "split the baby" mentality that has haunted this administration since its earliest days.

In political life it is difficult to publicly challenge the decisions of allies who stray into unacceptable territory. For the most part the president has been our friend on AIDS. Funding levels for AIDS programs and research have increased dramatically, even when overall discretionary spending has stagnated. Drug approvals come faster, research is better coordinated, services are expanding. All of this deserves our praise. Unfortunately, good is not good enough in the fight against AIDS. Until a cure and a vaccine are found, the HIV epidemic must be treated as the health crisis that it is.

JANA BIRCHUM

Dirty needles are the cause of more than half of all new HIV infections—needle exchange is needed now.

Since dirty needles are the cause of more than half of all new HIV infections, needle exchange is needed now. Annually more than 20,000 people in this nation alone contract HIV directly or indirectly through dirty needles. Without funds to effectively combat this mode of transmission, thousands will continue to be infected, and many will die.

In 1995 Clinton articulated his goal of "[reducing] the number of new [HIV] infections each year until there are no more new infections." His decision to withhold federal funds for needle exchange will make it impossible to achieve his stated goal.

This issue requires political courage and, most important, leadership to educate people about the lives that could be saved. Fifteen years ago, then–surgeon general C. Everett Koop refused to be politically intimidated and insisted that this nation follow the science with respect to HIV. Koop set the standard for political courage. The Administration could have done the same, allowing individual communities the choice as to how best to use their federal prevention money, including funding the exchange of clean needles to injection-drug users. But instead the president stepped in and, ignoring the unanimous advice of AIDS czar Thurman, Health and Human Services secretary Shalala, National Institutes of Health director Varmus, and Surgeon General Satcher, said that no federal dollars could be used by local communities to implement these lifesaving programs.

So to whom did the president listen? Remarkably, he followed the biased, conventional, and conservative advice of Gen. Barry McCaffrey, a drug policy czar with no public health or medical experience. All McCaffrey could say was, "It sends the wrong message." The general could be a major force in coordinating HIV-prevention programs, but his prejudice and narrow-mindedness have proved to be major stumbling blocks. Clinton and Congress must rise above political rhetoric, respect good science, and communicate the facts directly to the nation. Any needle-exchange policy would likely face an uphill battle on Capitol Hill, with Republicans eager to cast Clinton as a "soft on drugs" demagogue by distorting this vital health care issue. But the chance of wasting some political currency by fighting for a program whose benefits are so clear should not deter the Administration. Until such leadership comes from a president or a Congress, the epidemic will rage on, fueled as much by political expedience as by HIV.

▶ Hitt is chairman of the Presidential Advisory Council on HIV/AIDS, which in March gave a unanimous vote of no confidence regarding the Administration's ability to carry out Clinton's stated goals on HIV prevention.

By R. Scott Hitt, MD

DEPARTMENT OF HEALTH & HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Public Health Service

Memorandum

Date JUN 11 1998

From Administrator

Subject Presidential Advisory Council on HIV/AIDS Recommendations

To Director, Office of National AIDS Policy

Thank you for the opportunity to review these recommendations. The Health Resources and Services Administration supports the Department of Health and Human Services' position on needle exchange and the declaration of a state of emergency in the African American Community concerning HIV.

Although none of the demands are specifically addressed to HRSA, it is important to note that HRSA has made equity access to health care for all populations disproportionately affected by HIV/AIDS one of its highest priorities.

We continue to support the Administration's fiscal year 1999 budget proposal for the Ryan White programs and are encouraged by the Presidential Advisory Council's recognition of the need to support primary medical care and other support services.

With regard to the privacy protection recommendation, HRSA's position is consistent with that of the Department.

The recommendation of the Research Subcommittee regarding an AIDS vaccine is addressed to the National Institutes of Health (NIH) primarily, and HRSA will work with the NIH as appropriate and necessary to accomplish its goals.

We look forward to continuing to work with your office and the Council.

Claude Earl Fox, M.D., M.P.H.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention

June 12, 1998

R. Scott Hitt, M.D.
Chair
Presidential Advisory Council on HIV/AIDS
736 Jackson Place, N.W.
Washington, D.C. 20503

Dear Dr. Hitt:

The enclosed information is in response to the recommendations made by the Surveillance Committee of the Presidential Advisory Council on HIV/AIDS (PACHA) at its December 1997 meeting.

We welcome PACHA's interest and comments on HIV surveillance. We agree with the Council that more research would be welcome and we will continue to support surveillance research. In the meantime, the routine public health practice of surveillance must continue for the provision of information, the targeting of prevention efforts, and evaluation purposes. We plan to publish our program guidance for expanded HIV/AIDS surveillance in the *Federal Register* for public comment later this year. The guidance will outline performance criteria to ensure both the quality and confidentiality of HIV data. We look forward to receiving your comments on that guidance. I would be happy to discuss this further with you and the Council at any time.

Sincerely yours,

Helene

Helene D. Gayle, M.D., M.P.H.
Director
National Center for HIV, STD,
and TB Prevention

Enclosures

Item I

We urge that the CDC issue a comprehensive public report on its analysis and scientific documentation of the impact of different surveillance systems on seeking/acceptance of HIV testing and care among and potential discriminatory impacts on, individuals and communities at risk for HIV infection. Such a report should also assess the accuracy, completeness and cost of data obtained under the various reporting systems. We recommend that any move to change reporting systems should not be made prior to the development and release of such a report and following an opportunity for community consultation.

We agree with the Council on the importance of evaluating the impact of HIV surveillance. CDC has and will continue to evaluate the effect of HIV surveillance on test-seeking behavior. In 1996, the University of California- San Francisco conducted a survey of 2,370 persons at high risk for HIV infection and 1,931 persons with AIDS in 9 States▒5 States with named reporting, 2 with unique identifier-based reporting, and 2 States without HIV reporting. A worry about name-based reporting was cited as a reason for having delayed testing by 19 percent of respondents, and as their major concern by 2 percent. However, of the 2,370 high-risk persons, only 15 percent knew whether HIV infection was reportable to the local health department. In the AIDS Patient Survey, conducted during 1995 and 1996, persons with AIDS were asked their reasons for delaying testing and seeking care after testing positive. Of persons who had delayed seeking care for more than 1 month after diagnosis, 0.5 percent responded that fear of being reported was the main reason for delay; 10 percent cited it as one among other reasons. [▒Does HIV reporting by name deter testing?▒ submitted to the *Journal of the American Medical Association*; ▒A Multi-State Evaluation of Anonymous HIV Testing and Access to Medical Care▒ accepted for publication in the *Journal of the American Medical Association*] This survey is being repeated and will start this summer. We realize that these results can change over time as people become more aware of State reporting practices and the impact of HIV reporting on programs and peoples lives, and will need to continue to follow this issue.

To assess the effect on test seeking and acceptance among communities, CDC researchers analyzed trends in the utilization of HIV testing services in publicly funded HIV counseling and testing programs before and after the implementation of HIV reporting policies. No significant declines occurred in the total number of HIV tests provided by counseling and testing sites in the months immediately after the implementation of HIV reporting policies in any State, other than the declines expected from trends that were present before HIV reporting. [▒Impact of HIV Reporting by Name Policies on Utilization of HIV Testing Services in Publicly Funded Counseling and Testing Programs▒

submitted to the *Journal of the American Medical Association*] Again, these trends need to be re-assessed over time as more experience is gained with HIV reporting.

Since 1981, there has only been one reported breach of confidentiality of a State AIDS reporting system and there have been no known breaches associated with the adoption of name-based HIV surveillance. Some of these States have been collecting and reporting HIV as an extension of AIDS surveillance for over 10 years. In the case of the one breach, there was no public release of the information and the individual responsible for the breach was prosecuted. The recent, highly publicized release of the names of two HIV-infected persons in Missouri and New York were unrelated to HIV or AIDS surveillance activities.

CDC has established performance criteria for HIV and AIDS surveillance to ensure that surveillance data are of sufficient quality to target prevention and care resources and to detect emerging trends in the HIV epidemic. We plan to publish these for public comment later this year. However, the data available to CDC at present suggest that routine surveillance systems using an individual's name as an identifier are more likely than any other system to provide data of the quality required for public health practice. Regardless of the approach to HIV surveillance adopted by a State, confidentiality protection will need to be of equal importance as the data quality.

Item II

We urge that, prior to recommending any changes in reporting systems for AIDS and HIV, the CDC be required to provide a comprehensive scientific justification that includes a detailed strategy and implementation plan about how it will obtain and present the data necessary to develop a comprehensive picture of the scope of the current and emerging HIV epidemic.

. . .

In development of such a plan, we recommend that the CDC recognize the inherent limitations, weaknesses, and potential for abuse of any HIV case surveillance system (named, unique identifier, or anonymous) and instead use much more innovative methods to collect and interpret data from a wide variety of sources necessary to fully characterize the complex HIV epidemic. Specifically, we urge expanded use of such currently underutilized tools as blinded seroprevalence studies, mathematical modeling techniques, sentinel and random serosurveys, a greatly enhanced portfolio of behavioral research and behavioral surveillance activities, and other similar, innovative methods. Such activities will require a well

coordinated strategy and a great deal of scientific creativity. Enhanced funding and technical assistance activities to allow States, localities, and various planning bodies to effectively utilize such data are essential and must be linked to these innovative efforts.

We agree with the Council that studies and data sources, in addition to HIV surveillance are essential to characterize the HIV epidemic as well as to design effective prevention strategies. CDC strives to provide a comprehensive picture of the HIV epidemic by analysis of data collected through HIV and AIDS surveillance, mortality data, blinded seroprevalence studies, surveillance for antiretroviral drug resistance, behavioral surveillance, and data collected through studies designed to answer specific questions. These techniques allow us to describe the epidemic in more detail than has been done for any other disease. As the epidemic changes and new studies and laboratory techniques are developed, we are always thinking about how to best integrate these data for public consumption.

HIV surveillance can be used to provide a minimum estimate of persons living with HIV (HIV prevalence), to identify emerging trends and patterns of infection, to characterize persons more recently infected than those with AIDS, and to evaluate prevention interventions. The feasibility of making minimum prevalence estimates for smaller areas will depend on the population density and whether the number of cases is sufficient to allow a reliable estimate. Demographics and risk behavior information are collected routinely as a part of surveillance.

Unlinked seroprevalence studies are conducted by CDC among high-risk populations, including persons attending sexually transmitted disease clinics and drug treatment centers. At many of these sites, incidence studies are being conducted concurrently. In addition, several States are piloting methods for detecting incidence among persons being tested in the HIV Counseling and Testing System. Estimates of the trends in national and regional incidence of HIV can be made indirectly by using data from HIV surveillance and focused studies; however, these methods will not quantify incidence.

New laboratory technology is being used in a variety of studies, surveillance systems and programs. Laboratory methods, for example, are being developed that may be able to detect recent infection. If these methods are perfected and put into widespread use, quantifying incidence may be possible. In addition, there are several new methods for determining the antiretroviral susceptibility of viral isolates, and CDC is using some of these to conduct surveillance for antiretroviral resistance among persons who have not been treated with antiretroviral chemotherapy. New testing technologies are also being used, or supported in concept, that would allow persons to

be tested without having blood drawn (oral fluid testing) or learn their infection status during the same visit (rapid tests).

The Adult Spectrum of Disease (ASD) project is a surveillance project in which medical records are abstracted in more than 100 medical facilities in 10 U.S. cities and Puerto Rico. This project provides information about the nature and trends in different opportunistic infections and other clinical information. Information has been collected from the medical records of more than 40,000 HIV-infected persons (18 percent women and more than 50 percent black or Hispanic.)

CDC also has a large portfolio of HIV behavioral research and surveillance projects. Information on behaviors related to HIV is collected through behavioral surveillance, behavioral determinants research, behavioral and social epidemiologic research, and through data reported from programs such as the HIV Counseling and Testing System.

Statistical models have been used to reconstruct the pattern of HIV incidence in the U.S. population; this is not surveillance, however, and the data to allow meaningful modeling are scarce (e.g., no population seroprevalence data has been available since 1994). Mathematical modeling, however, has limited utility in predicting the future of the epidemic or for estimating the current prevalence and incidence of HIV. This poor ability to predict the epidemic is revealed when different mathematical models that fit historical epidemiologic data equally well have very different projections for the short or the longer term.

Item III

Whatever changes, if any, are made in HIV reporting policies at the national level, we strongly believe that several issues must be addressed. These include the following:

- *Identification and implementation of steps to retain and expand anonymous testing options in all jurisdictions receiving CDC prevention and surveillance funding.*

CDC agrees that continued support for anonymous testing is important. Unless specifically prohibited by law, CDC requires that States receiving prevention funds make anonymous testing available in order to make testing as accessible as possible. CDC studies indicate that the lack of anonymous testing options serves as a major deterrent to testing in some high risk populations. Maintaining an anonymous testing option will help ensure that more people learn their status and if infected, seek early treatment and care. We will continue to work with States to preserve anonymous testing along with HIV reporting.

- *Development and incorporation of confidentiality protection standards as part of any reporting system, including model laws and regulations, comprehensive record-keeping and database procedures, standards on use and matching of datasets, and penalties for improper use.*

CDC agrees strongly that protecting the confidentiality of HIV/AIDS data is as important assuring a high quality of data and has stressed this issue, both with our partners and with the media. CDC has also held a series of internal meetings to determine what can be done to further assure the confidentiality of HIV data. Outcomes of these discussions include: CDC will require that name data must be encrypted when stored and when carried in the field; CDC is funding a study of the feasibility of encoding names for long term storage; CDC is exploring the possibility of encryption of names for storage that would be protected by two keys held in different sites and be legally protected from non-public health uses. We agree that any surveillance system should assure strict confidentiality of the data, establish controlled access and penalties for abuse of data that have no links to non-public health uses. These issues will be addressed in the draft guidance on HIV surveillance.

In addition, to promote strong and uniform legal protections of confidentiality, CDC, in collaboration with the Council of State and Territorial Epidemiologists, the Association of State and Territorial Health Officers, and the National Conference of State Legislatures, is developing model confidentiality language for State and local legislation. The proposed model legislation will be available late in 1998.

- *Development of appropriate public information efforts to explain the system, especially to members of affected communities and health care providers.*

- *Technical assistance to health departments, community planning groups, Ryan White planning bodies and consortia, and other appropriate groups on the meaning, limitations, and potential uses of this data.*

Since 1989, CDC has held numerous technical workshops for State health departments (for States with or without HIV reporting), on HIV surveillance systems and the uses of HIV surveillance data. Most recently, in November 1997, CDC convened a meeting of representatives of the HIV and AIDS surveillance programs from all 50 States and 6 cities for a consultation on HIV reporting. CDC has contracted with the Academy for Educational Development to produce technical materials for use by State and local health departments. (Tab A contains a list of other groups CDC has met with on this issue.) As of June 1998, 31 States have implemented HIV reporting. We are also working with our Office of Communications to develop a

communications strategy to educate the community more broadly about HIV information systems.

Health departments are responsible for ensuring that HIV prevention community planning groups have access to current information related on HIV prevention and to analyses of the information. As a part of the development of a comprehensive HIV prevention plan, project areas are expected to periodically review, revise, and refine the plans, as indicated by any new or enhanced surveillance data or other relevant information. State and local health departments are also responsible for informing local health care providers or organizations about HIV surveillance. We will continue to work with health departments to ensure that data on HIV trends get incorporated into the planning process.

National data are provided to the Health Resources and Services Administration (HRSA). CDC has sponsored State and local staff to provide data on request to the Ryan White Consortia. CDC staff have attended the national meeting of Ryan White grantees to discuss surveillance data and the role of community planning groups. We see working together on this issue with HRSA and Ryan White grantees to be a key priority.

- *Adequate funding to States and local jurisdictions for the work of collecting, maintaining, and interpreting the collected data.*

Funding for these purposes is available through the CDC HIV surveillance and HIV prevention cooperative agreements. We will continue to work to ensure adequate funding for these priority activities.

Identification of steps to guarantee access to appropriate care and services for all individuals who test positive in any system.

We agree that access to care and services is important. CDC does not provide the care and services required by persons infected with HIV. However, HIV surveillance and other targeted studies can evaluate access to care. CDC is working with the Health Resources and Services Administration to evaluate referrals and access to care among persons who test positive for HIV through the Counseling and Testing System. We recognize that more than ever, it is critical that CDC and HRSA work towards greater continuity between prevention and care services. We are working with colleagues at HRSA towards this goal.

In conclusion, PACHA has raised many important issues that are useful for CDC to reflect upon and take into account as technical guidelines are developed for public comment.

Tab A

CDC has met with the following organizations regarding the implementation of national HIV surveillance:

State and Local Health Departments (on-site or teleconference)

Alaska, California, Connecticut, Florida, Georgia, Hawaii, Indiana, Kansas, Los Angeles, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, New Jersey, New York State Advisory Committee (4 discussions), Pennsylvania, Puerto Rico, South Carolina, Texas, Vermont, Washington, Wyoming

<u>AIDS-Related Organizations (or their representatives)</u>
AIDS Action Foundation (2 discussions)
AIDS National Interfaith Network
AIDS Policy Center for Children, Youth and Families (2 discussions)
AIDS Research Consortium of Atlanta
Gay and Lesbian Medical Association
Gay Men's Health Crisis - New York City
Human Rights Campaign (2 discussions)
National AIDS Fund
National Association of People with AIDS
National Minority AIDS Council (2 discussions)
National Native American AIDS Prevention Center
National Task Force on AIDS Prevention

<u>Other Groups (or their representatives)</u>
100 Black Men of America
Academy for Educational Development
Advocates for Youth
American Civil Liberties Union
American Medical Association
American Psychological Association
American Red Cross
Asian Pacific Islander Wellness Center
Council of State and Territorial Epidemiologists (2 discussions)
Harlem Directors
Human Rights Campaign Fund
Interviews in gay/lesbian publications
Interviews with other media
National Advocacy Coalition on Youth and Sexual Orientation
National Alliance of State and Territorial AIDS Directors (3 discussions)
National Association of State Alcohol and Drug Abuse Directors
National Coalition of STD Directors
National Coalition of Hispanic Health and Human Services
National Conference of State Legislators
National Council of Negro Women
National Latino/a Lesbian and Gay Association
Office of AIDS Policy (2 discussions)
U.S. Conference of Mayors

Date: June 12, 1998

To: Steve Lew
From: Robert Soliz

Subject: Summary of PACHA Services Sub-Committee Recommendations Discussion

Hi, Steve, below is a summary of our discussion which I sent to Daniel. Hope this is a little more readable than an e-mail.

I discussed several recommendations may by the Services Subcommittee with Steve Lew on Wednesday (6/9/98). I explained that any recommendations that we did not discuss had been reviewed by ONAP and that we considered those recommendations resolved. The ones that we did discuss we assumed the services subcommittee needed to discuss, re-examine, refer, etc..

The recommendations that we discussed and the conclusions that we came to are summarized below (the letter in the number of all services subcommittee recommendations has been changed from "B" to "S"):

III.S.1 (re: having CDC ensure that all States offer the option of geographically accessible anonymous testing for all CDC funded counseling and testing programs):

This recommendation needs to be referred to the Prevention Subcommittee.

III.S.3 (re: having SSA include in all SS Disability Award Notices language about health benefits continuation under COBRA)

Alternative strategies were given by the Administration concerning how best to implement the intent of this recommendation, and the Services Subcommittee needs information clarifying the extent to which this recommendation is being implemented.

III.S.4 (re: having the administration recommend substantial increase in the NIH OA '97 budget):

This is more of a follow-up recommendation and associated with III.S.V (see below), and the Services Subcommittee needs a progress report from NIH and OAM concerning what they've been doing around these issues (increased funding and alternative/complementary therapy reimbursement).

III.S.5 (re; having Medicaid and Medicare determine which alternative/complementary therapies can be immediately reimburse directly to qualified health care providers):

(ONAP suggested that this recommendation be combined with II.S.7 (re: having the President direct appropriate agencies to support investigation of the efficacy of complementary therapies, and having therapies shown to have benefits be reimbursed under Medicaid)).

The Services Subcommittee agrees that the two recommendations can be combined, but it still needs responses to II.S.7 and II.S.5. The Services Subcommittee needs a progress report on these two recommendations.

III.S.6 (re: having the administration direct OAM and OAR convene a working group --comprised of a variety of individuals/groups -- to investigate new/innovative ways to research and make available to people therapies that anecdotally are being identified as treatments for HIV):

This recommendations has become somewhat of a lower priority, but the Services Subcommittee still needs follow-up/information on this. The Services Subcommittee still needs

- the report prepared by the "Sub-panel" on evaluation (see 8/30/97 response), chaired by the Director of the OAM and comprised of researchers and advocates interested in this issues (see 8/30/97 ONAP response), and

- a status report on the recommendations made by the NIH AIDS Research Evaluation Task Force (see ONAP 8/30/97 response) around these issues.

Recommendations passed at the December 7, 1997 PACHA meeting;

V.B.1 (re encouraging HRSA to explore strategies by which States can purchase health insurance coverage using ADAP funding):

The Services Subcommittee needs to know HRSA policy on this,

V.B.2 (re: having HRSA strength TA in drug pricing negotiation to all ADAP programs that have not achieved comparable prices from the O.D.P. Section 602 program):

Agree that HRSA has been doing this, would urge HRSA to do more.

V.B.3: (re; urging the VP to continue his work with pharmaceutical companies re: the price of drugs):

The Services Subcommittee wants an ONAP response to this. Not yet resolved.

V.B.4 (re: expanding /intensifying White House leadership on all options for expanding access to treatment):

This is a Leadership recommendations, and the Services Subcommittee wants the President, the VP, and ONAP to address this.

In 1984, when scientists finally nabbed HIV, it instantly raised prospects that a

vaccine would follow. Even to hope that the new disease might soon join the list of deadly epidemics stopped cold by a vaccine was no inventive leap. If anything in medicine seems like a magic bullet, it's these tried-and-true weapons. But in the

Dying for a Vaccine

[illegible]

[illegible] the stakes are bigger than ever

by [illegible]

[illegible]

[illegible]

heady flush of success over identifying HIV, Margaret Heckler, then secretary of the Health and Human Services Department, blithely served up a science-fiction scenario of a quick fix when she said that a candidate would be ready to test within two years. After all, in the real world even a decade is turbo speed for a new vaccine.

Fourteen years later, a vaccine is nowhere in sight; in fact, even the fantasy has faded. During these years, while AIDS activists—desperate to save lives—pushed the National Institutes of Health (NIH) toward a massive research effort on treatments, there was no one fighting with such passion for a vaccine. In fact, many in the AIDS community cast a cold eye on the vaccine cause, fearful that research into, let alone development of, a shot that protected against HIV would dash the hopes of the already infected. Moreover, some scientists even grew skeptical that a vaccine was possible. And most drug companies steered clear, anticipating a long, difficult scientific path fraught with uncertain profits and a political and ethical minefield.

Now, with some big successes in anti-HIV therapy but the virus still spreading like wildfire worldwide, vaccines are starting to make a comeback—although so far there's still more talk than action. Take, for example, President Clinton's 1997 call for an HIV vaccine within the decade, which invoked "can do" images of a man-on-the-moon-type effort. Yet he offered no Apollo-esque strategies to support it, nor has NIH come up with a concrete plan for trying to meet the deadline.

Is "10 years till a vaccine" remotely realistic? NIH top brass are wary. "I'll be happy if we can get a good candidate to the point of large-scale clinical trials in that time," says Dr. Carole Heilman, deputy director of the agency's Division of AIDS. Others are eager to go for it, but say that far more energy and focus are necessary. "The whole mentality of how we're looking has to change," says Dr. Margaret Johnston, scientific director of the International AIDS Vaccine Initiative (IAVI), a new nonprofit group dedicated to pushing vaccines forward. "We have to be much more aggressive. People haven't woken up yet to what making a vaccine really means."

Re-invigorating the national vaccine effort has been a rocky road since 1996, when a blue-ribbon panel of AIDS researchers diagnosed the federal program as "in crisis": It was deemed too small, of low priority and poorly funded, and too narrowly focused on basic science while neglecting targeted research. Added to this is not only the huge cost but the very slow and long development pipeline that leads promising vaccine candidates out of academic labs, into manufacture for human use, through early clinical tests for safety and ability to stimulate immune responses, and then finally into a Phase 3 efficacy trial, which tests if the candidate works.

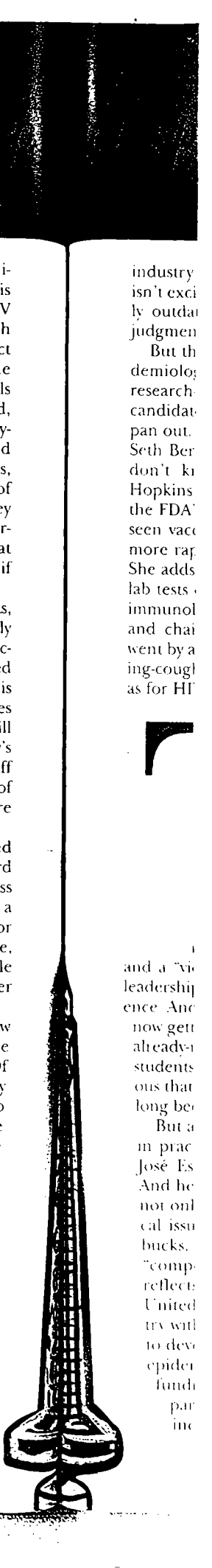
Yet many scientists view the biggest obstacle as the formidable scientific challenge of HIV itself. A major mystery is that people usually show strong immune responses to HIV but still eventually get sick, so no one knows for sure which type of immunity a vaccine should stimulate to protect against disease. One emerging view suggests that a vaccine should aim at several arms of the immune system: The cells producing antibodies that destroy free virus in the blood, the cytotoxic T lymphocytes (CTL) that target already-infected cells, and also perhaps the dimly understood immune responses in the body's mucosal membranes, including those lining the vagina and rectum—ports of entry for sexually transmitted HIV—and the gut, likely a key destination of HIV soon after infection. Another high hurdle: Since no animal immune system perfectly mirrors that of humans infected with the virus, there's no way to know if a vaccine works without testing it in people.

Although daunting, none of this is new to vaccinologists, who rarely know all they'd like to about their prey. So they rely instead on educated trial and error, where experimental vaccines are tested in people and their designs improved based on the results. Another way they've sidestepped ignorance is to stick with the strategy that produced the very first vaccines and is still hard to beat: Take the whole virus, weaken or kill it so it can't make people sick, and then count on the body's own immune response to do the rest. But there's a tradeoff because weakened whole-virus vaccines still carry a tiny risk of causing disease. For example, in the United States, there are about eight cases a year of vaccine-induced polio.

With HIV, fears about potential risks have steered researchers away from this traditional strategy and toward genetically engineered "designer" vaccines that are harmless because they use only parts of the virus. Again, there's a price—these vaccines, even if they work, may give weaker or less long-lasting immunity. Most types will also be expensive, adding to the problem of making an AIDS vaccine available to those most in need—in developing countries, where over 90 percent of the world's 31 million with HIV live.

But a more immediate worry in the vaccine field is how few candidates have even made it out of the lab and into the pipeline. And sadly, once in it, they don't flow through: Of the more than two dozen products tested in Phase 1 safety trials, only three have made it to the next step, and none to Phase 3, a record that prompted Dr. William Heyward of the Centers for Disease Control and Prevention (CDC), to write in *The Journal of the International Association of Physicians in AIDS Care* (IAPAC), that the pipeline is more like a pipette.

The reason for this paltry trickle is one of the most contentious issues in the vaccine field. For many basic researchers, the bottom line is that current candidates are simply not good enough. Even Dr. David Baltimore, the retrovirologist and Nobel laureate who chairs NIH's new AIDS Vaccine Research Committee, doubts that 14 years of R&D have produced anything worth large-scale tests. To him and others in the "theorist" camp, the key isn't "big trials now" but more basic research and small trials aimed at understanding what's needed for an effective vaccine. This is also the way to pull in drug and biotech companies, Baltimore says. "We need to face



industry with real opportunities. Right now the pipeline isn't exciting enough—we're testing concepts that are clearly outdated. Drug companies have made the reasonable judgment that the time isn't right."

But the "empiricists"—mostly public health experts, epidemiologists and vaccinologists favoring more applied research—counter that it's too soon to write off current candidates, since basic science can't predict which ones will pan out. "We don't know what works, end of story," says Dr. Seth Berkley, president of IAVI. "We have theories, but we don't know." Dr. Mary Lou Clements-Mann of Johns Hopkins University, a vaccine researcher and member of the FDA's vaccine advisory committee, agrees, saying, "I've seen vaccines moved from small- to large-scale tests much more rapidly, without answers as to why they might work." She adds, "After licensing, often we still don't know." Some lab tests can even be misleading, says Dr. Barry Bloom, an immunologist at the Albert Einstein College of Medicine and chair of the UNAIDS vaccine subcommittee. "If we went by animal models we wouldn't have the newest whooping-cough vaccine," he says. "If we'd used the same criteria as for HIV, it would never have gotten off the ground."

This long-simmering debate erupted last March when Dr. Jonathan Mann, former head of the World Health Organization's Global Program on AIDS, attacked the "theorists" in a passionate speech before Clinton's AIDS advisory council. Mann criticized the failure to mount efficacy trials as "unethical" and a "violation of human rights," and called on the NIH leadership to involve more people who have vaccine experience. And he accused the NIH of indifference to the people now getting HIV in this country, most of whom come from already-marginalized groups. "Very simply, if 40,000 college students were becoming HIV infected each year, it's obvious that field trials of AIDS vaccine candidates would have long been underway," he said.

But as polarized and ideological as the debate sounds, in practice there's a well-occupied middle ground, says José Esparza, vaccine team leader at UNAIDS Geneva. And he points out that opinions on efficacy trials reflect not only "theorist" vs. "empiricist" arguments but practical issues as well—such as money. These tests take big bucks, and with limited funds it becomes a matter of "competing priorities," he says. Funding, in turn, reflects HIV vaccine research's low priority in the United States. "The fact of the matter is that the country with the financial resources and scientific know-how to develop the vaccine does not feel the urgency of the epidemic," he says. "The only solution is to increase funding for HIV vaccine research and proceed with parallel development of several vaccine concepts, including several large-scale efficacy trials."

Lurking in the shadows of this battle is the spectre of fallout from a large trial that fails, a common occurrence with experimental vaccines but much feared in the HIV field. Given the public attention to AIDS, a bust would give HIV vaccine trials "a bad name," says Baltimore. IAVI's Berkley disagrees. "Politically it's considered too risky to have negative vaccine trials," he says. "But why? With malaria, we've tested a lot of vaccines that didn't work. We need a big shift in mind-set." And if a trial is well designed, says vaccinologist Clements-Mann, a negative result can give crucial information on how to make a better one.

That means a reality check on public expectations. "The public is looking for an immediate, spectacular success," says immunologist Bloom. "But you don't pull a vaccine out of a test tube and it works. It takes constant modification. You're not going to get it right the first time. A 99 percent effective vaccine? I don't see it on the horizon. But even 50 percent effectiveness would be enormously useful."

Amid the clash of views, one vaccine is now inching its way toward that historical milestone—the first Phase 3 trial, likely underway within a year or so. The figure behind the trial is Dr. Donald Francis, who, at the CDC in the early '80s, was one of the first voices trying to awaken the world to the tragedy ahead. In 1993 he joined the HIV vaccine program at Genentech, a biotech behemoth based in South San Francisco. Researchers there had adopted the same strategy as nearly all early HIV vaccine makers—focusing on a genetically engineered version of the so-called gp120 protein, which makes up the surface of HIV. These scientists had already succeeded in making a vaccine that prevented HIV from infecting chimpanzees. Early trials with small numbers of people found it to be safe in humans and able to stimulate a strong antibody response. The NIH's National Institutes for Allergy and Infectious Diseases (NIAID) was prepared to pump $20 million into a Phase 3 trial.

And then NIAID wasn't. In a stunning reversal, the agency pulled out. New data in early 1994 raised fears that differences among gp120 proteins in HIV strains directly from people and those grown in the lab—used to make Francis' vaccine—might doom the vaccine to failure. Many voiced doubts about whether gp120s stimulated the "right" kind of antibodies. And even the chimp data didn't convince everyone, since HIV can infect chimps but doesn't give them AIDS. As scientists feverishly debated the meaning of the new findings, NIAID finally bailed out in June, saying that its limited funds should be saved for better candidates. The decision cast a pall over the whole field and led some companies to shrink or shut down their HIV vaccine work (including Genentech, which spun off Francis and the vaccine to a small new company, VaxGen).

Francis persisted, convinced that the vaccine's ability to protect chimps meant more than the lab tests that gave NIAID cold feet. Now he's ready once again, with his own funds—$20 million raised privately so far—and modified vaccines. These newest vaccines stimulate the type of antibodies NIAID wanted to see and, along with gp120 from the lab strain, contains gp120s representative of common strains at each of the two likely trial sites (Thailand and the United

States). And he expects to get the official go-aheads soon. In the U.S., FDA approval for a Phase 3 trial is nearly certain, he says, once data from the ongoing Phase 2 trial are in. Meanwhile, in February an international group of scientists recommended to Thai officials that the Phase 3 trial there go forward. Together, the two trials would follow 7,500 high-risk volunteers for three years.

These trials-to-be have triggered the full range of reactions. Skeptics point to a growing belief that an HIV vaccine should induce strong CTL responses, and Francis' doesn't. "Seriously wanting" is how Dr. John Moore of the Aaron Diamond AIDS Research Center rates the vaccine. "I'm absolutely certain that the vaccine's efficacy would be immeasurably low," he says. "There is also a moral issue," he adds, arguing, "It's simply not appropriate to immunize human volunteers with a protein that has no chance of protecting them from HIV." Others are more supportive of Francis' trials. "I'm delighted that VaxGen is moving ahead," says IAVI's Margaret Johnston. "It's important to know if gp120 works at all based on data rather than on what people see in a crystal ball. Any answer is worthwhile."

However the gp120 story ends, its cautionary moral—don't put all your eggs in one basket—has already spurred those in the vaccine field to pursue several other strategies. One is to put selected HIV genes into harmless viruses that infect the cells of vaccinated people and make them churn out HIV proteins, which should stimulate immunity. Since these viral "vectors" often evoke good CTL responses, some experimental strategies combine them with the antibody-stimulating gp120 for a one-two immunizing punch. And high hopes are pinned on the concept of vaccinating with HIV genes in the form of "naked" DNA. Although at least a decade away, this technology is a potentially revolutionary way to make vaccines cheaply and simply, which would be ideal for the developing world.

Increasingly, these new approaches turn on the old-fashioned idea of presenting the immune system with many different parts of HIV (working "top down" from whole virus) rather than the "bottom up" approach of selecting only one or two targets, as with gp120. This would hopefully give the wily, changeable virus fewer chances to evade immune attack. And that shift has sparked pockets of interest in a strategy long viewed as unthinkable—using live HIV.

Estimated HIV Infections

Sub-Saharan Africa	20.8 million
South & Southeast Asia	6 million
Latin America	1.3 million
North America	860,000
Western Europe	530,000
Eastern Asia & Pacific	440,000
Caribbean	310,000
North Africa & Middle East Asia	210,000
Eastern Europe & Central Asia	150,000
Australia & New Zealand	12,000
GLOBAL TOTAL	**30.6 MILLION**

Source: Joint United Nations Programme on AIDS (UNAIDS)

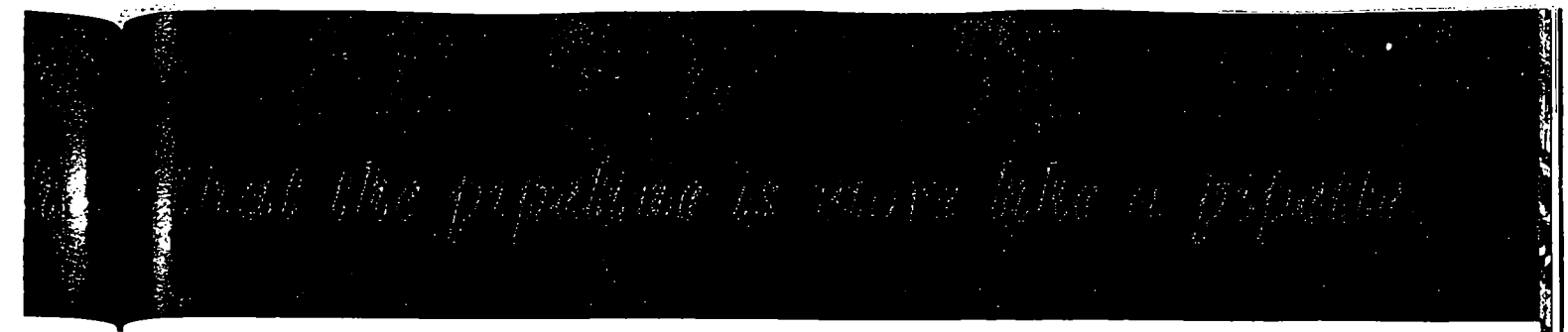
From their backwater in the HIV field, live but weakened ("attenuated") AIDS vaccines made a sudden, dramatic appearance in the headlines last September when IAPAC announced an initiative to push for a Phase 1 human trial by the year 2000. But that wasn't all. Recognizing the potential risk—and the public fears—of a live HIV vaccine, several IAPAC members volunteered to be the first guinea pigs, following the tradition of Louis Pasteur, Walter Reed and other vaccine pioneers. It was a vivid, startling gesture showing that the need for a vaccine was so great worldwide that people were willing to accept the risk of getting AIDS (although IAPAC considers this low). And since IAPAC's announcement, more than 270 people have volunteered to join them in rolling up their sleeves (a first trial would probably involve 10 or less).

IAPAC's attempt to put live vaccines on the agenda isn't a stab in the dark: There's already powerful evidence that they may work. In 1992, Ronald Desrosiers of the Harvard Medical School injected monkeys with a weakened version of SIV, a simian virus related to HIV, made by clipping out several genes. When the same animals were infected later with the intact, nasty SIV, they were fully protected from disease—just as a good vaccine should do. No other vaccine candidate has come close to matching this stellar performance.

Yet most AIDS researchers reacted to IAPAC's announcement with alarm, aware of then-emerging data that some attenuated SIV strains cause full-blown simian AIDS in baby monkeys and in a small proportion of adults. And even though IAPAC proposed using a more weakened strain, critics say that too little is known about HIV genetics to ensure that the virus can be made meek enough to not cause disease.

Whether a U.S. trial kicks off by the year 2000 or later depends on the FDA, whose primary concern is public safety, not necessarily the shortest road to an effective vaccine. Vaccinologist Clements-Mann ticks off some of the concerns: Could vaccinated people get sick from the attenuated virus years later? What happens when their immune systems weaken from age or illness? Is attenuated HIV transmissible, even at a low frequency? None of these questions can be tackled in short human trials.

IAPAC's deputy director, José Zuniga, acknowledges these fears. "I don't envy the FDA's position. We're not asking them to throw caution to the wind, to say we don't need more data. But we need to move from animals and ask what the vaccine does in humans." And he cites an accidental experiment in humans that suggests that a safe attenuated HIV is possible. Eight people, including seven in Australia, were found to be infected with weakened forms of HIV since the early '80s, without any apparent ill effects.



Yet for the FDA to even consider trials, and to ensure that potential volunteers are fully aware of the possible consequences, more animal data will be needed. Enter IAVI. Although the organization sees a trial in healthy volunteers as premature, it also believes strongly that the live-attenuated approach should be pursued, and have funded a pilot project to design a large safety study involving hundreds of monkeys. Similar studies were done for other live vaccines, such as polio. "I would consider enrolling in a trial if there was more data," says IAVI's scientific director, Margaret Johnston. "I'm not willing to make the leap of faith now."

In the meantime, Dr. John Sullivan of the University of Massachusetts has proposed an alternative plan for the first human trial, one that may be more acceptable to the FDA. Rather than vaccinating healthy volunteers, Sullivan suggests recruiting terminally ill cancer patients with still-intact immune systems. This plan, dubbed "a very reasonable first step" by IAVI's Johnston, could throw light on key issues, such as whether the chosen attenuated HIV strain replicates in humans, what types of immune responses it stimulates, and how its behavior in people compares to that of attenuated SIV in monkeys.

Researchers in Australia are also pursuing plans to test a live-attenuated vaccine within the next few years. Dr. John Mills, director of the Macfarlane Burnet Centre for Medical Research, is modeling his candidate on the naturally weakened HIV strain found in the seven Australians (who got it through blood from a single donor), with this speculative twist: He hopes to vaccinate with DNA only, not with whole virus. If that works, it would make vaccine preparation vastly simpler, safer and cheaper. With funding from IAVI, he's now working on safety studies in monkeys.

In the United States, despite both outside criticism and Clinton's 10-year call, the NIH is sticking with its present strategy, beefed up with some extra funds and the involvement of big gun David Baltimore. Several new mechanisms are also in place to help researchers negotiate the arduous vaccine development pipeline. But there's no specific 10-year plan, and a proposed NIH Vaccine Center, meant as a cornerstone of NIH's born-again vaccine effort, has yet to get on its feet.

IAVI will likely shake things up when it presents its "scientific blueprint" for an HIV vaccine in 10 years at the World AIDS Conference in Geneva. Based on a 1994 brainstorming meeting of big vaccine players worldwide, the plan is "a very different approach from the basic science one," says IAVI president Berkley. Its central elements: "Work on different things in parallel. Work top down. And go fast into humans—don't sit around and argue about animal models."

IAVI's plan is based on a key assumption: Getting a vaccine in 10 years means starting with a concept that's already out there, since the development pipeline is so long. IAVI's idea is to fund parallel work comparing several candidates that use a common strategy and to advance the best ones. For example, comparing lab and animal data for candidates based on viral vectors, choosing some for Phase 1 trials, and so on, eventually testing the best of different strategies in Phase 3 trials.

IAVI is also tackling some of the business issues that slow vaccine development. Liability and intellectual property are big concerns, since one vaccine can touch on a dozen or more patents. Another problem is ensuring a market. Companies that invest in vaccines want to be able to sell them, yet the major demand will be in poor countries, which will desperately need them to be affordable. One solution being discussed is an international vaccine purchasing fund of around $1 billion guaranteed by the World Bank.

As the vaccine effort gears up, developing countries will face another set of difficulties. They are the most likely places for large-scale efficacy trials, which can be done faster and with fewer people where the infection rate is high. Yet that scenario promises some painful ethical dilemmas—for example, the "guinea pig" issue. In the United States, vaccine trial participants who become infected would be able to start drug treatment right away. In most developing countries, though, cost, adherence difficulties and the lack of medical care conspire to make combination therapy unavailable. Yet no treatment enables researchers to monitor not only whether a vaccine prevents people from getting infected, but also whether it keeps them from getting sick or makes the disease less severe, which is just what many scientists think a vaccine will do.

Efforts are underway to tackle this and other problems before large trials begin, when public attention will be high and mistakes potentially disastrous. The prime push is by the UNAIDS ethics subcommittee, now finishing a set of guidelines for efficacy trials after a series of "community consultation" workshops worldwide that brought together scientists, community groups and local reps. According to Dr. Ruth Macklin, the Albert Einstein College of Medicine bioethicist chair, many countries want to contribute to the vaccine effort, as long as it's on terms they help to write. "Developing countries must be more empowered to make their own decisions about trials," says WHO's José Esparza. Otherwise, they are dependent on whichever vaccines the industrialized world decides to test at home—where the sense of urgency is less and could lead to different decisions about which candidates to pursue.

To date, initial recruiting efforts in the developing world for HIV vaccine trials have been received better than officials may have expected. Natth Bhamarapravati, a member of the National AIDS Commission of Thailand, told *The IAVI Report*, "We expected that our volunteers would be uneducated people who received some incentive, financial or otherwise. But so far the profile is much different. Three-fourths of them are university educated. Some are doctors and nurses. People are interested in participating in AIDS vaccine trials because it can help end this horrible epidemic."

All these developments cast a ray of optimism on the slow, sad story of AIDS vaccines. If a just partnership between rich and poor countries can evolve, dreams of the ultimate weapon against AIDS could become reality not only for the world's privileged but also for its destitute. ■

"Martin, R. Frank" <RMartin @ HQE.IHS.GOV>
06/09/98 03:08:14 PM

Record Type: Record

To: Daniel C. Montoya/OPD/EOP

cc:
Subject: PAC on HIV/AIDS Recommendations

I just received the memo and recommendations from Dr. Trujillo to review for comments from the IHS. Since there were no specific recommendations concerning American Indians and Alaska Natives (AI/AN) none of the recommendations are pertinent to the IHS to comment on. The Agency does endorse the recommendations as they pertain to AI/AN as part of the U.S. population. The IHS will do its best to see that they are followed in Indian Country.

I am E-mailing since they are due tomorrow.

Frank Martin

Clark Moore <cmoore @ aidspolicycenter.org>
06/03/98 01:13:27 PM

Record Type: Record

To: "Sean Sasser (w)" <ssasser @ stopaids.org>, Sean Sasser <Mojo1025 @ aol.com>

cc: David Harvey <harveyapc @ aol.com>, Daniel C. Montoya/OPD/EOP
Subject: Draft Youth Recommendations

Draft Recommendations for the Presidential Advisory Council on HIV/AIDS
Youth Issues

1) In March 1996, the White House Office of National AIDS Policy issued a report to the President titled, Youth & HIV/AIDS: An American Agenda. The report, written with input from youth, service providers, researchers and advocates, contained a variety of recommendations to strengthen the nation's response to the HIV/AIDS epidemic among young people. Two years later, the extent to which these recommendations have been implemented is not clear. The Council requests that the Office of National AIDS Policy present a detailed status report on the implementation of these recommendations.

The recommendations in the report include, but are not limited to, the following (some recommendations have been combined):

General Recommendations

DHHS should create a forum of young people who are infected with or affected by HIV along with their advocates and providers. This group should work with relevant federal agencies to help identify and articulate the needs of adolescents in fashioning Federal responses to HIV/AIDS (page 13).

Prevention

Innovative, creative prevention efforts aimed at young people must be encouraged, adequately funded, and evaluated, and -- when found to be effective -- broadly disseminated (13);

Beginning at the earliest appropriate age, young people should receive sexuality and HIV/AIDS education as part of a comprehensive curriculum of health education. Such a curriculum should include accurate information about HIV and modes of transmission, the opportunity to assess personal risk of infection, and skills training. HIV prevention information should be age-, language-, and culturally-relevant and designed to accommodate the context of the lives of young people and their families (6);

Comprehensive HIV/AIDS education - as part of comprehensive health education - should be available to all young people in all fifty states and U.S. territories (13). The Federal government should help the nation's schools and other youth serving agencies implement comprehensive programs to prevent the spread of HIV among young people (14);

CDC should encourage the inclusion of young people and their advocates in

all HIV prevention planning councils to provide their unique perspective on the needs of youth in prevention efforts (ii, 14);

SAMHSA, CDC, and HRSA should collaborate on substance abuse treatment and prevention strategies affecting adolescents to ensure a coordinated effort (ii);

Counseling and Testing

Routine counseling and voluntary HIV testing should be made more accessible, developmentally appropriate, and affordable to young people (13);

The Federal government should support expanded access to testing and counseling for young people. The CDC guidelines for testing and counseling should acknowledge and address the special needs of adolescents, such as developmental issues, processes for consent, confidentiality, and payment for services. The guidance should be integrated into the training of all personnel at CDC-funded counseling and testing sites (ii, 14);

CDC should require that, as part of the grant application for counseling and testing funds, states demonstrate the availability of counseling and testing for young people (14);

Care and Services

HIV-positive adolescents should be linked to a continuum of care and services that will extend their life span and provide them with the information and skills they need to reduce the likelihood of further transmission (13);

The Federal government and states should examine opportunities to ensure that all Medicaid-eligible HIV-positive youth have access to appropriate treatment and care (10);

PHS should work with the researchers, clinicians, medical community, and patients to develop appropriate clinical practice guidelines for adolescents with HIV/AIDS (ii);

HRSA should encourage the inclusion of young people and their advocates on AIDS care planning councils to help identify local needs and ways to target Federal funds to help meet the distinct developmental and comprehensive care needs of youth (13);

Research

The family of HIV seroprevalence surveys should be expanded to target and teach us more about the epidemic as it affects young people (12);

Adolescent-specific biomedical and behavioral research should be increased to enhance our knowledge of the progress of HIV disease in adolescents and of effective AIDS prevention approaches (13). Additional studies are needed to understand the natural history of HIV in adolescents as well as expanded study of youth and their behaviors (11);

NIH and FDA should encourage government and industry sponsors to enroll adolescents, when feasible and appropriate, in HIV/AIDS clinical trials (ii, 14);

In releasing data from clinical trials, NIH and FDA should include specific

data related to adolescents. When the number of adolescents participating in a trial is too small, anecdotal data should be released on a limited basis to allow clinicians an opportunity to begin building a base of information for their use in treatment (14).

2. On December 1, 1997, President Clinton issued a memorandum to heads of executive departments and agencies regarding the integration of HIV prevention in Federal programs serving youth. This directive was to be implemented by the end of May 1998. The Council requests that the Office of National AIDS Policy present a detailed status report on the implementation of these recommendations.

The President's directive includes the following:

That each Federal agency, within 90 days, working with the HHS and ONAP, identify all programs under its control that serve young people ages 13-21 and that offer a significant opportunity for preventing HIV infection; and

That each Federal agency, in collaboration with the HHS and ONAP, develop within 180 days a specific plan through which said programs could increase access to HIV prevention and education information, as well as to supportive services and care for those already infected.

3. The President should appoint at least one young person under age 24, particularly an individual who is HIV infected, and a youth service provider to the Presidential Advisory Council on HIV/AIDS.

4. Additional Recommendations (Draft)

The following recommendations expand on key issues and recommendations contained in the 1996 White House Report, Youth & HIV/AIDS: An American Agenda. The recommendations also summarize some of the top policy issues which have consistently been identified by young people, service providers, and advocacy organizations.

Prevention

The Administration should direct CDC to ensure that HIV prevention activities, including CDC-funded activities at the local level, more equitably address the needs of youth at highest risk for HIV infection, including youth of color, young women, and young men who have sex with men.

The President must provide strong and vocal support for federal funding for comprehensive HIV/STD prevention and family planning programs that include information about disease and pregnancy prevention methods other than abstinence.

Counseling and Testing

The Administration should direct the CDC to ensure that all CDC-funded HIV counseling and testing programs are accessible and appropriate for young people. Funding and support for youth-specific casefinding and counseling/testing programs should be expanded.

The Administration should direct HHS to expand training and assistance programs for health care providers on improving the quality and availability of HIV counseling and testing for youth.

Care and Treatment

The President should seek expanded funding and support under the Ryan White CARE Act and other Federal programs for comprehensive, community-based health care services that address the medical and psychosocial needs of HIV infected youth.

The Administration should work to expand eligibility under the Children's Health Insurance Program (CHIP) and Medicaid to ensure that all youth in all states and territories have comprehensive health coverage.

The Administration should direct HRSA to expand and strengthen training and technical assistance for HIV service providers and youth service providers to help them respond to the unique needs of young people living with and at risk for HIV.

Research

The President should direct HHS to convene a working group consisting of representatives from Federal agencies, researchers, youth service providers, advocates and young people to develop a coordinated Federal agenda for HIV/AIDS research on adolescents and young adults. This agenda, which should be updated regularly, would help to coordinate existing efforts and to identify key research gaps. It should address the full range of research related to HIV/AIDS epidemiology, prevention, care and treatment.

The Administration should direct NIH to provide incentives, training and technical assistance to units of the Adult AIDS Clinical Trials Group (AACTG), the Pediatric AIDS Clinical Trials Group (PACTG) and Clinical Programs for Clinical Research on AIDS (CPCRA) to promote access to clinical research opportunities for HIV infected adolescents and young adults.