

Presidential Advisi

July

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Council Members Present: Dr. R. Scott Hitt, Ms. Mary Boland, Mr. Nicholas Bollman, Mr. Mr. Edward Gould, Ms. Phyllis Greenberger, Landau, Dr. Alexandra Mary Levine, Mr. Ste Robinson, Ms. Debbie Runions, Mr. Benjami The Honorable Charles Quincy Troupe, Dr. F

Opening Remarks

Ms. Patricia S. Fleming, Director, Office of N welcomed the Presidential Advisory Council
Donna E. Shalala, Secretary, Department of E

Dr. Hitt called attention to a summary of responses from Council members and other key persons concerning common themes and constitute a starting point for members would meet later in the day to draft recommendations presented to President Clinton. The day's agenda included several key government officials, who would be joined by Council members.

Ms. Fleming

Ms. Fleming noted that the Clinton Administration is addressing the HIV/AIDS epidemic, with a focus on three goals: (1) a vaccine; (2) creative and forward-thinking prevention strategies; and (3) the-art treatment and care for persons living with HIV. She noted that the Office of AIDS Research (OAR) and make recommendations to State and local governments and private organizations to address specific communities (e.g., people of color and women). She also mentioned Opportunities for People with AIDS (HOPWA) and Medicaid coverage of HIV-infected persons. She noted that the Health Care Financing Administration (HCFA) is using managed care for AIDS patients covering the development of policies related to voluntary testing and counseling.

Robert L. Fogel is a Chicago attorney who is concerned with AIDS education and needle-exchange programs. He plans to focus on AIDS education and needle-exchange programs.

Debra Frazer-Howze is the President/CEO of the National Black Leadership Initiative on AIDS. She is concerned with self-help initiatives and community development.

Edward Gould is a former banker who is a fundraiser, and community activist concerned with HIV/AIDS care services.

Phyllis Greenberger is a social worker with the National Center for the Advancement of Women's Health Research. Her research includes gender-based biology and AIDS.

Bob Hattoy is White House Liaison at the National Center for the Living with AIDS. He believes that the key to the fight against AIDS is education.

Carole LeFevre is a Native American living in Chicago.

Ms. Debbie Runions is a journalist and concerned with easing bigotry and fear, pr assume the role of leader in the fight again **Mr. Benjamin Schatz** is an activist who i Medical Association. He is concerned wit workers, and the second wave of infection

Denise Stokes is a 26-year-old AIDS and with HIV for 10 years. She is an advocate care, such as the homeless and low-income

Sandra Thurman is Director of the Task formerly Executive Director of AIDS Atla

Charles Quincy Troupe is a Missouri Sta pregnancy, STDs, and HIV/AIDS among l education and prevention issues.

Bruce Weniger is a Government epidemic He advocates practical applied research str a preventive vaccine.

legislative proposals. Because payments to Medicaid would be cut, costs would be to decrease the number of

Mr. Chris Jennings, Special Assistant to the President, continued the discussion of the implications of the proposed \$270 billion cut in Medicaid out-of-pocket costs (\$2,825 per beneficiary). Republican proposals would be only 4.9 percent compared with 7.1 percent for private sector health insurance safety net; from 1989 to 1994, private sector health insurance while Medicaid increased from 9 to 14 percent of total health care proposal to provide affordable health insurance for 100 million people.

During discussion with the Council, the following

- Medicaid will pay for off-label uses of drugs if medically necessary. HCFA plans to survey states for support for such off-label uses.
- Most children now eligible for Medicaid by age 18 will continue to be eligible. Persons most hurt

(AHCPR), which focuses on delivery and utilization of the development of practice guidelines. Prevention education programs to prevent STDs); the Family Planning (FP) supply); the Substance Abuse and Mental Health Services Administration (SAMHSA) prevention efforts directed at substance abuse; the National Institute of Health (NIH) development of drugs effective against drug abuse; the Task Force on AIDS Drug Development, the National Institute of Health (NIH) vaccine development efforts, and the Indian Health Service (IHS).

As an example of how these efforts cross age groups, the AIDS Clinical Trial Group (ACTG) Protocol 5201, which focuses on the transmission of HIV from a pregnant woman to her fetus, includes counseling and testing all pregnant women, and is funded by the Health Resources and Services Administration (HRSA), which administers the Ryan White HIV/AIDS Program.

In answer to questions from the Council, Dr. [Name]

- The PHS can provide the best information on the importance of HIV prevention, especially in planning HIV prevention efforts.
- While getting drug companies to work together, some companies have indicated a willingness to

Bureau of Health Resources Development, H
for AIDS, SAMHSA.

Dr. Goosby explained that his office coordina
has budgetary oversight of all DHHS AIDS b
next 1 to 2 years to incorporate information fi
and substance-abuse areas into community-ba
as substance-abuse programs. These program

Dr. Valdiserri said that current systems to trai
programs are inadequate and that training anc
is working with the Academy for Educational
community planning groups and technical ass
flexibility at the State and local levels and bet
proposing prevention partnership grants (PPC
substance-abuse funding.

Mr. Levi added that an increasing proportion
community planning and local programs will ;
prevention and education. After 2 to 3 years,
to cover STDs and tuberculosis.

- **Prevention Programs for Minority Groups.** Dr. Goosby noted the need for more of resources to develop culturally sensitive prevention programs for women and children. Ms. Fraser-Howze noted that organizations for *all* groups must be supported and encouraged to help each other. Mr. Lew noted the need for more resources for populations, such as Asian Americans, Pacific Islanders, and Native Americans. Ms. Fraser-Howze responded that a needs assessment protocol for such populations (she can supply further information) could include all ethnic/racial groups. Dr. Goosby noted that epidemiology help the Council make recommendations.
- **Needle-Exchange Programs.** Asked what the status of needle-exchange programs, Dr. Goosby responded that they are restricted until the PHS Surgeon General can determine the use of drugs by program participants in their immediate program environment. However, he noted that some states use their own resources to develop needle-exchange programs. Dr. Goosby is attempting to keep alive the discussion on this issue from a public health perspective. For example, it has funded projects in the U.S. House of Representatives and the U.S. Conference of Mayors.

prioritized HIV as number 17 (malaria was number 1 for fiscal years 1986 to 1996, Col. Rauch noted in FY 1996. In the other years, Congress had requested "plus-ups"). The largest, \$50.1 million, was to start a Phase III trial of the gp160 vaccine, with research.

Col. Burke said that the DoD program focuses on applied basic research. This complements the domestic needs, therapeutics, and basic research. The dollars are devoted to research on preventive and long-term DoD research program in Thailand.

Col. Burke said that 50 percent of HIV-positive persons are men and 5 to 6 percent are women. These persons are reviewed by race/ethnicity and gender (research).

Dr. Weniger expressed concern that the down-sizing of a valuable program to lose its infrastructure. This is in anticipation of decreased budgets.

Mr. Levi added that some language in the 1996

Department of Housing and Urban Development

Mr. Fred Karnas, Jr., Director, Office of HIV Development (HUD), said that the Administration advocates for safe, stable, decent, and affordable HUD programs for this population are serious. Cuts would reduce the total HUD budget by 46 percent. The following programs would be included:

- Housing Opportunities for Persons with AIDS (HOPWA) for low-income persons with HIV/AIDS and their families. HUD provides formula-based grants to States and metropolitan areas (totaling \$1.5 billion) to localities and nonprofit organizations to assist persons with HIV/AIDS. Cuts being considered by Congress would reduce the program subject to rescission. (The next Congress is expected to pass an amendment to HOPWA that restored the program.)
- The Stewart B. McKinney Homeless Assistance Act provides for the Homeless Assistance Program's Permanent Housing for Persons with Disabilities. \$900 million was awarded for these programs in FY 1995. HUD is currently reviewing HIV/AIDS Congressional proposals would

governments, and public accommodations (such as movie theaters).

Mr. Wodach said that part of the mission of the Division is to address discrimination that still clearly exists in this country. He introduced two Division attorneys who have been successful. One attorney chooses cases on the basis of complaints, has won a case against a city that had revoked its contract with patients with HIV/AIDS (the city was denied damages); a case against a city that had revoked its contract with AIDS; and one involving discrimination in the workplace. Other cases involve funeral homes that reject persons with AIDS; nursing homes that deny admission to AIDS patients; a case won in an area (e.g., dental), the persons in the area.

Mr. Wodach also noted that the Equal Employment Opportunity Commission is actively dealing with discrimination in areas such as health care. He noted that on what health plans will provide for AIDS patients. A large percentage of the EEOC cases involve persons with life-threatening illnesses.

The following points were made during the discussion:

Formulation of Report and Recommendation

Dr. Hitt discussed the draft opening statement with several Council members the previous evening. Dr. Hitt then circulated the draft for both minor and substantial changes. These changes ultimately became part of the final recommendation. See the attachment for the final opening statement to the President.

Dr. Hitt proposed a general outline of what the report would contain and discussed logistical issues. The meeting was adjourned at the White House; the meeting resumed at 1:30 p.m.

Research and Drug Development Panel

Food and Drug Administration

Mr. Levi, moderator of the afternoon session.

Dr. Kessler discussed the dramatic changes required to expand access to drugs being studied and to improve the Mechanisms that will give people access to drugs. He discussed the investigational new drug (IND) process, which

- Companies make decisions based on market and clinical trials are expensive. The Orphan exclusivity. The Council suggested that V pharmaceutical companies to work together
- Some minority populations may be distrust informed consent. There currently is no in
- Patients should have the cost of trial drugs "standard of care." Drug costs might be p
- While some complementary therapies—su under FDA jurisdiction, the FDA has made by not requiring manufacturing information consultants who can help drug developers. was established to promote study of altern
- The question about when 3TC will be avai confidential until the company announces i

submit a report of its recommendations to the single report early next year.

In response to questions from the Council, Dr.

- The NIH has no authority over the DoD's .
mention of the House proposal to have NI
additional funds for this purpose. The imp
funded in order to allow funding of DoD p
decisions be made by the peer review proc
- Dr. Paul views the "single appropriation" f
implementation of OAR's annual plan and
bill supports the OAR, it would discontinu
would identify the total allocated for AIDS
- The OAM (which, like OAR, is within the
persons promoting alternative therapies use
before the therapies can be part of clinical
of alternative therapies.
- The AIDS Research Evaluation Working C

Mr. Levi asked members to call him or Mr. S for information. He added that the Council had r for additional paperwork. He thanked the OA Systems to organize the meeting.

In response to concern about the limited Cou limited (about \$150,000 per year), and she su collaborations with private nonprofit organiza fundraising would be premature, since the Co raises funds. Dr. Hitt will start by exploring p

The Council discussion focused on several iss mission. It was suggested that there be three Research—as well as "point people" to coord leadership, and public/private partnerships (fu motion to establish these subcommittees was

Dr. Hitt asked that members fax him their firs within 10 days and also to indicate whether tl conference calls. He will then ask new Coun balanced list of assignments. Some members Dr. Hitt should make these assignments. Dr

- The subcommittees can flesh out their initiatives. They should realize that there will be many challenges in actually implementing them (e.g., the Council will have to be involved).
- The subcommittees will report to each other at the next meeting and phone. The Council will respond as a whole.
- The next full meeting of the Council will be on [date].

As the meeting ended, Council members applauded them for accomplishing a great deal in a short time.