

Presidential Advisory Council on HIV/AIDS

September 8-10, 1996

Bethesda Marriott Hotel
Bethesda, Maryland

Members Present: R. Scott Hitt, M.D., Chair; Stephen N. Abel, D.D.S.; Terje Anderson; Judith Billings; Nicholas Bollman; Tonio Burgos; Jerry Cade, M.D.; Robert Fogel; Kathleen Gerus; Edward Gould; Phyllis Greenberger; Robert Hattoy; B. Thomas Henderson; Michael Isbell; Ronald Johnson; Jeremy Landau; Alexandra Mary Levine, M.D.; Steve Lew; Helen H. Miramontes; Altagracia Perez; Michael Rankin, M.D.; H. Alexander Robinson; Debbie Runions; Benjamin Schatz; Denise Stokes; and Bruce Weniger, M.D. Also present: Patricia Fleming, Jeffrey Levi, Daniel Montoya, and Jane Sanville, Office of National AIDS Policy (ONAP).

Members Absent: Regina Aragon, Mary Boland, Debra Fraser-Howze, Carole laFavor, Richard W. Stafford, Sandra Thurman, Charles Quincy Troupe.

Dr. Hitt opened the fourth meeting of the Presidential Advisory Council on HIV/AIDS (PACHA) by welcoming new members, Ms. Billings, Mr. Isbell, and Mr. Johnson, and reviewing Council actions since the April meeting.

He thanked Mr. Anderson, Ms. Aragon, Dr. Cade, Mr. Gould, Dr. Levine, Mr. Henderson, Ms. Miramontes, Mr. Robinson, and Mr. Schatz for their contributions to the Assessment and Executive Reports, which were distributed to community-based AIDS Service Organizations (ASOs), State and Territorial associations, and attendees at the White House Conference on AIDS. Other activities included the International AIDS Conference and Vice President Gore's Keystone Conference, which resulted in a plan for collaboration between the pharmaceutical industry and Government on development of optimal AIDS drugs. Council members Runions and Perez were noted for their participation at the Democratic National Convention.

ONAP Report

Ms. Fleming thanked the Council for its help to ONAP and the President, whom she described as "optimistic" about a national goal of giving people with HIV/AIDS (PWAs) a normal life span. The Administration, aware of the concerns of PWAs and other adversely affected groups, is working to save Medicaid benefits. The Administration's recent legislative agenda include the Kennedy-Kassebaum bill and the Welfare Reform bill, and ONAP is working to ensure that AIDS issues are included in all immigrant programs. The Health Care Finance Administration (HCFA) is working with New York on a landmark waiver on Medicaid managed care and has been very responsive to housing concerns of people with long-term illnesses.

The major unfinished business of Congress remains in the area of appropriations, which affect AIDS issues such as labor and housing. The President has submitted two add-on budget

resolutions of concern: (1) redirection of \$25 million from other programs in Housing and Urban Development (HUD) to its Housing Opportunities for People with AIDS (HOPWA) program, which Ms. Fleming called "the result of a new level of visibility," and (2) increases in funding of the Ryan White Title II AIDS Drug Assistance Program (ADAP) by \$65 million. This is an indication of the Administration's intent to meet needs as they arise. Council members emphasized that stable housing and living environments are significant in both treatment and prevention of AIDS. ONAP hopes to obtain a single budget appropriation this year for the Office of AIDS Research (OAR) to give it more budget authority and urged PACHA to contact Congress on this issue.

The ONAP meeting in Tampa on substance abuse and AIDS prevention and treatment, during which Mr. Anderson represented PACHA, and a session with the Deputy Director of the Office of National Control Policy are seen as significant in formulating greater collaboration on these twin epidemics. The main message in Tampa was that the Government creates many obstacles to the integration of both HIV and substance abuse programs at the community level.

Results of the Vancouver Conference were mixed. More hope is seen for the future through new protease inhibitors, but major questions arise about their durability. Approval of these expensive drugs creates other public policy needs: (1) more ADAP funding; (2) an adjustment in the Medicaid/Centers for Disease Control and Prevention (CDC) definition of HIV/AIDS to ensure the earliest possible treatment for infected persons; (3) a restructuring of care systems to provide more flexibility in allowing patients to go on and off disability as needed; and (4) a way to convince vulnerable populations to seek early testing and counseling voluntarily.

The newly created Forum for Collaborative HIV Research resulting from the Keystone Conference may help answer questions arising over the potential long-term effects of new AIDS drugs. The inclusion of third-party payers such as programs under HCFA, Medicaid, Medicare, and private insurers will extend the reach of clinical trials to heretofore unaccessed populations. Dr. Levine represented PACHA in this effort.

Other issues include the President's request for full-prevention programs within the CDC and the microbicide initiative, a "giant step" toward prevention through empowerment. The ONAP regional briefings were productive and informative, and Ms. Fleming thanked Council members for participating in these meetings.

National AIDS Strategy

ONAP's long-promised national plan was introduced by Ms. Fleming as "The National AIDS Strategy." The term "strategy" was used to signify that this is a "living document" that can be updated periodically rather than an implementation plan. It is "historic" because it is the first Government-wide strategy involving an Interdepartmental Task Force (IDTF) representing every agency that supports AIDS activities in the Executive Branch and the first time goals have been linked with budget levels. Ms. Fleming asked for Council input and recommendations but did not guarantee that suggestions would be included in the final draft.

Ms. Sanville reviewed the draft Strategy policy areas: prevention, research, care and services, civil rights (including discrimination issues), international activities, and translation of research advances into practice. Objectives and recommendations of other groups, including PACHA, are represented. Highlights are the following: major Presidential/national goals, recent Administration accomplishments, and areas requiring special attention or proposed future actions. No time lines are included, so it is incumbent upon the Council and ONAP to work with agencies to determine how goals can be met. The Appendices describe recent and ongoing agency goals and actions.

The process for finalizing the Strategy is to obtain suggestions and comments from the Council during this meeting and through conference calls with Committees over the next few days, followed by release of a draft National AIDS Strategy to the AIDS community and private sectors for review and comment. ONAP hopes to present the final draft at the December PACHA meeting.

During subsequent discussions, the Council raised concerns and made suggestions about the release and content of the document: It needs much work; it may be ill-timed; and it must be made clear to all concerned, including the media, that this is not an implementation plan to end the epidemic but that a second process is required to identify implementation steps. Also, the community must understand its ability to affect the Strategy. It was also suggested that more attention be given to funding and implementation of prevention programs and that the relevant activities of such agencies as the Office of Civil Rights of Health and Human Services (HHS), Housing and Urban Development (HUD), Veterans Affairs (VA), the State Department, the military, and the Civil Rights Commission be included.

Dr. Hitt asked what further information was needed from the Council, and Ms. Fleming and Mr. Levi said that ONAP would crosswalk the PACHA Recommendations against the Strategy to see whether anything has been omitted. Comments and suggestions for implementation of the Strategy should be made in writing by individuals or Committees by November 1. Committees were asked to discuss this in their next conference calls and to draft responses to ONAP. ONAP will not circulate the Strategy to the public before the Council suggestions are made and the document has been revised accordingly. Volunteers to help in revising and planning release are Ms. Miramontes, Mr. Landau, Dr. Rankin, Mr. Johnson, and Mr. Anderson.

Four-Year Plan

During several discussions, the Council developed a "Four-Year Plan" to show the White House and the AIDS community what it hopes to accomplish in the future. Major issues were the following:

- **Should the Council's Charter be extended past July 1997?** Yes—to address issues that have not been covered (e.g., managed care, drug abuse, new medications) and new ones that arise, and to ensure implementation of strategies and recommendations.
- **What do we want the legacy of this Council to be?** To be seen as an outspoken voice of the community; a moral conscience holding the Administration accountable; an aid to

restructuring Administrative structures as needed; the initiator of actions that led to changes in the epidemic and decreases in infections; and as a force in increasing the visibility of AIDS within the Government, bringing together creative thinking of many groups, and helping the Administration grapple with changes in the epidemic.

- **How are we different from other groups?** We provide diversity and effective cross-communication; the President listens and responds to us; we can talk to all groups involved; and the community comes directly to us with input and we respond.
- **What are our long-term goals?**

Four-year outcome goals: to be a catalyst for bringing the epidemic to an end—by decreasing the rate of infection by at least one-half—by the end of the century, and to ensure universal access to optimal AIDS treatment and care.

Strategies for achieving these goals involve developing proactive plans and community involvement/support (e.g., needle-exchange programs), making prevention a higher Government priority, protecting and following up on current programs and recommendations, facilitating the National Strategy, finding new strategies to respond to epidemic changes, and continuing high-level discussions.

Longer term/wider scope goals: to develop strategies for more effective international collaboration and to develop a structure for dealing expeditiously with future epidemics.

- **What are our roles?** Identify recommendations; advisory; prioritization; continued evaluation and assessment and Executive Branch oversight and monitoring; bidirectional communications in consensus building, consciousness-raising, and personalizing HIV; conduit for information and recommendations; and constituency building in outreach, mobilization, and education.

The Council agreed that it should act as a facilitator for the Executive Branch in AIDS-related efforts, advise the President on domestic and foreign issues of the pandemic, stay in touch with all contingencies and interest groups, and gain better access to the private sector.

Short-Term Goals

An action plan through December includes scenarios for either election outcome:

- **All-case goals:** Committees to identify recommendations needing updated responses, follow up on timed recommendations, continue high-level meetings with the Administration to discuss strategies, and identify what can be signed and implemented ("stroke of the pen" strategy) by January 15 (before a White House transition). The Council will start immediately on transition plans to educate new legislators, implement "friendly" appointments, target allies for the Council, and formalize its resources request.

- **"Scenario 1" goals** (President re-elected): Write the President and Vice President requesting they interpret the election results vis-à-vis AIDS efforts, report on Council activities and resources to new Congressional members, and invite Congressional leadership to the next Council meeting.
- **"Scenario 2" goals** (President not re-elected): Discuss immediate strategy by conference call, finalize a "stroke-of-the-pen" strategy, and draft an Exit Document.

Other issues for consideration in the short term include continuing resolutions, international concerns, prisons, substance abuse, and youth and HIV. New Council Committees were established for discrimination and prison issues, and members volunteered to work on international concerns with Mr. Fogel. In addition, Dr. Cade and Mr. Anderson will draft a preliminary plan for covering substance abuse for the December meeting. The Council discussed Quilt activities and will make recommendations to the White House regarding Administration participation.

A questionnaire drafted by Mr. Henderson and Dr. Hitt was proposed for surveying AIDS service organizations (ASOs) and White House Conference participants by the end of the year to continue a dialogue with the AIDS community, evaluate the Council's work to date, and seek input on prioritization of AIDS issues. The Council could not decide on timing, circulation, wording of the questionnaire, or uses and value of the results, and the issue was tabled until the December meeting. Ms. Billings will redraft the questionnaire with Dr. Hitt.

Staffing and Budget Issues

Support staff and funding are needed to continue Council work, even on an interim basis, as volunteer burnout is inevitable and communications must be improved. Funding is needed for staff, consultation with outside experts, member travel to other meetings, communications, and research. Staff—one full-time employee (FTE), requested through HHS, and a person capable of performing analytical, organizational, and other substantive work—are needed to handle administrative work, communications, community outreach, coordination and documentation of meetings and conference calls, action reminders, research, and information gathering. ONAP can provide office space for Council staff but cannot share personnel. Ms. Fleming suggested that a Government Fellow possibly could be assigned to PACHA. The Council will draft an interim working plan, with long-term needs to be delineated if PACHA is to continue. Dr. Hitt asked Committees to prepare 6-month plans for staffing and resource needs.

Process Issues

- **Information production and dissemination processes** need to be improved through better staffing and funding.
- **Communications protocols and proper coordination** must be developed. Council communications should not be duplicative or burdensome to members, outside agencies,

or ONAP, and a mechanism for followup is needed. On an interim basis, Council communications with Government entities, especially those concerning information or meetings and requiring followup, will go through Mr. Montoya, excluding conference calls that involve other ONAP personnel.

- **A new Discrimination Committee** was established to help identify and keep up with related issues. Members are Mr. Schatz, Chair, and liaisons from existing Committees—Ms. Gerus, Mr. Henderson, and Mr. Johnson.
- **Interim action plan.** A non-urgent issue, such as a resolution or a letter, can be put in the *Federal Register*; however, if urgent, it should be handled by conference call.
- **Committee participation and structure.** Problems have arisen with members who are absent from meetings and conference calls and do not respond to urgent communications. Members were urged to change or drop out of Committee assignments if they are not able to complete tasks and follow up on action items. Committees agreed to send advance information on the topics and participants of conference calls.
- **Absentee policy.** Suggested ways of dealing with absenteeism include using an attendance chart for meetings and conference calls; creating an environment wherein members feel safe to say "I can't do it"; asking those who have missed meetings not to revisit issues that have already been resolved; having Chairs self-police their meetings; setting a limit on the number of times a Council member can miss for other than excused absences and/or in case of illness (two should be the maximum); and replacing non-participating members with others who can participate. Dr. Hitt will develop a device for tracking attendance and a guideline for participation and absenteeism. ONAP will research the legalities of removing Presidential Council members, and Dr. Hitt will check policy with the White House.
- **Lobbying.** Members were reminded that they cannot lobby while on Government-paid travel; if members choose not to accept Government funding, they can do as they please.
- **International issues.** Mr. Fogel asked for help in researching the issues surrounding U.S. leadership and AIDS in the international community, and Mr. Rankin and Dr. Weniger volunteered. The Council deferred a decision whether this will be a full or ad hoc committee or remain a cross-cutting issue with Mr. Fogel as the point person.

International Issues Update Panel

A panel representing 14 AIDS-related organizations discussed major issues in the international arena and made recommendations for actions by PACHA and the Administration. Mr. Fogel chaired the panel and noted that the AIDS pandemic is not only a matter of numbers of people infected and orphans created, but also of the economic disasters it causes in emerging economies.

In addition, it affects issues of civil rights, gender, and social justice. Speakers were the following:

Victor Barnes, Acting Director of the Division of HIV/AIDS of the U.S. Agency for International Development (USAID), presented an overview of the global epidemic and the USAID's past and future response to it. He also summarized the AIDSCAP Satellite Symposium at the Vancouver Conference, covering the status and trends of the epidemic outside the United States: From 1990 through the present, HIV infections worldwide doubled, with 94 percent in developing countries, where HIV/AIDS is spreading rapidly even as it declines in the United States. Heterosexual transmission is the major route of infection; the average age of newly infected persons is declining; rates of newly infected women and youth in urban settings are disproportionately high; economic impact is high; available resources for care and treatment are much smaller than in the United States; and morbidity and mortality have forced the growth of a community-based infrastructure that is missing from the United States.

Eric L. Sawyer, ACT UP/New York, discussed human rights abuses, which continue to kill millions of impoverished PWAs. These include drug company profiteering, government isolation of the rich from the poor and the uninfected from the infected with immigration barriers and quarantines, and hatred of the poor and disenfranchised communities.

Stuart Burden, MacArthur Foundation, gave a private sector perspective, focusing on U.S. leadership in worldwide collaboration; resources, including new funding and equipment donations; and development of ideas through new methods of exchange.

Lori Heise, Health and Development Policy Project, addressed integration of gender and social justice issues into international health policy and practices and suggested that increased funding could come from foreign-aid budgets.

Cynthia Mariel, National Council for International Health, discussed the roles of private voluntary organizations (PVOs) and nongovernmental organizations (NGOs) in the fight against AIDS. More than 100 organizations in the United States are involved in international AIDS programs, and she stressed the need for funding for these community-based groups.

Paul Boneberg, Global AIDS Action Network (GAAN), addressed U.S. global AIDS programs and gave recommendations for USAID, the Department of State, the President, and PACHA.

Jairo Pedraza, Global Network of People Living with HIV/AIDS (GNP+), discussed international access to treatment and the mission of GNP+ in World Health Organization (WHO) regions.

Harold Phillips, National Minority AIDS Council (NMAC), spoke on the exchange between domestic and international NGOs, the Joint South Africa/U.S. Collaboration Conference, and the mission of NMAC in providing technical assistance to AIDS-related organizations.

Patricia Fleming, Director of ONAP and a delegate to the joint United Nations Programme on HIV/AIDS (UNAIDS), discussed the creation and mission of UNAIDS: to amplify national programs, help eliminate the tangle of programs, and reduce overlapping among government organizations globally. With a total budget of \$60 million, UNAIDS provides technical assistance

to governments, promotes research and exchange of prevention ideas, coordinates AIDS programs within companies, and promotes strong AIDS programs in foreign countries.

John Y. Killen, Jr., M.D., National Institute of Allergy and Infectious Diseases (NIAID), gave an international perspective to the issue of prevention research and vaccine development. Finding an effective HIV/AIDS vaccine is an enormously challenging but feasible goal, with scientific, logistic, social, and economic issues that are different in other parts of the world. He provided a copy of NIAID's strategic plan for vaccine research and development and described the Institute's infrastructure for worldwide vaccine efficacy trials, HIVNET.

Deborah L. Birx, M.D., Department of HIV Vaccine Development of the Department of Defense (DoD) and the Walter Reed Institute of Research, described the Army's vaccine research and development program and its coordinated efforts with the Navy and other countries.

Phillip K. Russell, M.D., The Johns Hopkins University, School of Public Health, talked about International AIDS Vaccine Initiative efforts to create a more favorable environment for development of a safe and effective vaccine around the world. The Initiative will help strategic planning and funding for underfunded research in conjunction with the private sector.

Elaine Daniels, M.D., Ph.D., U.S. Department of Health and Human Services (HHS), discussed the Trilateral Joint Declaration on HIV/AIDS, a meeting of high-level Administration personnel from the United States, Mexico, and Canada, and the U.S./Canada Initiative on Palliative Care. She focused on incorporation of input of PWAs in all phases of the AIDS epidemic and partnerships between PWAs and health care workers.

Nancy Carter-Foster, Director of Emerging Infectious Diseases and HIV/AIDS Office of the Department of State (DOS), discussed the changing attitudes and status of the disease at high levels. The DOS educates high-level personnel such as ambassadors and all of its Foreign Service personnel on AIDS in international populations and human rights issues. She described the establishment of the Global Surveillance and Response Network and the U.S. International Strategy on HIV/AIDS, which includes prevention of new infections, reduction of personal and social impacts, and mobilization and unification of national and international efforts.

The following were common themes and recommendations:

- Because the disease is an issue of development, poverty, and power dynamics, USAID is the heart of the response to global AIDS. It should be strong, well funded, and fully staffed, and its agenda should be expanded to include care and treatment with prevention efforts and protection of human rights. Vacancies in the Office of AIDS must be filled with people with global HIV/AIDS experience.
- Collaboration among all National Governments and NGOs is necessary to provide effective exchange of ideas and techniques, to develop preventions and treatments, and to eliminate costly overlapping.
- Money is the critical factor in halting the spread of AIDS; the international effort needs

five to ten times more funding than it currently has. The President should seek a huge increase in global AIDS funds for both prevention and care. The United States also needs a vehicle to manage its AIDS funding.

- The United States must increase its leadership in linking worldwide efforts and information. The President and Vice President must become more involved in leadership, such as working with the private sector to increase resources for the worldwide fight against AIDS.
- In order to stop the pandemic, the United States must have a global perspective. We have a moral obligation to help other countries, as AIDS can destroy emerging economies in such areas as Africa, Asia, and the former Soviet Union.
- Access for all people to prevention and care is of greatest importance.
- Drug pricing must be curbed; the Administration can help by asking for cooperation from pharmaceutical companies to increase access and promote public health worldwide.
- The ratio of global research investment in treatments versus prevention is five to one; the development of vaccines and other preventive measures needs to be emphasized.
- NGOs, PVOs, and other community-based programs around the world need support.
- Human rights and social justice must be considered, and the development of a human rights protection program for PWAs must be developed.
- Gender issues, such as female microbicides and empowerment, must be addressed.
- All travel restrictions against PWAs should be removed. Unrestricted travel is a basic human right and allows people with important messages to enter this country.
- This Update is seen as a "first step" in the development of U.S. international collaborative efforts; however, PACHA needs to continue to educate members on the global pandemic, include the international agenda in all meetings, and add members with international experience.

In summary, Mr. Barnes said that prevention cannot be provided in isolation. He outlined some of USAID's responses to these issues: adding discrimination to its agenda; seeking to fund small, community-based programs by involving NGOs and PVOs in implementing its programs locally; and fully staffing the Office of AIDS by the end of this year.

Dr. Hitt thanked the Panel and asked each of the speakers to select three to five major recommendations, reformatting them to match PACHA recommendations, including both actions that the Executive Branch can take alone and those that need cooperative effort. PACHA will use these to develop international Council recommendations to the Administration.

Committee Meetings

Research and Prevention Committees Joint Meeting

Committee Attendees

Research Committee: Alexandra Mary Levine, M.D.; Jerry Cade, M.D.; Ms. Phyllis Greenberger; Scott Hitt, M.D.; Mr. Ronald Johnson; Ms. Helen H. Miramontes.

Prevention Committee: Mr. Terje Anderson, Mr. Robert Fogel, Ms. Kathleen Gerus, Mr. Mike Isbell, Mr. Jeremy Landau, Mr. Steve Lew, Rev. Altagracia Perez, Ms. Debbie Runions, Mr. Benjamin Schatz.

Presenters/Panelists: Judith D. Auerbach, Ph.D., Behavioral and Social Science Coordinator, Office of AIDS Research, NIH; Don Des Jarlais, Ph.D., Director of Research, Chemical Dependency Institute, NDRI; Margaret Chesney, Ph.D., Co-Director of the Center for AIDS Prevention Studies, University of California, San Francisco.

Dr. Levine opened the meeting with an overview of the joint committee panel meeting. She introduced the guest presenters and thanked them for sharing their expertise with the Council. She noted that Dr. Hortensia Amaro from the School of Public Health, Boston University, who was to speak on social issues of behavior, race, and ethnicity, was unable to attend the conference.

She briefly outlined the research priorities developed in the NIH Plan for HIV-Related Research, considered to be the consensus document of where the field should be going. Dr. Auerbach went on to discuss the genesis and mission of the Evaluation Working Group Area Review Panels, which, after a year-long review of AIDS research at the NIH, developed the recommendations incorporated in the "Report of the NIH AIDS Research Program Evaluation Task Force." The mission of the Panels, she said, was to look critically at the NIH Plan and determine how to develop specific recommendations that address the priorities.

Dr. Auerbach emphasized the focus of the science and the themes imbedded in each of the four priorities.

- The first priority is primary prevention through intervention research.
- The second is to support the basic social sciences and behavioral research underlying interventions: neurobiological and the neuropsychological factors.
- The third is to address the consequences of HIV from the individual to the societal level.
- The fourth is to advance innovative methodologies to enhance behavioral research.

The key issues for OAR, she said, are better representation across the range of behavioral and social sciences disciplines; integration of disciplines such as anthropology, sociology, and political science (impact of policy decisions); augmentation of the units of analysis to include couples, families, communities; clarification of the basic science of HIV prevention and intervention; greater knowledge of the mechanics of sexuality, sexual behavior, addiction, individual behavior change; more attempts to integrate behavioral and biomedical approaches where appropriate; attention to populations that have been underrepresented to date; recognition of the individuals and communities affected and created by HIV/AIDS.

Dr. Des Jarlais' presentation dealt with the worldwide spread of HIV disease among injection drug users (IDUs) and the need to implement an effective, preventive needle-exchange program. Recent studies point to the rapid and widespread increase in drug use and HIV disease over the past 10 years. In cities where there was an explosive rise in HIV, studies found that IDUs were not aware of the connection between needle sharing and HIV; there were strong restrictions on access to sterile equipment; and IDUs were sharing needles with strangers. Conversely, cities with a stable, low-HIV seroincidence among IDUs showed that prevention efforts were begun early (before the disease grew out of hand), and there was early access through syringe-exchange programs and community outreach. Data show that there are very effective interventions for IDUs to reduce risk behavior and HIV transmission. However, although the National Commission on AIDS in 1991 recommended treatment upon request for IDUs and removing legal barriers to syringe exchange in pharmacies, neither of these recommendations has been implemented.

Dr. Chesney discussed the challenges facing the research and prevention community that will affect issues of adherence for IDUs. The latest clinical trials show that protease and reverse transcriptase inhibitors have achieved sustained reduction of plasma HIV RNA; that triple therapy, including antiretrovirals and protease inhibitors, has led to significant decreases in viral load. The issues that need to be addressed are the extent to which (1) reductions in viral load will lead to survival and (2) noncompliance with therapy will lead to resistance, cross-resistance strains of the virus, and multidrug resistance strains to the virus.

Recent studies have raised some challenging issues for behavior and social science research: (1) identifying and recruiting persons into triple-therapy care as early as possible during the acute infection stage to lower the virus levels; (2) maintaining compliance to new triple-therapy regimens; (3) focusing prevention intervention (early counseling, access to care, making compliance a life priority) on HIV-positive individuals; (4) testing the effects of primary prevention intervention on HIV seroincidence.

Discussion

Dr. Levine opened the floor for questions from the Committee. An intensive question and answer period followed, and the following are some of the points made:

- Certification of needle-exchange efficacy must come from the Surgeon General before an effective Federally funded needle-exchange program can be put in place.
- There are no data to show an increase in drug use as a result of a needle-exchange program.
- Mandatory testing will not work; there is no way to determine how often a person should be tested. What should be considered is targeted testing and targeted intervention. Substantial evidence exists that links needle exchange with getting IDUs into treatment; however, most cities do not have sufficient treatment centers.
- The NIH is working on a multidisciplinary approach, bringing together the various ICDs to develop an AIDS prevention science agenda and linking it to the CDC and other agencies with similar agendas.
- Accessibility to clinical trials is necessary to increase enrollment and ensure participation and retention.
- NIDA is conducting studies on such issues as how to make the local syringe-exchange programs more effective and how to reach the most people.
- There are questions that remain unanswered concerning early intervention and the proposed three-drug treatment. How long should the treatment last? When should treatment be stopped? Should it be stopped?
- Adherence counseling (maintaining correct dosage, staying on therapy regimen, knowledge of what the drugs are and how they work, etc.) is very important for therapy to be effective.
- Questions that still remain unanswered: Why is risk behavior occurring? What underlying cause of risk behavior are we trying to determine? Are randomized trials worthwhile?
- Societal problems need to be solved if HIV/AIDS prevention problems are to be solved.

Conclusion

Dr. Levine and the Committee members thanked the speakers for their contributions to a most interesting and informative meeting, and adjourned the meeting.

Services Committee Meeting

Members Present: Mr. Gould, Chair; Dr. Abel; Mr. Bollman; Mr. Burgos; Ms. Fleming; Mr. Henderson; Dr. Hitt; Mr. Levi; Mr. Lew; and Dr. Rankin. Mr. Gould introduced the Committee and guest speakers, who briefed the Committee on various aspects of health care services.

Drug Pricing: John Coster, National Association of Chain Pharmacies; Paul Kim, American Foundation for AIDS Research (AMFAR); and Steve Schondelmeyer, University of Minnesota, gave an overview of drug-pricing methods, trends, problems, and abuses.

Housing: Jacquie Lawing, Deputy Assistant Secretary for Economic Development, HUD; and David Vos, HUD Office of HIV/AIDS, discussed the HOPWA program and HUD's plans and commitment to increase its budget and provide housing for PWAs.

AIDS Drug Assistant Program (ADAP): Joseph O'Neill, Associate Administrator for AIDS, and Anita Eichler, Head of AIDS Services, HRSA, gave an overview of ADAP, its current financial crisis, and cost-savings and monitoring programs it is initiating. Annette Burn, Director, and Robert Stealey, Office of Drug Pricing, described the drug-pricing program and voluntary discounting practices under the 602 pricing program. Joe Kelley, National Alliance of State and Territorial AIDS Directors, presented a "Fiscal Status Update of State ADAPs," discussing gaps in coverage and challenges facing these programs. These include large shortfalls created by rapidly increasing patient enrollments and escalating drug costs, especially in programs that cover protease inhibitors.

From the ADAP Working Group, Gary Rose, AIDS Action Council, and Kara Lindeman, Director of Public Affairs, Merck & Co., gave an advocacy perspective on the need for interim solutions to the escalating costs of medications and the shortfalls and gaps in States' funding.

Ryan White CARE Act Reauthorization Implementation Issues: Mr. O'Neill reviewed the Act and the issues of implementing the significant changes being made in it under the Reauthorization of 1995. Other HRSA officials described activities and changes in individual funding programs.

- Title I, funding for cities, and Title II, States, were described by Ms. Eichler.
- Title IIIB, community and individual health care providers, described by Dr. Deborah Parham, Chief of the HIV and Substance Abuse Service Branch, now specifies that 50 percent of funding is to go to primary care for HIV.

- Title IV, pediatric care providers, discussed by Lauren Deigh, Deputy Chief for the Pediatric AIDS Program Branch, puts new emphasis on women and pediatric research.
- Significant Programs of National Significance (SPNS), research and development of new models of care, reported Kathy Marconi, Director of Science and Epidemiology, Bureau of Health Resources Development, is now linked more closely to other programs.
- The AIDS Education Training Centers (AETCs) program for health care workers, discussed by Bruce Martell, Acting Director of the program, is shifting patients into managed care.
- The new AIDS Dental Reimbursement Program, giving support to dental schools and hospitals, was described by Stuart Bernstein, Bureau of Health Professions.

Other business included a discussion with Nancy-Ann Min, Associate Director, Office of Management and Budget (OMB), who discussed the commitment of the OMB and the Executive Branch to increase budgets for AIDS programs.

Committee Reports to the Council

Joint Research Prevention Committees Report

Dr. Levine, Chair, reviewed a new OAR portfolio, which responds to PACHA Recommendation II.D.4 on HIV/AIDS clinical research. The portfolio, "Prevention Science," relates to behavioral and social sciences issues and delineates the following goals: researching interventions that are effective, as measured in the community; studying reasons why persons continue risk behaviors after education; evaluating research methods; and finding ways to minimize social consequences of HIV infection. Dr. Paul is establishing an Advisory Committee to help the NIH develop a coordinated prevention science agenda, and Dr. Auerbach asked PACHA to recommend a coordinated behavioral and social sciences program at the NIH.

Studies on injection drug users (IDUs) presented by Dr. Des Jarlais may clear the way for Federal- or State-funded needle-exchange programs. Several of the studies show that in cities with the highest incidence of IDU seroconversions, IDUs were not educated to the association of sharing equipment and HIV seroconversion; users had many opportunities to share equipment with others, including strangers; and there was no needle-exchange program. Cities with lower rates of infection began prevention strategies early, had tremendous community outreach, made education a priority, and had practical needle-exchange programs.

Under a current Labor/HHS bill affecting CDC and other funding, Federal money cannot be spent on syringe-exchange programs until the Surgeon General can prove the following: (1) that they are effective in preventing or decreasing HIV transmission and (2) that they do not lead to increased drug use. Another bill, affecting only NIDA funds, adds a requirement for associated decreased drug use. The studies quoted above prove points 1 and 2; another study, in Tacoma,

Washington, also showed decreased drug usage, because exchange sites have become drug treatment centers as well.

Research and Prevention Committees will draft a recommendation for the Surgeon General to state that these requirements have been met and ask for Federal money for a syringe-exchange program. Even if the Government does not comply, this will allow States to set up their own programs. This recommendation should be ready to go to the President in December, before any White House transition. Committee members will meet with personnel from the office of Secretary Shalala for assistance with the recommendation.

Dr. Chesney's key issues were compliance and early detection and treatment of potential HIV infections, which dramatically affect survival and transmission rates. Of particular concern is compliance with protease inhibitor treatments, which are extremely difficult. Also, it was found that health care workers who receive needle sticks do not seroconvert if given AZT within 72 hours. Although using this method for sexual exposure might prove successful, it would remain problematic.

Research Committee Report

Dr. Paul has set up six groups to plan methods and set a timetable for implementing the recommendations made by the OAR Area Review Panels, to be submitted by December 16. A consolidated OAR budget has not been established yet, perhaps because it is believed that the current Congress would not respond well to the fact that 12 percent of NIH money is already directed to AIDS.

Although Dr. Paul does not favor microbicide development, Dr. Levine pointed out that PACHA should continue to recommend it because it is easy and practical to develop and effective as prevention. She will meet with Dr. Fauci on this subject after the Council meeting.

Suggested Council Recommendation followup concerns II.D.1. on the Vice President's efforts on drug development. The focus of the Keystone Group has been on treatment; microbicides and vaccines should now be added.

The Committee's short-term plans are to meet with the Prevention Committee to draft a recommendation on needle exchange and arrange for speakers for the next meeting on social issues. In the future, it will develop a vaccine agenda. Conference calls will be made September 24 (external vaccine briefing), October 9 (general research), and October 25 (external vaccine briefing) at 10 a.m. EST, and December 6 (with Prevention on syringe exchange) at 11 a.m. EST.

Prevention Committee Report

Mr. Anderson made the report in Mr. Robinson's absence, saying that the integration between the Research and Prevention Committees was very helpful. Recent actions by the Committee included a meeting with the Office of National Drug Control Policy (ONDCP) that was "open and

honest," and it was recommended to ONDCP that someone with HIV expertise be added to their staff. Council members are invited to submit recommendations and resumes. A conference call with the head of the HIV Office of the CDC resulted in the Committee's belief that CDC's AIDS programs are "underdeveloped, unfocused, and overly timid." The Committee will request a full-day meeting with the CDC in December to obtain a better understanding of the CDC's AIDS programs so that more targeted recommendations can be made.

Followup is needed for: (1) Recommendation I.C.1, asking that prevention be designated by the President as an investment priority (The Committee feels that clarification is needed for the term "investment priorities"), and (2) the Recommendation specifying how to address the issue on research of the safety of oral sex relative to transmission. Followup is requested on surveillance and prevalence, testing, and training, particularly by the CDC.

On the Defense of Marriage Act (DOMA), the Committee drafted a letter asking the President to support the Act as a prevention measure. Conference calls were scheduled for October 7 (review National Strategy), November 19 (preparation for CDC meeting), and December 6 (syringe exchange); all are at 11 a.m. EST.

Services Committee Report

Mr. Gould, Chair, distributed the final draft of a letter on welfare reform (the Personal Responsibility and Work Opportunity Reconciliation Act of 1996) as concerns PWAs, and the Council voted unanimously to send it to the President immediately.

Mr. Bollman reviewed reports on the economics of drug development, marketing, and sales, and the current status of the AIDS Drug Assistance Program (ADAP). Drug prices continue to escalate, especially for protease inhibitors, and there is great need to seek government assistance in monitoring and controlling these prices. ADAP's financial crisis began before the advent of protease inhibitors, whose costs have escalated the problem; no State can meet the demand for these expensive drugs at the present levels of funding and vary in their coverage, from none to that of a limited number of drugs and/or patients. Program advocates say \$140 million is needed next year but find it difficult to justify because the demand and need are not truly known. New finance strategies are needed, and the Committee will look at issues for future recommendations: (1) actual costs of drugs and whether they can be reduced through cooperative efforts between the Government and drug companies by cost reduction or leverage in bulk purchasing, (2) pricing issues, and (3) who will pay for these drugs. Services should stay abreast of ADAP advocate activities to see whether a national consensus develops. An emergent problem is that AIDS service funds in all or most States are being diverted to ADAP to pay for drug costs. The Committee was urged not to let this happen, since other service delivery system needs are increasing. Dr. Hitt noted that the Council report had omitted the status of ADAP; however, there seems to be no clear-cut consensus on which to base a recommendation.

Regarding HOPWA, Mr. Gould said that, although the Council has raised HUD's consciousness about housing needs, money is very difficult to find. A request for reprogramming of \$15 million into HOPWA from other HUD programs was turned down, but HUD staff are

hopeful that the \$25 million reprogramming supplement to this year's budget will be accepted.

Dr. Abel reported on significant modifications to the Ryan White CARE program, among them that SPNS now includes Native Americans. A new Dental Reimbursement Act provides \$6 million to dental schools and hospital residency programs to train dentists in working with patients with HIV disease; however, larger dental centers, which treat the greatest number of AIDS patients, are not eligible for these funds. The AETC program has a 25 percent budget cut, necessitating revision of training and standardization across the country to reduce costs. Title IV is linking 20,000 women, youth, and children into research protocols for the first time, and Title IIIB has changed from intervention into a primary care program. Discussion of Titles I and II raised issues of where money is best spent and whether outcome measures can be developed to answer this. Should it be left to the Federal Government, the States, the advocates, or the ethicists? The Service Committee votes for the ethicists.

Conference calls were set for October 3 (review of National Strategy) and October 24 (update) at 10 a.m. EST. Reports will be given in December on issues under review, including youth and alternative therapies. Regarding existing Service recommendations, the Committee agreed that all or most are in progress; if shortfalls are perceived, the Committee will contact Mr. Levi. Services hopes to have additional recommendations on drug pricing and ADAP by December.

Discrimination Committee Report

Mr. Schatz reported that the Committee found the following areas of the National Strategy needed expanded coverage: discrimination issues other than employment, such as education, housing, and denial of care; a broader role of Government in fighting discrimination even in nontraditional areas such as family law; a more systemic agency approach toward education; and the list of agencies responding to discrimination issues in the Appendices.

"Stroke-of-the-pen" items for immediate Administration response include Recommendations II.E.1. (discrimination in Government agencies) and II.E.2. (health care workers). The Committee proposed to meet with the Domestic Policy Council regarding II.E.1. and the CDC and the Prevention Committee on II.E.2. Ms. Fleming said ONAP briefed the President on discriminatory practices in the Peace Corps and other agencies and met with the Job Corps, which has agreed to remove restrictions such as mandatory HIV testing. ONAP will follow up with other agencies, and Mr. Henderson said that contact was being made with the Department of State.

For the December meeting, the Committee will put together information from outside sources, including the Discrimination Subcommittee of the White House Conference. Mr. Lew will assess immigration discrimination issues. Conference calls were set for September 26 and November 18 at 12 noon EST.

Prison Committee Report

Mr. Landau, Chair, introduced the new Committee members—Dr. Abel, Ms. Gerus, Mr. Cade, Dr. Ranking, and Patricia Milon, HRSA Liaison—and said they will send an information packet and proposed recommendations to the Council prior to the December meeting. The Committee will put together a panel with three or four speakers to review the material; discuss legal, prison, international, and inmate issues; and make recommendations for 1997. Conference planning calls are set for October 31 and November 21 at 11 a.m. EST, through Ms. Milon's office.

International Update Review

The Council viewed the International Update Panel as a good format for future information sessions; however, speakers and material should be limited, reasonable time limits imposed, and time reserved for questions. Speakers should answer the question, "What do you want the Council to do for you?" and give specific recommendations. Background material and recommendations, if possible, should be sent to Council members in advance. Dr. Hitt asked Mr. Fogel to collect, assess, and put recommendations from the speakers into proper format for Council consideration. Two proposed "urgent-message" international recommendations were put before the Council; one was approved as follows:

Because of the extraordinary number of vacancies in the Agency for International Development (USAID) HIV/AIDS program and the potential impact of these vacancies on its effectiveness, the President should direct USAID immediately to fill the existing vacancies in the Division of HIV/AIDS with personnel expert in global AIDS issues. USAID should incorporate in its future AIDS programs greater emphasis on skills exchange between domestic AIDS groups and their counterparts in other nations and expand its AIDS efforts to include issues relative to care, treatment, and the protection of the human rights of those infected.

A recommendation for a meeting between the President and the Director of USAID was tabled for additional consideration. A second recommendation, to fill a current vacancy on the Council with someone with international experience, will be made to the Administration.

Other Business

National Strategy Resolution

A resolution on the National AIDS Strategy was reviewed and approved by Council members:

The Council is appreciative that ONAP has sought our feedback on the internal working draft of the National AIDS Strategy and requests an opportunity to review the document and provide our responses no later than November 15 [or November 1 as requested by Ms. Fleming], 1996. It is our understanding that ONAP will take our comments under consideration, report back to the Council, and circulate the subsequent draft for community comment by the time of the Advisory Council's December 1996 meeting.

DOMA

The Discrimination Committee stated that DOMA should be covered in the Prevention Committee, since it is not being targeted as a Civil Rights issue, but rather for the impact of homophobia on HIV research. Prevention stated that a public ban on same-sex marriage will establish "a phobia that makes it difficult to send the message to high-risk gay men that their lives are worth protecting." The Committee's letter would put the Council on record as considering this a prevention issue. Unanimously approved, it was to be sent to the President immediately.

Gramm Amendment/SSDI Issues

Mr. Anderson reviewed these issues and asked that the Council send an information request to the Administration before the next meeting concerning what HHS is doing to implement the Gramm Amendment to the Welfare Reform bill to provide access to certain public benefits to people convicted of drug felonies. Additionally, an imminent change in the determination of Social Security Disability Insurance (SSDI) benefits based on substance abuse will separate PWAs in need of public assistance (Medicaid) from health care. The Council should ask the Social Services Administration (SSA) what is happening and how they will ensure access to services for HIV/AIDS patients. These issues should be addressed in December, and the Service Committee should monitor them as well as any response from the President to the letter regarding the welfare bill.

Long-Range and Short-Term Goals

Possible public uses of the Four-Year Plan are to reference the two main objectives in a survey to White House Conference attendees and as background for a meeting with the Administration to discuss staffing and funding needs. Members were asked to review the Plan and send changes to Dr. Hitt for further refinement at the next meeting. Short-term action goals include the following:

- Committees submit new followup action plans for appropriate recommendations.
- Members look for suggested action items in the transition phase.
- Interim staffing and budget requests finalized, and during Quilt weekend a meeting set with Kevin Thurm^[2] to discuss resource needs.
- The Administration advised regarding possible Quilt activities.
- A letter to the President and Vice President interpreting election results drafted by Mr. Anderson, Mr. Fogel, and Dr. Hitt.
- The Process Committee develops a legislative agenda and invitee list to send with Council reports to new and old Congressional leaders after the election, along with an invitation to the December Council meeting.
- "Stroke-of-the-pen" strategy finalized and an Exit Document written by the Process Committee.

Town Hall Meetings

Richard Sorian, ONAP, reported on the regional "Town Hall Meetings" held to brief community leaders and organizations. He thanked the Council for the idea and the direct participation of 17 members. The project, which took 24 weeks and covered 39 ASOs and 3,500 to 4,000 people in 11 cities, was highly successful and provided many benefits, including the opportunity to contact local philanthropists and develop a list of community-based organizations (in Appendix to Report).

Conclusions were as follows: (1) Communities value and publicly support programs like the Ryan White CARE Act, HOPWA, and prevention programs supported by the CDC and other agencies. (2) Individuals, especially PWAs, and local organizations appreciate the contact with Council members and Government officials and having a public forum. (3) Increased funding over the last few years is appreciated, but there are rising needs and competition for funds. Some emerging populations, such as youth and women, are struggling to get funds and learn skills needed to gain them. ADAP is very popular, but people do not know how to get into it, or how much and what it will cover.

ONAP found many successful community models for working with under-covered populations (e.g., peer counseling programs work well with youth) and is working with the CDC to set up a consortium to study and replicate some of them. Conflict between the advocates of HIV prevention and some community entities such as city councils and school boards exists, but ASOs are finding innovative ways to avoid the conflicts.

Followup is essential and ONAP staff and the 21 participants from other agencies are working on issues such as Social Security eligibility problems. The draft report will be refined and sent to agency participants and White House conferees, who inspired this program.

No more trips are planned between now and December, and Mr. Sorian asked the Council to consider whether this process should be continued. Dr. Hitt said it will be on the December agenda and a thank-you letter will be sent from the Council to agency participants.

Members Representing the Council

Two issues surround Council representation in outside meetings: funding and participation. Currently, there is no formal process for raising funds and determining which meetings should be attended and by whom. The current Council budget covers only the PACHA meetings and conference calls. If a Council member is invited by a group to attend and expenses are paid, there is no problem. Mr. Levi said it is legal for the Council to accept private and agency funds for this, but there is no Government agency to administer these funds. He will research regulations about traveling abroad for members. Also needed are processes for obtaining information from meetings that the Council does not attend and inviting outside advisory council members and others to PACHA meetings. This will be addressed in the staffing and funding requests; for now, members should coordinate with Dr. Hitt when representing the Council.

Regarding the current staffing crunch, an agency representative from the CDC, Ms. Sherry Darden, and Ms. Milon from HRSA are available to help the Council. Mr. Levi will write a protocol for communications between Council members and ONAP for this purpose.

Ms. Fleming thanked her staff for working with the Council, and Dr. Hitt thanked Council members, Assessment and Process Ad Hoc Committees, and ONAP for their participation. The meeting was adjourned at 1:30 p.m. September 10, 1996.