

## **Presidential Advisory Council on HIV/AIDS**

April 24-26, 1996

Radisson Plaza Hotel

Alexandria, VA

### **Members present**

R. Scott Hitt, M.D., Chair, Stephen N. Abel, D.D.S., Terje Anderson, Regina Aragon, Mary Boland, Nicholas Bollman, Tonio Burgos, Jerry Cade, M.D., Robert Fogel, Debra Fraser-Howze, Kathleen Gerus, Edward Gould, Phyllis Greenberger, Bob Hattoy, B. Thomas Henderson, Carole laFavor, Jeremy Landau, Alexandra Mary Levine, Steve Lew, Helen H. Miramontes, Altagracia Perez, Michael Rankin, M.D., H. Alexander Robinson, Debbie Runions, Benjamin Schatz, Richard W. Stafford, Denise Stokes, Sandra Thurman, Bruce Weniger, M.D.

### **Opening Remarks**

Chair Dr. Scott Hitt welcomed members of the Presidential Advisory Council on HIV/AIDS to the third meeting of the Council, voicing his certainty that the meeting would be very productive. He then introduced Ms. Patsy Fleming, Director, Office of National AIDS Policy (ONAP).

### **Administration Presentation**

Ms. Fleming reported that the Administration had won a major victory the preceding evening, when Congress repealed the amendment to the Department of Defense reauthorization bill that would have mandated the discharge of all military service personnel who test positive for HIV. She said that the Continuing Resolution passed by Congress contained favorable figures for AIDS for this fiscal year. Funding for the Ryan White CARE Act program was increased by more than \$100 million over its FY 1995 level. The Continuing Resolution did meet the President's budget request for all other AIDS programs. There was a funding decrease of \$4 million in the AIDS Education and Training Centers program in the Health Resources and Services Administration (HRSA), however.

Ms. Fleming also recounted the Administration's accomplishments in AIDS policy, including a 40-percent increase in funding commitment to AIDS research, prevention, and care at a time when virtually all government programs have been cut. She also credited the Administration with strengthening the Office of AIDS Research (OAR) at the National Institutes of Health (NIH) and the Administration's use of enforcement authority to confront AIDS-related discrimination. She also noted the accelerated approval process for AIDS drugs by the Food and Drug Administration (FDA) and President Clinton's request, which was granted by Congress, for an additional \$52 million in funding for the AIDS Drug Assistance Program.

Ms. Fleming reported that Vice President Gore has met with pharmaceutical manufacturers to spur communication and cooperation in the development of vaccines, therapeutics, and

microbicides. In the summer of 1996, officials from around the United States will meet in Atlanta to discuss coordinating AIDS prevention and substance abuse prevention.

She also discussed Administration efforts to build on the momentum established at the December 1995 White House Conference on AIDS through visits by senior Administration officials and Council members to local communities and AIDS service organizations. Other Administration efforts establish and maintain a strong partnership between Government and populations affected by HIV and AIDS and involve persons outside Government to assess and suggest improvements in AIDS programs at the Centers for Disease Control and Prevention (CDC) and the NIH.

ONAP is trying to focus attention on people most vulnerable for HIV infection, such as women, communities of color, and young people, especially young gay and bisexual men, Ms. Fleming said. The recent report to the President on youth and AIDS has sparked discussion throughout the country. More than 30,000 copies of the report have been requested.

Ms. Fleming said that, despite its recent victories in Congress, the Administration did not achieve all of its goals and that much remains to be done. The Administration believes that funding for AIDS prevention should be increased and will fight for such increases in the FY 1997 budget. Other priorities include full budget authority for the OAR and protection of the Medicaid program. She noted that The President has withstood tremendous pressure from the Republicans in Washington and in the States who want to dismantle Medicaid. While grateful for the support of Council members and others throughout the country for their efforts to preserve Medicaid, she warned that they must continue to oppose the efforts of the Republican leadership in Congress to destroy Medicaid.

Ms. Fleming concluded her presentation by outlining the following major challenges facing the Council:

- How to provide quality care and services in a changing delivery system—not only by protecting Medicaid and increasing Ryan White CARE Act funding but also by addressing a host of issues associated with the trend toward managed care.
- How to address more effectively the dual epidemics of HIV and substance abuse.
- How to slow the epidemic among young people—especially young gay men of color.
- How to further strengthen AIDS research efforts by implementing the report of the NIH AIDS Program Evaluation Working Group, by reauthorizing OAR, and by compelling Congress to restore OAR's budget authority.
- How to ensure that housing needs are addressed so that housing programs keep pace with the epidemic.
- How, in a climate increasingly hostile toward international aid cooperation, to maintain support for the international effort against AIDS.

## **Council Discussion**

Council members expressed thanks to the ONAP staff for their hard work and their appreciation to the Administration for its efforts to repeal successfully the Department of Defense amendment that would have resulted in HIV-infected military personnel being forced out of the armed services. They also noted that, for the first time in the AIDS epidemic, there has been a rapid response to AIDS policy recommendations from the Administration.

Council members then discussed its role and relationship to previous advisory bodies on AIDS, such as the National Commission on AIDS (NCOA). Dr. Hitt noted that, so far, the Council has made 37 recommendations. Unlike previous groups that have made recommendations for action, the Council has asked for and incorporated the Administration's response to the recommendations and provided assessments and action plans that are continually updated. He then outlined the recommendations and steps taken by other advisory groups and efforts to determine which of these recommendations remain relevant to the Council's work today. NCOA, for example, made 210 recommendations, many of which were not directed toward the Executive branch, he said. Many of these recommendations are no longer timely, such as those written before the implementation of the Housing Opportunities for Persons with AIDS (HOPWA) program or passage of the Ryan White CARE Act.

Council members discussed how best to proceed with their recommendations, such as how to distribute them in order to obtain feedback. Dr. Hitt said that the set of recommendations developed at the Council's December meeting has been distributed to the 300 participants at the White House Conference on AIDS and that feedback has been very positive. Others suggested that the Council focus on its action plan in order to avoid the impression that it is simply repeating what previous commissions have done.

Members then discussed and voted on a series of proposed new recommendations to the President before breaking into meetings of the Council's Services, Prevention, and Research Subcommittees. The Prevention and Research Subcommittees had met the previous evening to review recommendations. The Services Subcommittee held a day-long meeting April 24 to hear from a variety of speakers on issues such as epidemiology, housing, substance abuse treatment, and managed care.

When the meeting resumed on April 26, Jeff Levi, Deputy Director of ONAP, noted that one of the issues to emerge from Vice President Gore's meeting with representatives from the pharmaceutical industry was how to conduct good post-marketing trials of new drugs. Vice President Gore has suggested that this issue should be addressed by a dialogue among Government officials, researchers, pharmaceutical companies, third party payers, and consumers. He has asked the Keystone Center to convene such a group to conduct a dialogue on this process. The group, slated to begin meeting the end of April 1996, is charged with issuing a report by August 1.

## **Presentation from the Research Subcommittee**

### **NIH AIDS Research**

Dr. Alexandra Levine, chair of the Council's Research Subcommittee, reported that it had met the previous afternoon with representatives from OAR and participants in the recently completed external review of NIH AIDS activities. She noted that OAR was established in 1988 but had no authority until 1993 and that the NIH budget for AIDS research totals \$1.4 billion per year and is spread out over its 24 Institutes, Centers, and Divisions.

A summary report of the extensive review by outside scientists and activists of all NIH-supported AIDS research activities was released in March. The report of the NIH AIDS Research Program Evaluation Working Group is also known as the Levine report, named after the Working Group's chair Dr. Arnold Levine, a respected researcher who was chosen because he is not involved in AIDS research. Dr. Alexandra Levine reported that the Working Group made 14 major recommendations on how NIH should conduct and support AIDS research:

1. Increase support for investigator-initiated research to double that of the current level.
2. Establish a trans-Institute vaccine development effort, with more funding and an increased emphasis on basic research.
3. Increase funding for studies of basic human immunology.
4. Develop a comprehensive HIV prevention agenda that includes behavioral, biomedical, and social components.
5. Integrate all NIH-supported adult clinical trials into one network. The NIH's current support of a variety of clinical trials networks, each with its own data bases, is inefficient.
6. Refocus and restructure of the National Cancer Institute's \$53 million per year AIDS drug screening program.
7. Increase basic research on opportunistic infections, such as cryptosporidiosis, and disseminate research findings for early clinical evaluation.
8. Strengthen the scientific base for the assessment of complementary and alternative therapies for AIDS. Establish an ad hoc advisory group to catalog studies currently being conducted with therapies and sponsor workshops on issues such as methodology.
9. Open NIH-supported Regional Primate Research Centers to the outside scientific community.
10. Increase funding by 50 percent for the NIH's 16 AIDS Research Centers to promote multidisciplinary research including psychosocial, behavioral, virology, and immunology research. Increase access by outside scientists to these centers.

11. Establish, coordinate, and make accessible national tissue banks and data bases.
12. Upgrade NIH AIDS information systems in order to track research activities and projects accurately.
13. Develop and implement a clear and uniform definition of AIDS and AIDS-related research to ensure that monies for AIDS research are being spent on such research.
14. Preserve a strong OAR.

Dr. Levine noted that the Research Subcommittee's final comments on the report will await the final reports from the six Area Review Panels of the Working Group, which will provide more detailed recommendations in specific areas of AIDS research as well as input from constituents.

Asked about the responsiveness of OAR to recommendations in the report, Dr. Levine said OAR appears to be very receptive but it still lacks the budget authority needed to implement the recommendations. Congress has not supported Administration efforts to consolidate the AIDS budget within OAR but instead gave OAR a 3 percent transfer authority to move funds. She said that congressional recognition of OAR's authority is very important, adding that the Subcommittee supports the Council's recommendation for budget authority for OAR. OAR cannot coordinate AIDS research activities unless it has the authority to determine where the money should be spent, she emphasized.

### **Vaccine Development**

Dr. Levine also reported on a recent conference call between Subcommittee members, participants in the NIH review, vaccine researchers, and advocates to discuss the status of AIDS vaccine research. She noted that extensive gaps remain in the research to date and that, for each year's delay in developing an effective vaccine, more than 50,000 people are lost. An ongoing controversy in the development of an effective AIDS vaccine continues to be the debate over the balance between basic and applied research and whether to proceed with large-scale testing of existing vaccines.

Dr. Levine also reported on a new international vaccine development initiative being headed by Dr. Peggy Johnston, a former official with the Division of AIDS at the National Institute of Allergy and Infectious Diseases. Funded with money from sources such as the Rockefeller Foundation and other countries, the initiative will distribute research funding to institutions and researchers throughout the world in an effort to accelerate vaccine development. Dr. Levine said the Subcommittee finds the new initiative to be an excellent model for collaboration and cooperation and supports it.

### **Council Discussion**

No formal presentations were made by the Services and Prevention Subcommittees.

Dr. Hitt discussed the need for an executive summary to accompany the Council's recommendations. The summary will contain an overview of the Administration's progress and

explain the Council's response. The summary and recommendations could be distributed both in print and electronically, by placement on a World Wide Web site such as the CDC's, he suggested.

Council members suggested the executive summary acknowledge the Administration's high degree of responsiveness but point out that much more needs to be done. They also suggested that the Council focus on listening to the community and seeking input from across the country. The Council will need to emphasize that this executive summary, and the recommendations, is an ongoing progress report and that the Council has only just begun to examine some areas, such as AIDS in adolescents and housing and services issues. Members advised that the executive summary state that prevention efforts have been difficult due to political pressures.

Dr. Hitt noted the importance of distinguishing between what the Council has done and its role in relation to NCOA and previous commissions. While the latter conducted hearings and fact-finding visits, this Council is focusing on a more fundamental and practical action plan, he said. Members added that the Council must assess the Administration's response to the previous recommendations, and decided to designate a person from each Subcommittee to carefully review the previous recommendations and identify which are still relevant and/or have not yet been addressed.

Council members then discussed the continuing need for additional staffing for ONAP and measures to relieve the overworked staff. They agreed that the lack of staffing has diminished the Council's effectiveness.

Members also considered how best to address crosscutting issues such as chemical dependency and substance abuse, Medicare and Medicaid funding and managed care, and the international dimension of the AIDS epidemic. Dr. Hitt asked Council members to send suggested topics for future meetings to him in writing.

Members suggested that the Council include community and other appropriate representatives at its September meeting. It was also suggested that regular conference calls between Subcommittee chairs could facilitate the development of recommendations in crosscutting areas.

### **ONAP Town Hall Meetings**

Mr. Richard Sorian told the Council about the regional "town hall" meetings that ONAP is holding across the country. To date, the office has held meetings in New York City and Texas, attended by ONAP staff, Council members, and Administration officials such as Health and Human Services Secretary Donna Shalala and Assistant to the President for Domestic Policy Carol Rakso. The meetings include discussions with representatives from the local communities as well as talks with local media and business representatives.

Council members applauded this effort but expressed concern about the apparent focus on urban areas and the exclusion of visits planned to the Plains and Mountain States as well as the Pacific Northwest and New England. Ms. Fleming noted that she has visited Vermont and that ONAP staff have been to rural areas. She and Mr. Sorian emphasized that the visits will continue beyond those projected through August and that additional sites can be added. Mr. Sorian added that the

meetings are based on funding assistance from outside organizations. Dr. Hitt asked Council members to be proactive and suggest ideas for locations for such meetings.

Council member Dr. Stephen Abel, who participated in the meeting in the South Bronx, said that the meetings represent a commitment on the part of the Council to act as the community's conduit to the White House. Members appeared to agree with Dr. Hitt's recommendation that the meetings remain open to the community, even though they may become "rough." Mr. Soriano noted that ONAP asks community members in the locations what type of meeting is best suited for that locale and that such meetings provide a needed opportunity for affected persons and communities to express their anger.

### **Other Business**

In other Council business, members voted to approve a recommendation that the Council ask for the Administration's position on proposed legislation that would address product liability issues for persons who have become HIV infected through blood products.

They also approved a new recommendation from the leadership Subcommittee that President Clinton and Vice President Gore accept an invitation to co-chair and attend the display of the AIDS Quilt in Washington, DC, in October.

Members also discussed gaps in representation on the Council, particularly the proportionally small representation of African Americans and youth, and ways to reach out to those communities in order to make their voices heard.

The Council adjourned at 3:30 p.m.