Presidential Advisory Council on HIV/AIDS
Full Council Meeting

October 4-5, 1999

Radisson Barcelo Hotel
Washington, DC

MINUTES

Present:

R. Scott Hitt, M.D., Chair
Stephen N. Abel, D.D.S.
Terje Anderson
Barbara Aranda-Naranjo, Ph.D., R.N.
Judith Billings, J.D.
Charles Blackwell, J.D.
Jerry Cade, M.D.
Lynne M. Cooper
Rabbi Joseph A. Edelheit
Robert Fogel
Debra Fraser-Howze
Kathleen Gerus
Phyllis Greenberger
Nilsa Gutierrez, M.D., M.P.H.
Robert Hattoy
B. Thomas Henderson
Michael T. Isbell, J.D.
Ronald Johnson
Jeremy Landau
Alexandra Mary Levine, M.D.
Steve Lew
Miguel Milanes, M.P.A.
Helen H. Miramontes, R.N.
Reverend Altagracia Perez
Michael Rankin, M.D.
H. Alexander Robinson, M.B.A.
Debbie Runions
Sean Sasser
Benjamin Schatz, J.D.
Denise Stokes
Charles Quincy Troupe
Bruce Weniger, M.D.

Present from ONAP:

Sandra Thurman, Director
Todd Summers, Deputy Director
Daniel Montoya, Executive Director, PACHA

Absent:

Regina Aragón
Nicholas Bollman

Monday, October 4, 1999
Morning General Council Session

Dr. R. Scott Hitt, Chair, opened the Fourteenth Meeting of the Presidential Advisory Council on HIV/AIDS (PACHA) by providing a summary of the Council's activities since the June meeting. He said he had met several times with Kevin Thurm of the Department of Health and Human Services (DHHS) to discuss progress on access to care, the "Know Your Status" campaign,

needle exchange, health care worker guidelines, the Department of Labor-DHHS appropriations bill, and Medicaid waivers. At their most recent meeting, Dr. Hitt and Mr. Thurm discussed DHHS Secretary Donna Shalala's presentation to the Council and specific issues the Council would like the Secretary to address.

Dr. Hitt reported that the Congressional Hispanic Caucus Health Care Task Force held hearings during Spanish Health Awareness Week in September, and a congressional hearing on HIV/AIDS in the Hispanic community was held in mid-September. He noted that Dr. Barbara Aranda-Naranjo testified at the congressional hearing and summarized the Council's priorities regarding HIV/AIDS and the Latino community. He praised her testimony and encouraged Council members to read it prior to the panel presentation on the "Severe and Ongoing HIV/AIDS Health Care Crisis in Latino Communities" scheduled for Monday afternoon.

Dr. Hitt noted that there had been a lot of activity over the summer on international issues and thanked Robert Fogel for bringing the compulsory licensing issue before the Council during the June meeting. He said Sandra Thurman had been doing a "phenomenal" amount of work on the international front and added that the administration had recently reached a "friendly resolution" on compulsory licensing.

Dr. Hitt summarized the day's agenda. Regarding Dr. Gary Nabel's presentation on the Vaccine Research Center (VRC) at the National Institutes of Health (NIH), Dr. Alexandra Mary Levine said Council members should ask Dr. Nabel to outline the VRC's goals over the next 1-2 years and any problems that may be encountered. Council members should also ask him if there is enough money going into vaccine research. Dr. Levine added that the Research Subcommittee would propose a resolution supporting the Vaccine Technology Act for the full Council's approval.

Rabbi Edelheit suggested that Council members raise the question of vaccine ownership with Dr. Nabel. Dr. Levine said she had not addressed the issue of ownership per se with Dr. Nabel but that part of the agenda for developing a vaccine would be to use it in resource-poor areas. Helen Miramontes noted that the International AIDS Vaccine Initiative (IAVI) is currently working on a vaccine candidate. Dr. Levine said Alan Schultz is now at IAVI, so there is a lot of cross-fertilization between NIH and IAVI.

Dr. Hitt asked the Council what questions might be posed to presenters during the Latino presentation. Miguel Milanes said Council members should not lose sight of what the next steps are and what actions the Council needs to take in coming months on Latino issues.

Dr. Hitt said Secretary Shalala would speak for 10-15 minutes, followed by a 45-minute question-and-answer period. Dr. Hitt asked Mr. Thurm to request that Secretary Shalala discuss some of the bureaucratic limitations faced by DHHS on actions requested by the Council. Specifically, he asked the Secretary to address access to care issues. Dr. Hitt noted that a DHHS document outlining the Department's accomplishments and goals on access to care had been distributed to

Council members in their supplemental meeting packets. The document makes it clear that much remains to be done on access to care.

He also asked that the Secretary address prevention and the expected outcome of the Centers for Disease Control and Prevention (CDC)/Institute of Medicine (IOM) review. He said he also expects the Secretary to make a pointed statement on needle exchange and the science supporting it, and report on the health care worker guidelines, DHHS regional meetings, and Medicaid waivers. Dr. Hitt said Council members should prepare specific questions in case the Secretary does not touch on each topic during her presentation. The Executive Subcommittee will meet during lunch to determine which questions to ask the Secretary.

Rabbi Edelheit asked if there would be a conversation about the membership and makeup of the Council. Daniel Montoya said Council members would receive a letter within minutes from Secretary Shalala informing them of their Council retirement date. Since the Council did not initially build in staggered terms for members, members will be "termed out" randomly. Mr. Montoya said replacements for retiring Council members would be determined based on geographic, racial/ethnic, and sexual orientation, as well as gender representation on the Council. He said the Council had already received 100 to 150 names of potential candidates. The first Council members to retire will do so at the end of 1999, marking the end of the 4-year term for many members. Half of the Council members slated to retire will do so as of December 1999. The other half will retire at staggered time periods so there is no mass exodus and the Council's momentum can be maintained.

Benjamin Schatz asked if any new candidates are ready to assume positions on the Council. Mr. Montoya said no new candidates have been chosen. He added that the DHHS Secretary's office and the White House wanted to ensure that Council members are rotated off "in the right way" to maintain the Council's integrity.

Sandra Thurman, Director, ONAP, and Todd Summers, Deputy Director, ONAP
Update on ONAP Activities

Ms. Thurman began by recognizing ONAP staff members and interns for their hard work in recent months. She also thanked Paul Gaist of the Office of AIDS Research at NIH, Rusty Bennett of the Department of Housing and Urban Development, and Erica Barth from the Department of State for helping ONAP manage a number of issues. She reported that the new ONAP and PACHA Web sites are now available online. She noted that Todd Summers was responsible for launching ONAP's Web site, which she called "the best Web site at the White House." She also reported that Matthew Murguia **[?]** had accepted the senior staff position at ONAP and that she is pleased to have him on board to work on minority issues.

Ms. Thurman noted that President Clinton attended a gay and lesbian fundraiser in Los Angeles on October 2, and that Dr. Hitt had been very involved in organizing the event. President Clinton was complimentary of Dr. Hitt's work and publicly thanked him during the fundraiser.

Ms. Thurman thanked Dr. Hitt as well for his leadership and enthusiasm in recent months.

Ms. Thurman then recognized her predecessor at ONAP, Patsy Fleming, who in turn introduced Elliott Johnson, the new director of the Whitman Walker Clinic, to the Council.

FY 2000 Budget: Ms. Thurman said ONAP had secured good funding levels for care and research in the FY 2000 budget, but the levels for prevention and treatment are not as good. Until ONAP gets a sense of direction on prevention, it will be difficult to justify making additional investments in this area. Thus, the CDC review process will be important in securing more prevention funding.

She said she was pleased that the President vetoed the Washington, DC, appropriations bill and pointed to the needle exchange language as one of the reasons for the veto.

Refugee Policy: Mr. Summers said ONAP has been working with the National Security Council and the Immigration and Naturalization Service (INS) on refugee policy. With the support of the INS, the waiver requirements have been streamlined. The Ryan White Act, Medicaid, and the Refugee Medical Assistance Act exist to provide care to refugees. The Surgeon General wrote a letter to the INS director stating that the public charge test could be satisfied en masse, so it does not have to be satisfied on an individual basis. ONAP is now examining how to apply the new refugee policy to asylees.

Prison Issues: Mr. Summers noted that the Council had a good meeting with Newt Kendig, the new medical director for the Bureau of Prisons, during the June Council meeting. Mr. Kendig has offered to brief the Council again on developments in HIV/AIDS and prisons. The Bureau of Prisons and the Health Resources and Services Administration (HRSA) have signed a memorandum of understanding to establish a pilot program to provide care to persons who are in pre-release programs. Attorneys for both the Bureau of Prisons and HRSA are looking at how to commingle funds for the program. Mr. Kendig and Joe O'Neil have been working aggressively to address the pre-release issue.

ONAP and CDC are working together to launch a new prisoner health Web site under the auspices of the National Prevention Information Network (NPIN) at CDC. The site will include information on HIV prevention and care. HRSA and the Bureau of Prisons are examining how to contribute financially to the site.

Minority Initiative: Ms. Thurman said ONAP had held a series of meetings with the Congressional Black Caucus (CBC) over the last 4 or 5 weeks. At the CBC weekend in late September, she made four speeches to the group in 4 days; she addressed the health braintrust, the Africa braintrust, and the women's group.

The Congressional Hispanic Caucus (CHC) held a hearing on HIV/AIDS in mid-September. Ms. Thurman was invited to testify but was not able to do so. The Surgeon General did testify

before the CHC. Ms. Thurman thanked Mr. Montoya for his help in organizing the hearing.

CDC: The prevention strategy development process is moving forward. The CDC community advisory board has been engaged in the review process. Ms. Thurman said CDC has been better about answering questions, but more information is needed to justify the dollars spent on prevention. CDC is talking about engaging IOM in an external review to lay out a vision for CDC over the next few years. Ms. Thurman said it is clear that the administration is not on the cutting edge of prevention but needs to be. IOM would be expected to provide some objective recommendations. She noted that she is not happy with the timeframe for the review process; it will take a long time. Mr. Summers and Terje Anderson have been heavily engaged in this issue.

Mr. Isbell said he appreciated ONAP's efforts on prevention, but he is concerned that the push for additional prevention funding is being held up pending the outcome of the CDC review process. He pointed out that communities of color badly need additional funding for community-based prevention, and there is only one more real budget coming out of the current administration. The next administration may not make HIV/AIDS a priority. He suggested that the administration insist that the strategic overview on prevention proceed, but that funding for prevention be made available at the same time.

Ms. Thurman agreed that the administration must continue to push for additional prevention funding but that it must be very specific about how the funds are spent. She said CBC met with John Podesta on October 1 and discussed the need to distribute funds to the communities that have been hardest hit by HIV/AIDS.

Ms. Miramontes said she attended the HIV Prevention Conference in Atlanta in August, and there was a lot of anger about the discriminatory nature of the criteria for granting funds through the CBC initiative. The feeling was that significant barriers had been set up that did not appear in other requests for proposals.

Ms. Thurman said the Council should address this issue with the Surgeon General and through frank discussions with people at the community level. She asked Ms. Miramontes if anyone specified what the criteria were. Ms. Miramontes said the representatives from CDC had acknowledged that the criteria for technical assistance were more stringent.

"Know Your Status" Campaign: Mr. Summers said representatives of ONAP, Alexander Robinson, Mr. Anderson, and representatives from CDC held an initial meeting on the campaign following the June Council meeting. Over the summer, the group conducted biweekly conference calls with Dr. Eric Goosby's staff to keep the campaign "on the front burner." He said CDC has produced an outline for the campaign, which identifies specific measurable outcomes over the next 3 years (i.e., identifying the number of people who are HIV-positive, don't know it, and will learn their status through the campaign).

He noted that the "Know Your Status" campaign is part of a larger initiative called Project

Impact. The project, implemented by CDC, NIH, and HRSA, will examine how the Public Health Service can better link prevention and care services.

Mr. Summers reported that Dr. Gaist is organizing a November 29 interagency briefing for Federal officials on the process by which the prevention science research agenda is developed. Questions to be addressed at the briefing will include: How does the Government articulate specific questions for prevention science researchers? Which questions do researchers themselves need answered? How are those questions translated into research projects? How are the results of research projects applied?

Attendees will include Ms. Thurman, U.S. Surgeon General David Satcher, Dr. Neal Nathanson of NIH, Dr. Jeffrey Koplan of CDC, Duff Gillespie of the U.S. Agency for International Development (USAID), and Dr. Goosby of DHHS. Briefers will include researchers from NIH, CDC, and USAID.

HIV Surveillance Guidelines: Ms. Thurman said it is her understanding that the guidelines are near completion and will include the ability to use unique identifiers.

Health Care Worker Guidelines: Ms. Thurman reported that the CDC ethics committee has completed its work, and the guidelines are back on the CDC director's desk. They are on the way to DHHS. Dr. Hitt said Mr. Thurm indicated that the process is moving forward, and the Department should be able to move on the guidelines within days, not months. Ms. Thurman said the DHHS Secretary's office has been adamant that CDC respond to community concerns, so the process has been delayed.

Treatment Access: Ms. Thurman reported that the Council's Executive Subcommittee has been discussing this issue with Mr. Thurm, and that the Surgeon General and Secretary Shalala are expected to address access in their presentations to the Council. ONAP's senior-level treatment access group will meet in November. She noted that Tim Westmoreland has been appointed as the new director of Medicaid and said he would be of great help to ONAP and the Council.

Jeffords-Kennedy Bill: Ms. Thurman said the bill had passed in the Senate but is still struggling in the House. It remains a top priority for the administration.

Health Care Bill of Rights: The bill will go to the floor this week. It is also a top priority for the administration.

Youth Report: Several groups are meeting to prepare an update to the 1996 Youth and HIV Agenda in time for World AIDS Day. Mr. Summers said ONAP has talked to a number of community groups and young people to formulate recommendations to strengthen prevention and care for young people.

FY 2001 Budget: Ms. Thurman said ONAP is just beginning to discuss the FY 2001 budget and

will solicit input from the Council on budget priorities.

International Issues: In July, ONAP released a *Report on the Presidential Mission on Children Orphaned by AIDS in Sub-Saharan Africa*. The report was well received by both Congress and the White House. The report requested an additional $100 million for international AIDS efforts and laid out a plan of action. Ms. Thurman said ONAP is currently fighting to secure the $100 million. The Senate has allocated more money than ONAP originally requested. It is the first multisectorial budget request ONAP has sent to Congress and includes CDC, USAID, DHHS, and the Department of Defense.

ONAP organized a meeting in early September with the First Lady and a small group of decision makers to discuss the international initiative and how to leverage additional support from other donor nations. Attendees included Secretary Shalala; Jim Wolfenson, president of the World Bank; Treasury Secretary Lawrence Summers; the president of Black Entertainment Television; the chief executive officer of Bristol Myers Squibb; Dr. Satcher; and representatives from the Gates Foundation, the Soros Foundation, and the Rockefeller Foundation.

On September 9, Rory Kennedy's 12-minute video of the White House-sponsored African trip was screened on Capitol Hill and was well received. Ms. Thurman said the video is an educational tool but may become a full-length documentary.

ONAP is also coordinating the administration's response to the Pelosi bill on vaccines.

Ms. Thurman reported that the U.S. Trade Representative's Office has reached agreement with South Africa on issues relative to the Medicines Act but added that the administration still needs to look at how to build infrastructures in the developing world to deliver AIDS drugs to those in need. She concluded by stating that ONAP's international efforts do not detract from its efforts on the domestic front; they are parallel tracks and the funding streams are different.

Questions/Comments: Rabbi Edelheit asked that copies of the report to the President be distributed to Council members. Ms. Thurman said she would bring in copies on Tuesday. Rabbi Edelheit also asked if the Council could view the 12-minute African video. Ms. Thurman said she would be happy to show the video.

Dr. Hitt confirmed that Council members received the report on the meeting with the First Lady.

Mr. Isbell thanked Ms. Thurman for her leadership and hard work on international AIDS issues. Ms. Thurman said it is gratifying to travel to the developing world to share the lessons that Americans have learned since the early days of the epidemic.

Steve Lew thanked Ms. Thurman and Mr. Summers for continuing to work on the refugee issue. He asked whether letters have been sent to INS field offices. Mr. Summers said the INS has issued a field guidance in memo form that incorporates the three-pronged public charge test.

Mr. Lew asked if a copy of the field guidance is available to send out to community-based organizations. Mr. Summers said a copy is available on the ONAP Web site (www.whitehouse.gov/ONAP), but ONAP is trying to maintain a low profile on the issue.

Lynne Cooper asked if the President and industry leaders have shown support for the "Know Your Status" campaign. Mr. Summers said ONAP is focusing on developing a framework for the campaign before soliciting outside support. Ms. Thurman said she has talked to Jesse Jackson, the National Football League, and Robert Johnson of Black Entertainment Television about becoming engaged in the campaign, but ONAP needs to have a plan of action before partnerships can be initiated. Mr. Summers said about $10 million of the administration's FY 2000 budget proposal was allocated for the campaign, but this funding was not included in the congressional markup.

Dr. Hitt noted that Regina Aragón will receive the AIDS Health Project Champion Award in late October from the University of California-San Francisco AIDS Health Project. Dr. Jerry Cade was honored at the recent Interscience Conference on Antimicrobial Agents and Chemotherapy **[correct organization?]** meeting with the Heroes in Medicine Award from the International Association of Physicians for AIDS Care. Dr. Aranda-Naranjo was appointed to a new position as the Special Projects of National Significance (SPNS) Branch Chief and will be leaving the Council.

Dr. Hitt thanked Council members for their thoughts and medical advice during the summer recess. He then introduced Dr. Gary Nabel of the University of Michigan and the VRC at NIH. Dr. Nabel is well known for his research in gene therapy and molecular biology. Dr. Hitt said he will bring an important scientific credibility to the AIDS vaccine effort and epitomizes the President's commitment to bringing the best minds together in that effort.

Dr. Gary Nabel
Director, Vaccine Research Center (VRC), National Institutes of Health (NIH)

Dr. Nabel began by stating that his presentation would summarize the functions and goals of the VRC, not only in terms of the science occurring within the Center itself, but including interaction with academic sites across the world and with various Federal agencies.

He showed a slide of an artist's rendition of the VRC building, which is scheduled to be completed in May 2000. The first laboratories will be functional as of fall 2000, and the personnel recruitment process has already begun.

A 2-day strategic planning retreat was held in May to bring together the best minds in HIV research and basic virology to develop a mission statement and a statement of goals for the Center. Dr. Nabel repeated the mission statement formulated by the strategic planning group: *To conduct research that facilitates the development of effective vaccines for human disease. The primary focus will be the development of a vaccine for AIDS.* He said the statement is phrased to convey the hope that development of an AIDS vaccine will pave the way for applications to other

diseases.

The strategic planning group formulated the following statement delineating the Center's goals for HIV:

The goals of the Center are: (1) To conduct basic research to establish mechanisms of inducing long-lasting protective immunity against HIV; (2) To conceive, design, and prepare vaccine candidates for HIV and related viruses; and (3) To perform laboratory analysis, animal testing, and clinical testing necessary to advance these products into the clinic.

Dr. Nabel said the Center will develop a comprehensive program of research and will facilitate interactions with industry to secure partners to help market and manufacture a vaccine once one becomes available. In sum, activities of the Center will include: (1) promotion of scientific opportunities; (2) development of regulatory guidelines; and (3) engagement of the biotechnology and pharmaceutical sector.

Dr. Nabel summarized three approaches that researchers are pursuing to develop an AIDS vaccine: (1) to stimulate cells of the immune system to recognize and kill the virus; (2) to stimulate cells of the immune system to make antibodies that circulate in the serum and react with the virus to neutralize it; and (3) to generate persistent expression of viral genes so that the above responses to the virus can be maintained chronically.

He noted that each approach has advantages and disadvantages, and researchers have not determined which approach is optimal. Using cell-based vaccines allows researchers to recognize and eliminate virally infected cells, and an intact virus is not needed for this to occur. It also allows for elimination of virus production and could provide a mechanism to eliminate a reservoir of unrecognized virus. But there are ways in which the virus can evade this type of immune response, and this approach requires maintenance of cells that are continually active. Specialized molecules are needed to present the virus to the immune system, and this approach can fail when the virus figures out how to eliminate that recognition.

Antibody-based vaccines are predicated on the view that if one can neutralize the virus with antibody, the virus isn't able to infect new cells. This approach has frustrated researchers and has been the rate-limiting step in the field of developing AIDS vaccines; it has not been possible to generate broadly neutralizing antibodies. It is important to remember that, in some cases, antibodies can make the disease worse. This remains a major scientific hurdle, and the VRC will spend a significant amount of time examining it.

Using a live attenuated vaccine has attracted a lot of attention and has worked in the past with viruses like polio, but the AIDS virus is a different animal: It is a long-lasting virus that is able to evolve into a more pathogenic form. Researchers have found that these long-lasting viruses can become toxic and cause disease in immunosuppressed individuals. When developing a live attenuated vaccine that will be administered to millions of people, the likelihood that adverse

events can occur is great.

Dr. Nabel said the VRC's scientific opportunities relate to what kind of vaccine should be developed, how researchers can enhance recognition of viral components, how researchers can expose regions of the virus that are hidden, how researchers can understand and optimize adjuvants for use in humans, how to use primates as a model for human infection, and how to use genetics and genomics to determine how humans respond to different antigens.

He added that the VRC must develop methods to facilitate the transition of studies from laboratory to clinic. Many techniques that are successful in animal studies are not translatable to humans, in part because animals have controlled genetic backgrounds while humans have different genetic backgrounds. The Center will focus on developing sensitive assays of human immune responses. One approach may be to examine immune responses in individuals who are taking highly active antiretroviral therapy (HAART) to learn whether those responses are comparable to those of an uninfected individual. Researchers must also investigate the range of clades that are medically important throughout the world.

Dr. Nabel said the VRC would address the lack of suitable production facilities for making clinical grade vectors and review how clinical trials are designed. The Center will also look at how to engage biotechnology and pharmaceutical companies in manufacturing a vaccine, considering that liability issues and low profit margins are significant deterrents. To provide incentives to pharmaceutical companies, the Center can help facilitate phase 1 and 2 development of vaccines and can collaborate with industry so that clinical trials yield results more quickly. Promoting communication among industry partners will be a priority.

Dr. Nabel said he was pleased to hear about the January 2000 White House conference to facilitate the efforts of the biotechnology and pharmaceutical industry. He said the AIDS community must consider how to sustain the outcomes of the conference. The VRC has already recruited several high-level individuals from industry.

The VRC hopes to engage in collaborative efforts with the CDC, the U.S. Army, the Food and Drug Administration, and other agencies.

The structure of the Center incorporates an NIH Executive Committee that includes Dr. Anthony Fauci, Dr. Michael Gottesman, Dr. Richard Klausner, Dr. Neal Nathanson, and Dr. Harold Varmus. The center's external Scientific Advisory Committee is largely drawn from the AIDS Vaccine Research Committee, and an NIH Board of Scientific Counselors will review the progress of the laboratory. The Center's programs include basic science, translation, and clinical science.

Dr. Nabel concluded by stating that the VRC's major activities will focus on addressing the problem of neutralizing antibodies and on clinical trials translation and facilitating new vaccine candidates. He emphasized that the research community needs to begin to educate the public

about a potential AIDS vaccine so that expectations are realistic. He said the public needs to recognize that a vaccine may not be completely protective and that complications can occur when a vaccine is administered en masse in the developing world.

Questions/Comments: Ms. Miramontes commented that it will be critical to retain people in AIDS vaccine clinical trials and asked Dr. Nabel if vaccine trials would combine the best minds in biomedical and behavioral research. Dr. Nabel agreed that it is important to pay attention to behavioral aspects and noted that there are a number of AIDS vaccine evaluation groups already in place that are focusing on behavioral and ethical issues.

Dr. Levine praised Dr. Nabel for his presentation and said she was pleased that the VRC's mission statement makes it clear that an AIDS vaccine is its top priority. She asked Dr. Nabel what the Center's budget is, what mechanisms are available to deal with liability issues, and how the Center will bring in other Federal agencies to assist in the vaccine effort.

Dr. Nabel responded that the VRC's budget was $16.5 million last year, with a $2 million supplement at year's end. He projects next year's budget to be approximately $22 million and hopes to reach $30 million within 3 or 4 years. He noted that the NIH leadership has been extremely supportive of the VRC and said that backing is critical. Dr. Levine commented that $30 million seems like an extremely small amount, especially if it includes funding of clinical trials. Dr. Nabel said some of the money supporting clinical trials will come from the VRC, but the AIDS Vaccine Trials Network and the National Institute of Allergy and Infectious Diseases (NIAID) will provide support for large-scale trials. He acknowledged that the VRC's costs could be higher than projected. He added the VRC staff is just beginning to explore liability issues and that he didn't have any answers yet.

Mr. Summers said ONAP's discussion on the Pelosi bill will lead to a broader discussion of liability issues. He said Dr. Goosby is organizing a briefing to which NIH leaders will be invited. He noted that when the President made his remarks at the opening of the VRC, he made it clear that HIV vaccine research is a priority for the administration. That statement was approved by Dr. Varmus.

Dr. Nabel said he was very pleased with the President's remarks at the VRC dedication, but he noted that it is important not to be so restrictive that the Center fails to take advantage of other models that may be informative for HIV or to extrapolate lessons from HIV to other viruses.

In response to Dr. Levine's third question, Dr. Nabel said an interagency group is already in place to facilitate cross-agency collaboration. He said he had started conversations with CDC and the U.S. Army.

Mr. Summers said some of ONAP's discussions with the World Bank have touched on vaccine research collaboration. He accompanied Dr. Nathanson and Bill Paul of NIH on a trip to St. Petersburg and Moscow, Russia, to look at the possibilities for collaboration with Russia. The

group discussed Russia's primate research capacity, vaccine production capacity, and the possibility of carrying out clinical trials cohorts in Russia.

Mr. Fogel asked Dr. Nabel what it would take to make quantities for vector candidates and how long it would take to develop the capability to manufacture vaccine on a large scale. He also asked Dr. Nabel to comment on whether the Federal Government ought to get into the business of manufacturing a vaccine and who would own an AIDS vaccine that was discovered at the VRC.

Dr. Nabel said his experience with pharmaceutical companies has been that when they see that something is likely to work, they get excited. It is a difficult problem because the vaccine needs to be distributed to the greatest number of people and therefore needs to be affordable. But as one does this, the liability risk increases. The World Bank and others have begun discussing ways to establish a buffer liability reserve fund or to support poor countries to allow them to buy vaccines at market prices. He said it may become necessary for the Government to manufacture large-scale vaccines, but the research is not close to that point. The question that must be answered now is: Do we have the capability to make enough vaccine to carry out an efficacy trial? If such a trial works, industry will step forward. He said he would prefer to see incentives for industry put in place rather than see Government laboratories engage in production.

Regarding the ownership question, Dr. Nabel said an AIDS vaccine would be handled in the same way as any other vaccine discovered at NIH: It is intellectual property and would be licensed out by NIH to whichever company wanted to develop it.

Mr. Fogel asked for Dr. Nabel's thoughts on licensing a vaccine to the World Health Organization (WHO) or the United Nations so it could be made available worldwide. Dr. Nabel said he could not imagine NIH denying the vaccine to the international community.

Rabbi Edelheit emphasized the need to begin ethical conversations now about issues such as ownership, testing, pricing, education, and the use of primates. He asked where these conversations are taking place and who is engaging in them. Dr. Nabel said such discussions are not currently taking place at the VRC; the Center does not have the expertise to handle them. He said the NIH bioethics program has become involved in these issues.

Mr. Summers said the Joint United Nations Programme on AIDS (UNAIDS) has been engaging in discussions on ethical issues related to vaccine research, and ONAP supports these discussions.

Dr. Bruce Weniger expressed his concern that the composition of the VRC strategic planning committee did not include people with career vaccine research and development experience. He recommended that at least half of any external committee be composed of scientists with career vaccine experience. Dr. Nabel told Dr. Weniger not to read too much into the composition of the committee. He said the committee was assembled on short notice, and many scientists with career vaccine experience were invited but declined to participate. He stressed that he values those with

career experience and that commitment would be evident as the vaccine research effort moves forward.

Mr. Fogel suggested that those participating in conversations about liability not forget that the ultimate impact of an adverse event rests with the consumer. Dr. Nabel said it would be helpful to look at other examples of product liability, such as cases involving automobile air bags, to learn how to be more constructive.

Appropriations Review

Dr. Hitt reminded the Council that Ms. Aragón is currently drafting a letter to the President on the congressional appropriations process. The Council will have the opportunity to approve the letter or make changes to it on Tuesday. He introduced Mr. Anderson, who gave the Council an overview of the appropriations process.

Mr. Anderson distributed an appropriations policy update drafted by the National Association of People With AIDS (NAPWA). He said this year's appropriations process has been extremely hard to decipher and the outcome is uncertain. Currently, the Government is operating under a 3-week continuing resolution, which holds funding at FY 1999 levels. The White House and Congress will continue to debate the budget over the next few weeks, and another continuing resolution may be necessary.

He summarized several key HIV/AIDS accounts that will be affected by the appropriations process:

Department of Labor-DHHS Bill: Committees in both the House and Senate have taken action. In the House, the subcommittee addressing Labor-DHHS appropriations has completed a markup. The Ryan White Act and NIH received more money than the President requested, but prevention programs and the Substance Abuse and Mental Health Services Administration (SAMHSA) were flat-funded from the previous year, and the Housing Opportunities for People With AIDS (HOPWA) program was level funded. Level funding HOPWA is problematic because it will translate into cuts in programs. Approximately 10-12 new cities will be eligible for HOPWA funding in the next year, so if HOPWA is level funded, existing programs will need to be cut.

On the Senate side, the full appropriations committee reported out a bill on a unanimous vote. The numbers are much better than on the House side. Prevention received a $5 million increase, and the Ryan White Act numbers are fairly good. NIH received a 13 percent increase, SAMHSA received an 8 percent increase, and HOPWA received a $7 million increase, which may be enough to absorb the 10-12 new cities.

It is the AIDS community's hope that the Labor-DHHS bill will be vetoed. It is likely to be vetoed because the President opposes certain education language in the bill.

Washington, DC, Appropriations Bill: The President vetoed this bill. It included strict language prohibiting any private entity receiving Federal funds from operating a needle exchange program. The bill will now go back to Congress where a number of riders will be renegotiated. It only passed by two votes in the House, so there was no veto-proof majority.

Veterans Administration (VA)-Department of Housing and Urban Development (HUD) Bill: HOPWA was level funded in the House version and received a $7 million increase in the Senate version. There are strong indications that this bill may be vetoed as well.

International Funding: Last week, the House and Senate Foreign Operations Committees met in conference and approved an increase in the foreign operations budget to $190 million for HIV/AIDS, up from $125 million. Mr. Anderson called this a significant increase. The Senate Labor-DHHS language includes $35 million to fund international activities.

Mr. Anderson said it is likely that the AIDS community will see final language that includes most or all of the $100 million international initiative.

CBC Initiative: This initiative was not included in any of the appropriations bills. The hope is that the CBC initiative will be funded as part of the veto negotiations. Last year, the initiative was funded at $156 million; it is expected to jump to $349 million this year.

Mr. Anderson recommended that the Council send a strong letter to the President thanking him for the Washington, DC, appropriations bill veto and urging him to stand firm on HIV/AIDS numbers in all areas.

Questions/Comments: Mr. Summers commented that the possible "trainwreck scenario" regarding the budget may provide an opportunity to add money in important areas, such as the HOPWA program. It is important to make sure that strong HIV/AIDS advocates are part of the final negotiation process.

Ms. Cooper reminded the Council that the administration had asked for $286 million for HOPWA, which HUD called a "rounding error." She said HRSA has come to realize that they are paying for $60 to $80 million worth of housing through the Ryan White Act and are becoming more restrictive about housing funds. That money accounts for 25 percent of all housing available to persons with HIV/AIDS, so the increase the HOPWA program received is not acceptable considering that AIDS housing is under fire from HRSA.

Mr. Summers said the HUD budget in particular has come under fire from conservative groups, so it will be a challenge to obtain more funding for HOPWA. Mr. Anderson noted that HRSA is also under congressional pressure for spending too much money on primary care and housing.

Charles Troupe asked how the CBC initiative would be put on the table. Mr. Anderson said the veto process opens up a number of funding opportunities, which is how the initiative was funded

last year. Mr. Summers clarified that the administration included a request for $171 million for the CBC initiative in the FY 2000 budget. Mr. Anderson added that last year's money was included in the base number, so only the increase is up for debate. Mr. Troupe suggested that the CBC initiative be made a line item in the budget to keep it on the table.

Mr. Robinson said the Council needs to express strong support for the CBC initiative, particularly because the CBC's clout has diminished over the last year.

Mr. Milanes asked about the chances of securing funding for a Latino initiative in this year's budget. Mr. Anderson said conversations with the CHC have not led to a separate Latino initiative. The understanding is that the CBC initiative will be expanded to include other communities of color.

Dr. Aranda-Naranjo asked if the Council's letter to the President on appropriations should include strong language on the CBC initiative. Mr. Robinson said yes, language on CBC should be included. He added that the Council needs to make sure that resources are used effectively. Mr. Troupe said the money should track the need and experience in the minority community. Mr. Summers said the CBC funds amount to a small percentage of the Government's total outlay on HIV/AIDS. The funds were meant to prime the larger system, not replace it.

Dr. Hitt reiterated that the Council needs to send a letter on appropriations to the President. Patsy Fleming requested that the Council include language in the letter requesting a new needle exchange rider in the Washington, DC, appropriations bill.

Mr. Montoya provided some background information on the afternoon panel presentation on Latino communities. He said speakers had been asked to address ethnic subpopulations within the Latino community, overall health indicators, education, labor and migration issues, lack of insurance, and substance abuse. He said the presentation is timely because the Congressional Hispanic Health Care Task Force and the CHC have held recent hearings and discussions on HIV/AIDS. In addition, the National Association of Latino Elected and Appointed Officials will hold a 2-day briefing this fall for State legislators on HIV/AIDS issues, and in November a Latino Critical Issues Forum will be held at the U.S. Conference on AIDS.

Mr. Montoya said Lucille Roybal-Allard, chair of the CHC, and Ciro Rodriguez, chair of the Hispanic Health Care Task Force, are very engaged on HIV/AIDS and hope to devise a strategy for a Latino HIV/AIDS initiative for FY 2001.

Dr. Levine asked Mr. Montoya to clarify that funding for Latino communities will come out of the CBC funding. Mr. Montoya said he was not certain of this, but the original CBC language included all communities of color.

Mr. Troupe said the Council needs to make sure that the CBC money is being spent, not being held by DHHS. Mr. Montoya said Secretary Shalala would address the CBC money in her

presentation. Mr. Summers said last year's CBC money was allocated through set-asides for various Federal agencies; it is not one block of money. Some of the money has been distributed, but there are questions about the way some of the funds have been handled. Because it is a new initiative, distribution of funds has been delayed. Questions about this should be directed to Dr. Satcher and Secretary Shalala.

Dr. Nilsa Gutierrez said one of the purposes of the Latino panel presentation is to ask agency directors about their agencies' commitment to allocating a certain amount of money toward minority initiatives. On Tuesday, representatives from community-based organizations will talk to the Racial and Ethnic Populations Subcommittee about what has transpired with the CBC funding.

Mr. Summers said Council members should ask presenters on the Latino panel to address how the CBC money is being distributed and how the agencies are addressing minority communities holistically.

Monday, October 4, 1999
Afternoon General Session

Full Council Presentation
Severe and Ongoing HIV/AIDS Health Care Crisis in Latino Communities

Dr. Gutierrez introduced the panel by describing the goals of the presentation as identified by the Racial and Ethnic Populations Subcommittee. She said the subcommittee wanted the Council to better understand the nature of Latino subpopulations in the United States, what Latinos' national roots are, how those roots affect health status and access to care, the problems of uninsured and undocumented individuals in the Latino population, and the impact of HIV on Latinos.

She introduced Dr. David Satcher and said his presence at the Council meeting sends a strong message about his commitment to Latino peoples in the United States.

Dr. David Satcher
Assistant Secretary for Health and U.S. Surgeon General
Department of Health and Human Services

Dr. Satcher thanked Council members and Ms. Thurman for their leadership in calling attention to the HIV epidemic and HIV's impact on communities of color in particular. He said the administration is committed to fighting the HIV pandemic and said he looked forward to strengthening the administration's relationship with the Council in enhancing community-based HIV prevention, care, and services in Latino communities.

Dr. Satcher emphasized that he does not always speak for the administration or Congress in his

position as the Surgeon General.

He pointed out that Latinos are disproportionately affected by HIV/AIDS. It is increasingly an epidemic of people of color, women, and the young. One out of two new infections occurs in people under 25 years old. According to the CDC, 46 percent of AIDS cases reported in the Latino community occur among men having sex with men, and 39 percent of Latino cases occur among injecting drug users. Among Hispanic women with AIDS, 52 percent of cases are due to heterosexual transmission, and 44 percent are due to injecting drug use. There is a growing trend of women becoming infected with HIV through a sexual partner who is using injection drugs.

Another area of concern is the growing number of Latinos who are incarcerated. Dr. Satcher said the issue of prison health is one of his priorities, and there is a lot of work to do in improving HIV prevention, treatment, and care in prisons.

He emphasized that the HIV epidemic is most virulent when it is ignored by leaders. When leaders do not acknowledge HIV is a problem, people suffer. For example, Uganda and Senegal have been much more successful in dealing with HIV than other African nations because leaders spoke out early. Leadership is also needed in the United States.

Dr. Satcher said people disagree about which cultural approaches to use in communities of color. He does not approach HIV from the standpoint of being black but from a public health standpoint. He said the church is an important institution in dealing with HIV, whether it is the white, black, or Latino church. He said his position is not based on any single culture but on leaders' responsibility to protect the people's health.

Dr. Satcher said he recently testified before the CHC on HIV in Latino communities and contributed, along with Congresswoman Roybal-Allard, to a video on HIV/AIDS and Latinos produced by the National Minority AIDS Council and NIH. He said the administration needs to increase the pool of leaders who are talking about the epidemic and reach out to populations who have not been reached before.

Last week, Representative Ciro Rodriguez and a coalition of Latino AIDS groups called for a state of emergency in recognition of the disproportionate impact of HIV on the Nation's Latino populations. Dr. Satcher said he would be looking at that proposal and the recommendations of the CHC in developing effective programs in the Latino community. One example of such a program is the crisis response team initiative, which is active in several communities

In February 1998, President Clinton announced the administration's commitment to work toward eliminating health disparities. This is one of two goals of *Healthy People 2010.* DHHS will focus on six areas to reach this goal: cancer, infant mortality, cardiovascular disease, childhood and adult immunization, diabetes, and HIV/AIDS. Last week, CDC announced the funding of 32 communities in the initial round of the Reaching for Excellence in Adolescent Care and Health (REACH) project. The project will emphasize eliminating disparities in one or two of the six

focus areas.

The administration is also working with the Congressional Latino Health Task Force to build better partnerships. The CBC initiative will be expanded to include Latino and other minority communities to enhance community-based HIV prevention services, capacity-building assistance programs, and curriculum development and training programs. Dr. Satcher said Latino communities will be directly affected by the 32 grants announced by the CDC; his staff can provide a list of these communities. About $1 million in targeted funds was directed to develop innovative service delivery models for HIV/AIDS through community health centers. Minority populations rely on these centers as a source of primary care. Approximately 44.3 million Americans are uninsured, and Hispanics are the group most likely to be uninsured, at a rate of 34 to 35 percent.

About $3 million was directed to Title III planning grants, which go to community health centers or new entities that are linked to community health centers with HIV primary care and services. These grants will reach African American and Hispanic populations who need services.

Dr. Satcher said he has also launched a new project to work with minority leaders to help overcome the stigma of AIDS in communities of color. This initiative, formerly called Project LEAD, has been renamed the Leadership Campaign on AIDS.

Access to care is a real problem. When DHHS launched the Child Health Insurance Program (CHIP), it became clear that many Latinos were afraid to come forward and receive benefits because they were afraid of repercussions from the INS. The INS has made it clear that enrolling a child in CHIP or Medicaid will not result in any penalty against families seeking citizenship. This is one example of a barrier to access.

It is critical to note that disparities also exist in access to HIV care among Latinos when compared with whites. The HIV Care and Service Utilization Survey, funded by DHHS, found that Latinos learn of their HIV status later in the course of their disease and are referred for care much later. The study also found that Latinos are slower to receive antiretroviral therapies once they are in care. The administration is working with States to develop opportunities to expand insurance coverage through Medicaid waivers for people living with HIV/AIDS, but insurance does not guarantee access. Finding culturally competent care can be a major barrier. There is a shortage of health care professionals who can provide care and counseling to the Latino population and, as a result, there is a shortage of Latino involvement in research. This translates into populations not benefiting to the fullest extent from recent advances in prevention and treatment.

Dr. Satcher noted that those outside the Latino community must be willing to recognize that there is diversity within Hispanic communities. There is a rich social texture that guides behaviors, beliefs, lifestyles, and responses. He said he started his career developing a primary care center in south central Los Angeles. When he wrote the proposal for the center, the patient population was

13 percent Hispanic, and by the time he left, the population was 60 percent Hispanic. In that context, providing quality, culturally appropriate health care services is a major challenge in this country. Other challenges include communication and language barriers and traditional gender roles that inhibit open discussion about sex, HIV/AIDS, and drug use.

In conclusion, Dr. Satcher said the white, African American, and Latino communities face common challenges despite their cultural differences. Leaders must educate, motivate, and mobilize their communities around effective prevention strategies. He quoted former Surgeon General Leonard Sheely, who said in 1948, "The world cannot exist half healthy and half sick." This is true for our nation and communities as well.

When Dr. Satcher spoke at the University of Texas-El Paso commencement in December 1998, he quoted his son: "We are one community." He emphasized that we are one community despite all of our struggles and differences.

Dr. Jane Delgado
Executive Director
National Coalition of Hispanic Health and Human Services Organizations (COSSMHO)

Dr. Jane Delgado noted that her assignment was to "provide a demographic overview of Latino communities, including insight on health indicators, the impact of the lack of health insurance on morbidity and mortality, education, labor, migration, immigration issues, and particularities of undocumented persons." She said COSSMHO is unique in three ways: (1) It supports the idea that the diversity of any community is its strength, (2) It is committed to funding local programs, and (3) It accepts no alcohol or tobacco funding.

By the year 2000, COSSMHO estimates that 25 percent of the U.S. population will be Hispanic or black (this figure includes population data from Puerto Rico). Dr. Delgado noted that this is an important number; it is changing the dynamics of many conversations because it is no longer a small number. As of July 1999, the number of Hispanic children was only exceeded by the number of non-Hispanic white children. Half of the Hispanic population lives in California and Texas, and in New Mexico, Hispanics make up 40 percent of the population.

Describing the demographics of various Hispanic population groups, she said Mexican Americans are the largest group, followed by Puerto Ricans. Median household income data show that all Hispanic groups make less money than non-Hispanic whites (data do not include Puerto Rico). For the last 25 to 30 years, Hispanics have had the highest high school dropout rate of any group.

Dr. Delgado summarized several access indicators for Hispanics. Hispanics are the group least likely to be insured because they work at jobs that do not provide insurance or make just enough money to be disqualified for public health insurance. Hispanics are also the group most likely to have no usual source of care. Hispanic representation in the health care professions is concentrated among social workers and dietitians. Less than 14 percent of managers in medicine

and health are black or Hispanic. Only 3.9 percent of full-time U.S. medical faculty are members of minority groups, according to the Association of American Medical Schools. These data factor in the three medical schools in Puerto Rico and medical schools at historically black colleges.

A 1993 Journal of the American Medical Association study showed that, after controlling for ethnicity, patient status, primary language, insurance status, and other covariates, Hispanic ethnicity is a strong predictor of no analgesic. This is not surprising; researchers have found that women do not get the care they want, and even white men say they are not getting the care they need.

The good news for Hispanics is that they live longer than non-Hispanic whites. Hispanic infant mortality rates, even in the low income Puerto Rican community, are not as high as the black community's, and Hispanics have less heart disease than other minority groups. Hypertension rates for Mexican Americans are the same as for non-Hispanic whites or blacks. High cholesterol levels are prevalent among one-third of Mexican American males, and undiagnosed diabetes occurs among 12 percent of Puerto Ricans. There is also a high incidence of cervical cancer among Hispanic women.

For HIV/AIDS, men having sex with men is the major mode of transmission among Hispanics, with the exception of the Puerto Rican community. Illicit drug use is higher among Mexican Americans and Puerto Ricans than it is among Cubans and Central and South Americans. Many of the latter group are immigrants, and immigrants tend to have better health outcomes than U.S.-born persons. Mexican Americans and Puerto Ricans have higher rates of heavy alcohol use than other subpopulations. Hispanic girls also have the highest number of suicide attempts of any group.

In her concluding remarks, Dr. Delgado quoted *Healthy People 2010,* which says "Recent research indicates that the preventive approaches that hold the greatest promise are community-based, community-wide, and focus on both individual behavior and societal influences." She recommended that public health professionals speak the language of targeted audiences, constantly perform needs assessments, be accessible, build trust, and support change, policy, and media efforts. Solutions should focus on local funding, aggressive programs to educate youth, and supporting community-based organizations.

Dr. Earl Fox
Administrator [?]
Health Resources and Services Administration (HRSA)

Dr. Fox said HRSA has adopted a goal of 100 percent access and 0 percent disparities. Universal insurance coverage is needed, but that doesn't guarantee access, so there is still a lot to do. HRSA established an HIV/AIDS bureau in 1997, and the majority of people hired for leadership positions in the bureau have been black or Hispanic. The agency will continue this hiring pattern. About 60 percent of people served by the Ryan White Act are minorities, and 20 percent of these

individuals are Hispanic. One problem HRSA faces is in gathering accurate data on minorities; there are often duplicated counts. HRSA funded six sentinel sites and spent a lot of money trying to collect data from those sites. These data are being extrapolated nationally.

In 1998, Latinos represented about 13 percent of the U.S. population and accounted for 20 percent of AIDS cases. The rate of AIDS in the Latino population is four times that of whites. Of all Latino HIV/AIDS cases, 68 percent report Spanish as their primary language. HRSA is trying to develop a service system that addresses language barriers.

Dr. Fox said HRSA continues to look at expanding access to care, reducing barriers to care, improving adherence to treatment, improving early detection, and promoting cultural competency among providers. Latinos make up a disproportionate number of AIDS cases, and HRSA is serving a large number of Latinos through the Ryan White Act. Twenty-one percent of services provided by Title I (emergency relief for metropolitan areas in 1997) and Title II (grants to States in 1997) of the Ryan White Act were delivered to Latinos, as were 23 percent of services provided by Title III (early intervention grants) and Title IV (services to women, children, and families) of the Act.

HRSA is examining several initiatives to improve services to minorities. Last year, the board of health initiative received an additional $4 million. HRSA continues to work to secure additional funding for this project. The agency is also targeting its Title III planning grants to communities of color, with an emphasis on community health centers. HRSA anticipates funding four grants under the SPNS project. These grants will address detection of HIV and increased access to care on the U.S.-Mexico border. The agency is working with the Environmental Protection Agency (EPA) to address environmental exposure issues on the border.

HRSA's Airbridge **[name?]** Project is aimed at providing quality medical and social services for HIV-positive individuals traveling between Puerto Rico, New York, and Connecticut. The agency has allocated $200,000 for this project. HRSA is also changing the way it funds its AIDS Education Training Centers; the agency will not fund activities that drug companies intend to fund.

HRSA is trying to improve the nation's community-based provider capacity and is working with George Washington University to develop easily translatable purchasing specifications that can be given to State Medicaid agencies. Data on adherence are being reviewed, and HRSA is working with the Health Care Financing Administration (HCFA) to make the system seamless at the community level. This involves collaborating with Medicare and Medicaid to reduce administrative barriers and streamline the application process. Dr. Fox said he and several colleagues are launching a formal working group with SAMHSA to address mental health and substance abuse issues and HIV/AIDS. HRSA and HCFA are also working together to facilitate 1115 waivers.

Dr. Helene Gayle

Director, National Center for HIV, STD, and TB Prevention
Centers for Disease Control and Prevention

Dr. Gayle began her presentation by discussing the demographics of Latino AIDS cases. Latinos represent 13 percent of the U.S. population and 20 percent of AIDS cases. Latino subpopulations exhibit different risk factors and different cultural issues. The majority of AIDS cases that are categorized as Hispanic occur in individuals born in the United States. Individuals born in Puerto Rico account for the largest proportion of AIDS cases among those born outside the United States. About 78 percent of Hispanic AIDS cases occur in men, 21 percent occur in women, and 1 percent occur in children.

When examining risk factors for men, it is clear that men who have sex with men is the leading mode of transmission for AIDS (60 percent of all male cases), followed by injecting drug use (22 percent of all male cases). For Latino men, men having sex with men is also the leading mode of transmission, but injecting drug use plays a much larger role. In women, 39 percent of AIDS cases occur through heterosexual contact, and 43 percent of cases occur through injecting drug use. Among Latino women, heterosexual transmission plays a much larger role.

Overall AIDS deaths have declined over the past 2 years, but AIDS deaths are not equally distributed. Since 1996, Hispanics have experienced 10 percent less of a decline in AIDS deaths than have whites.

Dr. Gayle said CDC needs to continue to track the HIV/AIDS epidemic as well as track how HIV/AIDS funding is allocated. The agency needs to look at the benefits of direct funding of community-based organizations versus funding of health departments. About $21 million of the CBC funding was distributed to communities of color other than the African American community. Of that amount, about 30 percent was distributed to Latino organizations. Announcements of exact awards are forthcoming.

The CDC is working to promote greater access to HIV testing services, encourage better collection of data, eliminate perinatal transmission of HIV, develop better HIV prevention and care programs in prisons, and secure funding for major international initiatives. As the line between HIV prevention and care becomes increasingly blurred, it is incumbent on CDC to work with its sister agencies (HRSA, SAMHSA, NIH) to eliminate duplication and coordinate efforts.

Dr. Joseph Autry
Deputy Administrator
Substance Abuse and Mental Health Services Administration

Dr. Autry began his talk by stating that data are essential but are not sufficient. The AIDS epidemic is a changing epidemic, and it is a political one because sex and drugs are at the root of it. HIV/AIDS is a growing area of interest for SAMHSA, and it is working with other Federal agencies to make an impact on the disease. Because HIV is increasingly spread by heterosexual

activity and injection drug use, it is important that SAMHSA become more involved.

The agency already has several programs in place that address HIV/AIDS. The Knowledge Development Application Program focuses on generating new knowledge that targets particular populations and implements best practices, while the Targeted Capacity Expansion Program aims to meet unmet needs at the local level. The Substance Abuse Block Grant set-aside requires States with more than 10 AIDS cases per 100,000 population to spend from 2 to 5 percent of block grant funds on HIV early intervention services. In FY 1999, 26 States fell under this category, and HIV service expenditures totaled $54 million.

HIV treatment services in the Targeted Capacity Expansion Program are funded at $16 billion, the Community-Based Substance Abuse and HIV/AIDS Program is funded at $7.5 billion, Grants to Expand Substance Abuse Treatment are funded at $2.5 billion, and the Targeted Capacity Expansion Program is funded at $13.25 billion **[note: two different numbers listed for this program]**.

SAMHSA is currently up for reauthorization, and the agency has requested a specific authorizing activity allowing allocation of money from the block grant set-aside for screening and testing for HIV, tuberculosis, sexually transmitted diseases, hepatitis C, and mental disorders. Dr. Autry emphasized that substance abuse prevention and treatment must be viewed as HIV prevention measures.

Panel Presentation Questions/Comments: Dr. Levine asked Dr. Gayle if CDC has broken out the data for AIDS deaths in minority women. Dr. Gayle said she did not have the data on hand, but CDC could provide those numbers. She said AIDS deaths have declined for all race, gender, and risk categories.

Rabbi Edelheit asked panel members what they are doing to disseminate the science on needle exchange and support local needle exchange programs. Dr. Delgado said the administration's position on needle exchange is an example of a decision being made purely on a political basis. She pointed out that DHHS wanted to support needle exchange. Dr. Autry said SAMHSA has taken an active stance on disseminating the research knowledge, but the administration made a funding decisions, and therefore SAMHSA encourages local communities to use funds from other sources.

Dr. Gayle said the decision on needle exchange was a painful episode in DHHS history, but the Department is committed to doing what is legally possible to support needle exchange. DHHS is planning to issue an update on the science and continues to fund research and evaluation on needle exchange. Department officials have not retreated from the issue but are legally prohibited from acting on it.

Mr. Lew asked Dr. Autry to describe specific examples of community-based SAMHSA programs targeted to HIV and substance abuse among Latinos. Dr. Autry said the block grant set-aside

money is used for early assessment and referral for HIV services for persons receiving substance abuse treatment. Under the Knowledge Development Application Program, there are several projects that are adapting integrated approaches to substance abuse and HIV screening and treatment. SAMHSA funded a series of grants to minority communities under the CBC initiative, and the Targeted Capacity Program aims to develop extra treatment capacity so that there are units set up specifically to deal with substance abuse and HIV.

Mr. Lew asked if any of these programs specifically target Latino populations. Dr. Autry answered yes. Within a week, SAMHSA will release a list of grants awarded in the last year.

Dr. Gutierrez asked Dr. Fox to comment on migrant health centers and the methods they are using to identify HIV-positive persons through testing and care. Dr. Fox said HRSA is hoping to secure an additional $100 million this year to fund migrant health centers. The agency is also examining Medicaid reciprocity for migrants; it is working with the Milbank Fund and the Reform States Group to get States interested in such a program.

Dr. Fox pointed out that Medicaid spends $4 for every $1 HRSA spends in AIDS Drug Assistance Program (ADAP) funding. The limited construction of Medicaid causes problems for States with drug shortfalls. HRSA is working with several Medicaid consulting firms to draw up a list of Medicaid options that a State can adopt if that State's legislature wants to expand care to HIV/AIDS-infected populations.

Mr. Troupe asked about the original purpose of the methadone program. Dr. Autry said the program aimed to provide a mechanism for medical treatment for opiate use. He said it is a complicated program because it is administered by both DHHS and the Drug Enforcement Agency (DEA), and stringent controls have been imposed on it. SAMHSA hopes to move the program to an office-based practice approach. Dr. Gayle stressed that American society does not view substance abuse as the disease that it is; it is seen as a moral failing or a criminal activity. It is not just a DHHS issue, it is a national issue of perception. Mr. Troupe said health care access must be expanded for drug users, regardless of the politics.

Dr. Delgado pointed out that HRSA and SAMHSA are constantly under attack because they deal with the substance abuse population. She added that HCFA needs to be at the table during such discussions. Mr. Montoya stated that Mike Hash of HCFA was unable to attend the Council meeting, but that does not mean the agency is not committed to the substance abuse or HIV/AIDS issue.

Mr. Robinson said the proposed new rules for methadone treatment must be examined. He said the movement toward office-based prescribing, given all of the barriers, is not an achievable goal. Methadone maintenance is another avenue of getting drug users into the system, and the hope is that their risk for HIV can be reduced. He urged Council members to read the proposed rulemaking and to submit comments.

Mr. Robinson asked panel members to describe how the CBC initiative is influencing the larger funding picture for HIV/AIDS and whether funding might be reallocated to where the infections are or where services are needed. Dr. Gayle said most of CDC's money flows through health departments. Health departments are required to implement a community planning process and allocate dollars proportionate to HIV/AIDS data on risk groups, minorities, and other factors.

Dr. Autry said States receiving SAMHSA block grant funds must perform needs assessments to determine where the money should be directed. Local coalitions are assembled to work with States to assure sustainability, current data are used to plan for the next budget submission, and demographics are used to guide policy decisions.

Mr. Fogel expressed dismay at Secretary Shalala's delay in disseminating the science on needle exchange. He asked whether the Secretary had issued any directives to SAMHSA to become actively involved in promoting the science on needle exchange. Dr. Autry said SAMHSA has to be involved in the issue and has tried to refocus itself and the Secretary on the fact that substance abuse prevention and treatment equal HIV prevention. Mr. Fogel noted that it is getting late for many people. Dr. Gayle said she would update the Council on the anticipated DHHS report on needle exchange.

Mr. Milanes asked panel members to describe specific steps taken to address the underrepresentation of Latinos in the community planning process. Dr. Gayle said capacity development grants funded through the 704 and CBC initiatives should help to increase representation of Latinos and African Americans. CDC has also become more stringent in requiring that funding be contingent on proportionate representation. She said CDC has seen an increase in representation among Latinos, but the effectiveness of individuals taking part in the planning process is just as important as satisfying the numbers.

Dr. Gutierrez asked Dr. Gayle to provide the Council with numbers showing how community planning group membership and related funding have changed, as well as a State-by-State disparity analysis. Dr. Gayle said she would provide that information.

Dr. Levine pleaded with panel members to start writing letters in support of needle exchange to educate the public and the medical community about the science. She asked whether the Federal Government would be able to work with State- or locally funded drug treatment centers to pick up individuals who want to get off the streets. She noted that in Los Angeles County, there is only one residential facility for drug-using women and their children, which means that women must often give up their children to enter treatment because housing is not available.

Dr. Gayle said CDC is forbidden to spend Federal funds on anything that is related to needle exchange. DHHS must continue to push for more of what is already available in the realm of substance abuse treatment. Dr. Autry added that several new SAMHSA grants are paying for assessment and referral programs that are attached to needle exchange programs. As knowledge comes out of those grants, the agency will disseminate that knowledge.

Tuesday, October 5, 1999
Morning General Council Session

Dr. Hitt introduced Dr. Shalala and thanked her for meeting with the Executive Subcommittee and making her staff available to talk to Council members.

Dr. Donna Shalala
Secretary, Department of Health and Human Services

Secretary Shalala began her remarks by thanking Dr. Hitt for his leadership and Council members for their outstanding work. She said history will give credit not only to AIDS activists but to the President, Vice President, Ms. Fleming, Ms. Thurman, and DHHS staffers who kept pushing on HIV/AIDS issues. She said she expected Council members to continue to hold her feet to the fire.

The Secretary said she would address the Department's progress on five or six issues that the Council had asked to be updated on. She said DHHS is preparing a draft strategic plan on HIV/AIDS. Mr. Thurm met last week with agency heads, their deputies, and agency HIV/AIDS experts. The group is working on a written document that will guide Federal AIDS activities for the next several years. The Secretary said the draft document should be ready for the Council's review by later this fall, and the final document should be ready by early next year.

The plan will offer principles that will guide Federal HIV/AIDS efforts, including prevention and access to care, elimination of racial disparities, research, and promoting awareness of HIV serostatus. Each agency will continue to work on its own strategic plan, but each plan must be consistent with the overall DHHS strategic plan. The CDC, for example, expects to set specific targets that set a course to decrease the number of new infections each year and to increase the number of HIV-positive persons who know their status. HRSA's part of the plan will call for moving into care a specific percentage of the 300,000 people who know their status but are not in care.

The strategic plan is not being drawn in a top-down fashion; every piece is based on experiences and ideas from community leaders. It will be very specific in terms of targets and holding DHHS accountable in a measurable way. The Department expects to set the bar very high and will work with the Council and community leaders to clear that bar.

Addressing access to care, the Secretary said DHHS had prepared and circulated to the Council a detailed summary of the Department's activities to enhance access to care for people living with HIV/AIDS. An updated version was sent to the Council last Thursday. It includes a discussion of the expansion of Title III of the Ryan White Act, the Department's efforts to improve care for uninsured workers, and the dispatch of crisis response teams in major urban areas.

Secretary Shalala noted that, on the positive side, more lives are being saved than ever before. Today the National Center on Health Statistics is releasing a new report showing that the age-

adjusted death rate from HIV fell another 21 percent last year, for a 2-year decline of more than 70 percent. Since 1987, AIDS has fallen from the number one killer overall to number 16, but these successes are not shared equally; AIDS is still the number one killer of African American men. The Department wants to see the resources follow the disease, and the strategic plan will reflect that.

DHHS is spending more money on HIV research than ever before, and the time for approving new AIDS drugs is shorter than ever before. There is more rural care, more primary care, and more treatment than ever before. The administration will not be satisfied until it does everything possible to prevent HIV or until everyone who needs care gets it early enough.

The Secretary acknowledged that there are still huge gaps in treatment, in access to care, and in resources but said she is proud of this administration's record on AIDS and its willingness to be candid on what remains to be done. The administration has increased funds for AIDS-related programs by more than 90 percent since 1993. When the President broke ground on the new VRC at NIH, he stated that finding an AIDS vaccine by 2007 will be the Center's top priority.

The administration is also investing $100 million in research to find a female microbicide, thanks to Ms. Fleming's advocacy. The Secretary added that one of the best things the administration had done in recent weeks was to appoint Tim Westmoreland as director of the Medicaid program. She gave credit to Nancy De Parle and Mike Hash for supporting Mr. Westmoreland's appointment.

Tinkering with the Medicaid law is not "on the agenda," but DHHS is working to establish 1115 waivers to expand eligibility to people with HIV who are not yet disabled. This will be a top DHHS priority this fall. The Maine waiver will not be the last waiver; a number of States are expected to follow.

The Secretary pointed out that the President and Vice President designated AIDS as one of the six areas in which DHHS will work to eliminate racial and ethnic disparities. This effort is part of the President's overall initiative on race. For the first time, the DHHS *Healthy People 2010* goals will not have separate targets for minorities and for whites. This is a high-risk move, because separate targets allowed the Department to measure hard-earned progress in minority groups across many diseases. As DHHS adds additional resources in the six areas, the goal will be to close the gaps completely, not simply to measure progress within separate ethnic groups.

Two weeks ago, the Secretary met with the CBC health braintrust and told them DHHS has requested an unprecedented $4.2 billion for minority health overall next year. The Department is also calling on Congress to expand the $156 million CBC initiative to $171 million next year. She said DHHS intends to get the full allocation even though there is no appropriations bill. The CBC funds are being distributed to community organizations for technical assistance and the development of service delivery infrastructures. DHHS wants to help community organizations at the front end so they have the expertise to respond to requests for proposals and administer

grants. It is clear that the Department only reaches a certain percentage of sophisticated organizations that know how to apply for funding. Now, the administration is reaching out to community organizations to try to broaden participation in prevention programs. The Department is making an effort to get the word out about CBC funds, but a lot more technical assistance is needed.

DHHS is also aware of the need to focus on the Hispanic community. Several Hispanic community organizations received funds from the CBC initiative this year, including the NSTAR **[spell out]** Human Services in Los Angeles, California; the Hispanic AIDS Forum in New York City; the Latino American Youth Center in Washington, DC; the Latino Health Institute in Massachusetts; and the University of Miami in Miami, Florida. The second round of funding will target new community organizations, and the application process will be streamlined.

To accomplish these goals, DHHS needs help from Congress. The budget rules require that DHHS identify cuts for every new spending item, but the Department will not "rob Peter to pay Paul." Congressional help is also needed on drug pricing. The Department wants to work with Congress and drug companies to reduce the cost of AIDS drugs as much as possible. The Secretary said Congress needs to get to work on the patients' bill of rights, the Kennedy-Jeffords bill, and medical privacy legislation.

With 40,000 new infections occurring each year, the administration needs to take a new look at prevention. CDC has established a working group to review funding priorities in prevention programs. The group has met a number of times and is looking at process, at funding gaps, and at management. CDC is exploring broader parameters of its HIV prevention strategy with the IOM. The willingness to look again at prevention programs should be seen as a positive step. The more people looking at these programs, the better.

Regarding CDC's "Know Your Status" campaign, the Secretary said the administration wants to convey the message that "knowing your status can save your life." The President has requested $10 million in his FY 2000 budget. The campaign will be bold and imaginative and will focus on high-risk populations. While Ryan White Act funding cannot be directed to the campaign, private funds must be leveraged to expand the campaign. The Secretary added that the campaign must ensure that people who learn their status be brought into the health care system.

In her concluding comments, the Secretary said she believes that the decision-making process must be conducted from the bottom up. DHHS for the first time has convened 10 regional meetings to engage consumers and providers of HIV services. Reports from these meetings are forthcoming. All agencies will read the regional reports, and a followup strategy will be implemented.

She emphasized that DHHS, the Council, and community-based organizations are part of one team. The administration has made progress in HIV/AIDS, but there are still huge gaps. There will be opportunities over the next year to fill some of these gaps, but most importantly there is an

opportunity to set a course so that the next administration has a very clear direction.

Questions/Comments: Mr. Robinson commented that many in the AIDS community feel that the Secretary and DHHS have ignored or avoided efforts to promote needle exchange. Council members and AIDS advocates have received numerous assurances from the Secretary and her staff that DHHS would disseminate the science on needle exchange, yet some Council members have heard that these efforts have been deliberately blocked. He asked the Secretary the following questions: Where is the five-page summary on needle exchange science that has been promised by Mr. Thurm and others? Where are the editorials in support of this lifesaving intervention? Where have you been when needle exchange efforts have come under attack from the White House and other opponents? When was the last time Dr. Varmus, Dr. Satcher, or any other DHHS staff member visited members of Congress to continue the effort to educate them about the value of this intervention? When was the last time you allowed anything about needle exchange to be distributed on CDC letterhead? Where is the leadership?

Secretary Shalala said DHHS has been consistent on the science and plans to issue an updated report that reinforces the conclusion that well designed needle exchange programs can reduce the incidence of HIV when implemented as part of a comprehensive strategy within a community. DHHS has never changed that position and has testified to that effect at congressional hearings. She said she has never left needle exchange out of her discussions with members of Congress when discussing the pieces of an overall prevention strategy. Dr. Satcher has repeatedly talked about the issue as he has traveled across the country.

The Secretary said she would check about Dr. Varmus, but said he has been consistent in repeating what he believes is the science on needle exchange. In every community she has visited, she has been consistent in what she says about the science.

Dr. Hitt said the Council has heard for about 4 months that the updated report on the science will be released within weeks. He asked the Secretary for a specific date. Dr. Goosby responded that the report should be made public within 2 weeks. Secretary Shalala clarified that the report may be issued in the form of a response to a Congressional inquiry.

Dr. Levine commented that it would be extremely valuable for the Secretary to send an editorial on needle exchange to a medical journal. Secretary Shalala said she had done that initially but would take another look at what she had written.

Mr. Anderson stated that SAMHSA has been “nearly an invisible player” in HIV prevention. This is especially clear in the lack of engagement by the director of SAMHSA on HIV/AIDS. He said members of the AIDS community have raised the issue with some of the Secretary’s senior staff.

The Secretary said no one had raised the issue directly with her. She said Dr. Chavez is one of the few people in the country who supports the integration of mental health, substance abuse, and HIV/AIDS treatment.

Mr. Anderson said there has been a complete downgrading of AIDS leadership within SAMHSA, and several staffers have left in disgust at the agency's inability to follow through on HIV/AIDS initiatives. He asked the Secretary to assemble an external panel of experts to review SAMHSA's role in HIV prevention and to report back within 3 or 4 months on what SAMHSA can and should be doing.

The Secretary said she would take a look at the recommendation but added that she may want to address the integration of substance abuse and HIV services as part of the strategic planning process.

Reverend Perez said the Council is pleased to hear that the strategic plan under development at DHHS will focus on prevention issues. She said the Council believes that an aggressive prevention plan could and would reduce new infections to the point of elimination. She said the Council expects the plan to include real, measurable objectives with a concrete timetable and a connection to job performance that is strong enough to hold anyone accountable.

Secretary Shalala responded that the plan will have measurable goals, and resources targeted to racial and ethnic minorities will be included. She added that DHHS is prepared to hold itself accountable in these areas.

Mr. Isbell stated that there are 40,000 new HIV infections each year and asked when the AIDS community can expect that level to be cut in half. The Secretary said DHHS is starting to recognize where the infections are coming from. Programs need to be more targeted, more community-based, and more accountable in terms of integration in order to reduce the number of new infections. It is clear that HIV services must be integrated with housing, substance abuse, and mental health services.

Reverend Perez said she is concerned because this issue is not new. The AIDS community has been advocating for integration of services and community-based programs for at least 10 years. Secretary Shalala said she does not disagree with Reverend Perez's concerns.

Mr. Isbell said there are at least 200,000 people living with HIV who have not yet been diagnosed, and there are at least 300,000 HIV-infected people who need to be in care but are not currently in care. He asked the Secretary whether the DHHS strategy will identify targets to reduce each of these numbers and set timelines to achieve these targets. The Secretary urged members to submit comments to DHHS if the draft strategic plan is not precise enough in terms of targets.

Reverend Perez reiterated that the AIDS community has waited 10 years and would like to make sure that the first draft includes specific targets. Secretary Shalala responded that this is "fair enough."

Mr. Henderson asked the Secretary what her plan is to encourage State submission of Medicaid

waiver requests and expedite their review and approval. Secretary Shalala responded that DHHS needs to find a creative way to develop the waiver process in a revenue neutral setting. She cannot add Medicaid expenditures as part of the waiver process. The Department needs to approve two or three "quick models" over the next year, which States can use to submit 1115 waivers. She said it is her experience that once two or three States have completed the process, the rest of the States will follow using those models.

Mr. Henderson pointed out that the issue of budget neutrality has been the major stumbling block throughout the process, and many experts have noted that drug pricing must be addressed first. The Secretary said the Department would need to work with the pharmaceutical companies on drug pricing; earlier intervention is needed, and that requires a very different strategy to address drug purchasing.

Mr. Henderson asked again what the timeframe is for completion of the process. Secretary Shalala said she could not answer that question at present, but she will get the answer.
Mr. Henderson said the Council is frustrated because it raised the issue 2 years ago when access to care guidelines were first discussed. The Secretary said DHHS has made enormous progress, but the last few things that need to be done are tough to carry out within the framework of the law. The best the administration can do is to get the most talented people to work within the law within a reasonable timeframe, and everything needs to be done within the next 5 or 6 months. This will be a tremendous push for DHHS because everything needs to be in place before the transition to the next administration begins.

Mr. Henderson asked what the Secretary intends to do as part of the access plan to extend quality HIV care to persons under managed care programs.

The Secretary said the quality issue is now fundamental; DHHS has spent a lot of time trying to extend insurance coverage only to discover, to no one's surprise, that coverage does not guarantee quality health care. DHHS is pushing the quality movement to develop measures by which the Government eventually can pay on the basis of quality outcomes, reach a consensus on those measures, and build in requirements for all managed care plans. States may be required to transfer Medicaid to managed care so that States can be held to a much higher standard based on quality outcomes. The Department has also encouraged States to leave the disabled outside the managed care system, particularly in cases where the managed care system is new. DHHS must develop a way in which quality is assured in all kinds of organized care. This is the only way to manage the Federal Government's health care expenditures in the long run. The Secretary said she has a completely different view from other experts; she would not pursue the traditional route of "beating on the industry" but would hold them accountable.

Mr. Troupe asked how, in the black community, one can have quality without access. The Secretary said it is necessary to have both. She stressed that ensuring access does not mean that seamless services are guaranteed. Mr. Troupe clarified that many minority communities do not have access to any hospitals or health care facilities. The Secretary said the administration has

promoted seamless health care networks by providing economic incentives to communities to join community health centers, public hospitals, private hospitals, and academic hospitals in one network. These networks are particularly important for those who do not have access to Medicaid or Medicare but do have access to an entry-level part of the system. This requires a different kind of funding, and it requires communities to come together to identify where the gaps are. The administration has requested an initial $25 million, which will lead to a $1 billion commitment over the next 3 to 4 years, to assemble these integrated networks.

Dr. Hitt asked for the Secretary's thoughts on how to achieve the 15 percent reduction in drug pricing to make everything revenue neutral. The Secretary emphasized that the drug pricing issue is one that affects all drugs, not just AIDS drugs. The administration must deal with how to get discounted drugs across the board, how to use the purchasing power of the Federal Government, and how to achieve fair pricing across national borders. The administration would like to see a pharmaceutical benefit this year. There are several measures in Congress that would allow access to discounted drugs and broader-based purchasing to achieve those discounts. The Secretary said the goal should be more than 15 percent; the administration needs to straighten out drug pricing in general.

Dr. Hitt said it would be helpful to update the Council and the public on drug pricing discussions being held behind the scenes and in Congress. The Secretary said DHHS could hold a briefing on drug pricing. Most of the focus is on long-term and chronic diseases. The issue is growing, and it is broad based.

Referring to the Council's panel presentation on AIDS in Hispanic communities and the need for better coordination of agencies in communities of color, Mr. Lew asked the Secretary how DHHS would measure its implementation of the CBC initiative to support community infrastructure and how it would mobilize its own infrastructure and resources in a coordinated approach to communities of color. The Secretary said Council members would be able to tell if the CBC initiative is making an impact; the interventions will be very measurable. She added that there are many organizations that need to participate but do not have an adequate infrastructure. These organizations need ongoing technical assistance, and that is what DHHS intends to provide.

Mr. Lew asked the Secretary to provide examples of where she would like to see coordination between DHHS, HRSA, CDC, and SAMHSA on the CBC initiative. She said coordination would be led by Dr. Satcher; he has chosen to lead the initiative, and he will be held accountable.

Mr. Schatz stated his disappointment in the administration's lack of meaningful action on HIV/AIDS during his 4.5 years on the Council. He cited a chronology of inaction and delay on guidelines for HIV-positive health care workers and asked the Secretary to provide a definitive date for release of the guidelines. The Secretary said she would not provide a date because DHHS has not resolved its internal debate on the guidelines. She said she would not make a promise she could not keep.

Dr. Hitt said he had been told that the CDC ethics committee had signed off on the health care guidelines, and they would be forwarded to DHHS within 1 to 2 weeks. Mr. Thurm told Dr. Hitt that DHHS could move on the guidelines within days once they reach the Secretary's office. Dr. Hitt asked the Secretary to confirm that there is still a substantial debate going on at DHHS. She said she would not make any more promises on the guidelines but assured the Council that she would not delay the guidelines once the pieces are in place. She said the Council should be "very unsatisfied" with that answer.

Mr. Blackwell said the Council's repeated requests for statistics and reports on HIV and Native Americans from the Indian Health Service (IHS), the CDC, and other agencies have been ignored. In April, the director of IHS announced at a top-level staff meeting that HIV/AIDS is "not a problem in Indian country, and IHS has it under control." The IHS director also stated that various people were "employing manipulative tactics to scare Native Americans unnecessarily." Mr. Blackwell stated that HIV is escalating at alarming rates on Indian reservations and in Alaskan villages and asked what actions the Secretary would take to address the IHS director's negative attitude and comply with the President's mandate on enhanced tribal services and tribal consultation. The Secretary said she needs to look at the facts that Mr. Blackwell presented but that the administration has a good record on tribal consultation. IHS will receive the largest increase in resources this year in the history of IHS.

Mr. Fogel suggested that the President call in the chairs of the board of pharmaceutical companies and ask them directly for a discount in drug prices. He went on to state his disappointment and dismay at the Secretary's lack of leadership on HIV/AIDS and the squandered opportunities to make an institutional difference. The Secretary said she was happy to hear Mr. Fogel's criticisms and stressed that it is important for the Council to hold her accountable. But she added that the Council needs to measure how far the administration has come on HIV/AIDS since 1993. She said DHHS has committed to a bottom-up process and has consulted extensively with community-based organizations. She acknowledged that "the final progress" has yet to be made, and the administration is willing to be held accountable for that progress. She said no administration has provided more leadership to get more resources on HIV/AIDS but admitted that the administration has not "gone all the way."

Mr. Fogel clarified that his criticism was aimed at squandered opportunities, such as failure to issue the health care worker guidelines. The Secretary said she was willing to accept that criticism. Regarding a date for the health care worker guidelines, she said she was not willing to lie to the Council.

Dr. Aranda-Naranjo concluded the question-and-answer session by telling the Secretary that she is one who "endures" for so many people who are HIV-infected. The Secretary assured the Council that she and the administration would "never give up" on HIV/AIDS.

Dr. Hitt thanked the Secretary for engaging in a candid discussion. He pointed out that the Council and the administration have a lot riding on the strategic plan being developed at DHHS,

and the sooner it is completed, the better. The Secretary reiterated that the plan would be completed by early next year.

Tuesday, October 5, 1999
Afternoon General Council Session

Subcommittee Reports

Dr. Hitt began the afternoon session by reviewing five documents up for discussion by the Council: the letter to Treasury Secretary Lawrence Summers, the letter stating Council members' retirement dates, the letter from Dr. Hitt, public comment from the Research Subcommittee, and the book on public health. Dr. Hitt also praised Ms. Aragón for her work on several HIV/AIDS issues in California.

Research Subcommittee: Ms. Miramontes asked the Council for its approval of a Subcommittee resolution in support of H.R. 1274, the Lifesaving Vaccine Technology Act. The Council approved the resolution on a unanimous voice vote. Dr. Hitt noted that the resolution states that the Council supports "the intent" of the legislation, in case the wording is changed.

Ms. Miramontes asked the Council to approve a statement of public comment in support of maintaining a separate study section and expedited process for HIV at NIH. NIH wants to spread HIV study sections across its Institutes again. The Council adopted the statement on a unanimous voice vote.

Racial and Ethnic Populations Subcommittee: Reverend Perez said the Subcommittee discussed the Latino panel presentation and concluded that it did not adequately inform the Council of the complexity of the HIV crisis in Latino communities. The Subcommittee will write letters to follow up with the panelists and will invite the CHC and other groups to a subsequent Subcommittee meeting to discuss how the Council can support activities on HIV and Latinos. The Subcommittee will also prepare a summary action statement on proposed next steps as guidance for new Council members.

The Subcommittee would like to organize a panel presentation on HIV and Asian/Pacific Islanders and will bring this up with the Executive Subcommittee. Reverend Perez said there is a movement to secure $349 million for the CBC initiative next year. She suggested that the Council send a letter to the President requesting his support of this number instead of $171.4 million. She also asked that the Council continue the Subcommittee's work after current members have retired.

Prevention Subcommittee: Mr. Robinson said the Subcommittee did not have a report because so many members would be retiring from the Council. He said it was clear from the Secretary's presentation that prevention still has not received priority status and emphasized that the Council must continue to press the issue.

International Subcommittee: Mr. Anderson reported that the Subcommittee discussed the appropriations process, the compulsory licensing agreement with South Africa, and the transition process as new Council members begin their terms. The Subcommittee would like the Council to write a letter to the U.S. Trade Representative's office prior to the World Trade Organization (WTO) Summit in November regarding the U.S. role in redrafting any WTO agreements on compulsory licensing. The subcommittee intends to invite representatives from the State Department and USAID to present testimony at the Council's February meeting. The Subcommittee will schedule a number of conference calls through the fall to review the State Department's worldwide strategy on AIDS.

Mr. Anderson asked for the Council's approval of a thank you letter to Treasury Secretary Lawrence Summers on the issue of debt relief. Last week the President gave a speech in which he pledged U.S. support for 100 percent debt relief for the 53 poorest nations, provided that they agree to carry out a dollar-for-dollar trade on domestic health and social spending. The letter encourages the administration to make that happen in an expedient manner and explore other opportunities to leverage U.S. international development funds to obtain funding for AIDS from other nations. The Council approved the letter on a unanimous voice vote.

Mr. Anderson thanked Mr. Fogel for his work on the Subcommittee.

Services Subcommittee: Mr. Henderson said the Subcommittee heard a presentation on reauthorization of the Ryan White Act from DHHS and from representatives of National Organizations Responding to AIDS (NORA). The good news is that the AIDS community is building a consensus around areas of concern regarding the Ryan White Act, and that process is going smoothly. The community has also begun to educate staff members on Capitol Hill.

Prisons Subcommittee: The Subcommittee did not meet, but Mr. Landau provided an update on prisons issues. He commented that the CBC initiative has unlocked some doors for AIDS in prisons issues. Several Federal agencies (e.g., CDC, HRSA, National Institute of Justice) are now including AIDS within their prison agendas.

Mr. Landau reviewed the Council's accomplishments and proposed next steps on prisons issues. In the area of prevention, the Council still has not received a copy of the curriculum that is supposed to be standardized by the Bureau of Prisons. The Council has not seen an internal memo calling for all health officials in prisons to use the Standards and Practices for Clinical Care of AIDS. The Council has not seen a review of public law on the disallowance of condoms in prisons, and the Bureau of Prisons has not responded to the Council's request on substance abuse treatment.

Mr. Landau encouraged the Council to make sure that Federal agencies continue to have an impact on State prison care. He said there are two issues that ONAP needs to address: discharge planning and continuity of care, and planning a national meeting on prisons. The meeting is not being planned by other organizations, so ONAP must sponsor it. Finally, Mr. Landau encouraged

the Council to meet next year with Marsha Mason of DHHS, John Miles of CDC, and Newt Kendig of the Bureau of Prisons to get an update on prisons issues. He added that the Subcommittee will submit a summary report to the full Council since the majority of Subcommittee members will be retiring.

CBC Letter and Discussion of Council Transition: Dr. Hitt recommended that the Council vote to support a CBC resolution regarding increased funding. The Council approved the resolution on a unanimous voice vote.

Mr. Montoya distributed a list of Council members' retirement dates. Dr. Hitt said the next Council meeting is tentatively scheduled for February. Mr. Montoya said subsequent meetings are planned for June and October 2000. Mr. Blackwell asked that time for new member orientation be incorporated into the February meeting schedule. Mr. Montoya said he would consider including an extra day for orientation.

Dr. Hitt's Closing Remarks

Dr. Hitt said his resignation letter to the Council reflects what he has felt for a while. He said he decided to leave the Council in June in part because 4 years is a long time to maintain a strong commitment. He said he feels strongly that the next Council chair should be a person of color because the epidemic is out of control in communities of color. He plans to stay on for a while to help with the transition. He will continue to follow up on issues and make calls to people in the administration. He also will try to meet with the Vice President to discuss the Council's role as an advisory source on HIV/AIDS issues. He said he is committed to working on the next Presidential campaign and will continue to work to "turn back" the House of Representatives. He has learned that the problem lies in Congress, and a few people are preventing a lot of good things from happening.

Dr. Hitt said goodbye to the Council members who are leaving. He reminded Council members that they should be proud of their accomplishments, such as pushing for a White House Conference on AIDS and the implementation of health care worker guidelines. He noted that the needle exchange issue did not go as planned, but he felt that the dollars in ADAP and other funding were allocated to keep the Council quiet. Hundreds of millions of dollars are in the budget because the Council was active on certain issues. The vaccine effort is moving in the direction the Council wanted it to go. The Council has given a voice to a lot of different organizations, such as IAVI and AIDS Action.

Dr. Hitt said new Council members will bring in a tremendous amount of energy, which is needed as complacency about AIDS sets in. He said Council members can be proud of the fact that they have been principled. He thanked the Council members for their support and patience. He said he had learned to be part of a team. He also said he appreciated Ms. Thurman's and Mr. Montoya's support and thanked them for their work.

Finally, Dr. Hitt charged the subcommittees with the task of writing summary documents that give an overview of each subcommittee's accomplishments, frustrations, and recommendations. He said he believes the Council needs to write a closing document to provide direction to the next administration. The document should include all current members' names, though the new Council will vote on it.

Dr. Hitt suggested a conference call with new Council members to impart some of the Council's history, in addition to an orientation meeting with new members the night before the February meeting begins. He stressed that the Council should take advantage of the White House transition that is already under way. There is an opportunity to accomplish a few things now that some of the Council's enemies have departed. He urged members not to give up.

Dr. Hitt adjourned the meeting at 4:00 p.m.