Presidential Advisory Council on HIV/AIDS
Eighth Full Council Meeting

December 4–7, 1997

Omni Shoreham Hotel
Washington, D.C.

MINUTES

Present: R. Scott Hitt, M.D., Chair; Stephen N. Abel, D.D.S.; Terje Anderson; Regina Aragon; Judith A. Billings, J.D.; Nicholas Bollman; Jerry Cade, M.D.; Rabbi Joseph A. Edelheit; Robert Fogel; Debra Fraser-Howze; Kathleen Gerus; Phyllis Greenberger, M.S.W.; Nilsa Gutierrez, M.D., M.P.H., M.S.W.; Robert Hattoy; B. Thomas Henderson; Michael Isbell, J.D.; Ronald Johnson; Jeremy Landau; Alexandra Mary Levine, M.D.; Steve Lew; Helen M. Miramontes, M.S.N.; H. Alexander Robinson, M.B.A.; Debbie Runions; Sean Sasser; Richard W. Stafford; Denise Stokes; Bruce Weniger, M.D.; and Daniel Montoya, Executive Director for the Presidential Advisory Council on HIV/AIDS. Present from the Office of National AIDS Policy were Sandra Thurman, Director; Todd A. Summers, Deputy Director; staff members Sarah Holewinski, Jeff Kramer, Matthew Murguia, and Bob Soliz; and interns Glenda Simmons and Anil Soni.

Absent: Mary Boland, M.S.N., R.N.; Rev. Altagracia Perez; Robert Michael Rankin, M.D., M.P.H.; Benjamin Schatz, J.D.; and Charles Quincy Troupe.

Opening and General Council Business

Dr. Scott Hitt, Chair, opened the Eighth Meeting of the Presidential Advisory Council on HIV/AIDS (PACHA) with a review of the agenda and interim activities. He thanked members for their commitment to PACHA's ongoing work; PACHA Executive Director Daniel Montoya, Office of National AIDS Policy (ONAP), Director Sandra Thurman, and ONAP's staff for their support; and individuals who are working within the Administration to move the Council's recommendations through the bureaucratic process. Many AIDS organizations also have been highly supportive of PACHA, helping the Council to be more effective at connecting with the AIDS community than ever.

Since August, the Council and its Subcommittees have concentrated on an Action Plan developed at the last meeting, prioritizing end-of-the-year activities, assessing Administration response to recommendations and formulating new ones, developing the Second PACHA Progress Report, and maintaining a presence in Washington, D.C. Interim activities included the following:

- Finalizing letters to President William J. Clinton and Secretary Donna E. Shalala, Department of Health and Human Services (HHS), regarding funding, the AIDS Drug Assistance Program (ADAP), and needle exchange.
- Obtaining public opinion regarding the congressional debate on needle exchange and working to preserve the authority of the HHS Secretary on these programs, including a memo to the President and key administration staff urging maintenance of this authority.
- Attending meetings with the AIDS Action Council (AAC) and other AIDS organizations, the National Organizations Responding to AIDS (NORA), administration officials, Dr. Eric P. Goosby and Secretary Shalala at HHS, and members of the Office of Management and Budget (OMB) staff, followed up with written reports on what each is committed to do.

Successes were realized in increased appropriations, maintaining the Secretary's authority, and World AIDS Day activities, including a Presidential proclamation and directive.

Dr. Hitt redefined the Council's role—advising and informing the President on programs and policies intended to promote the effective prevention of HIV disease, advanced research, and quality services to persons living with HIV/AIDS. He reminded members that Mr. Montoya is not a Council employee but, rather, a Federal representative, whose duties include calling meetings, maintaining records, and ensuring that regulations regarding Council activities are followed.

Primary goals of the meeting were to finalize the Progress Report and a number of subcommittee recommendations; develop talking points for the Council in discussing the Progress Report with the public and the press; obtain a better understanding of surveillance and substance abuse issues; and develop subcommittee action plans for the next 3 months.

ONAP Update

Ms. Thurman presented an update on agency activities and status of HIV/AIDS. She thanked the Council and its members, Mr. Montoya, Mr. Todd Summers (Deputy Director of ONAP), and other ONAP staff members for their dedicated work. Specific points covered were the following:

Budgets for HIV/AIDS programs have made the following increases since the start of this Administrative term: discretionary AIDS funding, 60 percent; AIDS research funding at the National Institutes of Health (NIH), 50 percent; Federal funding for ADAP, 450 percent; Ryan White CARE Act programs, nearly 300 percent; and HIV prevention funding at the Centers for Disease Control and Prevention (CDC), 27 percent. Appropriations for FY 1998 are better than expected in the context of a balanced budget, with increases in Ryan White, 15 percent; NIH research funding, 7 percent; CDC, 3 percent; and Housing Opportunities for People With AIDS (HOPWA), 16 percent. The process of developing the FY 1999 budget has begun and will be an uphill battle. The impact should be clear within the next 1 to 3 years, and the community must work together to develop strategies to protect funding for AIDS programs.

The vaccine initiative is getting a great deal of attention, both in the U.S. and overseas. The search for a director of the NIH vaccine program has now moved to a list of five or six candidates to be announced soon. Funding for the new Vaccine Center has been approved, and the Office of

AIDS Research (OAR) is working to implement the initiative through its AIDS Vaccine Research Committee (AVRC), headed by Dr. David Baltimore. ONAP will set up meetings at HHS and other agencies involved in AIDS vaccine research to work more directly on PACHA's recommendations in this area as soon as they are finalized.

World AIDS Day focused on Children Living in a World with AIDS and was a great event, with mainstream children's activists and the President, Vice President, and their wives participating directly. The focus on faith, hope, and healing was timely, with the grim news that the disease is much wider spread than was anticipated. The President signed a proclamation reaffirming the commitment to fighting AIDS and a directive asking agencies to include youth in all of their HIV/AIDS programs. Next year's focus will be on youth, and ONAP is planning an appropriate curriculum that will be more powerful than those in the past.

As to Council recommendations, some, but not enough, progress has been made. The recent PACHA letter to the President has been used as an effective working document within the Administration to make advances in some areas.

Internationally, the epidemic is moving twice as fast as originally anticipated, with 5.8 million new infections globally. Ms. Thurman, who led the United Nations delegation to the Joint United Nations Programme on HIV/AIDS (UNAIDS) meeting in Nairobi, stressed the need to share resources and information around the globe, especially in developing countries. Ethical issues are sobering and very important, especially with regard to vaccine development and technology sharing, and there is a need to work with the U.S. Agency for International Development (USAID), the U.S. Information Agency, the State Department, and others to send people with expertise to international areas to help develop basic infrastructures for services and sustain efforts at the grass roots. Ms. Thurman will visit South Africa, and possibly India and states of the former Soviet Union, to discuss methods for U.S. technology transfer and to help elevate HIV/AIDS on the international agenda.

For the **UNAIDS/WHO Global Report**, Mr. Summers gave statistical highlights from the recent UNAIDS/World Health Organization (WHO) Report on the Global HIV/AIDS Epidemic. The large discrepancy found in numbers of infected people is most likely because of improved methods of reporting and extrapolating AIDS figures worldwide. More than 90 percent of new infections are in developing countries, primarily sub-Saharan Africa, and one-tenth are children younger than 15 years old. The number of people living with HIV/AIDS is now estimated to be 30.6 million, with 2.3 million AIDS deaths in 1997. Numbers among women and youth are increasing rapidly, and there are now about 8.2 million AIDS orphans (HIV-negative children younger than 15 who have lost a mother or both parents to AIDS). While new infection levels have stabilized in the United States and West Africa, there is rapid growth in China (especially among injecting drug users [IDUs]), India, the former Soviet Union (IDUs and young people), and Cambodia, which has no prevention program in place. Thailand is showing improvement with an aggressive prevention campaign. Latin America and the Caribbean still have significant numbers of AIDS-related deaths. The basic message is that prevention and better health programs do significantly reduce deaths, sickness, and devastation caused by the epidemic. Council members discussed the credibility of the numbers, the unraveling of the social fabric in these societies, and the need to look at this as an issue not only of humanity but of economics and national security. Questions

were raised about whether the U.S. military and State Department are aware of the ramifications of these statistics, and Ms. Thurman said that she has been asked to brief Secretary of State Madeleine K. Albright on the status of AIDS after her visit to South Africa.

On **Medicaid expansion**, Mr. Summers has led the effort, with Mr. Terje Anderson and other Council members assisting, working the Vice President Albert Gore, Jr., Health Care Financing Administration (HCFA), HHS, and OMB to expand coverage to all people with HIV/AIDS. In a meeting at HCFA, Nancy-Ann Min DeParle, recently appointed Administrator, said that every opportunity is being explored through comprehensive financial analysis to provide this support. The initial study found that the total cost for expansion would be more than $3 billion over the next 5 years. (Note: During the PACHA meeting, a top HHS Administrator was quoted in the *New York Times* as saying that Medicaid expansion is dead, which both Vice President Gore and Ms. Thurman denied. (See discussion below.) Meanwhile, ONAP is studying ways to fill this gap through such mechanisms as State Medicaid waivers; helping HCFA obtain better actuarial data, and seeking alternative, reduced-cost assistance programs. Dr. Hitt and Mr. Thomas Henderson reported on a meeting on this subject in Washington with approximately 25 representatives from both HHS and the AIDS community. Pertinent data are difficult to obtain, in part, because of such unanswered questions about how long the drugs will work and if there can be an end point to treatment. Council members questioned whether HHS and the Administration are serious about expansion, and ONAP said that both the Vice President and some people at HHS—notably Ms. DeParle—are committed to the effort. The impression of Secretary Shalala's commitment is not as strong.

Needle exchange is a tough issue, and a great deal of work needs to be done by March to help people understand the need to follow the science (i.e., that needle exchange does not promote drug abuse but helps prevent transmission of AIDS) rather than the politics. Ms. Thurman expects Congress to hold hearings on needle exchange soon after it reconvenes and also expects that there probably will be a negative response because of political pressure and because many in Congress believe it will send the wrong message about drug use. In answer to Council questions about who in Government is willing to depend on the science, Ms. Thurman said that the Secretary could position this as a public health issue and that the AIDS community needs to help her be comfortable with this assessment. General Barry R. McCaffrey, Director, Office of National Drug Control Policy, and his staff are not working against it, and he is willing to discuss the subject. Also, the designee Surgeon General is on record as supporting needle exchange. Council members pointed out that it is crucial for the President and the Administration to speak out on the issue and that it is important to develop a viable political strategy against a possible extension of the moratorium.

ONAP Future Plans

ONAP remains understaffed, but representatives from other agencies have helped. More are expected from the Substance Abuse and Mental Health Services Administration (SAMHSA), CDC, NIH, and USAID to work on international issues. Ongoing and future ONAP activities include the following:

- Progress has been made in cooperation with CDC on content restriction and accountability for dollars spent on HIV prevention.

- An interdepartmental AIDS Task Force was reconstituted, and during its first meeting at the White House, everyone seemed energized, enthusiastic, and committed.
- Upcoming round table conferences are planned and include leadership, women and HIV, housing, and HIV and race. (Mr. Sean Sasser proposed adding a conference on youth, and Mr. Summers said that work had already begun on that topic.)
- A proposed prayer breakfast on the Hill, cohosted by ONAP with the national interfaith network, will focus on how best to call attention to AIDS within religious communities.
- A world issues guidance committee is being established with the Business Council for Africa and others to consider the economic impact of AIDS on international corporations.
- Ongoing outreach is planned through staff appearances on talk shows and in other media, and plans are to do more direct work with community groups.

Mr. Alexander Robinson suggested that ONAP consider addressing the response of the AIDS community to the President's new directive; i.e., that this is a repeat and that little or no progress is being made. He also asked that the epidemic among young gay men of color be covered. Dr. Hitt commented that additional ONAP staff is desperately needed to do more work in all of these areas and that PACHA must try to show the AIDS community the advantages of having a stronger ONAP, which means stronger advocacy within the White House. Mr. Robert Fogel expressed Council thanks for Ms. Thurman's tireless efforts, energy, and bold and aggressive leadership, much needed in ONAP.

Progress Report Process

In the first of several sessions to finalize PACHA's Second Progress Report, Dr. Hitt reviewed the format and process of developing the document. Unlike the first Progress Report (July 1996), which included an Executive Summary and appendix with every Council recommendation and Administrative response, this document will be a general summary of progress. In lieu of the appendix, Mr. Summers put all recommendations, responses, and followup into a database, which was provided to Council members. The goal is to document every activity on each recommendation and to make the database available on disk as well. Time limitations precluded development of a major state of the global epidemic, as had been proposed at the August meeting. The document, which focused on key issues of what needs to be done, was drafted by Process Committee members Mr. Henderson, Mr. Michael Isbell, and Dr. Jerry Cade, with input from Subcommittees. It was important that the report be totally factual and correct, with a tone that is firm, respectful, and balanced. Subsequent drafts were circulated among the Council and ONAP and distributed to some administration officials and throughout the AIDS community for input.

Subcommittee Meetings, December 4

Prevention Subcommittee: Members present were Mr. Robinson, Chair; Mr. Anderson; Ms. Judith Billings; Mr. Fogel; Ms. Kathleen Gerus; Mr. Isbell; Ms. Debbie Runions; and Mr. Sasser. Discussions focused on the issue of surveillance, Subcommittee recommendations, and the Progress Report.

Research Subcommittee: Members present were Dr. Cade, Ms. Phyllis Greenberger, Dr. Hitt, Mr. Ronald Johnson, Ms. Helen Miramontes, and Dr. Bruce Weniger. Others present were Dr. Donald S. Burke, Johns Hopkins University; Dr. Bonnie J. Mathieson and Ms. Wendy

Wertheimer, OAR; and several members of the press. Dr. Mathieson updated the Subcommittee on NIH vaccine activities, including the scope of the new Vaccine Research Center and clinical trials. Twenty million dollars is being spent on attenuated virus research, phase I trials with DNA vaccines are being conducted, and a phase II study in humans is in place; however, funding for phase III efficacy trials is not yet sufficient, and she did not know whether NIH would consider cosponsoring these clinical trials in the Thailand project.

The Subcommittee discussed Dr. Baltimore's response to PACHA's draft Progress Report, that a vaccine czar is not necessary to oversee the vaccine effort. Dr. Burke concurred, saying that coordination and balance between the empirical and basic sciences approach is appropriate. Concern was expressed over Dr. Baltimore's role and authority in the NIH vaccine effort, the lack of consensus as to when to move from basic science to product development and testing, and inadequate budgeting for this effort. Other questions were raised about the efficacy of the interdepartmental vaccine coordination group among NIH, HHS, the Public Health Service (PHS), CDC, and the Department of Defense (DOD). Dr. Mathieson and others commented that the Subcommittee's proposed new recommendations may not reflect all the current facts about vaccine research, and members agreed to obtain additional information before these are presented as formal recommendations.

Services Subcommittee: Members present were Mr. Nicholas Bollman, Chair; Dr. Stephen Abel; Ms. Regina Aragon; Rabbi Joseph Edelheit; Dr. Nilsa Gutierrez; Mr. Henderson; Mr. Steve Lew; and Mr. Richard Stafford. Also present were a number of agency representatives and AIDS organizations who presented information to the Subcommittee on a variety of issues of concern:

- **Youth and HIV**: Mr. David Harvey, Executive Director, AIDS Policy Center for Children, Youth, and Families (APC), who discussed Ryan White programs and other efforts that address youth. Mr. Harvey recommended that this population must become more visible and that more Federal funding be allocated to youth services, counseling, and testing. Efforts should be made by the Health Resources and Services Administration (HRSA), CDC, or others to create a formal national network of HIV-positive youth to increase the presence and effectiveness of youth advisers and consultants to planning bodies.
- **FY 1998 appropriations**: Ms. Miguelina Maldonado, National Organizations Responding to AIDS.
- **National policy dialogue on early medical intervention services**: Dr. Sophia Chang, Director, HIV Programs for the Henry J. Kaiser Family Foundation.
- **Access to treatment**: Mr. Gary Claxton, HHS, who described departmental health policies; Ms. Kathleen King, HCFA, who reported on Medicaid expansion and waivers, costs, budget neutrality, and States' roles; Dr. Joseph F. O'Neill, HRSA, who spoke of Ryan White Titles I and II, ADAP, appropriate roles of HHS in guiding programs versus local control, and State contributions; and Joseph Kelly, National Alliance of State and Territorial AIDS Directors (NASTAD), who reported on cost and availability of pharmaceuticals.

Others guests included Mr. Charles W. Blackwell, Ambassador to the United States of America from the Chickasaw Nation and nominee to the Council, who discussed Native American issues

and the Indian Health Service (IHS); Ms. Annette Byrne, Chief of the ADAP branch; Ms. Lynne M. Cooper, Director, Doorways, and PACHA nominee; Mr. Arnold Doyle, Research Associate, NASTAD; Ms. Anita Eichler, Director, Division of Services Systems, HIV/AIDS Bureau, HRSA; Ms. Christine Lubinski, AAC; Mr. Thomas Martin, President, Martin Medical Services; Mr. Miguel Milanes, Coordinator of HIV/AIDS Programs, Miami-Dade County Department of Health; and the press.

Substance Abuse Panel

On December 5, a full Council presentation, convened by the Prevention Subcommittee, was given on epidemiology and other activities involved in substance abuse activities. Mr. Anderson, Chair, introduced speakers and gave a brief overview of the topic, saying that the focus has been on needle exchange and now the Council needs to look at a larger program.

Dr. T. Stephen Jones, Associate Director for Science and Acting Director of the HIV/AIDS Prevention, Intervention, Research, and Support of the National Center for HIV, STD, and TB Prevention, CDC, discussed the epidemiology of HIV in relation to IDUs in the United States. There has been a steady increase in IDU-associated AIDS since 1983, although the numbers began to stabilize after 1990, partially as a result of prevention efforts. Increases have been seen among heterosexual men, women, and adolescents in particular, with a disproportionate increase among heterosexual minorities, particularly African Americans. The highest number of cases continues to occur in the Northeast, although the rate is slowing, and increases continue in the South and West.

Proposed prevention strategies include (1) preventing the initiation of injecting drug use through education and counseling; (2) increasing the number of IDUs in drug treatment; (3) encouraging current IDUs to adopt safer injection practices; and (4) encouraging safer sexual behaviors among IDUs and their partners. Dr. Jones advocates changing laws restricting or criminalizing the sale and possession of syringes, increasing syringe exchange programs (SEPs), and educating pharmacists and police about HIV prevention and the value of sterile syringes. CDC activities include establishing a better system of registering all AIDS cases and gathering accurate data; issuing HIV prevention bulletins as part of interdepartmental efforts among CDC, SAMHSA, National Institute on Drug Abuse (NIDA), and HRSA; providing information for heads of agencies and Attorney General Janet Reno on syringe exchange; and working with States in looking at science-related issues that might lead to decriminalization of possession and sale of drug paraphernalia. The Council voiced concerns that much of the material from the Government showed doublespeak and a lack of understanding of the realities about needle exchange. It was noted that an anomaly in public health is that health workers are advised to counsel their clients to seek drug-abuse treatment, but this is not a priority in the Federal budget.

Dr. Camille Barry, SAMHSA, profiled IDUs, describing how one becomes a consumer through such avenues as self-medication and partner/peer pressure. Major needs in this area are more block grants to study substance abuse involvement in AIDS; additional funding for States; reduction of crime and risky sexual behavior; and focus on youth in all systems of prevention and intervention. SAMHSA's mission is to improve the quality and availability of substance abuse prevention, addiction treatment, and mental health services. Twenty percent of SAMHSA block

grants go to community substance abuse prevention. With increases in women and adolescent girls among IDUs, SAMHSA's most recent program is Girl Power!, a major campaign against drug abuse among 14-year-old girls.

Dr. Steven W. Gust, Acting Director, Office on AIDS, NIDA, commended the Council on its willingness to address drug abuse, noting its significance in the overall epidemic. This has helped encourage those in public health to address the attendant problems. NIDA's goals are to (1) look at educational and other strategies to change risk behaviors; (2) research how to improve existing drug abuse treatment approaches, including both pharmacologic and nonpharmacologic therapies; (3) research the epidemiology and natural history of HIV infection in IDUs, their sex partners, and children; and (4) study basic behavioral and neuroimmunologic processes underlying HIV risk behaviors and AIDS. Emerging needs include targeting interventions to high-risk groups, HIV prevention in drug treatment programs, improvement of community outreach, expansion of research on needle exchange, and better utilization of network analysis. PACHA can help, he said, by supporting NIDA in its research and continuing to gather information on addiction and HIV.

Questions were raised about access to methadone, and Dr. Barry agreed that the regulations, made 25 years ago, were stringent to the point of denying access to treatment and that SAMHSA has been asked to look at ways of minimizing the restrictions. A pilot program for a proposed accreditation system is now in 40 sites across the country, and emphasis is on States' working with HIV/AIDS communities. Other discussion focused on making States accountable for money set aside for substance abuse programs and the efficacy of and understanding of issues at the Center for Substance Abuse. Members asked speakers to provide any research findings that estimate the impact of needle exchange and prove effects of lifting the ban on funding, and Dr. Barry promised to send PACHA findings from SAMHSA's latest study. Emphasis was placed on the importance of linking in communities, integration of services, and increased funding. It was noted that current regulations were inhibiting SAMHSA's ability to see how funds are being used. As to how much the Clinton Administration had requested for substance abuse programs, she said, "it was more than we got." The Council asked for a copy of the White House budget requests.

Mr. Harry Simpson, Executive Director, Community Health Awareness Group, Detroit, described integration of harm reduction and drug treatment. Issues include understanding the demographics and living dynamics of addicts; the context in which harm reduction occurs and the need to respect participants' right to decide what is best for them, rather than to coerce and mandate; and the stigma and discrimination IDUs routinely face, making them wary of service providers and, often, ineligible for Federal aid. Programs need to be low threshold, with few or no barriers to service, anonymous, safe, accessible on a walk-in basis, available in communities where need exists, and flexible in order to adapt to changing circumstances. Harm reduction programs must be seen by users as gateways to other resources, and, therefore, a vital component of the drug treatment continuum. He stressed the importance of using indigenous leader outreach models as effective means of linking out-of-treatment users to the established public health system. Recommendations to the Council are as follows:

- Insist on the inclusion of IDUs or recovering IDUs on decision-making bodies such as PACHA and in the development of Federal guidelines for clean needle programs.

- Push for increased funding for drug treatment sufficient to support treatment on demand and to provide direct access treatment slots for harm reduction program participants.
- More effectively address problems of addiction and HIV infection through a coordinated effort among the drug-using community, public health, drug treatment, and HIV/AIDS professionals.
- Continue efforts in support of harm reduction programs by calling on Secretary Shalala to make a decision on needle exchange by January 27 and to develop criteria for such programs that truly serve the needs of the participants.

Ms. Lubinski discussed the need for everyone to be held accountable for the continuing deaths from AIDS. She advised the Council to look hard at what improvement, if any, is being made within the Administration. AAC activities include efforts to get legislated treatment for pregnant women and woman with small children and change the attitude of Government toward alcoholics and drug users. She believes that agencies such as SAMHSA have been difficult to approach and not as interested as necessary in fighting drug abuse; the AIDS community lacks aggressive opposition; the abuse community is weak, fractured, and without effective leadership; little work is being done on civil rights; and the conservative community is obsessed with white, suburban teenagers. Other problems are lack of program integration, welfare reform inadequacies, inadequate oversight in women's set-aside grants, and the disproportionate amount of money being spent on basic research rather than prevention. Further, the AIDS community has little advocacy in substance abuse, does not monitor SAMHSA, and resists even modest changes in the Ryan White CARE Act to treat drug addicts. The AIDS community gave very little support to the President's budget request that $15 million be dedicated to drug abuse, and the funding was lost. Recommendations to the Council are to

- Support increased funding for drug abuse and treatment services.
- Remember that drug abusers and people living with HIV need similar services.
- Emphasize SAMHSA reorganization, to include critical subpopulations.
- Work with women and women's policy issues.
- Provide access for the community to the Administration.
- Be more challenging on needle exchange.

Ms. Greenberger noted that at a recent NIDA conference many of these issues were discussed, but there must be more dialogue between NIDA and the AIDS community. She recommended that AAC, in particular, try to get more cooperation from NIDA.

Mr. R. John Gregrich, Senior Policy Analyst, Office of National Drug Control Policy (ONDCP), described what the Office of Demand Reductions wants to accomplish: (1) take a systemic approach to deal with substance abuse, (2) make treatment an essential part of all strategies, (3) make better use of existing programs and funding, and (4) set a 5-year budget and a 10-year strategy. His recommendations focused on ending limits regarding drug treatments, reducing waiting time for treatment, reducing incidence of tuberculosis, setting national standards for health care personnel training, better identifying areas of greatest needs, systematizing resource allocations required to meet targets, and seeking more funds to study abuse behavior patterns and treatment outcomes. The goal is to treat all of the 3.6 million IDUs most immediately in need (about 40 percent can be treated with current funds). Recommendations to the Council

are to keep asking for more money for treatment and fight to expand the number of programs available. Asked about General McCaffrey's stance on needle exchange, Mr. Gregrich said that the Director is "interested in the sciences," but that he is "very concerned about deaths involved in drugs." It is a complicated, emotional issue, with people speaking passionately on each side. The Government, he believes, must continue its message about the dangers of all drug use.

Open-Microphone Public Comment, December 5

Mr. Anthony Perri and Ms. Angela Daigle, Moving Equipment/Clean Needle Program, Brooklyn, described the life of an IDU as "expendable to society," and they called for gaining a better understanding of the population through social analysis and for letting people know that they are not disposable, through effective harm reduction programs. Other recommendations were to include IDU input in setting up guidelines; make services low threshold, at the grass roots level; and open up client-based dialogues (long forced underground) in which IDUs are shown how to protect themselves from HIV, other diseases, and overdosing. It is important to remember that each community's drug scene is different, with different needs.

Mr. Louis Mazzarela, Lower East Side Needle Exchange and Harm Reduction Centers, said that HIV is manageable, but clean needles are mandatory to save lives; public education is needed to stop spreading HIV/AIDS and loss of lives.

Mr. Melvin Steven, Home Health Care Registered Nurse, ACT UP/New York, said that politicians have shifted away from addressing the real problems, that we are losing political and middle-management advocates, and that the status quo is being perpetuated. PACHA, which called for Federal funding for syringe exchange programs, should walk out in protest if Secretary Shalala does not lift the ban.

Mr. Michael K. Swarski, ACT UP/New York, voiced concerns about AIDS name/face reporting, asking whether this would actually help stem HIV transmission or get infected persons into treatment. Studies prove that name reporting deters persons from obtaining HIV screening for fear of confidentiality leaks and discrimination. With so many people refusing to be tested, the information that is being recorded is not accurate, and fewer infected persons are getting the education and treatment they need. Anonymous unique identifier codes for AIDS-related reporting would encourage more people to be screened and fewer to give false or incorrect information. He urged PACHA to recommend that the President, the CDC, and other pertinent executive and administrative bodies oppose HIV case-name reporting.

Mr. Bob Lederer, Senior Editor, *POZ* magazine, expressed concern over future policies on needle exchange and Secretary Shalala's drawing up guidelines if the ban is lifted. He urged the Council to continue to advocate for near-term resolution. (Dr. Hitt replied that this is being done all the time and that the Council needs better input from the AIDS community on these issues.) Mr. Lederer asked what steps the Council is taking toward educating the public and increasing pressure to decriminalize the possession of paraphernalia. (Mr. Anderson said that the Council has asked to talk to Secretary Shalala and Attorney General Reno to help them move forward on this matter. Recommendations have been made to the Administration, although they have not been fulfilled.) Mr. Lederer then asked if the Council had addressed the Alaska Study on Exchange

being done by NIH, and Dr. Hitt and Mr. Jeremy Landau said that PACHA has not been informed about this. The speaker's final comments concerned whether, in the absence of action by Secretary Shalala, the Administration will be aware of and act on the science. He recommended that the Council take drastic measures, such as maintaining a "Shalala death list," as *POZ* does, to increase public pressure.

Others attending the open-mike session were Mr. Joao M. DaSilva, New York City, and Mr. Randy Terter, ACT UP/New York. Dr. Hitt thanked public speakers, assuring them that the Council is not for the status quo. He asked for input on Council recommendations, preferably in writing, as to what we should be saying to whom, as well as for specifics on the Alaska study.

HIV Surveillance

An overview of HIV surveillance in the United States and proposed recommendations on information collection in the HIV/AIDS populations were presented to the Council by Mr. Anderson, Mr. Isbell, and Mr. Robinson of the Prevention Subcommittee. Mr. Anderson began with background on the current surveillance system, which consists of several methods designed to gather diagnostic and demographic information on HIV/AIDS in the population. Surveillance is, and will continue to be, done on a State-by-State basis; there is no national, legal standard, although suggestions are given by CDC and the Council of State and Territorial Epidemiologists (CSTE) about medical conditions that should be studied.

AIDS reporting occurs in all 50 States, the District of Columbia, and territories; anyone diagnosed with AIDS is reported by name to the State or local health department, which maintains name-bearing records. In this passive system, physicians are required to report these diagnoses; however, much data are lost or delayed in the interim. In some areas more active surveillance techniques are used, such as through laboratories that run certain types of tests and other health care providers and matching data. In 30 States, being diagnosed as HIV-positive is reportable by name in one form or another. This, however, excludes most of the higher population States, with the result that about 70 percent of HIV-infected people live in areas where there is no reporting. Also, because diagnosis often occurs long after infection, there are limitations on how comprehensive and timely the data are. Contrary to conventional thought, reported names do not go to the CDC. Instead, the CDC maintains a database with an algorithmic code for each person, relating demographic and diagnostic information. Another myth is that all health departments visit each diagnosed person to offer counseling and care referrals; this situation is not always true. People who believe reporting is a link into services are not always correct.
Currently, discussions are being held at the CDC and in many other organizations about changing this to a full-name–face reporting system, primarily because the AIDS case-reporting system has always been flawed as a method of understanding where this epidemic is, with information collected not always valid for making decisions about planning prevention and services. For good data for planning, a better collection system is needed; however, there is a great deal of controversy over methodology, and a major problem in public health is that there is little advocacy for better surveillance. The following are some proposed methods and the concerns about each:

- An effort is being made to adopt **the reporting of all HIV infections by names** as the national standard because it would provide a much larger data set than is now available.

Many argue that these data will provide better tools to make decisions; others think that it will scare people away from the testing process and, subsequently, health care. The Council needs to challenge the CDC to produce the best possible information on what the impact will be on actual testing behaviors in changing to a name-reporting system. We ask that the needle exchange decision be driven by the science; we have to ask the Federal Government to do the same with surveillance. Results of ongoing studies show some measurable disincentive for testing in name reporting, but it is not known how significant or uniform that is across affected populations. As we move into a paradigm around care based on early intervention and getting people into treatment, this alternative must be studied seriously. If it increases the number of cases going into the health care system, it will be useful; if it deters them, it will not.

- **Computer-generated unique identifiers** based on combinations of letters and numbers rather than names is an alternative. Trials are being done in Maryland and Texas, and other countries have used it, with two issues arising: How much will it cost, and how accurate are the data? Again, the Council must challenge the CDC to show data about what works and what doesn't, as well as potential costs in terms of staffing, computer programming, etc. One argument against the use of identifiers is that the accuracy will not be as high as with name-based reporting; another is that the discrepancy will be of little consequence and that this will give us a broader picture. Another concern is that many infected people do not have the documentation, such as a Social Security number, to generate the identifier.

- Another method is to collect raw data without any identifiers—**anonymous reporting**. This strategy has been done in New Hampshire and has proven to have flaws. A major concern is over multiple markers, with some people being tested more than once, which can invalidate findings. Advocates say that double markers do not matter, that this system provides general ideas of where the epidemic is going. It works better in a large urban area, less well in smaller populations where duplicate figures can skew results significantly.

- The **classic individual case reporting** can provide valuable detailed information on the epidemic; however, this tactic cannot be used to obtain an overall picture of the AIDS population, because only certain types of people have the self-confidence and wherewithal to get into these systems. For example, IDUs seldom enter these systems, which means that resources will not be extended to certain populations.

- Among other testing and information-gathering tools that have been used is the politically vulnerable **blinded seroprevalence** study, in which blood samples are taken anonymously from neonates to find out whether mothers were infected. Because of political pressure, that method has been stopped in some places, losing one of the few population-based samplers. Many ethical issues are involved, and care must be taken not to abuse this information and to offer individuals volunteer testing and access to health care. This is a valuable way of getting information not available from other sources. Sampling of this type is happening in many places, for example, through the Family Surveys of the CDC, in some sexually transmitted disease (STD) clinics around the country, and in methadone

clinics. This method merits consideration, and it is recommended that the Council encourage members of Congress who support it.

Many things can be used creatively with and in communities to obtain data about where in the community the disease is located. For example, work can be done with sentinel sites to help them do data collection and encourage additional testing. Whatever directions we go in, those methods that provide broad-based, valuable information about HIV incidence prevalence in particular populations must be part of the equation. The definition of what surveillance is must be expanded, and the Council must become an advocate for obtaining good data that local, State, and national groups can use to make decisions about where to put resources.

Mr. Robinson commented on the process of collecting the data for this report, noting that copies of all documents with recommendations on surveillance from the various national and community-based organizations were supplied to the Council. The Subcommittee membership had diverse opinions on this matter; however, it came to a consensus that the CDC has not laid out its case for what is needed to accomplish its stated objective: to give a good estimate and sense of where the epidemic is now and the communities it is moving toward. Following the science, the Subcommittee developed three recommendations that ask the CDC to devise a comprehensive analysis of the impact of different surveillance systems on seeking/acceptance of HIV testing, to give scientific justification for the chosen method and a detailed strategy and implementation plan, and to address key issues of confidentiality protection, public information on the system, adequate funding, technical assistance to those agencies that will be conducting data collection, and guarantee of access to appropriate care for all individuals who test positive.

Council members agreed that the Subcommittee had done an excellent job of compiling the facts and that information collection is needed for prevention and health care planning. A number of members, as well as guests, discussed the fears inherent in name-based reporting and the problems this can cause in the system. Others spoke about the discrepancies and inadequacies of the facts presented by the CDC to date in their rationale for use of this system. Mr. Henderson noted that keeping names at State or local levels scares him even more than having them maintained by the CDC because of the opportunity for breaches of confidentiality and discrimination. If names are on file locally, what is accomplished by sending anonymous material to the CDC? Mr. Anderson said that the local health department system of maintaining names has a very good record, with only one documented breach of those systems (Florida). In answer to this, Mr. Henderson pointed out that in the early days of the system, persons were not reported until they were obviously very ill; with HIV reporting, this is not the case, so that the potential of having name disclosure becomes much more problematic for the test subjects. Dr. Gutierrez, other members, and one guest stressed that the Council must go on record against name reporting, no matter what evidence the CDC provides for its use, because discrimination does exist. Putting some other, more innovative strategies into the recommendation was endorsed, providing proper documentation of their safety and efficacy is presented.

Mr. Bollman asked if there is any evidence in the 30 States that name reporting has resulted in better HIV planning; and Mr. Anderson said some evidence points to effective use of the data for awarding service grants, although some places have good data but use it ineffectively. Ms. Gerus said that this issue is now being debated in the State of Washington and that the fear of misuse is

not directed at health departments, but at legislators. A possible solution is a Federal prohibition against any use of these names. One proposed system is to have names reported to the State public health department, coded, and then destroyed and never linked with the identifiers. Also, coded identifiers are not without their own set of problems because people can break the code.

Extenuating factors in data collection methodology are the definition of being HIV positive, the need to put some parameters on this for purposes of having more valid comparative information, and the monitoring of treatment resistance. Comments also were made about the efficacy of numbers that could be obtained in totally anonymous testing and whether ways to prevent the inclusion of multiple markers numbers could be developed. (One suggestion was the use of a pretest questionnaire.)

Mr. Isbell noted that New York's health department had done an excellent job in maintaining confidential records. He also commented on the problems created by use of a flawed epidemiologic approach worldwide, which caused the gross underestimate of the number of people with HIV infection, significantly lowering levels of care provided to affected populations. Surveillance is extremely important to prevention; the main need is not for names, but for other information needed to craft a rational, effective public health response to the epidemic. The reasoning behind the Subcommittee recommendations is to try to shift the focus of the debate in order to allow movement toward development of adequate surveillance. Mr. Anderson said that the intent was to indicate that no changes in the current system should be made until an analysis of impact had been completed.

Dr. Weniger noted that he had not heard any argument for name reporting and offered one of his own: the opportunity to offer counseling and assistance to identified people. Ms. Aragon said that names are not needed for linkages, funds are.

HIV/AIDS Meeting in Cuba

Mr. Landau, who spent 3 weeks as a visiting scholar in Cuba, reported on an international HIV/AIDS meeting held in Havana and his observations of the country's health care system, which he described as advanced and based on choice. Cuba has a very low rate of HIV infection, primarily because of early intervention and testing programs, the U.S. embargo that limits tourism, condoms made available by the Government, and ongoing clinical and vaccine trials. This visit precipitated the proposal of a Council recommendation that the embargo be lifted in order to allow medical supplies to be sent into Cuba. Members, however, agreed that its mandate did not extend into this area, which some called State Department business, and that including unrelated recommendations of this type diluted the overall efforts of PACHA to make recommendations concerning the primary issue of HIV/AIDS. The recommendation was tabled (see below).

Subcommittee Meetings, December 5

Communities of African and Latino Descent Subcommittee: Members present were Ms. Debra Fraser-Howze, Chair; Ms. Aragon; and Mr. Robinson. Also present were Mr. Montoya and Mr. Matthew Murguia. Discussions focused on the Progress Report draft, recommendation assessment, and followup actions.

Discrimination Subcommittee: Members present were Ms. Gerus, Mr. Henderson, and Mr. Johnson. Discussions centered on the Progress Report and recommendation assessment and followup.

International Subcommittee: Members present included Mr. Fogel, Chair. Also present were Paul Boneberg, Global AIDS Action Network (GAAN), and Glenda Simmons, ONAP. Discussion included Progress Report input and recommendation development and assessment.

Prison Issues Subcommittee: Members present were Mr. Landau, Chair; Dr. Abel; and Dr. Cade. Others present were Ms. Rebecca Adams, National Minority AIDS Council; Mr. Willie Byrd, HIV Community Coalition (HCC); Ms. Lin Hagood, CURE; Ms. Aurie Hall, DC Prisoners' Legal Services; Mr. Jason Medina, National Puerto Rican Coalition; Mr. Anthony Rawls, Hopkins House Health and Wellness; Ms. Yvonne M. Veney, Baltimore City Health Department, Jail Outreach Program; and Jackie Walker, American Civil Liberties Union (ACLU), National Prison Project. Outside attendees provided input on prison issues to the Subcommittee, and discussion included Progress Report and recommendation assessment.

Subcommittee Meetings, December 6

Prevention Subcommittee: Members present were Mr. Robinson, Mr. Anderson, Ms. Billings, Mr. Fogel, Ms. Gerus, Mr. Isbell, Ms. Runions, and Mr. Sasser. The primary purpose of the meeting was to revise Subcommittee recommendations on surveillance.

Research Subcommittee: Members present were Dr. Alexandra Mary Levine, Chair; Dr. Cade; Mr. Greenberger; Dr. Hitt; Mr. Johnson; Mr. Miramontes; and Dr. Weniger; as well as Mr. Murguia from ONAP. Discussion centered around the drafted recommendations and a plan of action to obtain necessary information before they are submitted to the Council for acceptance.

Services Subcommittee: Members present were Mr. Bollman, Dr. Abel, Ms. Aragon, Rabbi Edelheit, Dr. Gutierrez, and Mr. Lew. Also present were Mr. Blackwell, Ms. Cooper, Mr. Milanes, Mr. Bob Soliz, and Mr. Summers. Discussion focused on Progress Report and recommendation updates.

Communities of African and Latino Descent Subcommittee: Members present were Ms. Fraser-Howze, Ms. Aragon, and Dr. Gutierrez. Also present were Monsanto R. Als, Special Assistant to Ms. Fraser-Howze, Black Leadership Commission on AIDS (BLCA); Mr. Milanes; and Mr. Murguia. Discussion focused on Subcommittee goals, priorities, and plans for the March meeting.

Discrimination Subcommittee: Members present were Mr. Henderson and Mr. Johnson.

1997 Progress Report Update/Discussion, December 6

Most final changes were made to the Report, and distribution and development of talking points for use by Council members were discussed. Distribution was set for December 8, through the CDC National AIDS Clearing House, which will put the Report on its Web site and send an

announcement to all agencies and national and local AIDS organizations. ONAP will release a statement to the media concerning the issuance of the Report and its response to the contents, with a copy of the release being submitted to Council members. Mr. Montoya, who will coordinate these efforts, encouraged Council members to distribute the Report personally to any other interested parties and State organizations. Dr. Weniger asked that the Clearing House make it easier to find on the Web than the previous Progress Report. Dr. Hitt asked members to submit key questions that will likely be asked by the press and others, with appropriate responses to him or Mr. Montoya, and ONAP will distribute these to the Council.

Medicaid Expansion Update

In view of the ongoing controversy over the recent news that Medicaid expansion will not move forward, Ms. Thurman said that she and Mr. Bollman each had talked to Ms. DeParle, who apologized for the misunderstanding and assured the Council that this question is not dead. ONAP was to release a statement as soon as possible to address the issue, and Vice President Gore had already publicly stated that these efforts had not ended. Ms. DeParle said that the initial method studied for expansion of Medicaid coverage to people affected with HIV/AIDS had failed; however, HCFA is continuing to seek other ways of achieving coverage, including potential stopgap expansion of ADAP funding and pilot programs at the State level to try methods such as covering drugs at earlier stages of the disease. The agency will study this on a State-by-State basis. ONAP will collect data needed to determine cost-effectiveness and continue to look at Medicaid in various venues. In addition, she and Dr. Hitt will meet with the Chief of Staff to the President, Erskine B. Bowles, to discuss this and other issues, including needle exchange, and have requested that the President meet with the Council within the next 6 months. The positive effects of this misunderstanding are that it pushes the Administration to talk more aggressively and directly with pharmaceutical companies to get drug prices down and unites similar interest groups, such as those with other long-term, disabling illnesses.

Members urged that the statements that come from ONAP and the White House must have some real meat to undo damage caused by these stories and that concrete steps must be taken. This should include an agreement by the HHS Secretary to meet with the Council on related issues. They asked HCFA to provide feasibility study numbers and assumptions, some of which may not be accurate, and to move ahead on its commitment to establish an ongoing internal/external working group to cover this issue. Mr. Bollman pointed out that there is no moral difference between providing a potentially life-saving therapy and one that is life enhancing, and Dr. Levine noted that it would be morally unacceptable to withhold insulin from a diabetic, no different than withholding HIV treatment. Ms. Thurman agreed that the heat should be turned up and that it is very important for the Council to apply this kind of pressure to the agencies and Administration.

The Council urged that a public comment be made by HHS explaining the misunderstanding and clarifying the issue, and several members noted that this situation proves that serious problems exist at HHS and with the Secretary. Further, the President should do something about an employee who is not carrying out his wishes. Ms. Thurman cautioned that ONAP does not want to foster internal push–pull. A number of members expressed frustration at the lack of communications from the Government, and Ms. Miramontes asked to be put on record as saying she was “sick of not getting answers.” She pointed out that the Council repeatedly asks for

comments and answers from various agencies but rarely gets them; if someone talks, it's off the record, and they won't put it in writing. This issue has been a problem not only with Medicaid, but research, vaccine, microbicides, and other issues. Mr. Isbell stated that the Council has no doubt about the Vice President's sincerity or the hard work of ONAP, but that there is major unhappiness about the lack of response from the HHS Secretary. The Council called for concrete proof of the existence of a "Plan B" for Medicaid expansion, giving the example of New York State's achievements through the State waiver process. Mr. Bollman urged that the Council step up its expectations from the Secretary and asked that this issue be put on the agenda for March. Others agreed. Mr. Anderson said that the proposed national dialogue also had stalled in the Secretary's office and should be moved forward. Mr. Fogel, who had suggested in the last meeting that the Council resign in protest if this attitude persisted, said that, perhaps, the Secretary should resign instead. For the record, Ms. Thurman said she will work on setting up meetings not only with the Secretary, but with the President as well, and will try to move the national dialogue process ahead.

Open-Microphone Public Comment, December 6

Mr. Perri followed up on his earlier comments by suggesting that the Council, in its communications and recommendations regarding services and prevention, look at these as a whole, rather than separate entities, and that drug treatment programs should include harm reduction as part of the system. He also suggested that Prevention and Services Subcommittees attend and endorse the annual syringe exchange conference to be held in Baltimore this spring.

Subcommittee Reports December 6 and 7

Communities of African and Latino Descent Subcommittee: Ms. Fraser-Howze reviewed the Subcommittee's mandate to critically review and make recommendations on the two ethnic communities representing the highest percentage of new infections in America. Specific goals are to examine HIV/AIDS relative to its unique effects and outcomes within these communities; address needs and recommendations in keeping with these populations; and make recommendations for inclusion in the Council's deliberations. Priority areas to be addressed for the March meeting are AIDS as a multigenerational epidemic for these communities, issues of orphans, family needs and services, the impact of heterosexual transmission, and epidemiology and surveillance data and how they are collected, broken down by communities. Specific areas targeted for recommendations include the following:

- Adequate reporting to community-based organizations for local planning and services.
- State and territorial patterns, trends, and projections and a move from behavioral to actual community-centered epidemiology.
- Substance abuse as a stand-alone epidemic and host for other diseases.
- Gay men of color and the perception of them in the communities, and the need to redefine the gay communities of African and Latino descent as to trends, patterns, family issues, and socialization, often different than in other parts of the neighborhoods and communities.
- Funding and policies and the Federal response to these communities, which need to be multi-tiered within the overall AIDS community.

Two other issues that will be integrated into all areas are welfare reform and access to treatment. In preparation for a full Council presentation, the Subcommittee is also including issues of leadership, volunteerism, and broader inclusion of Latino and African communities' perspectives in the deliberations of PACHA. Ms. Fraser-Howze said that the Subcommittee will make an outrageous effort to put all of these topics into an integrated form so that the panels will be cohesive, keeping within the allotted time frame and allowing for a question-and-answer period. She also pledged that the recommendations will not attempt to micromanage agencies.

The suggestion was made to invite members of the President's Advisory Council on Racial Relations in America to the March meeting, and it was agreed that the Chair and Vice Chair will be asked. Ms. Fraser-Howze mentioned that ONAP is deliberating on having a summit on communities of color and volunteered that the Subcommittee will be willing to participate in such a meeting. Members also will be involved in other meetings with Presidential councils, including one on volunteerism chaired by Retired General Colin Powell.

Prison Issues Subcommittee: Mr. Landau said that the primary work of the Subcommittee recently has been on the issues of the Progress Report and thanked Dr. Cade for his editorial work on the document. Other ongoing areas of concern include model programs within prisons; the CDC draft report on prisons; international issues on prison reform; and the Federal Bureau of Prisons (FBP). The Subcommittee is working with Ms. Kathleen M. Hawk, Director of FBP, at the Department of Justice on oversight of the FBP and hopes to set up Federal prison site visits soon. Contact has been made at DOD, with Dr. Robert Michael Rankin as point person in targeting conditions in military brigs and jails. At the CDC the Subcommittee's primary contact is Mr. John Myles, who is as anxious as the Subcommittee is to have access to prisons for prevention and surveillance projects. Internationally, the Subcommittee has sought models of prison reform and prevention/treatment programs in other countries and through the UN; however, this is not a major priority until domestic issues are settled. Meetings with key officials at the Department of Justice and CDC are being planned to discuss possibilities for areas of improvement in services and to attempt to set up direct monitoring on the implementation of the NIH treatment guidelines in Federal prisons. An invaluable resource has been letters from infected inmates, which indicate that many are being prohibited from personal testimony in their own compassionate release hearings and are receiving improper treatment and information about therapy.

International Subcommittee: Mr. Fogel said that the Subcommittee's prime focus has been the Progress Report, with particular interest in following up on the failure of the Department of State to assess and analyze its 1995 International Strategy. The hope is that the Department will recognize the severity of the global AIDS crisis and begin to develop a strategy for the next 2 to 3 years. International recommendations were discussed and voted on by the Council (see below).

Discrimination Subcommittee: In Mr. Benjamin Schatz's absence, Mr. Henderson presented a report that outlined findings of the Subcommittee following its recommendation that mandatory HIV testing and/or discriminatory policies of specific agencies be either rescinded or justified through a compelling health rationale. He noted that it had taken a long time to obtain adequate

information to make assessments and thanked Mr. Montoya for his assistance in this area. The Subcommittee's assessment is as follows:

- The **Job Corps**, in response to the recommendation, changed its policy on HIV testing as a special requirement to part of its routine entry process and is retaining 80 percent of those who test HIV-positive, providing counseling and referral to medical care. The Corps is to be commended.
- The **DOD** maintains stringent standards for appointment, enlistment, or induction; however, policies regarding HIV-infected individuals are comparable with those for people with similar medical disqualifications and are not, therefore, discriminatory. Its policies regarding those subsequently infected are exemplary and to be commended.
- The **U.S. Foreign Service** was the least responsive agency, saying that they have a worldwide availability requirement for placement, which excludes most people with chronic illnesses. The Subcommittee believes that more data are needed to prove the practical application of this placement criteria. HIV-infected applicants and those who subsequently become HIV-infected, however, appear to be treated comparably with those with similar serious medical conditions, although more clarification is needed on this point.
- The **Peace Corps** requires HIV testing as part of pre-entry assessment, and HIV is one of a group of serious medical conditions that prohibit entry. There is, however, a deferred entry category that allows entry to people with other, comparable medical conditions, and the Subcommittee has suggested that, in light of the new therapies, the Corps might want to revisit this possibility for HIV-infected individuals.
- On the currently discriminatory guidelines for **health care workers**, the Subcommittee understands that there is a meeting on February 11 for review of the CDC's revised and, it is hoped, less discriminatory guide.

The Subcommittee presented one recommendation, which was tabled until March (see below), because most Council members thought that they did not have enough background to assess the statement. It was the opinion of some Council members and visitors that these policies, particularly in the military, are discriminatory toward people with all progressive diseases.

Services Subcommittee: Mr. Bollman reviewed Subcommittee activities and recommendations, which were written by Ms. Aragon (budget), Mr. Lew (drug pricing), and Mr. Bollman (access to treatment). Activities other than the recommendations of the Subcommittee include the following:

- **National policy dialogue**: Active encouragement is needed for a continuing national dialogue, and the Subcommittee is working with ONAP to move this forward. Mr. Lew has discussed possible venues with Dr. Chang of Kaiser, and the Subcommittee has heard from Mr. O'Neill that HRSA will survey local planning councils to identify those that have begun to address some of the large systemic change issues.
- **Managed care**: Discussion is under way with ONAP and the White House on how the recently released recommendations of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry can be codified through legislation. Dr. Levine noted that clinical research is not taken into consideration in managed care and that someone should be vigilant to watch for this issue.

- **Youth:** The Subcommittee proposed to convene a full Council presentation for the March meeting, with input from Mr. Harvey and Mr. Sasser. (Following later discussion, it was decided that this presentation would be held in June.) The White House Report on Youth will be provided by the Subcommittee to members for review.
- **Transition-to-work:** Rabbi Edelheit and Mr. Johnson are spearheading an investigation of possible policy steps and reforms that might ease the transition for people who can return to work because of the new therapies. The Subcommittee hopes to have a report and recommendations at the March meeting.

Research Subcommittee: Dr. Levine said that a great deal of work had been done by the Subcommittee on vaccine issues and that much has been accomplished—with much credit due Ms. Miramontes and Dr. Weniger, whose efforts resulted in contact with major researchers worldwide who shared progress, problems, and information. The Subcommittee, however, has decided that it does not have sufficient background to totally substantiate its proposed recommendations, which will be tabled until March. Particularly complicated are matters of science, policies, and who should take the lead administratively in vaccine issues. Major controversies exist among the leaders in every aspect of vaccine research. There are no easy answers and the concept of ego hinders progress. The Subcommittee hopes to resolve a number of issues through the following action plan:

- All Council members are asked to obtain responses from major sources—within NIH, CDC, DOD, communities of affected individuals, and international entities—on the Subcommittee's recommendation document.
- The Subcommittee will meet, with any other member who is willing, through four conference calls of 2 hours each (10–12 a.m. Eastern time, weekends), to deal with specific items in the document.
- A meeting called for by Secretary Shalala will be held at the White House in February, in which the Subcommittee will meet with major representatives from the various constituencies—e.g., Dr. Harold E. Varmus, Director of NIH, Dr. Baltimore, and Dr. Peter Piot, Executive Director of UNAIDS—to review the issues of the document.
- A revised recommendations document will be presented to the Council in March, at which time the Subcommittee hopes to convene a plenary session to focus on the document and the controversy around it.

Although the NIH portfolio of basic research has been moved forward successfully, other components in the development process are not in place; e.g., who will deal with support issues, pay for vaccine for the Developing World, and large-scale field testing. It is necessary to bring in the expertise of other agencies, and although NIH claims there has been an ongoing dialogue with these other entities, it has not happened. The Subcommittee needs Council input on the administrative framework on which a vaccine could be generated, rather than the scientific issues. In order to have participation from as many Council members as possible, Mr. Montoya will send out a grid of potential conference call meeting dates, and the Subcommittee will establish a call schedule based on availability of the most members. Background information will be sent to the whole Council so that it can make informed decisions.

Prevention Subcommittee: Mr. Robinson led a discussion on the Subcommittee's proposed letter to President Clinton urging immediate determination of the needle exchange issue within the HHS by January 27, 1998. The letter stressed the urgent need to lift the moratorium on Federal funding, with interim guidelines to be developed prior to the April 1, 1998, moratorium deadline. The letter, adopted unanimously, is to be hand delivered December 8 to the White House Chief of Staff, and Council members were told that they could share contents of the letter with outside sources immediately. Prevention Subcommittee recommendations on surveillance were described as complex, controversial, and time-consuming, and there ensued a great deal of discussion on this issue. Recommendations were accepted as amended with a vote of 16 for, 4 against, and 1 abstention (see below).

Open-Microphone Public Comment, December 6

Specialist David Miller, Army National Guard, Veterans Against AIDS, ACT UP/New York, Mt. Sinai Community Advisory Board (CAB), a veteran of Desert Storm, holder of three Purple Hearts, and HIV-positive, called the policies of the DOD discriminatory. Specialist Miller has been excluded from HIV clinical trials because he has the unspecified symptoms of Gulf War sickness as well as HIV. There is no AIDS service organization in New York City with outreach to veterans, no AIDS treatment/education program for veterans, and no representation on community constituency groups. Veterans are, however, organizing, and he demanded that PACHA take veterans' issues into account in its recommendations to help obtain the care, attention, and benefits that they need.

Ms. Jennie Gibbs, ACT UP/New York and Mt. Sinai CAB, commented on the importance of using CABs and AIDS Clinical Trials Groups, (ACTGs) to let the AIDS organizations know about Council meetings and activities, so they can be there and disseminate information down to the community. Dr. Hitt asked for suggestions about getting the message out to groups, and Ms. Gibbs suggested Web sites from AIDS clinical trials and ACTGs, local AIDS Service Organizations (ASOs), and newsletters. Dr. Hitt said that this information does go out on the Web and through mailings to CAB chairs.

PACHA's Second Progress Report, Final Version

On December 7, PACHA adopted the Second Progress Report of Government response to its recommended actions. The 12-page document begins with a preamble highlighting progress by the Administration since 1993, primarily during President Clinton's first term, and outlining areas that still need major effort, because the Federal response to AIDS has stalled in recent months. These areas include inadequacy of staff and status for ONAP; risk of losing funding for ADAP; lack of action on Medicaid expansion; lack of a coherent strategic national plan of action; inadequate funding for HIV prevention; and inadequate access to new, effective medications and treatments. The Council called for bold and courageous leadership within the Administration to bring the epidemic to an end and a renewed dedication to action. Following the preamble are assessments by Subcommittees of specific problem areas.

Prevention concentrates on the need for a national prevention strategy; disproportionate funding; failure to make optimum use of the limited investment in HIV prevention through outdated

restrictions; need for better targeting and education of youth at high risk by the CDC; and better tracking of CDC expenditures in addressing needs of persons at greatest risk. The Subcommittee commends the leadership of Dr. Helen D. Gayle, Director of the National Center for HIV, STD, and TB Prevention, CDC, in the CDC's HIV/AIDS programs.

Research commends the President and Vice President on continuing involvement and leadership efforts in expediting the work of developing an AIDS vaccine and the Food and Drug Administration (FDA) for its efforts in addressing issues of women and children infected with or affected by HIV/AIDS and publishing proposed guidelines on inclusion of both genders in drug development and analyses. Although some progress has been made in microbicide research, particularly in the allocation of $100 million in funding from the HHS, little else has happened. Some progress has been made by NIH in rapid translation of breakthrough findings into clinical practice; however, mechanisms are still lacking in behavioral and social sciences. Other recommendations that need action concern funding, data collection, coordinated involvement of all Federal agencies, and collaboration with the private sector and international community.

Services' assessment of leadership on funding for HIV treatment, care, and housing services is that it is inadequate; on expansion of Medicaid coverage, the Administration has sent out mixed and conflicting messages and Secretary Shalala has not given the personal leadership needed. Some success is seen in drug cost reduction, although new therapies are still prohibitively high. On monitoring of access to therapies and associated medical services in private managed care health systems, the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry has released recommendations, endorsed by the President, that are sensitive to the needs of people with HIV/AIDS. Secretary of Labor Alexis M. Herman and Secretary Shalala and members of the Commission are commended for this. Despite significant efforts to promote a national policy dialogue, progress has stalled, and this needs to be moved forward. There is also concern that the IHS has not developed adequate HIV/AIDS prevention and treatment programs and communications with Native American organizations.

Discrimination assesses mandatory HIV testing and/or discriminatory polices of various agencies, as summarized in its Subcommittee report above.

Prisons stated that, although the Department of Justice has been forthcoming with good data in the area of Federal prisons, the FBP has not provided complete or satisfactory information to ensure that the well-being of inmates in the Nation's prisons is not at risk. Essential programs that currently are nonexistent or inadequate include discharge planning, prerelease case management, access to comprehensive, current medical therapy during incarceration, realistic programs for substance abusers linked with HIV infection, and availability of protective sexual barriers. The FBP needs to change its policies and administer them uniformly.

International states that, with the global epidemic being far worse than predicted and a concurrent threat to the economic and strategic interests of the United States, the inclusion of HIV/AIDS on the agendas of bilateral and multilateral meetings is mandatory. The dialogue between USAID and nongovernmental organizations (NGOs) is to be commended; however, the Department of State needs to evaluate its 1995 International Strategy on HIV/AIDS and develop a new strategy. The United States must consistently and affirmatively reestablish its commitment to lead a worldwide effort to reduce the rate of new infections.

New PACHA Recommendations

Proposed recommendations adopted during the meeting include the following:

Prevention: Recommendations on national HIV surveillance were based on interim fact-finding and a presentation to the Council by Subcommittee members, as follows.

In order to better monitor progress toward the President's declared goal of decreasing the number of new infections (incidence) each year and to better target prevention, services, care, and research efforts, the Council is strongly committed to improving the accuracy and usefulness of surveillance systems for the HIV/AIDS epidemic.

To ensure that whatever systems ultimately designed fulfill the desired needs, we are convinced that more considered research must be done.

The Council expresses its strong reservations regarding the use of a national HIV names reporting surveillance system. However, our concern is not simply Names Reporting versus Unique Identifiers, but rather what is(are) the best way(s) to collect meaningful, accurate data, in the least intrusive manner, that will enable us to bring this epidemic to an end.

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

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

    It is essential that adequate data about the prevalence and incidence of HIV infection be available to policymakers, service and prevention planners and providers, and various advisory and planning bodies at the national, State, and local levels. Only with such accurate data can we make appropriate resource and programmatic decisions necessary for effective prevention and care programs.

    We recommend that such a plan address scientifically valid information about HIV incidence and that prevalence will be obtained, with particular emphasis on understanding the spread of HIV, stratified by race/ethnicity, age, gender, geography, sexual orientation, and risk factors. In addition, we believe that efforts

also are warranted to utilize better laboratory methods for newly diagnosed persons with HIV infections to classify the clinical stage of the disease and resistance to antiviral agents. Ongoing efforts should be enhanced to monitor changing patterns of opportunistic infections and natural history of HIV disease in light of treatment advances.

In development of such a plan, we recommend that the CDC recognize the inherent limitations, weaknesses, and potential for abuse of any HIV case surveillance system (named, unique identifier, or anonymous) and instead use much more innovative methods to collect and interpret data from a wide variety of sources necessary to fully characterize the complex HIV epidemic. Specifically, we urge expanded use of such currently underutilized tools as blinded seroprevalence studies, mathematical modeling techniques, sentinel and random serosurveys, a greatly enhanced portfolio of behavioral research and behavioral surveillance activities, and other similar, innovative methods. Such activities will require a well coordinated strategy and a great deal of scientific creativity. Enhanced funding and technical assistance activities to allow States, localities, and various planning bodies to effectively utilize such data are essential and must be linked to these innovative efforts.

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

- Identification and implementation of steps to retain and expand anonymous testing options in all jurisdictions receiving CDC prevention and surveillance funding;
- Development and incorporation of confidentiality protection standards as part of any reporting system, including model laws and regulations, comprehensive record-keeping and database procedures, standards on use and matching of data sets, and penalties for improper use;
- Development of appropriate public information efforts to explain the system, especially to members of affected communities and health care providers;
- Adequate funding to States and local jurisdictions for the work of collecting, maintaining, and interpreting the collected data;
- Technical assistance to health departments, community planning groups, Ryan White planning bodies and consortia, and other appropriate groups on the meaning, limitations, and potential uses of this data; and
- Identification of steps to guarantee access to appropriate care and services for all individuals who test positive in any system.

Services: A new Recommendation builds on the Council's previous Recommendation regarding Federal funding for HIV/AIDS services (IV.A.1).

V.A.1 The Council urges the President to include in his FY 1999 budget request to Congress adequate increases in funding for Federal HIV/AIDS programs, in order to appropriately address the increasingly complex health and service needs of

people living with HIV/AIDS in America. In particular, the Council strongly recommends substantial increases in funding for the AIDS Drug Assistance Program (ADAP) and other medical and support services provided through the Ryan White CARE Act, the Housing Opportunities for People with AIDS (HOPWA) program and other housing programs serving the homeless and persons with disabilities. In keeping with the President's goal of reducing the number of new HIV infections until there are none, the Council also urges the President to propose a significant increase in Federal funding for HIV prevention activities. The Council also strongly supports additional funding for substance abuse treatment services funded through the Substance Abuse and Mental Health Services Administration (SAMHSA). The President has already committed new dollars for vaccine development and microbicide research as well as for other relevant HIV/AIDS research interests. However, despite these increases, the monies committed remain inadequate, especially in the area of vaccine development. We urge the President to continue to increase funds for AIDS research in the FY 1999 budget. These budget increases would reflect this Administration's continued commitment to AIDS, as well as its stated commitment to expand access to early coverage for promising new therapies.

New Recommendations based on Council assessment of earlier Recommendations involving ADAP and drug access and pricing include the following:

V.B.1 We encourage HRSA to fully explore the strategy by which States can purchase health insurance coverage or continue health insurance payments using ADAP funding, when this is the optimal cost-saving strategy.

V.B.2 HRSA should strengthen technical assistance in the area of drug price negotiation to all State ADAP programs that have not achieved comparable prices from the ODP Section 602 program.

V.B.3 The price of drugs is directly related to the cost that taxpayers and other payors must incur and is directly related to the access of people with HIV/AIDS to the new therapies. We urge that the Vice President continue his work with pharmaceutical companies, in collaboration with ONAP. We request that he vigorously assume a leadership role in reducing the price of HIV drugs.

One recommendation is based on Council assessment of access to treatment for HIV-infected persons:

V.B.4 We urge continued and intensified leadership from the White House (the President, the Vice President, and the Office of National AIDS Policy) to explore all possible options for expanding access to the new therapies and associated medical services. These efforts should be directed from the White House itself, through a multiagency policy team; this will provide the strong evidence of a political will to continue this effort and the technical proficiency to leave no possible alternative unexamined. In particular, we urge continued efforts to develop a national

Medicaid expansion pilot program, which could go beyond the current "budget neutrality" paradigm, testing the proposition that we should count all budget savings from any source associated with the new interventions and over the lifetime of care. We also urge the White House to engage Governors and their State officials in the development of Medicaid waiver applications (modeled after the fast-track process used early in the Administration to encourage welfare reform waiver applications). In addition, as reflected in the Council's recommendation regarding the FY 99 budget, we must have increases in ADAP and other Ryan White CARE Act titles to expand access now for those who can benefit from the new therapies.

Prisons: The Council recommends that the Director of ONAP convene a community and Government meeting on AIDS in Prisons as soon as possible. Key constituencies should include advocates and experts, ex-offenders, representatives of relevant Government agencies, correctional health providers and departments, international experts, and other relevant persons or organizations.

International: The Council recommends that the President direct the Department of State to promptly conduct an evaluation of the actions and outcomes resulting from its 1995 "International Strategy on HIV/AIDS" and to provide a copy of the assessment to PACHA as soon as possible.

Tabled Recommendations

The Council voted to table the following recommendations until the March meeting, asking that more information be provided to better substantiate the need for and/or content of the recommendations.

Discrimination: The Administration should work with Congress to create stronger projections for medical privacy and should revise legislative proposals on the subject to permit law enforcement authorities access to patient records only after they have obtained a warrant or meaningful and informed patient consent.

Prisons: The Administration should direct the CDC to conduct a study of HIV prevalence in all prisoners within the Federal correction system. Specific funding should be earmarked for this project. The data collected should be used to plan for improving health and psychosocial needs of inmates, to develop appropriate prevention strategies, and to make informed decisions with regard to funding allocations.

International: The Council recommends that the President support efforts in Congress directed at amending the Embargo Authority in the Foreign Assistance Act of 1961 so that any such embargo shall not apply to the export of any food, medicines, medical supplies, medical instruments, or medical equipment, or to travel incident to the delivery of food, medicines, medical supplies, medical instruments, or medical equipment. The embargo of such supplies contributes to the suffering of persons with HIV/AIDS and other diseases and is contrary to international humanitarian principles by which the United States should abide.

Research:

Background: Since late 1995, the Research Committee of PACHA has devoted significant time and effort to issues concerning the development of an AIDS vaccine. The Committee consulted with numerous experts in AIDS research and vaccinology and solicited and received written input from these and other experts. The Committee focused on identifying the obstacles and impediments to an AIDS vaccine and analyzed the complex, diverse issues that must be addressed in order to achieve the President's goal of an AIDS vaccine within a decade.

Comprehensive Plan: It has become increasingly clear that a comprehensive plan is essential to achieve the goal of an AIDS vaccine and that no Federal agency, national or international organization, nor any private-sector corporation alone has the expertise, the capacity, or the resources to accomplish all the steps needed to achieve this goal. These include, but are not limited to, (1) basic scientific research in order to better understand the human immune response to HIV; (2) product development of vaccine candidates suitably manufactured and approved for human testing; (3) small-scale (phase I and II) clinical studies in humans to determine the safety and immune response of candidate vaccines; (4) large-scale (phase III) longitudinal field trials to determine efficacy; and (5) resolution of various supporting issues, such as product liability, incentives for private research and development investment, and financing mechanisms to ensure access to successful vaccines worldwide.

Leadership: It has also become obvious that strong, visible, high-level leadership is desperately needed to accelerate the vaccine effort by overseeing the development and implementation of a comprehensive plan and by elevating the vaccine effort to the highest priority in order to stop an epidemic that continues to infect 8,000 to 10,000 people every day worldwide. The Vice President has the necessary interest and standing to engage the cooperation and collaboration of the private sector, the international community, and the appropriate Federal agencies in order to oversee the development of an effective plan. The Office of the Vice President also has the authority to hold the relevant Federal agencies accountable for their vaccine efforts and their willingness to collaborate with other essential agencies, organizations, and participants.

To complement the Vice President's role, the President should appoint a respected and accomplished leader in public health/medical science as the National Director for AIDS Vaccine Development. This should be a full-time position in a semiautonomous environment sufficiently high in the Government hierarchy to (1) be an advocate for AIDS vaccine development, (2) have fiscal authority over all government AIDS vaccine efforts, (3) provide strong leadership and coordinate all government organizations involved in this field, (4) maintain close relationships with vaccine developers in the private sector, and (5) martial the resources and cooperation of other nations, international organizations, and the philanthropic community.

Planning Process and Goals: The development and implementation of a comprehensive plan for accelerated AIDS vaccine development will require a systematic, coordinated process, with defined timelines, and must include all appropriate constituencies representing relevant Federal agencies/institutions (e.g., NIH, CDC, DOD, USAID), the private sector (biotechnology and pharmaceutical industries), and the international community (e.g., UNAIDS, International AIDS Vaccine Initiative [IAVI], World Bank, G-7 countries). The first phase would include a series of

focused meetings, with establishment of working groups and committees, each with specific objectives and deadlines for action and performance.

The comprehensive plan must include not only the vision and process for vaccine development but also the specific objectives, responsibilities, strategies, and outcomes for the implementation of the plan. It is essential that the plan reflect the integration of the special skills and expertise of all appropriate Federal agencies, NGOs, and the international community, as well as set forth a process for collaboration among the various participants. Some of the issues which must be addressed include (1) how to coordinate the relationships and form partnerships with other major industrialized nations, UNAIDS, and NGOs; (2) funding and financial incentives; (3) management controls; (4) clear milestones and target goals; (5) regulatory issues; (6) intellectual property rights; (7) liability issues; and (8) the roles of the various U.S. Federal agencies so that established programs and experience in field testing of candidate vaccine products can be used effectively.

Basic Science Research: A major area that must be addressed within the comprehensive plan concerns basic scientific research. The NIH, the world's premier biomedical research agency, should maintain its essential role in promoting basic research in virology, immunology, behavioral, and related sciences which provides the knowledge base for vaccine development. However, the NIH should utilize more of its in-house experience and expertise in vaccine development for this effort. NIH experts outside of the Division of AIDS could provide much needed knowledge and advice in vaccine development.

The establishment of the proposed [AIDS] Vaccine Center within the NIH may facilitate expansion of basic scientific knowledge. It is essential that the director of this Center be an accomplished vaccinologist and that this director have full responsibility and authority to allocate, prioritize, and manage *all* NIH funding designated as "AIDS vaccine" research. Additionally, the NIH must substantially increase the amount of AIDS research funds allocated to vaccines.

Vaccine Development Approach: There is a serious lack of candidate AIDS vaccines in the "pipeline" to test in clinical trials, and it is imperative to overcome this lack. Basic science research may not reveal, within the desired timelines, all the answers to the complex mechanisms of immune control of HIV-1 to permit the rational design of an AIDS vaccine certain to work in advance of human testing. Without knowing the "correlates of protection" (the human immune responses to a vaccine that indicates protection from HIV-1, if exposed) and without having a laboratory animal that closely mimics human HIV infection, researchers will need to test various traditional and novel vaccine design strategies in human clinical trials to assess safety, immune response, and efficacy. This process of "thoughtful empiricism," a hallmark in the history of vaccine development, may provide vitally needed answers. The risk that a tested vaccine may fail to work is a reality, but the benefit for future studies from the knowledge gained may outweigh the time, cost, and effort in determining a vaccine unsuccessful.

Product Development: Product development refers to the translation of promising concepts from laboratory and animal experiments to actual vaccine products made according to "good manufacturing practices" (GMP) under FDA guidelines before they are approved by the FDA for human testing under "investigational new drug" (IND) protocols.

Product development requires the infrastructure and expertise residing primarily in the private sector (pharmaceutical and biotechnology industries) and is an area in need of leadership and innovation. Government leadership may be required to effectively subsidize private industry needs. Such support ideally would involve the commissioning of targeted applied research, the facilitation of cooperative agreements for pilot manufacture of new vaccine candidates, and the support of Phase I, II, and III trials. This could be accomplished by experienced companies or nongovernmental research institutes working with a minimal amount of governmental interference. Federal leadership will also be required to address a host of essential related issues, such as intellectual property rights, financial incentives for the government vaccine purchase market, international vaccine development and purchase funds, tax rebates, subsidies for vaccine approaches not commercially attractive, patent extensions, and liability issues. These are issues which are not within the traditional role of NIH, but are essential to the development of an effective vaccine.

Phase III Field Efficacy Trials: A third major area of concern relates to the implementation of large-scale field trials to determine vaccine efficacy. It will be important to conduct multiple field trials of various candidate vaccines concurrently, not waiting for the results of one before starting others. Many such trials will likely occur in developing countries, where the incidence of new infections is higher. As a result, true partnerships with investigators in these countries must be developed. Critical to the success of large field trials in developing countries will be the involvement and "ownership" of the testing program by scientists living in these developing countries.

Agencies such as the CDC, DOD, and USAID have extensive experience and expertise in field epidemiology, surveillance, and the conduct of vaccine efficacy trials, especially in developing countries. In addition, DOD and CDC currently maintain several long-term overseas field research infrastructures operating through government-to-government collaborations with foreign ministries of health and other agencies. These ongoing field research stations can provide tremendous capacity for the multiple vaccine trials which are likely to extend over decades. For this process to be facilitated, the comprehensive plan must address the complex issues of communication, cooperation, and collaboration among the diverse agencies and organizations that will be required in this international effort.

New Business

The **next Council meeting** will be held March 16–18, 1998, in Washington, D.C. Two full-Council plenary sessions will be held, on communities of color and vaccine, and Dr. Hitt said that Subcommittees should provide Mr. Montoya with agendas and speakers by February 1. If this information is not receive, the plenary slot will be given to another group, in this case, youth. As it stands, the youth presentation is scheduled for the June meeting.

Subcommittees should inform Dr. Hitt if they have **special needs** for the next meeting; e.g., if one needs to meet for more hours than normally allotted.

On the subject of **surveillance**, Mr. Isbell went on record as feeling "uncomfortable with being associated with the recommendations."

The subject of **Council resignation** was revisited by Mr. Fogel and once again tabled.

Critical issues between now and the next meeting include needle exchange and Medicaid expansion. It was noted that these are on the verge of being lost and that the Council must continue to give a substantive amount of pressure over the next few weeks. It is also crucial to disseminate the Progress Report as widely as possible in the next week.

Mr. Montoya said that he needs **updates for all contact information**, contact files, member biographies, receipts for past meetings, and Subcommittee conference call schedules.

Mr. Stafford thanked Dr. Hitt for his leadership and his patience and the conference staff and Mr. Montoya for their efforts in making this meeting successful.

Closing

Dr. Hitt thanked Council members, ONAP staff, and guests for their participation, and the Eighth Meeting of PACHA was adjourned at 12:20 p.m. on December 7, 1997.