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**Presidential Advisory Council on HIV/AIDS
Full Council Meeting**

March 15–18, 1998

Madison Hotel
Washington, D.C.

MINUTES

Present: R. Scott Hitt, M.D., Chair; Stephen N. Abel, D.D.S.; Terje Anderson; Regina Aragon; Judith Billings; Charles Blackwell, J.D.; Nicholas Bollman; Jerry Cade, M.D.; Lynne M. Cooper; Rabbi Joseph A. Edelmet; Robert Fogel; Debra Fraser-Howse; Kathleen Gerus; Phyllis Greenberger; Robert Hattoy; B. Thomas Henderson; Michael T. Isbell; Ronald Johnson; Jeremy Landau; Alexandra Mary Levine, M.D.; Miguel Milanés, M.P.A.; Helen H. Miramontes; Rev. Altagracia Perez; Robert Michael Rankin, M.D.; H. Alexander Robinson; Debbie Runions; Sean Sasser; Benjamin Schatz, J.D.; Richard W. Stafford; Denise Stokes; Bruce Weniger, M.D.; and Daniel Montoya, Executive Director for PACHA within the Office of National AIDS Policy (ONAP). **Present from ONAP:** Sandra Thurman, Director; Todd Summers, Deputy Director; Brad Austin, representative from Substance Abuse and Mental Health Services Administration (SAMHSA); Matthew Murguia, Office on Minority Health (OMH); Robert Soliz, Health Resources and Services Administration (HRSA); Todd Weber, Centers for Disease Control and Prevention (CDC); and staff members Sarah Holewinski and Jeff Kamen.

Absent: Nilsa Gutierrez, M.D., M.P.H.; Steve Lew; and Charles Quincy Troupe.

**March 15
Opening and General Council Business**

Dr. Hitt, Chair, opened the Ninth Meeting of the Presidential Advisory Council on HIV/AIDS (PACHA) with a review of interim activities and meeting goals. He thanked members and ONAP staff for their ongoing efforts on behalf of PACHA and HIV/AIDS issues and welcomed all guest speakers slated to address the Council during this meeting.

New Members

Three new members were welcomed to the Council: Charles Blackwell, J.D., President of Native Affairs and Development Group, Washington, D.C., and Ambassador to the United States of America from the Chickasaw Nation; Ms. Lynne M. Cooper, President of DOORWAYS, St. Louis, Missouri; and Miguel Milanés, M.P.A., Coordinator of HIV/AIDS Programs, Dade/Monroe Counties, Florida Department of Health. Two new agency representatives to ONAP—Mr. Brad Austin, SAMHSA, and Mr. Todd Weber, CDC—also were introduced.

Ms. Mary Boland has resigned to fulfill other professional commitments, leaving a vacant Council seat and a gap in coverage of pediatric issues. Dr. Hitt said that Ms. Boland had provided suggestions for her replacement and recommendations for all PACHA issues she was covering, and he asked members to submit additional names of potential candidates to fill this vacancy.

Interim PACHA Activities

- PACHA's Second Progress Report was issued directly following the December meeting, garnering a large amount of press coverage, with overall balanced reporting.
- Following its issuance, Dr. Hitt met with Mr. Erskine B. Bowles, Chief of Staff to the President, who promised to schedule a meeting for PACHA with President William J. Clinton this year.
- Council members have been involved with 1998 appropriations, and budget increases have been realized across the board, although allocations for prevention were lower than anticipated.
- Subcommittees have had exponentially increased workloads over recent months, with major issues coming to mature recommendations. Dr. Hitt encouraged members to cross-visit during breakout sessions to study other Subcommittee issues in depth. He said that perspectives of those outside of PACHA were helpful in formulating recommendations, citing recent involvement by Mr. Henderson, Mr. Lew, and Dr. Rankin with the Research Subcommittee in finalizing the forthcoming vaccine report.

The Council's Role and Ongoing Tasks

Dr. Hitt restated the Council's role of providing frank and informed advice to the President regarding global prevention and treatment for HIV/AIDS. PACHA, he said, has received positive feedback from the Administration and the HIV/AIDS community on its fulfillment of this role. Now, the Council should revisit its mission statement and long-range planning to determine its primary focus during the remainder of this administrative period and what form, if any, a final PACHA report should take. The Process Committee was asked to develop a procedure for this planning, and adequate time will be allotted for full-Council discussion during the June meeting.

ONAP Update

Ms. Thurman, ONAP Director, thanked her staff and PACHA members for their work and support, welcomed new Council members, and presented an update on agency activities and the global status of HIV/AIDS. Overall, there has been some great news, she said; however, incredible challenges continue to exist as well. Successes include:

- **Budget increases.** This year's appropriations show the largest percentage increases ever, including \$165 million for Ryan White programs (with help from the Office of Management and Budget [OMB] leaders); \$21 million for Housing Opportunities for People With AIDS (HOPWA); and \$124 million for National Institutes of Health (NIH) research. The most disappointing allotment was the \$5 million increase in prevention funds involving the "race and health initiative."

- **International leadership.** ONAP is taking a more visible leadership role on the international front, working with Vice President Albert Gore, Jr., and his staff and visiting health ministers on issues such as technology transfer and access to treatment. ONAP also briefed President Clinton on the global status of AIDS prior to his recent visit to Africa. In addition, the Office has initiated several small programs through the White House, including (1) facilitation of an HIV training program for African chemical plant workers, cosponsored by the America Federation of Labor and Congress of Industrial Organizations (AFL/CIO) and the U.S. Agency for International Development (USAID), an example of building public/private partnerships; (2) site visits to Russia and, possibly, India; and (3) use of recent findings on zidovudine (AZT) and neonatal transmission to help formulate programs for providing drugs to pregnant women in developing countries.
- **PACHA recommendations database.** The database of all PACHA recommendations and Administration responses made to date is complete; Dr. Hitt thanked Mr. Summers for developing this useful and thorough compilation.
- **ONAP offices.** New, expanded offices for ONAP on Lafayette Square and for Ms. Thurman in the Old Executive Office Building (OEOB) indicate that ONAP has moved ahead in its inclusion within the White House complex.
- **Confirmation of Surgeon General.** Dr. David Satcher's confirmation as Surgeon General is good news for the AIDS community and a positive sign for future progress.

Ongoing ONAP activities include the following:

- **President's youth directive.** Mr. Summers reported that President Clinton's directive has given ONAP an opportunity to make connections for HIV prevention within all the Department of Health and Human Services (HHS) programs involving 13- to 21-year-old youths. Mr. Soliz is leading the effort to inventory HHS programs and focus on HIV prevention and health care services for young people with HIV/AIDS. ONAP set up a task force, comprising representatives from CDC, HRSA, and other agencies, to integrate youth concerns and will make recommendations to the President within the next 2 months.
- **Indian Health Service (IHS).** Ms. Thurman met with IHS to reinvigorate a program on HIV in Native Americans, with the agency agreeing to co-chair an interagency working group on this significant issue. Mr. Blackwell is assisting ONAP in the process.
- **Names reporting and surveillance.** Although the CDC is moving forward on names reporting, neither the White House nor HHS is currently in support of this form of data collection, Ms. Thurman said. There is agreement that a better collection method is needed; however, the Administration must be convinced that there is no better way to collect the data. ONAP is monitoring the issue closely.
- **Medicaid expansion.** Efforts to date have been unsuccessful. In response, Vice President Gore was adamant that money be added to the AIDS Drug Assistance Program (ADAP)

as a stopgap method of providing new drug treatments to persons with AIDS. ONAP continues to try to determine feasible methods for delivering full health care services and integrating current vertical programs into the larger context. An internal task force of senior staff personnel has been established, including Ms. Thurman; Mr. Christopher C. Jennings, Special Assistant to the President for Health Policy Development; Mr. Donald Gips, Domestic Policy Advisor to the Vice President; Dr. Eric Goosby, Director, Office of HIV/AIDS Policy, HHS; Dr. Marsha Martin, Special Assistant to the Secretary of HHS; Ms. Nancy-Ann Min DeParle, Administrator, Health Care Financing Administration (HCFA); and Mr. Earl Fox, Director, HRSA. On a positive note, HCFA is enthusiastic about working with States to obtain Medicaid waivers for local programs as interim or long-term measures.

- **Interdepartmental AIDS task force.** A task force established several years ago has been revived, with ONAP bringing together 40 to 50 representatives involved in the epidemic to discuss back-to-work issues (including Federal personnel policy). The Services Subcommittee asked for notes from this and future meetings, and ONAP agreed to provide them.
- **Leadership meetings.** A series of leadership meetings are being co-chaired by ONAP, with the first—on women and AIDS—scheduled for April 9. Women political leaders and women's organizations, as well as the media, will be briefed by ONAP and asked to include epidemic issues on their broader agendas in the future. ONAP has formed a strong alliance with the White House Office for Women's Initiatives and Outreach, co-sponsor of the upcoming leadership session, and future leadership meetings will cover the race and health initiative and other such areas.
- **Prisons issues.** Mr. Summers reported that ONAP met with Dr. Kathleen M. Hawk, Director of the Federal Bureau of Prisons (FBP), along with the head of the FBP Infectious Diseases Program and other personnel from the Department of Justice, to address PACHA's concerns. The FBP has agreed to meet with ONAP, HRSA, and HCFA to find ways to cover gaps in entitlement services for persons on parole and discharged.
- **Vaccines.** The AIDS vaccine initiative is not moving as quickly as hoped, although ONAP had a good meeting with Dr. Harold Varmus, Director of NIH, and a building site has been identified for the new AIDS Vaccine Center. Members of the PACHA Research Committee were thanked for their help with the overall process. ONAP will co-chair an internal working group of all Federal agencies involved and is keeping the White House apprized of vaccine development progress.
- **Needle exchange.** Progress on needle exchange funding is the bad news. Ms. Thurman restated her personal commitment to having the moratorium on Federal funds for needle exchange programs lifted and said that this issue has become "a symbol of politics, rather than science, driving policy." The President remains firmly committed to achieving his prevention goals, and she is optimistic that progress will be made. In answer to member queries, Ms. Thurman said she did not believe that HHS Secretary Donna E. Shalala has

met with the President on this issue, nor is a meeting planned. She could not say what the Secretary's stance and strategies concerning needle exchange might be.

Council Response to ONAP on Needle Exchange and Other Issues

The lack of progress on needle exchange brought a strong response from Council members, who indicated that Secretary Shalala's failure to address the issue is not acceptable and that this brings into serious question the Administration's commitment to prevention. It is becoming increasingly difficult to support and defend the President and his goal of stopping the spread of the epidemic within a decade, Mr. Anderson said. Council members are frustrated with the continuing silence from the Administration, and Mr. Robinson called for a moratorium on meetings and working groups and the beginning of real action. It was agreed that science has proved that needle exchange prevents the spread of infection without increasing drug use, but that the issue is being driven by politics. Although the Council appreciates ONAP's views on the difficulties of dealing with the twin epidemics of HIV and drug addiction, Rabbi Edelheit said the American public is open to dealing honestly with these issues now.

Whereas ONAP and General Barry R. McCaffrey, Director, Office of National Drug Control Policy (ONDCP), have made their opinions clear, it is not known what the beliefs or strategies are at HHS, which has working responsibility for the program. Additionally, conflicting views have been coming from different areas of HHS. Although Ms. Thurman has not communicated with Secretary Shalala directly, she has discussed needle exchange with Mr. Kevin Thurm, Deputy Director of HHS, and believes that the agency understands the significance of making a decision on this issue in the near future.

Ms. Aragon noted that the National Organizations Responding to AIDS (NORA) has asked the Council to issue publicly a strong statement about needle exchange during this meeting, and members concurred that immediate action is warranted. It was decided to address Secretary Shalala and President Clinton and to hold a press conference denouncing the Administration's lack of leadership if responses were not forthcoming.

Ms. Miramontes pointed out that the lack of commitment by the Administration is also seen in the slow progress in vaccine and microbicide development and the insignificant appropriations for the race and health initiative and for prevention education. Dr. Hitt reminded ONAP that a similar issue with HHS—on Medicaid expansion—had arisen during the December PACHA meeting and that seemingly little has happened on that subject to date.

Ms. Thurman noted that discussions are taking place, and Mr. Summers reminded the Council that progress has been made, citing HCFA's commitment to States' Medicaid options. Mr. Henderson also noted that Medicaid models are being developed between HCFA and other entities, such as the Kaiser Foundation. The Council, however, called for a more concrete plan of action, with specific deadlines, and asked that HCFA take a greater leadership role. Ms. Thurman promised that any progress would be conveyed immediately to the Council.

Subcommittee Meetings

Communities for African and Latino Descent. Members present were Ms. Aragon, acting Chair; Mr. Milanes; Reverend Perez; Mr. Robinson; Mr. Sasser; and Mr. Stafford. Also present were Mr. Murguia; Mr. Ryan LaLonde, assistant to Mr. Blackwell; and Mr. George Roberts, Dr. Dawn Smith, and Dr. Imani Thompson, CDC.

Discrimination. Members present were Mr. Schatz, Chair; Ms. Gerus; Mr. Henderson; and Mr. Johnson.

International Issues. Members present were Mr. Fogel, Chair; Mr. Anderson; Ms. Cooper; Rabbi Edelheit; Ms. Greenberger; Ms. Miramontes; Ms. Runions; and Dr. Weniger. Also present were Mr. Andrew Barrer, The World Bank; Dr. Mary Lou Clements-Mann, Johns Hopkins School of Public Health; Ms. Patsy Fleming, Joint United Nations Programme on HIV/AIDS (UNAIDS); Mr. Jerry Gottlick, *U.S. Medicine*; Mr. Jeff Morley, Agouron Pharmaceuticals, Inc.; Mr. H.R. Shepherd and Mr. Alfred Rabow, Sabin Vaccine Institute; Mr. Bob Rohr, *Bay Area Reporter*; Mr. Soliz; Ms. Patricia Thomas, independent journalist; and Mr. Mike Tobin, Ortho Biotech. Invited speakers were Ms. Thurman, who gave a briefing on the global status of HIV/AIDS, and Dr. Jonathan Mann, Dean of the School of Public Health, Allegheny University of the Health Sciences, who discussed ethics and human rights issues in AIDS vaccine trials.

Prisons Issues. Members present were Mr. Landau, Chair; Dr. Abel; Mr. Blackwell; Dr. Cade; and Mr. Rankin. Others present were Mr. Austin; Ms. Rebecca Helem, National Minority AIDS Council (NMAC) and NORA; and Mr. Summers, who reviewed the PACHA Prison Assessment and provided an update on Federal brigs and prisons.

Prevention. Members present were Mr. Robinson, Chair; Mr. Anderson; Ms. Aragon; Ms. Billings; Mr. Fogel; Ms. Gerus; Dr. Hitt; Mr. Isbell; Reverend Perez; Ms. Runions; and Mr. Schatz. Also present were Mr. Austin; Ms. Heidi Ecker, *AIDS/STD News Report*; Mr. Bill Haworth, Bentley Health Care; Mr. Ernest Hopkins, San Francisco AIDS Foundation; Mr. LaLonde; Ms. Miguelina Maldonado, NMAC/NORA; Mr. Rohr, Ms. Eva Seiler, CDC; Ms. Thurman; and Mr. Weber. Ms. Jane Silver, NORA/AmFAR (American Foundation for AIDS Research), briefed the Subcommittee on the Federal funding for a needle exchange moratorium.

Research. Members present were Dr. Levine, Chair; Ms. Greenberger; Mr. Hattoy; Ms. Miramontes; and Dr. Weniger. Mr. Claude Kamenga, FHI, was also present. The primary focus was the Subcommittee's forthcoming report to the Council.

Services. Members present were Mr. Henderson, acting Chair; Dr. Abel; Ms. Aragon; Mr. Blackwell; Ms. Cooper; Rabbi Edelheit; Mr. Milanes; Dr. Rankin; Mr. Sasser; and Mr. Stafford. Also present were Ms. Fleming; Mr. Montoya; Dr. Smith; Mr. Soliz; and Mr. Summers. Outside panelists were invited to brief the Subcommittee on the major issues being considered by the Council:

- **National policy dialogue on early medical intervention services/regional meetings.** Panelists were Dr. Goosby, Dr. Martin, and Mr. Joseph Kelly, National Alliance of State and Territorial AIDS Directors (NASTAD).
- **Access to treatment and Medicaid waiver process.** Panelists were Dr. Martin and Ms. Kathy King and Mr. Gary Claxton, HCFA.
- **Drug pricing update.** Mr. Kelly discussed pharmaceutical company issues (e.g., liability, antitrust, profitability) and presented a strategy based on a study at the University of California, San Francisco (UCSF), showing that Medicaid expansion could be achieved with an 18-percent reduction in drug costs.

Emergency Full-Council Meeting

After informally polling members, Dr. Hitt convened an unscheduled, full-Council session to discuss details of the proposed press conference to address the needle exchange issue. Discussion covered timing, substance of the PACHA message, possible civil disobedience in conjunction with the conference, and what action to take regarding Secretary Shalala. It was recommended that Secretary Shalala be informed of the Council's intention to make a public statement and to give HHS an opportunity to meet with PACHA regarding its plans for the needle exchange issue, with the hope of forestalling the public action. Concerns were raised as to whether the Council could reach a consensus on the text of a public statement in time for a public conference on March 17 and whether this event would interfere with other scheduled activities that day, including a public comment period and an address to the Council by Dr. Satcher. The consensus was that the matter should not be delayed.

Dr. Martin and Dr. Goosby, who attended the emergency session, had been apprized of the Council's concerns during the Services Subcommittee meeting earlier in the day, and both committed to take PACHA's message back to HHS. They did note that this issue is being reviewed at the highest levels in the Administration and that action will be forthcoming, although no date or strategy could be given at this time. Dr. Martin said that Secretary Shalala is very concerned. She assured the Council that HHS was trying to stick with the science. Dr. Goosby indicated that PACHA would not be unhappy with the final outcome on this matter; however, he urged the Council to continue to articulate its frustration.

March 16 Full Council Session—General Business

Dr. Hitt announced that the White House had been informed of the Council's proposed public actions and that Ms. Thurman was currently at HHS to discuss needle exchange and the vaccine initiative. Options for the press conference were discussed, including whether to use civil disobedience and whether to hold the conference in front of the White House or at the Madison Hotel. The latter option was chosen, in view of current restrictions on visits to the White House associated with potential terrorist activities. Actions considered were a vote of no confidence in the Administration's commitment to end the epidemic; a public letter to the President; demand for a meeting with Secretary Shalala; demand for the Secretary's immediate resignation; demand for the Secretary's resignation if a negative opinion on needle exchange is forthcoming; and/or Council members' resignations if inaction continues.

A statement drafted by Mr. Henderson became the core of the message to be delivered to the public: “That . . . it is time for leadership on the part of Secretary Shalala. The science is clear; and it is time for her to get out in front of this parade. . . . Clearly, General McCaffrey is marshaling his forces quite effectively. We do not have a general on our side, and this Council feels that it is time for Secretary Shalala to take that role, if this battle is going to be won with the President.” A letter to Secretary Shalala was drafted, calling for an unequivocal public statement on the scientific evidence of needle exchange and its role in HIV prevention and further action on needle exchange. The letter was approved and hand-delivered to the Secretary. (A copy is included in the Addenda to the Minutes.)

Full-Council Panel Presentation: HIV/AIDS in African-American and Latino Populations

A panel discussion was convened by the Communities for African and Latino Descent Subcommittee to inform the Council on the unique aspects and issues of the epidemic within these communities. Ms. Fraser-Howse, Chair, opened the session by thanking the Subcommittee and Mr. Montoya for developing the presentation. Pointing out that these communities have the fastest growing percentage of infection, she described the current national environment as “ready for the issues.”

Mr. Robinson reported on a meeting March 3–4 (referred to by panelists) between 33 leading African-American AIDS advocates and top officials of the CDC. The outcome was a set of formal demands from the advocates concerning the need to find strategies and funding to fight HIV/AIDS in this community (full text is in the Addenda to Minutes). The demands also called for action by Secretary Shalala and the President and the declaration of a state of AIDS emergency within the community. As a result, a core group of public and private entities are taking a critical look at what the epidemic is doing to this community, and how it can be stopped.

Ms. Aragon introduced the panel presentation and guest speakers:

Monina Klevens, D.D.S., M.P.H., HIV Surveillance Unit of the CDC, discussed the epidemiology of AIDS among Hispanics in the United States, characteristics of the infected population, trends in the disease, and the complex issues surrounding the Latino community. She also described CDC surveillance, which occurs within all States and U.S. dependencies: a standard case definition, without name and address reported to the CDC, with strict security and confidentiality measures to ensure that information is protected.

The Hispanic population, Dr. Klevens said, is overrepresented among people with HIV/AIDS, with the ratio of Latino men, women, and children becoming infected far higher than that of white, non-Hispanics; and these ratios are increasing. Additionally, the current decline in deaths from AIDS is less among Hispanics than in the white population. The highest rates of Hispanics with AIDS are found in the Northeast, Florida, and Puerto Rico. Unique issues that must be faced in HIV prevention among Hispanics include ancestry, place of birth, primary language, access to health care, socioeconomic status, acculturation, and determination of what interventions can be effective in this context. Further study and more prevention activities, including earlier monitoring, appropriate for each subgroup affected, are needed.

Dawn Smith, M.D., M.P.H., M.S., Division of HIV/AIDS Prevention, Surveillance, and Epidemiology, CDC, focused on the impact of HIV and AIDS-related deaths in the African-American community and presented “ideas about where CDC is going with its data.” The increase in the proportion of cases among African Americans in the United States began in 1987, affecting all parts of the community. Primary risk groups are injecting drug users (IDUs), representing 44 percent of new infections; men who have sex with men (MSM), 29 percent; and heterosexual men and women, 23 percent. By gender and age groups, the highest rate of AIDS cases is among African-American men. Among African-American women, numbers are rising; but among children, especially with new treatments to reduce neonatal transmission, rates are falling.

Although infections and deaths are declining overall, the rate of decline is much lower among African Americans than in any other ethnic group, and the epidemic disproportionately impacts this community, in both urban and rural settings. The implication is that quality care is not as accessible within minority communities as it is in white communities. The mortality rate continues to be higher among African-American men than in any other group, with AIDS being the leading cause of death. Problems exist in estimating the true impact because HIV reporting is more consistent in States where the black population is lower, and because African Americans are less likely to report HIV infections.

The numbers indicate that things are bad and getting worse, and the impact is particularly severe because of multiple risks and interrelationships among the risk groups, in both youths and older people. To deal with this crisis, resources—people and money—are needed to match the urgency, severity, and epidemiology of the epidemic. Resources must be used to address known facilitators of infection, such as injection drug use and socioeconomic status factors, and to provide services—including improved counseling and testing—that increase intervention strategies and disseminate those that have proven effective.

Imani Thompson, Ph.D., HIV Prevention Unit, CDC, discussed the African-American Initiative developed by the Community Assistance Planning and National Partnerships Branch, National Center for HIV, STD, and TB Prevention. This is the first leg of an overall people-of-color initiative that ultimately will include Hispanics, Native Americans, and Asian/Pacific Islanders. The initiative was developed to review the targeted CDC spending for programs that do not seem to reflect the true nature of this epidemiology. A budget analysis for the advocate leaders showed that appropriate correlations within the targeted programs do not exist. For example, two of the largest funding categories for State health departments are health education/risk reduction (HERR) and counseling and partner notification programs. Of this, about 33 percent in HERR and 24 percent of counseling/notification funds are targeted to African Americans, who represent 43 percent of all AIDS cases and 54 percent of new infections.

As a result of the meeting with African-American leaders, the internal working group and others at CDC have been reenergized, Dr. Thompson said. With an overarching goal of reducing the impact of HIV/AIDS among African Americans, the strategy is to utilize effective, evidence-based HIV prevention approaches. Four critical steps have been identified by CDC: define the problems, assess current programs, design new strategies, and implement strategies. Focus

groups of targeted populations (youths, women, MSMs, and substance abusers as well as workers, laborers, and Haitians in Miami) have already begun to meet. A review of programs that focus on the epidemic in the community has begun, and an assessment of national and regional minority organizations and the technical assistance network among community planning groups is nearing completion. Short- and long-term recommendations have been made for potential action steps by the CDC in five categories: health communications and social marketing, partnerships and advocacy, program development and evaluation, technology transfer, and research. Since the meeting, the CDC has communicated with Secretary Shalala and the Surgeon General, Dr. Satcher, about the emergency status of the epidemic in the community, forwarded budget analysis data to the advocates, held a telephone consultation among the internal working group and an ad hoc committee of 11 outside consultants, and set up a planning meeting in April for a leadership summit to be held in June to review HIV/AIDS prevention implementation strategies for African-American communities.

Still needed are enhanced partnerships between CDC and community organizations, more money, more creative strategies, and assessment of recommendations by the outside consultants. As long as the epidemic continues to spread in the African-American communities, these programs must continue, and even more must be done. It is clear that the public sector alone cannot successfully combat HIV/AIDS; overcoming the current barriers to HIV prevention and treatment in this community requires that leaders in the community themselves acknowledge the severity of the epidemic and play an even greater role in combating HIV/AIDS.

Questions from Council members concerned prison issues (to be addressed at the June summit); intervention strategies that have proven successful in these communities (for example, provision of skills for women in negotiating use of condoms in sex); differences in transmission factors within geographical areas; detailed accounting of the CDC budget; results of a study among African-American youths; trends in death rates among young adults 18 through 25 years of age; and the effects of language and literacy in prevention programs. Mr. Milanes suggested the need to review the community planning process and to revisit cooperative agreements with States to rectify such gaps as are found in Miami, the largest metropolitan area without CDC funding.

Mindy Fullilove, M.D., New York State Psychiatric Institute, discussed community infrastructures and environments and how they affect health care and public health strategies. Community collapse, such as has happened in Harlem, is a "spiraling process," resulting in a loose collection of individuals not working together, not taking care of each other, and without viable lines of communications. This leads to increased incidence of epidemics. In these communities, people "medicate dysphoria"—e.g., rootlessness and confusion—with such things as sex and drugs, which become their only means of identification with others.

Dr. Fullilove spoke not only of the differences, but also of the similarities among the various AIDS communities. In all communities (ethnic groups, gays, IDUs, etc.), there is a history of upheaval and sense of displacement; all experience discrimination, abandonment, and usually a loss of housing. In most urban renewal, there is little planning as to where the displaced will go, a particularly critical issue for IDUs, as no one wants these people around. Where housing is lost, the greatest number of drug-related deaths occur, and AIDS is where the drugs are; AIDS is "where the displaced people went." Prevention efforts must be carried out in these areas, and

more money and resources must be used for social science research that will explain the unique issues of the African-American and Hispanic communities.

Ms. Fraser-Howse thanked the panel and summarized the information, including the alarming state of emergency within these communities, the need for more realistic strategies and resources targeting them, and the need to get people to the table who understand the full story. Many Council members expressed anger and concern at the situation, and all agreed that PACHA should take strong and specific stands on this issue. Several asked what the Council can do to help, and Ms. Fraser-Howse said that the Subcommittee would come back with recommendations. One suggestion was that PACHA respond to the insignificant appropriation for the race and health initiative; another was to strongly urge that the CDC critically assess its programs and shift priorities and funds for both research and intervention programs, based on the percentages of infections. It was agreed that the Council, as an interim action, would issue a resolution in support of the demands of the African-American leaders (see Subcommittee Report, March 18).

General Business/Services Subcommittee Initial Report

The Council met to finalize details of the press conference, the letter to the President, and the PACHA resolution. Dr. Hitt announced that a press release on needle exchange had already gone out with a statement from ONAP and that the Council's letter to Secretary Shalala had been delivered.

Subcommittee Meetings

Communities for African and Latino Descent. Members present were Ms. Aragon, Mr. Milanes, Reverend Perez, Mr. Robinson, Mr. Sasser, and Mr. Stafford.

International Issues. Members present were Mr. Fogel, Mr. Anderson, Ms. Cooper, Rabbi Edelheit, Ms. Greenberger, Ms. Miramontes, Ms. Runions, and Dr. Weniger. Others present included Mr. Mochine Alami, Ms. Martina S. Awoke, Mr. Gillette Conner, and Ms. Sheila Mudhani, National Council for International Health (NCIH); Ms. Alice Blair and Ms. Karen Peterson, American Red Cross (ARC); Ms. Dominique DeSantis, UNAIDS; Ms. Keirsten Giles, World Vision; Ms. Chris Heash, Episcopal Caring Response to AIDS (ECRA); and Ms. Seiler. AZT efficacy in clinical trials was discussed by panelists Dr. Helen Cornman, AIDS Program Director, NCIH; Ms. Fleming; Dr. Paul DeLay, USAID; Dr. Timothy Dondero, CDC; and Ms. Maldonado.

Prisons Issues. Members present were Mr. Landau, Dr. Abel, Mr. Anderson, Mr. Blackwell, Dr. Cade, Ms. Cooper, and Dr. Rankin. Also present were Mr. Austin and Mr. Eric L. Turner, HIV Community Coalition (HCC). Mr. John Miles, CDC, reviewed surveillance methods currently being used and others being considered for use in the future.

Prevention. Members present were Mr. Robinson, Mr. Anderson, Ms. Billings, Mr. Blackwell, Ms. Gerus, Mr. Henderson, Mr. Isbell, Mr. Landau, Reverend Perez, Ms. Runions, Mr. Sasser, and Mr. Schatz. Also present were Mr. Austin, Ms. Seiler, and Mr. Weber. Guest speakers

Dr. Patricia Fleming, CDC, and Professors Lawrence O. Gofin and James G. Hodge, Jr., Georgetown University Law Center, discussed the current status of HIV surveillance.

Services. Members Mr. Blackwell, Ms. Cooper, and Rabbi Edelheit, with guest speakers Mr. David Harvey and Ms. Maldonado of NORA, Ms. Chris Collins of Congresswoman Nancy Pelosi's office, and Ms. Christine Lubinski, AIDS Action Council (AAC), discussed return-to-work issues and the HIV Treatment Improvement Act of 1997.

Research. Members present were Dr. Levine, Dr. Cade, Mr. Johnson, Mr. Miramontes, and Dr. Weniger.

March 17 Press Conference

A formal press conference was held on Tuesday, March 17, at the Madison Hotel. With the full Council in attendance, Dr. Hitt introduced the issues of needle exchange to local, national and international media: the Administration's lack of action and commitment, evidence from the scientific community showing that needle exchange can play a crucial role in prevention, the vote of "no confidence" in the Administration, and a call for President Clinton to take action. Following this introduction, Mr. Johnson, Ms. Aragon, Mr. Anderson, and Ms. Stokes made personal statements to the media, and copies of the Council's letter to the President and the Resolution on Needle Exchange Programs were made available. (Text of the press conference statements, letter, and resolution are included in the Addenda to Minutes.)

The consensus of the Council was that the session was well attended by the press and that followup coverage was widespread and beneficial to the interests of PACHA and the AIDS community. (A list of media in attendance is included in the Addenda to Minutes.) Dr. Hitt expressed his appreciation for the Council members' participation and to consultant Mr. Bill Hayworth for his help in getting the message to the press.

Full-Council Panel Presentation: Research Subcommittee Vaccine Update

Dr. Hitt opened by saying that the Research Subcommittee has worked for more than 2 years and taken dozens of hours of testimony from the best sources in the world to bring this vaccine development update and proposed recommendations to the Council. The recommendations have been reviewed by outside sources and contain input from all of the diverse interests involved. He thanked the Subcommittee for its exhaustive work.

Dr. Levine also thanked the Subcommittee, in particular Ms. Miramontes and Dr. Weniger, who worked with the Chair on every draft of the recommendations. She then reviewed the major questions and problems that face the development of an AIDS vaccine:

- Is there such a thing as a protective immune response? Positive indications have been seen through use of a chimpanzee model. This, in turn, leads to another complication: there may be a vaccine that either prevents initial infection (as in the polio vaccine) or does not prevent infection, but does prevent progression to disease (as in rabies).

- If there is a protective immune response, is it antibody-related? If so, is antibody the whole answer? Or, is it a cell-mediated response?
- What, if any, adjuvants should be used to make the vaccine even more effective? The problem is that manufacturers of the vaccine(s) must work from the start of development with the producers of the adjuvant(s), and this is not a standard procedure in the pharmaceutical industry.
- The lack of an effective animal model for HIV promulgates the controversial issue of human testing and has slowed the development process significantly.

Other, practical issues that have arisen include the following:

- Although the Administration seems to believe that the answer lies solely within NIH, there are other entities with much experience in making vaccine, in both the Government (CDC, Department of Defense [DoD], and others) and private industry, that have not been involved. Since private industry traditionally has brought new products from development to implementation, these companies have to be involved in the early stages of developing and making both vaccines and adjuvants.
- Major problems exist in testing the products. For phase I and II (toxicity and side effects), initial safety testing can be done in the United States. For phase III (efficacy), however, the normal procedure is to study subjects in large numbers with placebo controls, but the incidence in the United States is not large enough to answer these questions in a timely fashion. Going outside the United States, where the prevalence is much higher, questions could be answered faster; however, this raises ethical implications.
- Issues related to industry include the extremely high cost involved in the development of a vaccine that will be used largely in poor, developing countries and the vast liability implications. The usual funding sources may not be available, which is a further complication.

Overall, there are tremendous issues, from the basic science to the very complicated ethical, practical, and financial issues, both in this country and worldwide. Even the administrative structure limits the development of an AIDS vaccine in this country. Dr. Levine presented the draft recommendations, including alternative verbiage, which was reviewed by the Council and approved on a paragraph-by-paragraph basis. Major disagreements centered around leadership of the new NIH AIDS vaccine program, ONAP's authority vis-à-vis the vaccine initiative, and the strength of the wording in calling for a plan of action coordinated among very high-level personnel. Most of the document was approved unanimously, except for paragraph one, to which one member was opposed, with the final revised paragraph and details being approved in a later session. The adopted text is included in the Addenda to Minutes under New PACHA Recommendations. The Council applauded the passage of the long-awaited vaccine policy recommendation.

Public Comment

Several organizations had asked to make public comments, primarily on needle exchange; however, with the advent of the PACHA press conference, it was noted that the Council is complying with the requests of the community, and most representatives canceled their comments.

Miguelina Maldonado, Executive Director of Public Policy and Government Relations for NMAC, commented on several other issues brought up in Subcommittee discussions. On perinatal transmission trials conducted in Africa and Asia (as discussed by the International Issues Subcommittee), she said that the budget for USAID has been level-funded since 1993 at \$120 million, and because of funding shortfalls, trials have been stopped. She urged the Council to consider making a recommendation that USAID's budget for HIV/AIDS be increased. She also suggested that the Subcommittee study the issue of whether the institution of these short-course therapies can be advocated and supported in developing nations. In addition to increased funding for programs to reduce perinatal transmission in the most hard-hit areas, sub-Saharan Africa, Asia, and Southeast Asia, it is important to study what can be done in prevention and treatment of the mothers of the children.

Regarding the report on African-American and Latino communities, she said, we must emphasize the point of the connection between substance abuse and HIV/AIDS. More focus should be given to the differences in modes of transmission within minority groups and the difference in impact on substance abusers by population. We must look at comprehensive strategies in these communities and study how SAMHSA and CDC can collaborate to address the problems.

Helen Cornman, NCIH, concurred with Ms. Maldonado's recommendations on the USAID budget. NCIH has been working with NORA to get this budget increased, and now PACHA's help is needed. She applauded what the Council has done with the needle exchange issue.

Mr. Hattoy recommended that PACHA consider establishing a formal working group to monitor the appropriations process, focusing on specific areas such as USAID funding. Dr. Hitt asked him to put together an ad hoc working group that would watch these issues.

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Discrimination Subcommittee Report

Mr. Schatz briefed the Council on areas of concentration by the Discrimination Subcommittee:

HIV-positive health care workers. Progress in this area has been made, apparently because of the Subcommittee's interest. In February, a meeting was convened to brief CDC advisory committees, and as a result, CDC agreed to revise its guidelines on HIV-positive health care workers: eliminating the so-called "informed consent" provision and the concept of "exposure from procedures" and moving toward a statement that a meaningful risk does not exist and that there is no need for a special set of rules for these workers. Quelling a long-held fear of enormous vocal backlash, only five people testified against the proposed revisions at the last

open meeting at the CDC. This is a very important first step; however, the Subcommittee must continue to push for a commitment for a deadline for CDC recommendations and action.

Assessment of military policy. In December, the Subcommittee assessed the written military policy on HIV-positive personnel as exemplary; however, concerns exist that the policy is not necessarily translated into reality. The Subcommittee, therefore, is continuing to monitor the issue, and Dr. Rankin volunteered to work with the group. A question has arisen regarding the mandate of the Subcommittee—that is, to find HIV-specific discrimination in policy. Should this mandate be broadened? For example, even if the exclusion policy toward HIV-positive personnel is consistent with exclusions for people with other disabilities, are these fair and valid overall? HIV has been in the forefront in making inequities known on a broader basis, and the Subcommittee welcomes other member opinions as they try to resolve this question.

ALSO
BEN
SCHATZ

Recommendation on medical privacy. A recommendation on strengthening medical privacy as concerns law enforcement, which was tabled in December, was submitted for Council review. Discussion focused on upcoming and competing legislation involving police access to medical records. The Subcommittee recommendation, in support of legislation that does not include a broader exemption for police agencies, was approved unanimously. (See Addenda to Minutes, New PACHA Recommendations, for full text.)

Communities for African and Latino Descent Subcommittee Report

Mr. Robinson reported that, as a followup to the panel presentation, the Subcommittee is drafting a resolution in support of the demands of the African-American activist group that met with the CDC. Reverend Perez asked that PACHA agree to adopt such a resolution, and it was accepted unanimously. Subsequently, the Council voted on the wording of the text, as follows:

The Presidential Advisory Council on HIV/AIDS endorses the [following] demands of the African-American Consultants to the Centers for Disease Control and Prevention African-American Initiative. These demands, along with the Council endorsement, will be transmitted to the President and the Secretary of Health and Human Services. (See Addenda to Minutes for list of demands.)

Mr. Robinson discussed process issues concerning the Subcommittee, including a definition of its primary role: to assist the larger PACHA Subcommittees (i.e., Services, Prevention, etc.) in addressing issues that have to do with all communities of color, with particular focus now on African-American and Latino populations. Under this redefinition, a checklist is being developed covering related issues which each of the broader Subcommittees should address. Further, it is being ascertained whether the interests of this Subcommittee have proper representation on each of the Subcommittees, and the suggestion has been made that Subcommittees meet jointly with the Communities Subcommittee to ensure inclusion of the interests of African Americans and Latinos in all coverage. In line with this philosophy, the Subcommittee will not have a large number of independent actions or recommendations; however, it suggests that future PACHA recommendations, whenever feasible, address the need for targeted services and prevention strategies for these communities.

ALEXANDER
ROBINSON

Mr. Blackwell expressed the opinion that the Council should also consider the inclusion of Native American issues in all recommendations and actions in the future, and Dr. Levine added that consideration be given to the inclusion of other populations such as adolescents, women, and IDUs as often as possible to keep a focus on the needs of all affected groups.

International Issues Subcommittee Report

Mr. Fogel briefed the Council on Subcommittee activities during its breakout sessions:

Findings in recent perinatal transmission studies. These findings in Africa were described by representatives from CDC, NMAC, NCIH, and UNAIDS. In line with this, a major conference will be held in Atlanta, Georgia, to develop an outline of action that is sensitive to cultural and economic issues of the different countries. The Subcommittee will bring results and any appropriate recommendations to the June PACHA meeting.

Other international issues. These issues were addressed: (1) India has become the number one country worldwide in new infections. (2) During the President's visit to Africa, HIV site visits were planned for congressional and cabinet members, and Mr. Clinton was to mention AIDS issues in some of his speeches. (3) USAID has offered to detail a person to staff an international position in ONAP, and the Subcommittee called on ONAP to agree to this as soon as possible.

Mr. Robinson noted the disparity in the fact that the President was to make comments about AIDS during his visit to Africa, but had not addressed the issue of AIDS in African Americans in the United States.

Prison Issues Subcommittee Report

Mr. Landau reported that the Subcommittee continues to work with the FBP and CDC to document the burden of disease in the incarcerated population. Issues of concern now and in the near future include (1) privatization in prisons, with more than 27,000 HIV-positive inmates in prisons (representing more than 2 percent of the total prison population) and (2) surveillance and safety of information in Federal prisons and how it translates into the State systems (with 16 States now doing mandatory testing). He welcomed Ms. Billings and Mr. Blackwell to the Subcommittee.

Proposed activities prior to the June meeting include continuing the ongoing study of surveillance, visiting one or more prison facilities with ONAP, continuing the review of the assessment document from ONAP, and studying model program issues. Following up on a recommendation approved in December, the Subcommittee is pursuing a national meeting on prison issues. Work is complete on the study of brigs and prisons within the DoD systems, and Mr. Landau said that the 10 to 15 inmates with HIV currently in that system are receiving good treatment.

Address by Surgeon General David Satcher

David Satcher, M.D., Ph.D., newly appointed Assistant Secretary for Health and Surgeon General of the United States, was introduced by Dr. Hitt to the Council. The former Director of the CDC, Dr. Satcher also has worked in private community health, concentrating on women's and children's health issues that include immunization and development of viral microbicides, and has been involved with the HIV/AIDS epidemic since 1981 when it was first defined by the CDC.

Dr. Satcher expressed deep appreciation for the work of the Council and stated his strong commitment to community participation in prevention planning, local programs with local control, and the early involvement of affected communities in formulating policy. This is an era of controversy and change, he said, and progress has been made; and much more is known about the disease, including how the virus moves through populations, which allows the targeting of resources in a proactive manner through behavioral studies. Unfortunately, there is no vaccine, and new antiviral therapies and health care services are not universally available to all populations, especially high-risk groups. Although there has been a dramatic decline in AIDS-related deaths and infections overall, the impact is growing in such populations as women and minorities, and there is much to be done in this area.

Coordinated effort is needed to move such programs as vaccine development and access to treatment forward. Dr. Satcher called for aggressive development of strategies that will increase our ability to (1) identify and target populations with high-risk behaviors; (2) bring HIV-positive individuals into care and services; (3) embrace individuals with nonjudgmental services that are designed to retain these individuals in care; and (4) work within each high-risk population to identify specific points of access into medical care and essential services that are acceptable and available. This means changing the delivery systems to afford affected populations an opportunity to regain control over their lives.

Of concern to Dr. Satcher is the risk that the controversy surrounding these issues will divide or delay the Nation in making significant progress in the fight to end the epidemic. Issues of specific immediate concern include access-to-treatment by all persons, efficacy trials of short-course therapy and perinatal transmission, and needle exchange. In his new roles, he will look to all of these as major public health issues and will work to "ensure that science informs the assumptions on which policy discussion occurs, in every aspect of the HIV/AIDS epidemic, from surveillance to research and care." The basis for speaking out on issues, he said, will be the public health science. In addition, positive communications among all communities is important as is maintaining a balance between public health science and the concerns of the people in the country. It is also essential to have cooperation among prevention programs and to find creative ways for businesses and foundations to form partnerships.

In discussion that followed, Mr. Anderson and other Council members expressed PACHA's loss of confidence in the Administration's commitment to HIV prevention. Dr. Satcher reminded the group of the progress that has occurred, including the establishment of ONAP, the NIH vaccine program, changes in CDC, and ongoing funding increases in the past 5 years even with overall

budget cuts, and asked that the Council not lose sight of these areas of progress. There are, however, some real concerns about the balancing of funding for programs.

Concerning substance abuse and mental health services, Dr. Satcher agreed that there are major problems, particularly the judgmental attitudes in this country. As to needle exchange, he understands the frustration and assured the Council that the Administration is very concerned and is looking critically at the science; the struggle is with the issue and attitudes toward substance abuse. The Surgeon General was reminded that it is difficult to reconcile the numbers of infections that are occurring while waiting for the Administration to reach a decision.

In answer to questions about the insignificant budget for the race and health initiative, Dr. Satcher said that the sole purpose of the initiative is to provide funds to select cities to set up models to try to close the gaps in access to treatment. The outcome will determine how to spend more money in the future. He asked the Council not to think of this as "token money," but rather the beginning of a much larger coordinated community effort.

Mr. Johnson asked Dr. Satcher about the controversies surrounding reporting and surveillance and asked for an update on where the decision-making responsibility is within HHS and his office on issuing Federal guidelines and setting up new methods of reporting at the CDC. Dr. Satcher mentioned the difficult challenge of monitoring the epidemic, and the need to know the status of the epidemic at any time. He asked the Council if it had looked at the science of this issue, the approximately 30 States that currently have a name-reporting system, and how this experience is shaping the Council's thinking. HHS wants to know what the States' experiences have been and to make a decision based on that experience. Dr. Hitt offered the Council to give the Surgeon General a briefing on their findings in such matters in the near future.

MEMO TO DAVID
RE: NAMES REPORTING

Mr. Isbell said that the Council is inspired by Dr. Satcher's life-long commitment to public health and is aware of the contributions this President and Administration have made in the fight against AIDS. On the issue of prevention, however, members are concerned that the infections continue. In addition, the Council believes that, given the current situation with States creating policy without guidance, it is very critical that there be movement on surveillance. Dr. Satcher said that he will take these messages to the Secretary.

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Concerning the limited access to treatment for many groups, Mr. Bollman asked how the Council can help Dr. Satcher's office move this issue forward. Dr. Satcher agreed that there is limited access and asked the Council to provide all ideas and information to his office.

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Dr. Levine mentioned specific mechanisms of prevention, such as the importance of providing a place for IDUs to go for needle exchange. She also apprised Dr. Satcher of the Council's recommendations on vaccine development and the Administration's perceived belief that NIH is the only answer to vaccine development. All private and public entities involved in vaccine development must be included from the outset, and a mechanism for doing this must be handled at the highest level of the Administration.

Regarding the current Supreme Court case on the Americans With Disabilities Act (ADA) and its impact on asymptomatic HIV-positive individuals, Mr. Henderson suggested that Dr. Satcher

make certain that this Administration is taking an active role in defending the coverage of the ADA for these individuals, and if that fails, it should actively support legislative solutions within HHS, CDC, and other agencies to remedy the problem.

Dr. Hitt and other members thanked Dr. Satcher and said that the Council looks forward to his efforts at making changes in the CDC that will regain the community's confidence in the commitment to prevention.

Subcommittee Meetings

Prevention. Members present were Mr. Robinson, Ms. Gerus, Mr. Isbell, Mr. Landau, Mr. Milanes, Reverend Perez, and Mr. Schatz. Also present were Mr. Monsanto Als, assistant to Ms. Fraser-Howse; Mr. Austin; Ms. Ecker; Ms. Maldonado; Ms. Seiler; and Mr. Weber. Dr. David Holtgrave, CDC, discussed specific CDC budget issues and tracking of funding.

Services. Members present were Mr. Bollman, Chair; Dr. Abel; Ms. Aragon; Mr. Blackwell; Ms. Cooper; Rabbi Edelheit; Mr. Hattoy; Mr. Henderson; Dr. Rankin; Mr. Sasser; and Mr. Stafford. Also present were Dr. Cornman; Mr. Heash; Dr. Allen Huff, ARC; Mr. Seth Kilbourn, NORA; Mr. LaLonde; Mr. Rohr; and Mr. Mike Shiver, National Association of People With AIDS (NAPWA). Guest panelists were invited to provide briefings on the following issues:

- **FY 1999 Budget/FY 2000 Appropriations**—Mr. Summers, Mr. Harvey, and Ms. Maldonado.
- **Reauthorization of HOPWA**—Mr. David Vos, Department of Housing and Urban Development (HUD).
- **Native American Issues**—Mr. Murguia.
- **Youth Directive/June Panel Presentation Update**—Mr. Soliz and Mr. Harvey. Mr. Sasser provided an outline of the proposed full-Council briefing session planned for the next PACHA meeting.
- **National Drug Control Strategy, 1998—A Ten-Year Plan**—Mr. John Gregrich, ONDCP.
- **HIV+ Healthcare Worker Guidelines**—Dr. Robert Janssen, CDC, by conference call.

Research. Present were Dr. Levine, Mr. Johnson, Mr. Miramontes, and Mr. Murguia.

March 18 Prevention Subcommittee Report

Mr. Isbell, Co-Chair, said that the Subcommittee had focused on three areas:

Needle exchange. Discussions included nongovernmental organizations to help formulate a strategy, with the result that the outcome of the press conference is positive.

Surveillance. Dr. Fleming briefed the Subcommittee on the background and current views at CDC of what surveillance should provide and discussed such issues as possible negative legislative action in the event of HIV reporting, feasibility of using unique identifiers, timing, and

the problems involved in the States' implementing different systems and collecting data that cannot be compared. A followup conference call schedule has been set to work on these issues and related recommendations. The Council, Mr. Isbell said, needs to encourage CDC in devising new ways of obtaining information while maintaining security. Dr. Goftin and Dr. Hodge discussed the development of a model confidentiality law with respect to public health information, with target dates for the first draft in June and a complete model in November 1998. Changes in the epidemic make the need for reporting even more important in finding areas of risk; concurrently, there is an increasingly significant need for greater protection. It was suggested that someone approach Microsoft® to see if there are any new developments in computer security.

*Follow
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Funding for prevention. Dr. Holtgrave discussed the CDC's \$250 million budget for State and local organizations in education and promotion of risk-reduction programs. The Council has long been frustrated by the lack of information at CDC as to how this money is spent; however, these data are now being compiled. Findings to date are of limited use, but additional information will be sent through Mr. Montoya to Council members as it is received. What is evident is that groups at highest risk seem to be undertargeted by CDC, although one group—heterosexual contact—seems to be overtargeted. A very large "other" category must be enumerated and carefully defined. Mr. Isbell thanked Dr. Holtgrave for starting the process of budget analysis.

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Prevention conference. Mr. Summers said that ONAP will host a conference at the White House for prevention research personnel within both NIH and CDC to determine the status of this research and to help build a better coordinated network through more effective communications channels. Ms. Miramontes noted that better communications are also needed among these groups and the AIDS community.

Services Subcommittee Report

Mr. Bollman and Mr. Henderson reported on a number of areas covered in the Subcommittee's breakout sessions, including:

National policy dialogue. The proposed dialogue was addressed by Dr. Martin, Dr. Goosby, and Mr. Kelly. The important news is that HHS is moving forward with plans for the dialogue, including regional meetings. The Subcommittee's greatest concern is that this movement leads to implementation of a real program within a feasible time frame and within this budget cycle.

Medicaid expansion update. An update was provided by Ms. King and Mr. Claxon from HCFA, and Dr. Martin, and included actuarial information on cost analysis to show budget neutrality. Mr. Henderson, Mr. Bollman, Dr. Hitt, and Mr. Montoya had had a conference call with Dr. Sophia Chang of the Kaiser Foundation, which has developed a model, working with HCFA actuarial information.

Drug pricing. Models are also being developed by Kaiser Foundation to provide the pharmaceutical companies with clear information as to what changes in drug pricing would do to expand their sales bases. Discussions will be held between the Subcommittee and Vice President Gore's office as to where talks with the pharmaceutical companies stand. Progress is being made,

but much more must be done. Mr. Summers said that the internal task force set up by ONAP will study short- and long-term strategy in this area. It was noted that the Subcommittee had started looking at these issues almost 2 years ago and it appears that these developments will lead to some action on universal access to the new treatments. HCFA has had meetings with States about the waiver process, and actual programs are close to being put into place, the first being in Massachusetts.

Return-to-work issues. There may be an opportunity for the Council to bring these issues, particularly in terms of Social Security disability coverage, through the Social Security reform process. The Social Security Administration has a staffed task force for the reform process. This also could lead to specific Subcommittee recommendations which would be reviewed by the Social Security task force.

Access to drug abuse treatment. Mr. Bollman said that the Subcommittee was unable to meet with anyone from the ONDCP. He pledged that the Subcommittee would come in June with specific thoughts or recommendations on access to high-quality drug abuse treatment services.

Reauthorization of HOPWA. Reauthorization is controversial, with many people believing that it should not be taken up this year. Because of the importance of the subject, however, the Subcommittee continues to monitor its status. As background, a draft paper addressing technical and policy issues on reauthorization and improvement of HOPWA was made available to Council members.

Native American issues. Mr. Blackwell, a new member of the Subcommittee, discussed these issues and suggested topics for a full-Council presentation in November. Mr. Bollman said that the Subcommittee would proceed to develop the presentation and recommendations.

Youth issues. These issues are seen as an area that the Subcommittee was not able to track closely until Mr. Sasser joined the group. A proposed outline of a full-Council presentation to be given in June was provided to the Council by Mr. Sasser, who will work with each of the Subcommittees to get recommendations associated with that presentation.

Budget process. The budget process was discussed with Mr. Summers and NORA personnel, and it became clear that there is a great deal of work to be done in order to obtain increased funding in currently underfunded areas. A budget recommendation was drafted asking the White House to get involved in negotiating for higher funds within Congress. Following discussion, the Subcommittee redrafted the recommendation, and it was adopted with changes. (The full text is in Addenda to Minutes, New PACHA Recommendations.)

Followup on Needle Exchange

Dr. Hitt reviewed the activities of the past 2 days and said that the "President has heard the message." The danger now is that, with the Council leaving town, the pressure will be lessened. In order to maintain momentum, the Council will ask NORA to keep pressure on the Administration. It still is necessary to ascertain who is at fault for the Administration's apathy and where the Secretary of HHS stands on this issue and push for action. Conflicting messages

from HHS appearing in the press must be clarified. One story indicated that the agency is now waiting for additional studies to prove the science. The Government's own studies already prove the efficacy of needle exchange.

Dr. Goosby volunteered to appear before the Council that morning to discuss these conflicts; however, at this point, members believed that answers need to come directly from Secretary Shalala or someone in her office who can speak for the Secretary. It was agreed that the Council would talk to Mr. Thurm by conference call during this final session of the meeting, and a set of questions and strategies was developed for the call.

Future action will include a followup full-Council conference call (subsequently set for March 31) to review what has transpired, with a message to be sent to Secretary Shalala asking specifically what she thinks, what she needs to know, and when she is going to act on this, if those questions have not already been answered. Some members urged a call for Secretary Shalala's resignation; others asked that a meeting with the President be demanded. Mr. Bollman pointed out that there are many issues for which he should be updated as to the Council's view. Dr. Hitt said that the request for the meeting is with the President's staff.

Ms. Thurman reported that Mr. Thurm at HHS said that the department is not waiting for additional studies—although they are still analyzing those that they have—and that the source for the story has been told by the Secretary that this is not true.

Discussion and Adoption of Leadership Recommendation

After much discussion, it was agreed that a recommendation on funding and the current state of emergency within the African-American and Latino communities proposed by the Services Subcommittee should be listed as a Leadership Recommendation. One area of controversy was that the recommendation could be seen as excluding Native Americans and other minorities. Mr. Blackwell said that it is his impression that the Council does not have integrated knowledge about the impact of the disease on Native Americans, Alaskan Natives, and Pacific Islanders and that these groups should be included in all recommendations regarding budget issues and other support. Members agreed that these groups should not be excluded; however, it was also pointed out that the Council, to be effective, must be relatively specific in its recommendations and not dilute them with too many generalities. In addition, the emergency at hand, in terms of numbers of new infections, lies specifically within the African-American and Latino communities.

It was agreed to include the four groups of color within the general statement of the recommendation, while reserving the context of an emergency state for the communities of African and Latino descent. The leadership recommendation was adopted with one member opposed.

Conference Call with Deputy Director of HHS Kevin Thurm

Mr. Thurm, speaking for Secretary Shalala, addressed PACHA through a full-Council conference call. Dr. Hitt began by reviewing what has happened in the past 24 hours and asked Mr. Thurm for clarification of the conflicting statements in the press about the need for "additional studies."

Mr. Thurm apologized for the misleading stories and said that the press had already been called to clarify that HHS is not waiting for results of any other particular studies to prove the science of needle exchange, nor is there any specific time frame set for analysis of the existing studies. He said that HHS “continually looks at results of any study that comes into the office.” Mr. Thurm went on to say that “everyone in the Administration is working to resolve these issues” and to provide a realistic time frame. He said that PACHA had been appropriately clear and direct and that the significance of this concern is appreciated.

Mr. Anderson asked who was speaking for the Secretary on this issue. A clear, single-point message is needed. In the case of the recent article in the press, a statement signed by the Secretary, saying that HHS is not looking at any other studies, should be submitted within 24 hours to clarify the misconceptions in the media.

Mr. Thurm said that a number of people were authorized to speak for the department, including Dr. Goosby and Dr. Martin; however, the point is well taken and future messages coming from the HHS need to be clearer and, if possible, in writing. Regarding a time frame for a needle exchange decision, Mr. Thurm said the agency is not in a position to provide this.

Council members asked again if a written clarification on the article in the press was forthcoming, and Mr. Thurm said that the department is “probably prepared to clarify” the conflicting statements about the studies.

Mr. Robinson reminded Mr. Thurm that 13 months ago the department promised a resolution on needle exchange within 6 months. Mr. Hattoy also noted that Dr. Goosby and Dr. Martin had laid out a relatively short time frame for something to happen during the Council meeting and asked whether Mr. Thurm would stand by those statements.

Asked what the problem was in analyzing the results of the Federal studies that have been completed, Mr. Thurm said that he is not a part of the research community and, therefore, cannot answer that question. Dr. Levine said that she assumed that this expertise does exist in the department and that she wanted to pose these questions to those experts: What are the flaws in the current research? What are the issues that create such difficulty in analyzing these completed, federally funded studies?

Mr. Thurm said he understood how the answers he was giving today are unacceptable to the Council; however, he assured the Council that the Secretary does follow the science.

Mr. Bollman noted that the Secretary has always been known as a leader in progressive causes and has made extraordinary leadership advances, which makes it even more difficult for us to understand why these issues—including many other than needle exchange—are not being resolved. New treatment protocols suggest that early intervention is an effective solution, and yet there are tens of thousands of people who cannot get access to them; and HHS is not taking a leadership role in making this happen.

Mr. Thurm said that his office is not happy to have these conversations and not happy to be unable to report resolution; however, the department wants to move cautiously and lay out an effective, longer term strategy.

Ms. Stokes asked Mr. Thurm to relay to Secretary Shalala that she has broken the promises she made personally 4 years ago, when she said that we have the knowledge and the technology and the strength to end unnecessary deaths now. Mr. Schatz noted that the Council is wasting its time, venting at the wrong person, and called for an immediate meeting with the Secretary. Mr. Thurm said that he cannot guarantee a meeting with the Secretary, but that he would check her schedule and get back to Dr. Hitt.

Dr. Hitt summarized by saying that the Council wants to know who is speaking for HHS and the Secretary, that it wants this and a retraction of the news story in writing almost immediately; further, the Council wants a meeting with Secretary Shalala as soon as possible. He thanked Mr. Thurm, and he hoped that the Deputy Secretary could get a real sense of the anger and frustration among the Council members and that he would take this back to the Secretary so that these issues can be addressed. The conference call was then ended.

Mr. Aragon noted that NORA's recent request for an urgent meeting with the Secretary had been denied and that even Mr. Thurm did not meet with the group. A number of members, including Mr. Isbell, Mr. Hattoy, and Mr. Henderson, said that they would be comfortable with calling for the Secretary's resignation if no word is received today.

New Business

Long-term planning. Dr. Hitt reminded the Council that PACHA has a finite term—about a year to complete this process. The last long-term planning exercise was done in December 1996, during which the Council tried to focus its efforts into a concise 4-year goal. (Copies of that document were made available to the members.) It is time to come back to that process, he said, and talk about what the Council should focus on in its limited time left and what the final PACHA product should be—a Progress Report or a set of Recommendations to the next Administration. Time will be set aside for planning at the next meeting, and Subcommittees were asked to limit their agendas for the breakout sessions accordingly.

Next Council meeting. The next Council meeting will be held June 15–18, 1998, at the Madison Hotel in Washington, D.C. Dr. Hitt asked members to contact Mr. Montoya if they wished to be included in any of the scheduled Subcommittee conference calls.

Closing

Dr. Hitt thanked Council members, Ms. Thurman and the ONAP staff, the PACHA meeting staff, and guests for their participation; the Ninth Meeting of PACHA was adjourned at 12:15 p.m. March 18, 1998.

ADDENDA TO THE MINUTES

- A. Letter to Secretary of HHS Donna Shalala, March 16, 1998
- B. Materials Delivered to the Media during the March 17, 1998, Press Conference
 - 1. Letter to the President
 - 2. PACHA Resolution on Needle Exchange Programs
 - 3. Statement by Dr. Scott Hitt
 - 4. Statement by Ronald Johnson
 - 5. Statement by Regina Aragon
 - 6. Statement by Terje Anderson
 - 7. Statement by Denise Stokes
- C. Demands of the African-American Community: Meeting with the CDC, March 3–4, 1998
- D. New PACHA Recommendations
- E. Private Organizations, Government Agencies, and Media Represented at the PACHA March 1998 Meeting

PRESIDENTIAL

ADVISORY

COUNCIL ON

HIV/AIDS

March 16, 1998

The Honorable Donna Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue
Washington, D.C.

Dear Secretary Shalala:

As the leading public health official in the country, it is your responsibility to exercise leadership on critical issues affecting the health of the nation. As the Presidential Advisory Council on HIV/AIDS, we urge you to demonstrate that leadership on the issue of needle exchange programs in our common fight against the transmission of HIV.

As you know, the statistics are compelling - injection drug use is directly responsible for half of all new HIV infections in this country annually, and indirectly responsible for the infection of thousands more people who are the sexual partners or children of infected users. HIV transmission related to needle sharing is, to a great extent, responsible for the frightening and disproportionate spread of HIV among African-Americans and Latinos, particularly women.

As you also know, the scientific evidence of the efficacy of needle exchange programs in preventing new infections is equally compelling, and there is no credible evidence that needle exchange programs lead to increased drug use.

We are, therefore, increasingly dismayed by your almost complete silence and continued inaction. This critical health issue demands your leadership, not only inside the government but also on a public level. Needle exchange programs have powerful and vocal opponents. As the nation's leading spokesperson on health you must insure that science, not unsubstantiated fears, guides this administration's policies.

It is imperative that you state, publicly and unequivocally, what the scientific evidence demonstrates: needle exchange programs meet the two-pronged test laid out in the law. By issuing such a determination you will send an important message to the American people, and will help to change the terms of debate and discussion on this issue.

The Honorable Donna Shalala
March 16, 1998
Page Two

It is equally imperative that you immediately engage the President on this matter, by providing him with a full briefing on the scientific data and stressing the critical role needle exchange programs can play in reaching his stated goal of reducing the number of new HIV infections until there are none. We are hopeful that, presented with such compelling evidence and your strong advocacy, the President will immediately act in the interest of public health and bring federal policy into line with current scientific knowledge.

Lack of political will can no longer justify ignoring the science. Every day that goes by means more needless new infections and more human suffering. We call upon you to make an immediate determination and to allow the local use of federal funds for needle exchange programs as part of a comprehensive HIV prevention program. To do anything less would be an abdication of your responsibilities.

Sincerely yours,

R. Scott Hitt, M.D.
Chair

March 17, 1998

The Honorable William Jefferson Clinton
President
The White House

Dear Mr. President,

When you told us at the White House Conference on HIV/AIDS in 1995 that you wanted to see our country “reduce the number of new infections each and every year until there are no more new infections,” we believed you. Thus, it is with great frustration and disappointment that we, the members of your Presidential Advisory Council on HIV/AIDS, find it necessary to write this letter to you. We must express, in the strongest terms possible, our profound dismay regarding the lack of progress on the critical issue of removing the prohibition on the use of federal funds for comprehensive needle exchange programs.

Despite years of study and an overwhelming preponderance of scientific evidence, no action has been forthcoming. All six federally funded reports, an NIH Consensus Conference report, and many other reputable studies have concluded that needle exchange programs reduce HIV transmission and do not encourage drug use. In light of this overwhelming evidence—as well as support for needle exchange programs by the American Medical Association, the American Public Health Association and numerous other public health organizations across the country—the continuing delay by Secretary Shalala is appalling.

Tragically, we must conclude that it is a lack of political will, not scientific evidence, that is creating this failure to act. This political treatment of a public health issue is killing people; and it must cease.

According to studies from the Centers for Disease Control and Prevention, half of the 40,000 annual new HIV infections in this country are transmitted through needle sharing. Thousands more are infected through sexual contact with needle users. Injection drug use also accounts for the overwhelming majority of the pediatric AIDS cases in this country.

That the populations hurt most by your Administration’s continued silence are largely poor African-Americans and Latinos is particularly shameful in light of your Race Initiative’s stated goal of ending health disparities among racial and ethnic groups. We as a nation will never succeed in this goal without your bold leadership and political courage.

The Honorable William Jefferson Clinton
March 17, 1998
Page Two

It will be impossible to bring the epidemic to an end until you take decisive and effective action on this issue. Access to uncontaminated injection equipment, in conjunction with outreach, education, and referral and access to effective substance abuse treatment, is essential.

Additionally, we have yet to see any other coherent strategies or initiatives by the Administration to deal with the rampaging HIV epidemic among injection drug users, their partners, and their children. We are left with the unfortunate conclusion that their lives are considered to be expendable by those with decision-making power within this Administration.

Without action on this important matter, it is increasingly difficult to believe that your Administration is truly committed to ending new infections. As your advisors, we must tell you that this goal cannot be reached without action on this important item.

Mr. President, where do you stand on this issue?

We must further tell you that failure to act on this matter is destroying this Administration's credibility with people concerned about AIDS and is overshadowing the many other positive steps that have been made in combating this epidemic.

When the history of the AIDS epidemic is finally written, we do not want your legacy to be one of having failed to take a necessary step at a critical time to save thousands of lives.

We know that this issue is viewed by many as controversial. It is your leadership obligation to hear the varying viewpoints, weigh the scientific evidence, and make a Presidential decision on the matter. We fully believe that careful and honest consideration of the case on the merits can lead to only one conclusion: needle exchange programs decrease the transmission of HIV without encouraging drug use and, as such, are one important part of a continuum of activities to combat HIV.

Secretary Shalala must issue an immediate determination that needle exchange programs meet the two-pronged test laid out in the law and must remove the restriction on the use of federal funds where desired by state and local officials.

The Honorable William Jefferson Clinton

March 17, 1998

Page Three

In the nearly three years of the Council's existence, we have issued numerous recommendations and letters on this issue, and there is tremendous impatience and anger in the community and among Council members that nothing has happened. Every day that passes without action can be measured in needless new infections, infections we know how to prevent. The time for study and unwarranted delay is over. We urgently implore you and Secretary Shalala to act immediately.

Sincerely,

Presidential Advisory Council on HIV/AIDS Members

R. Scott Hitt, M.D., Chair
Stephen N. Abel, D.D.S.
Terje Anderson
Regina Aragon, M.P.P.
Judith A. Billings, Esq.
Nicholas Bollman
Jerry Cade, M.D.
Rabbi Joseph Edelheit
Robert Fogel, Esq.
Debra Fraser-Howze, M.P.A.
Kathleen Gerus
Phyllis Greenberger, M.S.W.
Nilsa Gutierrez, M.D., M.P.H.
Bob Hattoy
B. Thomas Henderson, Esq.
Michael Isbell, Esq.
Ronald Johnson
Jeremy Landau
Alexandra Mary Levine, M.D.
Steve Lew
Helen M. Miramontes, M.S.N., R.N., F.A.A.N.
Rev. Altagracia Perez
Robert M. Rankin, M.D., M.P.H.
H. Alexander Robinson, Esq.
Debbie Runions
Sean Sasser
Benjamin Schatz, Esq.
Richard W. Stafford
Denise Stokes
Charles Quincy Troupe
Bruce Weniger, M.D., M.P.H.

PACHA RESOLUTION ON NEEDLE EXCHANGE PROGRAMS

March 17, 1998

WHEREAS we the members of the Presidential Advisory Council on HIV/AIDS have on several occasions advised the President and Health and Human Services Secretary Donna Shalala that the Administration's current policy on needle exchange programs threatens the public health, and directly contradicts current scientific evidence regarding the efficacy of such programs; and

WHEREAS this Administration has yet to put forward a coherent plan to increase access to substance abuse treatment or to combat the spread of HIV among injection drug users and their partners; and

WHEREAS nearly 50% of all new HIV infections, and 44%, 44%, and 61% of all reported AIDS cases among African-Americans, Latinos, and women, respectively, are related to injection drug use; and

WHEREAS the Congress in 1997 reaffirmed Secretary Shalala's authority to make Federal funds available for needle exchange programs, provided that she first determine that needle exchange programs reduce HIV transmission and do not encourage drug use; and

WHEREAS no fewer than six federally funded reports (including a 1997 Consensus Report prepared by the National Institutes of Health) and numerous other scientific studies have concluded that the above two criteria have been met; and

WHEREAS the nation's leading public health groups, including the American Medical Association, the American Public Health Association, the National Academy of Sciences, and the Association of State and Territorial Health Officers support needle exchange programs and the elimination of federal funding restrictions; and

WHEREAS 61% of Americans surveyed believe that decisions regarding the use of Federal funds for needle exchange programs should be made by local communities and not the Federal government; and

WHEREAS it is essential that the nation's health policies be based on sound, scientific evidence rather than on unsubstantiated fears or politics; and

WHEREAS in light of the disproportionate impact of injection drug-related HIV on communities of color in the United States, the Secretary's continuing inaction undermines the credibility of the Administration's stated goal of reducing racial and ethnic health disparities; therefore

BE IT RESOLVED that, in the interest of the public health, and in our capacity as independent advisors to the Administration, we unanimously express "no confidence" in the Administration's commitment and willingness to achieve the President's stated goal of "reducing the number of new infections annually until there are no new infections"; and

BE IT FURTHER RESOLVED that the Council urges Secretary Shalala to issue an immediate determination declaring the efficacy of needle exchange programs in preventing the spread of HIV while not encouraging the use of illegal drugs.

STATEMENT BY DR. SCOTT HITT
CHAIR PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS
March 17, 1998

Good morning. My name is Scott Hitt. I serve as Chair of the Council. In addition, I am a practicing physician, and have cared for more than 1,000 patients with HIV disease.

During the 3 days that this Council will meet, dozens of people's lives will have been forever changed because this Administration has failed to adopt a strategy that we know prevents HIV infection. In the 14 months since the Secretary of the HHS spoke about this issue, thousands of people have become infected as a result of injection drug use.

In December 1995, at the White House Conference on HIV/AIDS, the President established a goal of "reducing the number of new infections each and every year until there are no new infections." He spoke eloquently and with obvious feeling about the devastating impact this disease has had on the country. He spoke of personal friends lost to this epidemic and of societal loss as its consequence.

Thirteen months ago, the National Institutes of Health issued a consensus report which states, and I quote, "An impressive body of evidence suggests powerful effects from needle exchange programs. There is no longer doubt that these programs work, yet there is striking disjunction between what science dictates and what policy delivers." In other words, the NIH panel said needle exchange programs work.

A year ago, the President appointed Sandra Thurman as Director of the Office of National AIDS Policy. In remarks made immediately following her appointment, Director Thurman was asked by the press about needle exchange programs and declared her firm conviction, speaking for the administration, that we should quote, "follow the science."

There is clear and convincing evidence that the scientific community has reached the conclusion that needle exchange programs have a crucial role as part of a continuum of activities needed to combat HIV infection. It is time that the Secretary of Health and Human Services, as the chief public health official of the country, clearly and vigorously tell the American people what the scientists have told her: that needle exchange programs can prevent many new HIV infections. And, in answer to the question "does needle exchange promote drug use?"—again, in the words of the NIH Consensus Statement, "a preponderance of evidence shows either no change or decreased drug use."

The American Medical Association, the American Public Health Assoc., National Academy of Sciences, and numerous other public health organizations across the country have added their voices in support of such programs. The U.S. Conference of Mayors, the American Bar Association, as well as the Chairs of the Congressional Black and Hispanic Caucuses, have urged action in this area. This Council has repeatedly urged the Administration to act.

Our patience is exhausted. We are angry at the inexcusable inaction by Secretary Shalala on this crucial issue affecting public health.

The Council unanimously passed a resolution expressing “no confidence” in the ADMINISTRATION’S commitment and willingness to achieve the PRESIDENT’S prevention goal. Today we are sending a letter to the President outlining our frustrations.

Mr. President, the time for study and delay is over; the science is indisputable; and the time for your action is now.

STATEMENT BY RONALD JOHNSON
PACHA Press Conference
March 17, 1998

Good morning. My name is Ronald Johnson. I am a member of the Presidential Advisory Council. I am also a Managing Director for Public Policy and Communications at the Gay Men's Health Crisis in New York City.

Injecting drug use is the driving force behind the continued growth of HIV infection nationwide, both in urban centers like New York City and Washington, D.C., and in rural areas. Nearly 50 percent of newly reported cases of HIV infection are related to injecting drug use.

We have all heard the good news that the number of AIDS-related deaths has decreased. We do not always hear the news that HIV infections continues to grow. Approximately 20,000 new HIV infections will occur this year, and next year, and the next year, as a result of injecting drug use—unless we do something. The overwhelming majority of these infections are among African Americans and Hispanics. We will not control the HIV/AIDS epidemic, and we will not stop new infections, until we stop the spread of HIV that results from injecting drug use. Comprehensive needle exchange programs have been shown to be effective in reducing transmission of HIV among injecting drug users. Every day that we delay implementing needle exchange programs, more men, women, and children will become infected. Because of this inaction, more mothers and fathers will lose their adult children to AIDS. More children will be orphaned as a result of AIDS. More of us will lose our brothers, our sisters, our friends. The devastation in African American and Hispanic communities resulting from AIDS will continue.

We cannot delay any more. We cannot hide behind fears and myths. We have to act now to save lives. We have to act now to save our African American and Hispanic communities; and we call on Secretary Shalala to act immediately to determine the efficacy of needle exchange programs and to lift the ban of the use of federal funds.

STATEMENT BY REGINA ARAGON
PACHA Press Conference
March 17, 1998

Good morning. My name is Regina Aragon. I am a member of the Presidential Advisory Council on HIV/AIDS and Policy Director for the San Francisco AIDS Foundation.

San Francisco is home to the largest needle exchange program in the nation, the San Francisco AIDS Foundation HIV Prevention Project (HPP). Last year, HPP exchanged more than 2.1 million syringes, with approximately 5,000 injection drug users. In addition to exchanging used, potentially contaminated syringes for clean ones, HPP staff and volunteers refer clients to other services, such as medical care, HIV testing, and drug treatment services. HPP is an important part of our city's comprehensive plan to prevent HIV transmission.

HPP has the full support of San Francisco's public health officials because they know that needle exchange has prevented thousands of new infections among injecting drug users and their sexual partners and children, and has enabled San Francisco to avoid the extremely high infection rates seen in New York and other East Coast cities.

If Secretary Shalala is to be believed, this Administration's continued delay in making a public health determination on the efficacy of needle exchange is purely a question of science. As members of this Advisory Council, we are here to say in no uncertain terms: the Empress has no clothes.

Two of the nation's most prominent scientific organizations—the Institutes of Medicine and the Secretary's own National Institutes of Health—have convened bodies of prestigious scientists to review all of the existing data. Both concluded that the preponderance of evidence shows either no change or decreased drug use associated with needle exchange programs.

In light of such compelling evidence, it is clear to this Body that Secretary Shalala's continued inaction on needle exchange is not at all about science, but about politics.

That the populations most hurt by the Secretary's continued silence are poor, African Americans and Latinos, including women of color, is particularly shameful in light of the Race Initiative's stated goal of ending health disparities among racial and ethnic groups. We as a nation will never succeed in reaching this goal without bold leadership and political courage.

We implore the Secretary and the White House to follow the science and issue an immediate public health determination on needle exchange. Further delay threatens the credibility of this Administration; and, more importantly, the future course of the epidemic.

STATEMENT BY TERJE ANDERSON
PACHA Press Conference
March 17, 1998

My name is Terje Anderson. I am Executive Director of the Southern Colorado AIDS Project located in Colorado Springs, and a member of the Council. I am also a recovering injection heroin user.

As someone who knows firsthand the damage that drugs did in my life, I want to make clear that I am emphatically anti-drug and pro-treatment. We are not advocating programs that encourage people to use drugs. Substance abuse treatment and needle exchange programs are complementary parts of a whole system of services that we need; services that can help people along the path to recovery.

But I also know from personal experience that quitting is rarely easy. In my own case, it took several years in and out of various treatment programs, arrest, multiple emergency room visits and other traumas. But I finally did quit—and I like to think my presence here is testament to that fact that recovery is possible, and that our lives are worth saving.

People do not begin using drugs because they have access to an uncontaminated needle any more than easy access to wine glasses is the cause of alcoholism or matches are the cause of teen smoking. It is not access to the means of administration that makes someone start an addictive, destructive behavior—it is much more complex, much deeper than that. Addiction is a chronic, progressive disease, and incredibly complex human factors influence who will and will not begin drug use.

There is a moral issue here, but not the one opponents of needle exchange programs are focusing on. The question should be: “Do you care about the lives of people like me? Are you willing to take steps—perhaps politically risky or unpopular steps—in order to save lives? Or, instead, are you willing to consider us expendable, disposable people?”

People with addictions can recover; we do recover. Please give us a chance to recover without first becoming infected with life-threatening diseases.

STATEMENT BY DENISE STOKES
PACHA Press Conference
March 17, 1998

In 1994, I sat a press conference as the federal government unveiled the America Responds To AIDS (prevention) Campaign. Having appeared in two of those ads, I shared the stage with the Secretary of Health, Donna Shalala. Her words that day reached me very deeply—as a person living with HIV—and as a young person there representing the Future of America. She made such profound declarations. I sat and listened to Secretary Shalala say, “Every new HIV infection is a needless infection. We have the knowledge and the technology to prevent the... spread of HIV. What we have lacked until now is the political will—because we have been too timid to talk openly about the prevention tools that are at your disposal.”

Her words resounded in me and I understood them as being a promise made to me and to the rest of the American people that no more lives would be squandered away because of a lack of action from our government.

That was over 4 years ago; and, while people are dropping like flies, the Secretary still refuses to do what really needs to be done.

Reputable scientific data clearly indicates that needle exchange programs prevent the spread of HIV and do not encourage drug use. This is the technology; these are the prevention tools at our disposal. When will this Administration truly take a leadership role and exert this political will?

Real people—each with immeasurable value—have been neglected by this Administration and left to die. Politics should not regulate the value of human lives.

Having been hit the hardest by the intravenous transmission of HIV, African American and Latino communities are outraged. Black AIDS leaders have declared a state of emergency because AIDS is killing us in such grossly disproportionate numbers. The Secretary of Health has at her immediate disposal the ability to begin a process which will save our lives.

Today, I am no longer speaking as the Future of America. I am now speaking for the dead and for the dying; because that is what we have become. At the age of 29, I have spent 16 years HIV positive. I have seen this disease gather momentum and devastate my community—our communities. On behalf of those most at risk for HIV, I vehemently demand the right to life.

DEMANDS OF THE AFRICAN-AMERICAN COMMUNITY

Meeting with the CDC, March 3–4, 1998

Leading Black AIDS advocates meeting with CDC officials declared a “state of emergency” in the African-American community regarding the AIDS epidemic. During the National Week of Prayer for the healing of AIDS in the African-American Community, this Body appeals to all persons of all faiths to join in this endeavor as we make the following demands:

1. That CDC Director Clare Broom communicate immediately to Secretary Donna Shalala and Surgeon General David Satcher about the emergency in the African-American community on HIV/AIDS, and that the Secretary and Surgeon General immediately communicate those concerns to President Bill Clinton.
2. That the President and Surgeon General declare a state of emergency in the African-American community concerning AIDS and public health.
3. That Director Broom and Dr. Satcher develop an emergency press strategy and implement same to alert the American public on the present state of HIV/AIDS and initiate a new booklet to the American public on AIDS in the African-American community.
4. That, within 90 days, the CDC Director, SAMSHA, and ONDCP report to Secretary Shalala a new strategy to interrupt the devastation of drug addiction and HIV/AIDS on the African-American community.
5. That the CDC Director immediately redirect current resources to address the long-standing HIV emergency in the African-American community.
6. That the Administration immediately convene an emergency meeting of national black leaders and organizations to develop their own plan(s) for AIDS and public health in the African-American community.
7. That demonstration funding designated to test alternative community planning models, as well as other program models that meet the needs of the African-American community be established immediately.
8. That the CDC Director undertake a specific and extensive external research program to identify those factors that cause and promulgate the diversity in reference to the impact of HIV disease on the African-American community.
9. That the CDC Director initiate extensive analysis of the correlation of funding and allocation to communities in relation to epidemiologic trends.

NEW PACHA RECOMMENDATIONS

Passed During the PACHA Meeting March 15–18, 1998

Discrimination Subcommittee. The following recommendation was passed unanimously.

The President should work with Congress to create stronger protection for medical privacy, and should veto any legislation that (1) permits law enforcement authorities access to patient records without having obtained a warrant or meaningful and informed patient consent or (2) fails to preserve the ability of the States to enact or maintain stronger privacy protection.

Services Subcommittee—Leadership Recommendation. The following recommendation was passed with one member opposed.

In its ongoing Congressional lobbying related to the FY 1999 budget and appropriations, the Council urges the Administration to advocate and fully support increased HIV/AIDS funding levels above those proposed in the President's own FY 1999 budget.

In so doing, the Council urges the Administration's full support for the FY 1999 budget and appropriations funding levels proposed by National Organizations Responding to AIDS (NORA), which reflect documented community funding needs across the federal HIV/AIDS portfolio, especially those programs impacting African Americans, Latinos, Native Americans, and Asian/Pacific Islanders.

Toward the goal of expanding access to promising new HIV therapies, the Council urges the Administration to consider the critical need for full funding for the ADAP program, as well as for primary medical care and other support services, including housing, which facilitate access to such treatments.

Considering the goal of reducing the number of new infections, the Council further urges the Administration to support efforts to provide substantial funding increases for prevention programs.

There is a state of emergency because of HIV/AIDS in African-American and Latino communities. Therefore, the Council urges the Administration's full support for meaningful and sufficient funding levels for prevention and care initiatives targeting these communities.

Research Subcommittee—Achieving the Goal of an AIDS Vaccine. The following background and recommendations were adopted by the Council unanimously with the exception of the first paragraph, which received one vote of opposition.

Background

Approximately 40,000 people become infected with HIV in the United States each year; worldwide, 6 million new infections occur annually. Although behavioral change to reduce the risk of HIV infection is a viable strategy for some, it is clear that this strategy will not work for

all. Only a preventive vaccine will ultimately be successful in stopping the AIDS pandemic. Commendably, President Clinton declared the goal, in May 1997, of a successful AIDS vaccine within the next decade. However, the current Federal AIDS vaccine effort is stalled in paralyzing scientific debate and bureaucratic delay.

Since late 1995, the Research Committee of the Presidential Advisory Council on HIV/AIDS 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 also solicited and received written input from these and other experts.

The scientific issues involved in vaccine development are extremely complex and controversial, and should be addressed by existing Federal agencies. NIH has an essential role to play in elucidating the basic scientific knowledge that underlies vaccine generation. However, this is only one aspect in the complete process of vaccine development. Additional administrative and policy structures will also be required to address the myriad public policy issues which must also be resolved, both nationally and internationally, to expedite development of a successful AIDS vaccine. These issues include development and implementation of mechanisms to ensure the active participation and coordination of all relevant agencies of the U.S. Government, as well as the pharmaceutical industry and the international community, where candidate vaccines must be tested for efficacy, and where the need for an effective vaccine is the greatest. The recommendations which follow concern these administrative issues, which must be planned and coordinated simultaneously with the actual generation of candidate vaccines.

Requisite participants in vaccine development

Federal agencies. The proposed restructuring of the AIDS vaccine program within NIH represents an important step in expanding the scientific leadership which will be necessary to expedite the development of candidate vaccines. The appointment of Dr. David Baltimore as Chair of the AIDS Vaccine Research Committee (AVRC), the expanded vaccine budget, and the proposed institution of a new Vaccine Research Laboratory at NIH can all serve to invigorate the scientific process. The appointment of a full-time Director of the Vaccine Research Laboratory could provide another mechanism for coordination of the vaccine development effort within NIH. However, the Council is very concerned that recent progress has been slowed substantially by the failure to appoint this individual, who must be at the highest level of expertise.

In addition to NIH, Federal agencies such as the Centers for Disease Control and Prevention (CDC), Department of Defense (DoD), and the U.S. Agency for International Development (USAID) have among them extensive experience and expertise in the area of vaccine development, field epidemiology, surveillance, and the conduct of vaccine efficacy trials, especially in developing countries. It would thus seem prudent to ensure the active cooperation, collaboration, and communication of all relevant Federal agencies in the areas of candidate vaccine development and testing, if the President's goal is to be met. Similar recommendations were made by the Levine Commission. However, although various NIH vaccine meetings have been attended by DoD and CDC representatives, and although an informal interagency group was formed, this group does not include senior leadership, and has not met on a regular basis. Thus, it is clear that no formal process of interagency coordination has been developed or implemented. If

the President's goal is to be met, such interagency communication and coordination must occur, involving the highest levels of leadership from each agency.

Pharmaceutical and biotechnology industries. It is clear that development of a successful AIDS vaccine will also require the active involvement of the pharmaceutical and biotechnology industries, working in a coordinated manner with relevant Federal agencies. The pharmaceutical industry traditionally has been a major leader in the creation and development of vaccines, and should be encouraged to participate actively in the pursuit of an AIDS vaccine. Further, eventual product development will require the infrastructure and expertise which reside primarily within the private sector of pharmaceutical and biotechnology industries. To ensure the requisite coordination of both public and private sectors, an administrative mechanism must be created. Multiple policy issues must also be addressed, in an attempt to overcome existing financial disincentives for involvement by the private sector. This may entail subsidies for targeted applied research, cooperative agreements for pilot manufacture of vaccine approaches not commercially attractive, support of phase III human efficacy trials, tax rebates, and/or patent extensions. Federal leadership will also be needed to address related issues, such as intellectual property rights, liability, and international vaccine development and purchase funds.

International community. Because there is a higher prevalence of HIV/AIDS in developing nations, the majority of clinical testing for efficacy of candidate vaccines (phase III) must be accomplished internationally. Further, the majority of AIDS vaccine use is expected to occur in nations outside the United States. It is thus apparent that mechanisms to develop true partnerships between the international community and the Federal AIDS vaccine effort must begin at once, with exchange of information and full coordination of combined efforts. Agencies such as the Joint United Nations Program on AIDS (UNAIDS), the World Bank, the International AIDS Vaccine Initiative (IAVI), and the leading developed countries (G-8), as well as those countries most affected, have critical roles to play in the final testing and implementation of an AIDS vaccine. A mechanism must be developed to provide a means for ongoing communication and collaboration among these groups, as well as the other critical constituencies listed above. Critical issues which must be addressed by these groups include active involvement in the process by scientists living in the countries involved, assurance of scientifically and ethically appropriate field testing of candidate vaccines, and mechanisms to ensure access to the vaccine product after successful field testing.

Leadership and coordination

Role of the President's Office. It is only within the Office of the President that sufficient authority exists to ensure leadership, through coordination and collaboration of all requisite constituencies, including Federal agencies, the private sector, and the international community. Responsibility for this effort should rest with the Office of National AIDS Policy (ONAP). The Council, therefore, recommends that the President formally charge the Director of ONAP with developing and maintaining administrative mechanisms for accomplishing the requisite communication and coordination among all relevant parties, including assurance of the involvement of senior leadership from all constituencies. Adequate resources must be made available for this function.

Generation of a comprehensive Federal plan for AIDS vaccine development. A comprehensive Federal AIDS vaccine plan must be developed and implemented. This plan must include the vision and process for vaccine development, and must also depict the specific objectives, responsibilities, strategies, and outcomes for the implementation of the plan. Additional requisites of the plan should include the framework by which competing issues may be addressed, an overall work schedule, and a specific time frame in which certain milestones are to be accomplished. The Council recommends that the process for development of this plan be organized within ONAP, working with relevant Federal agencies.

Moving candidate vaccines into human trials

Differences of opinion on the appropriate time for bringing AIDS vaccine strategies into human efficacy trials result from two divergent philosophical approaches. The “basic science” approach pursues knowledge of the underlying biological mechanisms of retroviral disease and immunity in animal models and limited human studies, in order to elucidate the protective immune response. Candidate vaccines are then designed to induce those specific responses, and only then do human efficacy trials proceed. The “empirical science” approach brings vaccines into human trials relatively earlier, if comparable vaccines were safe and effective in animals, even without a clear understanding of their biological mechanisms of action. This has been the case for many existing vaccines in current use. With the gravity of the current AIDS pandemic in the world, and the need to proceed with vaccine development as quickly as possible, the Council acknowledges that it will be necessary to test various traditional and novel vaccine design strategies in human clinical trials, even before the scientific correlates of protection have been fully deciphered. The Council thus advocates the simultaneous implementation of both basic and empiric scientific approaches. These parallel approaches should be recognized within the comprehensive Federal plan for AIDS vaccine development.

Summary of Recommendations

1. Substantive involvement, coordination, and collaboration among all relevant Federal agencies, the private sector, and the international community are critical to the development of an effective AIDS vaccine.
2. Federal leadership at the highest level will be required, through the Office of National AIDS Policy, ensuring that adequate resources are provided for the coordination process necessary to achieve the goal of an effective AIDS vaccine.
3. The Office of National AIDS Policy should ensure the development and implementation of a comprehensive Federal plan to achieve the goal of an effective AIDS vaccine.
4. The process of defining the structure and mission of the proposed (AIDS) Vaccine Center at NIH, and the appointment of a director with the highest level of expertise, should proceed promptly.
5. The urgent need for an AIDS vaccine mandates the simultaneous implementation of both basic and empiric scientific approaches.

Private Organizations, Government Agencies, and Media Represented at the PACHA March 1998 Meeting

Private Organizations

Agouron Pharmaceuticals, Inc.
AIDS Action Council
AIDS Policy Center
Allegheny University of the Health Sciences
American Association of Dental Schools
American Red Cross (ARC)
American Foundation for AIDS Research (AmFAR)
Bently Health Care
Community Health Awareness Group (Detroit)
Dwayne S. Brown Foundation
Episcopal Caring Response to AIDS (ECRA)
FHI
Friends Seminary
Georgetown University Law Center
Harvard University School of Social Work
The HIV Community Coalition
Hunter College Center on AIDS
Johns Hopkins School of Public Health
National Alliance of State and Territorial AIDS Directors (NASTAD)
National Association of People With HIV/AIDS (NAPWA)
National Black Leadership Coalition on AIDS
National Council of International Health (NCIH)
NEAC
National Hemophiliac Foundation
National Minority AIDS Council (NMAC)
National Organizations Responding to AIDS (NORA)
New York State Psychiatric Institute
Ortho-Biotech/Johnson & Johnson
Pan American Health Organization (PAHO)
Sabin Vaccine Institute, Georgetown University
San Francisco AIDS Foundation
World Bank
World Vision

Government Agencies

Centers for Disease Control and Prevention (CDC)
Congresswoman Nancy Pelosi's Office
Department of Health and Human Services (HHS)
Health Care Financing Administration (HCFA)
Health Resources and Services Administration (HRSA)
Joint United Nations Programme on HIV/AIDS (UNAIDS)
Office of HIV/AIDS Policy, HHS
Office of Disease Prevention and Health Promotion, HHS
Office of Housing for People with AIDS, HUD
Office of Management and Budget (OMB)
Office of National AIDS Policy (ONAP)
Office of National Drug Control Policy (ONDCP)
Office on Minority Health, HHS
Office for Women's Health, HHS
Substance Abuse and Mental Health Services Administration (SAMHSA)
Social Security Administration
U.S. Agency for International Development (USAID)

Media

AIDS/STD News Report
Associated Press
Bay Area Reporter
Capitol Publications
CBS Network
CNN
Conus
DRCNet
National Public Radio
Reuters
The Scientist
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