

Presidential Advisory Council on HIV/AIDS

April 5-8, 1997

Madison Hotel
Washington, DC

MINUTES

Present: R. Scott Hitt, M.D., Chair; Stephen N. Abel, D.D.S.; Terje Anderson; Judith Billings; Tonio Burgos; Jerry Cade, M.D.; Rabbi Joseph A. Edelheit; Robert Fogel; Debra Fraser-Howze; Kathleen Gerus; Phyllis Greenberger; Robert Hattoy; B. Thomas Henderson; Michael Isbell; Ronald Johnson; Jeremy Landau; Alexandra Mary Levine, M.D.; Steve Lew; Helen M. Miramontes; Rev. Altagracia Perez; Robert Michael Rankin, M.D.; H. Alexander Robinson; Debbie Runions; Benjamin Schatz; Richard W. Stafford; Denise Stokes; Sandra Thurman; and Bruce Weniger, M.D. Also present from the Office of National AIDS Policy (ONAP): Eric P. Goosby, M.D., Acting Director; Daniel Montoya, Executive Director; Tiffany Bronson; and Jason Wright.

Absent: Regina Aragon, Mary Boland, Nicholas Bollman (participated in Committee meetings via conference call), and Charles Quincy Troupe.

Opening and General Council Business

Dr. Hitt, Chair, opened the sixth meeting of the Presidential Advisory Council on HIV/AIDS (PACHA) with a review of the agenda and report on interim activities. A number of significant issues and actions were addressed during the 4-day meeting, including the following:

New ONAP Director and Staff: On April 7, members attended a press conference at the White House during which the President named the new Director for the Office of National AIDS Policy (ONAP)—Ms. Sandra (Sandy) Thurman, PACHA member and former Executive Director of AID Atlanta. Dr. Eric Goosby, Director of the Office of AIDS in the Department of Health and Human Services (HHS) was named Deputy Director, having served as ONAP's Acting Director since Patsy Fleming left the position in February. Daniel Montoya was named Executive Director, serving as liaison with PACHA. Other new ONAP staffers introduced at the Council meeting were Jason Wright and Tiffany Bronson. Dr. Hitt said that PACHA expects important changes in ONAP, including better coordination between HHS and the White House, and ONAP pledged to continue to support the Council and to work "more aggressively with the Administration." A reception in the Indian Treaty Room of the Old Executive Office Building that night honored Ms. Thurman, Dr. Goosby, Mr. Montoya, Ms. Fleming, and Jeff Levi, former Deputy Director.

Responses to Recommendations: Responses from the last PACHA meeting have been provided by HHS (collated by Dr. Goosby), the Office of the Under Secretary of Defense, the Department of Housing and Urban Development (HUD), the United States Agency for International Development (USAID), and the Department of State. The Council agreed that a new evaluation of Administration responses to all Recommendations should be conducted before the next meeting (see New Business, below).

PACHA Charter: The Council has been rechartered automatically for another term.

ONAP Update

Dr. Goosby, thanked by the Council for his help during a “difficult transition,” discussed HIV/AIDS-related issues and activities, including his recent experience working with the White House. Describing “high levels of activity and anxiety” surrounding White House staff and the number of opportunities for mistakes that can impact HIV/AIDS programs, he stressed the ongoing need for PACHA to have a “clear and constant dialogue” with the Administration, especially regarding domestic policy. ONAP’s continuing mission is to foster this dialogue and to work across all agencies and organizations dedicated to HIV/AIDS research. He said “this is an extraordinary time” when a convergence of unique forces, long in evolution, are impacting the epidemic. Difficulties exist because of the differences in treatment and delivery systems and in patient populations; however, infrastructures are being augmented, protease inhibitors (PIs) seem to be decreasing death rates, risk behaviors are being considered more in prevention, and HIV transmissions are lessening in this country, including a 27-percent drop in the number of children acquiring the virus through vertical transmission. The possibility of immunopotentiators and their roles are very promising, and collaborative efforts to look at indirect evidence support the idea that a drop in viral load is in correlation with one’s ability to infect another individual.

Gaps are seen in technology and in determining and delivering effective therapeutic interventions, and filling service capability holes must be a priority of every budgetary consideration. Other important converging issues include Welfare Reform, Medicaid eligibility, definition of disability, and the role and evolution of managed care. Of great impact are the diametrically opposed concepts of providing adequate response to the needs of diverse populations and maintaining efforts to contain costs. The Federal Government is less effective than it should be, in large part because the leadership lacks the experience and understanding of the issues. The AIDS community must monitor and stress quality of care with sensitivity to population differences as the country moves from Federal to State and local programs, with the potential for people to become lost in or hurt by the system. Knowledgeable health care providers with the ability to design effective programs for individual patients and manage multiple therapy protocols are needed, and the knowledge base must be distributed across all populations. Additionally, a better mechanism is needed for allocation decisions that correlate with the demographics of the epidemic. The potential for effective and meaningful work is available within the White House.

Survey/Questionnaire Review

Dr. Hitt thanked Ms. Billings for help in developing the questionnaire for PACHA’s “HIV/AIDS Federal Support Survey” and Mr. Wright for compiling the responses. Ms. Billings said that more than 30 responses were received out of 300 surveys sent to White House conferees, local organizers of community briefings, and AIDS organizations around the country. Respondents included health care workers, academics, politicians, researchers, and persons with HIV/AIDS, most representing community-based organizations (CBOs) and health services. A “fair amount of agreement” with Council priorities and its role was found, and common themes included the need for more emphasis on new high-risk populations, realism about prevention efforts, affirmative

action on approving needle exchange, and strong congressional and Presidential leadership and response to controversial issues.

Mr. Fogel believed that the response base was too low for statistical use, but Ms. Billings said that answers were consistent enough to offer broad guidelines. Dr. Hitt noted that most responses reflected the opinions of large organizations, and Mr. Henderson called this “sound input from effective people” and an important evaluation. Dr. Hitt, Dr. Levine, and Rev. Perez asked participants in a recent Los Angeles meeting of CBOs the survey questions and found that their answers corresponded with the written responses. He encouraged all members to go back to their communities to get input about “what we are doing and where we should be going.”

Mr. Wright will perform a further breakdown of respondents by ethnicity and other factors for Council use, and ONAP will furnish copies of all responses to committee chairs and other members who want them. Committee-specific recommendations will be highlighted, if requested by Chairs.

Needle Exchange and Substance Abuse Updates

Dr. Goosby provided the Council with a report—*Needle Exchange Programs in America: Review of Published Studies and Ongoing Research*—made to the Committee on Appropriations for the Departments of Labor, HHS, Education, and other agencies in February by HHS Secretary Donna E. Shalala. Other background was provided, including a national survey on needle exchange programs in the United States in the *Journal of the American Medical Association (JAMA)* and an overview of vaccines and politics in the *Wall Street Journal*.

During meetings of the Prevention and Research Committees, outside panelists discussed the need for a national HIV/AIDS and substance abuse prevention strategy, particularly through lifting Federal bans on funding and modification of State and local regulations on purchase and possession of clean syringes. Studies indicate that clean needles save lives, and integration of needle exchange into a comprehensive strategy to reduce HIV infection related to injection drug use can produce significant savings.

Coburn Bill Update

The Coburn Bill—the HIV Prevention Act of 1997—has been submitted to Congress, and a resolution may be forthcoming, Dr. Hitt said. A Statement of Policy on HIV/AIDS by the National Governors’ Association regarding the bill was provided to PACHA, which developed a Recommendation regarding the HIV Prevention Act conference (see New Council Recommendations, below).

New Assistant to HHS Secretary

Ms. Fleming introduced Marsha Martin, D.S.W., recently appointed Special Assistant to Secretary Shalala. The former director of homeless activities under HUD and at the Department of Veterans Affairs (VA) was commended by Dr. Rankin for “a superb job with homeless veterans,” and Dr. Martin thanked ONAP for helping her get up to speed in her new job. Calling

homelessness “unacceptable” and funds from the Federal budget “too small for such a big problem,” she admonished government to face its responsibility in this arena. The VA, the single largest provider of HIV treatment because of the number of veterans with the disease, is developing a care plan that will be open to the total community and will include sharing agreements and bartering for services such as clinical and hospital facilities. Dr. Martin asked PACHA to provide input to her office and to call on her for assistance (212-690-5400).

Discussion of Domestic Policy

Dr. Hitt said that the AIDS community is finding that it has good access to and response from Bruce Reed, recently named Assistant to the President for Domestic Policy. Dr. Hitt thanked Mr. Reed for his advocacy and help, including facilitating a meeting between the National Organization Responding to AIDS (NORA) and the Deputy Chief of Staff to the President, speeding the appointment of the ONAP Director, and meeting with PACHA prior to the Council session to discuss major issues, Recommendations, and Welfare Reform.

Mr. Reed addressed the Council on new ONAP leadership, the state of HIV/AIDS programs, and the Administration’s commitment to finding a cure and a vaccine. He thanked the Council for its contributions and Dr. Goosby for an “outstanding job in a tough situation.” He said that Ms. Thurman is a “tribute to the Council,” with both proven experience and the support of the President to make a success of the Director’s job. For the first time, the ONAP Director will have an office in the White House and meet regularly with the President’s staff.

Mr. Reed described the progress made in HIV/AIDS research over the past 4 years, calling the advances a “sign for us to do more, not less.” The Administration has an ambitious AIDS agenda, a good budget, and a commitment to continue fighting for increases in funding for National Institutes of Health (NIH) research, Ryan White programs, and the Centers for Disease Control and Prevention (CDC) programs. Battles ahead include needle exchange, restoring Medicaid cuts for immigrants, and monitoring Welfare Reform; the Council’s help is needed in tracking these issues. It is encouraging to see that many States are using their own money to extend Medicaid to legal immigrants, and a coalition of Governors and mayors is being built to try to put this money back into the budget.

Major issues brought up by Council members in discussion with Mr. Reed included the following:

- Concerning ONAP, Mr. Burgos suggested empowering Ms. Thurman by giving her an appropriate title and staff and better recognizing Dr. Goosby for his efforts as well as giving him more opportunities to contribute. Mr. Reed concurred.
- Mr. Reed said that the Administration will try to incorporate new Public Health Service (PHS) standards of care guidelines into the prison system.
- Mr. Schatz asked how the President’s efforts to respond to PACHA Recommendations on discrimination manifest in mandatory testing in Government entities could be increased, saying that nothing has happened in more than 2 years. Mr. Reed responded that PACHA has a good case on this, and the Council should “hold our feet to the fire.”
- Mr. Isbell said that, in order to reach the President’s goal of zero seroconversion, the Federal ban on needle exchange programs must be lifted. Mr. Reed acknowledged that

this is an important and highly charged issue that the Administration is “committed to review”; however, the office does not want to do something that will backfire.

- It was noted that the “national prevention strategy” is inadequate and in need of an implementation plan. The Council asked Mr. Reed to work with PACHA in its efforts with the CDC and the Substance Abuse and Mental Health Services Administration (SAMHSA) to develop a real strategy. SAMHSA has not been as accountable as necessary for spending resources and responding to the problem, and the Council is particularly concerned that the position of Associate Director for AIDS Programs might not be filled.
- Dr. Hitt noted that the Council feels a sense of frustration, having spent 2½ years developing Recommendations at the President’s request only to have many of them go unaddressed. More high-level leadership is needed to address difficult issues.

AIDS Vaccine Panel Presentation

Introducing a full-Council panel briefing on AIDS vaccines, Dr. Hitt noted that this is one of the most difficult issues of the epidemic and that the Council has spent 2 years becoming educated on the subject to develop appropriate Recommendations to the Administration. “The time seems right now,” he said, and the community mandate is clear—that the Administration must put more emphasis, effort, and direction into the development of an effective vaccine against HIV/AIDS. Dr. Levine, Chair of the Research Committee, introduced speakers, who were asked to discuss their organization’s vaccine activities as well as proposed PACHA Recommendations on vaccine development. The general agreement was that an effective vaccine can be developed, and it offers the only reasonable hope for controlling the epidemic of AIDS.

John G. McNeil, M.D., M.P.H., Director of the Department of Defense (DOD) HIV-1/AIDS vaccine development program, Walter Reed Army Institute of Research, said that the research and development of candidate vaccines by DOD was initiated to deal with problems within the U.S. Armed Forces worldwide. Through collaborative partnerships, the program has had successes with such diseases as hepatitis A and meningitis. Its small annual budget (\$20 million from the President’s request, with about \$15 million from Congressional “plus-ups”) is devoted mostly (57 percent) to HIV vaccine development. The strategy is to use basic research to build trials based on plausible immune effectors of virologic control, select candidates that induce indicated immune responses, and conduct proof-of-concept efficacy trials. Searching for an AIDS vaccine has problems similar to those of malaria: Protective immunity and pathogen–host interactions are not clearly understood, good animal models do not exist, and the diseases cause catastrophic pandemics. The process is long, and a problem exists in the advancement of products from Phase II to Phase III clinical trials; the “pipeline is seriously constricted at the end.”

William E. Paul, M.D., Director, Office of AIDS Research (OAR), NIH, and Chief of the Laboratory of Immunology of the National Institute of Allergy and Infectious Diseases (NIAID), said that the OAR Advisory Council (OARAC) considers vaccine development among its leading mandates. NIH funding for vaccine research will have increased in FY 1998 by 33 percent over FY 1996, from \$110 million to approximately \$150 million, even as other HIV research budgets have remained rather flat. Adding to this large investment in fundamental research (on issues of the structure of, immune response to, and mechanisms of the virus that cause disease) makes the

actual funding for AIDS research much greater. Congress may accord an even greater increase in the overall HIV/AIDS budget than what has been requested, and the OAR pledges to see that increases are sustained annually. Money needs to be stockpiled for efficacy trials, which will be substantially more expensive than those for many other vaccines, and a funding screen is needed for planning over the next few years.

For progress to be made, a combined effort of targeted vaccine research and increased input into the “pipeline” is needed. To this end, the OAR is stressing investigator-initiated research, with the number of grants increasing 50 percent from 1994 to 1998. Tremendous advances have been made in understanding the mechanisms of the immune response, and the NIH is moving into Phase II trials on the prime/boost strategy to determine whether it warrants advance into Phase III. Opportunities exist for a close collaboration among NIH, DOD, CDC, and others, and Dr. Paul advocates using the OAR’s new AIDS Vaccine Research Committee (AVRC) as the facilitator.

Jerald C. Sadoff, M.D., Executive Director of Vaccine Research, Merck Research Laboratories, said that an HIV vaccine can be developed, based on epidemiological clues such as the existence of long-term nonprogressors and certain persons who seem to be immune. One major hurdle is the lack of an acceptable surrogate marker that can guide the choice and quantity of antigens in the vaccine, permit rational experiments with termination of dose and regimens, and guide assays to determine vaccine stability and reproducibility. Current debate concerns whether cellular immunity alone is enough, and there are several promising approaches using live vectors, the so-called “naked DNA.” Development of clues to the nature of surrogate markers through investigation of animal models and epidemiologic leads, therefore, should be the highest priority. Another hurdle is the definition of success: The ideal vaccine would provide long-term sterile immunity, while an acceptable one might prevent progression. The market size has been seen as a barrier in terms of industry incentive; however, although development of vaccines is dependent on Government- and foundation-sponsored research, the sooner industry becomes involved, the sooner a transferable process yielding similar results will be developed. At least several hundred million dollars per year are needed even for a narrow approach.

Margaret Johnston, Ph.D., Scientific Director, International AIDS Vaccine Initiative (IAVI) and former Director of the Division of AIDS for NIAID, said that insufficient attention is being paid to HIV vaccine development, private sector talents are not being used appropriately, and development of vaccines appropriate for use in developing countries is being ignored. IAVI’s mission is to ensure development of safe, effective, preventive vaccines suitable worldwide, using advocacy in both industrialized and developing countries, working with other organizations to create a better environment for increased investment in HIV vaccine development, and raising funds to fill gaps in the current research and development effort. Success in HIV vaccine development requires that the United States increase its leadership and participation in international efforts and work to attract additional involvement of the private sector, especially in designing promising new candidate vaccines for human testing. IAVI supports NIAID’s two-pronged strategy of both fundamental and empirical research and urged that this direction not be lost in the effort to beef up the knowledge base. The NIH should go beyond its traditional role and help apply fundamental knowledge to vaccine strategies, provide additional funds for targeted vaccine development, and take responsibility for immunogen design and product production.

Obstacles include its move toward more investigator-initiated basic research and cumbersome Government regulations and budget process.

Yichen Lu, Ph.D., Senior Scientist and Manager of the HIV program, Virus Research Institute, Inc., said that 5 years ago there were 40 companies looking for a vaccine; now there are fewer than 10, with no newcomers. Large drug companies are not collaborating with biotechnology companies, which do the basic research but cannot afford to advance on their own. Private investors have been intimidated by the high price of developing an HIV vaccine candidate into Phase III trials. (Although the average vaccine development program takes \$100 million and 10 years, some HIV vaccine programs have spent 15 years and \$700 million without reaching Phase III trials.) The pipeline is dangerously empty, and the Government needs to rescue this effort. Dr. Lu is working on producing a prototype vaccine in Thailand (in 3 years) because the local government is supportive and because funding has come from an industrialized source, the Japanese Government. The local and Japanese governments will take the program to Phase II and III trials.

Anthony S. Fauci, M.D., Director and Chief of the Laboratory of Immunoregulation, NIAID, agrees that a firm and passionate commitment to the development of a vaccine is needed but that the ability to predict what will be successful is not now available. There must be a combination of basic science to understand mechanisms, immunological correlates, and the best candidates (the NIH has a major mandate to continue a steady stream of science) and an empirical approach to determine the right paths. To develop a vaccine successfully, an infrastructure has to be available; NIAID has that in its assayed populations and its data on rates of infection, mechanisms to determine immunological response, HIVNET, commitment in resources, and manpower available both domestically and internationally to take a proven candidate to advanced phases. Currently, the prime/boost approach is farthest along, but multiple candidates are studied constantly. The NIH also recognizes the need to forge partnerships between industry and Government to bring vaccines to final phases.

David M. Gold, J.D., Cofounder of the AIDS Vaccine Advocacy Coalition (AVAC), emphasized the need to increase support for vaccine research among CBOs and investment by industry. Additional resources are needed, but they should be used more efficiently than in the past. Since industry researchers say the leading barrier to private sector investment is the scientific feasibility of developing an HIV vaccine at this time, Government advancement of the science will drive investment capital. He applauded the early efforts of the AVRC, and believes it must be supported widely. He noted that PACHA's Recommendations "barely mentioned" the committee, which risks weakening the NIH's efforts and the impact of its own report. The NIH should continue to lead the country's AIDS vaccine research program, and there is no need to spend valuable research dollars to expand Food and Drug Administration (FDA) and CDC programs, although DOD's program should be supported. Significant gaps in AIDS research can be filled through investigator-initiated research, targeted research, and effective scientific leadership. The following areas need attention: useful, comparative animal and Phase I human studies; a focus on broad-based outreach to fill the studies; dissemination of information on immune responses seen in trial participants; and a broad range of vaccine approaches and combinations. Large pharmaceutical and vaccine manufacturers must increase investment in vaccine development; the actual private investment is relatively minuscule.

Philip K. Russell, M.D., President, Albert B. Sabin Vaccine Foundation, Professor, Johns Hopkins University Center for Immunization Research, and former head of military and World Health Organization vaccine development programs, said that an AIDS vaccine is the most important public health issue of our time. He is in general agreement with much of the PACHA report and many issues discussed in this meeting. There are common elements in all successful vaccine programs: a strong research program underpinning product development, based on both basic and empiric science; effective collaborations between Government agencies and industrial development, with a commitment by both parties to a common goal and an involved leadership capable of directing a very complex program; and recognition of the value of conducting early efficacy trials. Information gathered in field trials, whether candidates are successful or not, is extremely valuable in guiding future efforts. Animal studies have limited value in predicting the immunogenicity or protective efficacy of a vaccine for humans, but clinical trials are essential.

Supported actions include parallel, multiple vaccine development and a coordinated national strategy, drawing on the strengths of Government agencies and fully utilizing the potential of technology and immunology industries. All elements needed for success—a powerful academic research community, a vigorous publicly funded research effort, and an immensely powerful vaccine development industry—exist. Lacking are leadership, sufficient financial commitment in both private and public sectors, and a mechanism for bringing the sectors together effectively, as has been done in space, defense, and SEMATECH consortia.

David Baltimore, Ph.D., Cochair, Professor of Molecular Biology and Immunology, Massachusetts Institute of Technology, Nobel Prize laureate, and Chair of the NIH AVRC, described the new group as a coordinating and advisory body for the overall NIH vaccine effort. The Committee's major focus is to identify opportunities for moving vaccine development forward and arranging for these research directions to receive increased attention. The first vehicle is a fast, simple grant program that supplies funds for targeted areas of research, particularly to recruit new scientists for HIV studies, and is available to individuals as well as through the Small Business Innovative Research (SBIR) program. Initial funding is \$6 million for \$150,000 direct-cost-maximum grants for 2 years, but additional sources are available. The total amount to be spent depends on the number of deserving grants reviewed. Targeted areas are animal models, envelope protein structure as it relates to immunogenicity, and optimization of antigen presentation for the development of cytotoxic T lymphocytes (CTLs). In the future, AVRC will focus on other areas, particularly on DNA and live-attenuated vaccine approaches. The grant deadline is May 23, 1997; applications will be reviewed by an internal panel in the Division of AIDS with the advice of a grant specialist.

An active program of vaccine testing in humans does exist, focused on the prime/boost strategy, and it is important to continue this and gain as much scientific knowledge as possible, even if it is not efficacious. AVRC sees as its major tasks ensuring that opportunities for clinical testing are being generated and that the United States has as broad and deep a program as possible so the full range of opportunities can be investigated, including study of viral pathogenesis, structure, and function; examination of modes of immune response; and evaluation of modes of eliciting immunity such as through proteins, peptides, DNA, vectors, and whole virus. It is known that vaccines work mainly by stimulating immunologic memory—most have worked through antibody-

mediated responses—and that the control of CTLs may be important but generally has not been studied. Antibodies can play an important role in the development of HIV immunity, but there is a likely need for a strong CTL-based response. Furthermore, other possible protective modes of response need to be studied, with significant concentration on how the body responds to an HIV infection. Historically, the best vaccines have been live-attenuated and whole-killed viruses; however, the differences between HIV, the first human lentivirus challenge, and other viruses cannot be minimized.

Issues and Answers: Council members brought up a number of issues, as follows:

- Asked how to pull in DOD and other agencies so there is mandated coordination, Dr. Paul suggested that AVRC could act as a nucleating factor.
- Ms. Miramontes raised a concern about the balance between basic and empirical research in study sections. Dr. Fauci said that this is a troubling problem and that the NIH is developing special emphasis panels to look at relative priorities in protocol applications.
- As to ethical issues, Dr. Fauci said that formal ethicists are used in the design of any institutional review board (IRB) or other safety group so that safety and ethical issues are being addressed before the fact. If there are international implications, the ethicists must have experience working with the World Health Organization (WHO) and The Joint United Nations Programme on HIV/AIDS (UNAIDS). IAVI has addressed some of these issues and will provide the Council with a report.
- Regarding Government agencies working on multiple vaccine approaches other than the prime/boost, Dr. Fauci said that the NIH does not have only “one egg in the basket” and it would not try to prohibit work on other candidates.
- Asked to describe the “pipeline,” Dr. Baltimore said AVRC believes it understands the concept but “we don’t know all of what private industry is doing, and probably shouldn’t.”
- Dr. Levine asked how to get more funds, but no answer was forthcoming. Dr. Fauci suggested that the Council support the NIH by emphasizing the need for new money, not moving funds from one area to another.
- Regarding implementation of the “Levine Committee” recommendations, Dr. Paul said that OAR has responded to all recommendations and that a plan has been written and reviewed by the OARAC and should be ready for public distribution shortly.
- On the issue of liability, Dr. Paul said that work at the NIH is limited to research and development and that liability should be left to other entities in the Government that are better equipped to handle these concerns. Ms. Greenberger pointed out that it is one of the top three impediments to vaccine development, and Dr. Sadoff agreed, but said it does not need to be addressed until the kind of vaccine to be used and its risks are known. Dr. Fauci also agreed that liability can impede vaccine development but that these matters are out of the scientists’ scope.
- Since industry ultimately must manufacture the vaccine, the Council questioned whether a group like ONAP could feed seed money to industry where it is needed to expand the pipeline rather than have it all go through the NIH. Dr. Paul said that the present spending process is designed to limit duplication and ensure that HIV money is spent fairly in both private and public sectors. The NIH has a good record in leading the development of vaccines. Dr. Fauci pointed out that national vaccine cooperative groups, which include consortia with industry, do exist and that the grant system factors in both industry and

academia in its review. Dr. Lu called the SBIR award funding program “more generous” than NIH R01 grants, but limited. For Phase I trials, a small company can be granted \$75,000 in funds for 6 months; if successful, it can request Phase II funding—\$750,000 for 3 years, not nearly enough to move a product into human testing.

Responses to PACHA Recommendations:

- Most speakers agreed that a public commitment from the President to develop a successful vaccine is very important but setting a time line is problematic. It is impossible to predict an actual time to development, and having an unrealistic deadline can lead to disappointment if it is not met. Most agreed, however, that 7 to 10 years was not out of the question and that setting some kind of reference lends to the urgency. The term “within a decade” can be depressing, especially in developing countries. Dr. McNeil believes that three first-generation vaccine strategies could be fully evaluated by the year 2005.
- More funding can always be used; however, it should be staged carefully. Dr. Baltimore suggested that any increased funding should take into consideration the importance of developing a stronger intramural vaccine program within the NIH. Dr. McNeil suggested that funding is not the primary issue keeping products out of the distal end of the pipeline; rather, it is a philosophical issue. A model can be driven for \$360 million per year—a sum that is available—based on preventing 30 percent of new infections in the United States, but much of this amount should be earmarked to underwrite leverage of contract with private industry.
- A full-time AIDS coordinator in the White House is not needed; there are already too many advisors and chiefs. No one person is capable of doing this; two would be better—one a basic scientist and the other a developer with an appreciation of basic science, working as a team. One suggestion was to have a Chief Executive Officer rather than a coordinator. Leave coordination at the agency level (within the NIH), and empower agencies and individuals by giving them sufficient resources. The Council asked how efforts can be coordinated and private/public sectors held accountable without a national coordinator. Dr. Baltimore’s view is that information moves fast enough on the scientific level and that coordination becomes more important as the vaccine moves forward into Phase III trials. Ethical and legal concerns then come into play. In actual development of candidates, however, there is no extensive coordination problem with industry. There already are too many meetings and too much time spent on airplanes. Dr. Lu said that the “Baltimore Committee” has the best scientists in the world, so there is no need for parallel coordination; rather, someone should pursue the business side.
- Having the Vice President lead a consortium of high-level private/public sector individuals through a dialog on HIV/AIDS subjects might be effective, but adding another level of organizational structure would not. To be productive, such an arrangement should involve informal, face-to-face meetings where serious discussions can take place, and it also needs an international scope. Some believed that industry might not respond openly at a table with Mr. Gore and the competition; others suggested leaving it to industry to decide how Government can help.

Committee Meetings, Actions, and Reports

Following are summaries of Committee and Subcommittee activities during the PACHA meeting and their reports to the Council.

Research Committee

The Committee met April 5, 6, and 7, with Dr. Levine, Chair and Dr. Cade, Mr. Fogel, Ms. Greenberger, Mr. Hattoy, Dr. Hitt, Mr. Johnson, Ms. Miramontes, Dr. Weniger, and ONAP staff present. Primary actions included finalization of new vaccine Recommendations (see New Council Recommendations, below) and facilitation of a presentation panel on vaccine development for the full Council (see AIDS Vaccine Panel Presentation, above). Following a lengthy discussion on the Recommendations and the presentations of the vaccine panel, Ms. Greenberger suggested that the Committee establish a list of major issue questions for the AVRC, and the Committee agreed.

Services Committee

The Committee met April 5, 6, and 7, with Mr. Bollman (via conference call), Chair; Mr. Henderson, facilitator; and Dr. Abel, Mr. Anderson, Mr. Lew, Dr. Rankin, and Mr. Stafford present. Mr. Henderson reported on Committee activities during the meeting:

Responses to Recommendations: Most Recommendations from the last meeting covering Ryan White programs and Housing Opportunities for People with AIDS (HOPWA) have produced responses.

Ryan White Update: During a Committee meeting, **Dr. Joe O'Neill**, Acting Director of the Bureau of Health Resources and Development, Health Resources and Services Administration (HRSA), reported on reorganization of Ryan White programs and introduced **Dr. Michael Kaiser**, new Director of Title IV. Consolidation of Titles I through V into one entity, headed by Dr. O'Neill, will allow HRSA to be more responsive, reduce costs and duplications, standardize technical strategies, coordinate resources, and improve grant applications and data collection. Administrative changes will be made within 6 months; the overall consolidation will take 3 to 5 years. Reorganization issues include developing a consistent policy and more aggressively determining the impact of Ryan White on the American public. Two recent HRSA appointments with positive impact on HIV/AIDS programs are Dr. Earl Fox, Administrator, and Joan Holloway, liaison to the Ryan White group for contact with groups such as PACHA. A permanent Director for the Title V AIDS Educational Training Program (AETP) should be appointed soon. The Committee applauded the changes and asked that the Ryan White group reevaluate Council Recommendations.

HOPWA Update: **Fred Karnas**, Director, Office of HIV/AIDS Housing, HUD, updated the Committee on the HOPWA program. Major problems include an inadequate budget (\$136 million for FY 1997, with no increases seen in the near future); realignment of funding among 80 jurisdictions, causing smaller communities to lose eligibility; and new definitions of eligibility that could result in people with HIV losing support. The Committee's main concern was loss of housing for patients whose health improves to the point of their being able to work part time (the

“cost of getting well”). HUD is undergoing a General Accounting Office (GAO) evaluation, and the Office of AIDS is analyzing its own program impact. Mr. Karnas asked PACHA to keep him informed of the needs of people with AIDS and housing.

Meeting with New HUD Secretary: The Committee met with the newly appointed HUD Secretary, Mr. Andrew Cuomo, to address housing issues. The most important concept expressed by the Secretary is that this is not just a programmatic issue in regard to HOPWA but a mindset that needs to be changed within all HUD programs. The Committee believes that PACHA will have good support from the new leadership.

Native American Issues: Mr. Landau reported that Recommendations on Native American issues have been partially addressed, although related Ryan White questions have not. Both Mr. Landau and Dr. Goosby noted that the Indian Health Service (IHS) is not responding to either PACHA Recommendations or Native American needs in the HIV/AIDS arena. It is a politically and logistically difficult area to cover in that IHS has different types of health care programs and funding methods than HRSA. IHS also does not designate funds for HIV prevention and treatment because it does not see HIV as a major problem in this population. Dr. O’Neill said that the Ryan White group is trying to develop joint “technical-assist” strategies with IHS because Ryan White group has no mechanism for funding the Indian Nations. HIV-related funding comes through States, although the Nations have a better relationship overall with the Federal Government. Dr. Goosby is instituting a working group, including IHS, CDC, the NIH, and American Foundation for AIDS Research (AmFAR), within the HHS AIDS Office to develop documentation on programs and health care issues of this population. The current modus of IHS is to move responsibility to tribes and provide technical assistance and block resources, which Dr. Goosby considers a shedding of responsibilities and fears that individuals will receive less than optimal care.

To cover this critical area better, the Services Committee needs a Native American on the Committee to replace Ms. laFavor, and the Council and ONAP were asked to help address this issue with the President.

Pharmaceutical Cost Reduction: To address the high cost of PIs, Dr. Goosby said that HRSA tries to lower the overall prices through 340B programs, which make funds available to seek the best prices, and to have Medicaid pick up more of the costs. This is difficult because States do not want to deal with these processes. HRSA is trying both to persuade States to tighten eligibility requirements and to obtain a formulation from the AIDS Drug Assistance Program (ADAP) on pricing and listing of drug categories. To date, prices have decreased minimally.

Pharmaceutical companies earn about six times their projections of profit on PIs, and Dr. Goosby calls them “powerful, extremely effective, and subtle,” with “very deep pockets and excellent legal and lobbying minds.” Approximately 9,000 indigents are being treated in company-sponsored compassionate care programs now, and many cities are trying to use this system. The Government, which makes up about 65 percent of the market share for PIs, does have some leverage, and the pharmaceutical companies are finally beginning to look at lowering the prices. These issues are difficult to address because legal and financial matters keep the companies from openly discussing pricing, a subject not covered in the Keystone Conference. Dr. Goosby

encouraged the Services Committee to frame a Recommendation on creating more pressure on pharmaceutical companies to lower prices. On the other hand, the AIDS community needs to provide good substantiating data on drug usage at funded centers. HRSA hopes to have statistics on increased utilization of multiple therapy in time for budget development.

Medical Marijuana: A Recommendation developed by the Services Committee with the Prevention Committee was finalized and approved (see New Council Recommendations, below).

Military Clinical Research: Mr. Henderson and Dr. Rankin will follow up on this issue, which now appears to be more than a programmatic difference between the Army and the Navy. It is believed that the military may be moving away from the clinical arena, and the issue bears monitoring.

Youth Issues: Most youth issues have been moved to the Prevention Committee because they primarily involve intervention, and the Services Committee does not have a member with experience in this area, although one Recommendation is being formulated in the Office of Alternative Medicine (OAM) by Mr. Lew. Rev. Perez said that the Prevention Committee also has a problem with adequate representation and is worried that youth issues will be lost. It is strongly recommended that a new Council member with youth experience be found to address these issues.

White House Advisory Council on Consumer Protection and Quality in Health: The “good news” is that Richard Sorian has been named Deputy Executive Director and that two members of the new council have direct HIV/AIDS experience—Nan Hunter and Sandra Hernandez.

Standards of Care: The final document will be called the “PHS Guidelines,” and it will complement the “NIH Principles.” The main difference is that the PHS document is drug specific.

Dr. Goosby, who has been responsible for much of the development of the so-called Standards of Care, explained that it is a basic guideline for all HIV/AIDS-related entities, developed by panels from the HHS and HRSA, with input from the NIH, CDC, and representatives from managed care and payer organizations. HRSA has a 3-year commitment on this project to publish the guidelines (within 6 months) and develop conduits for providers. Dr. O’Neill said that PACHA and ONAP can contribute significantly by providing the guidelines with a level of prestige and influence that the Agency cannot achieve.

Standards of Care Assessment/Facilitation Process: The possibility of having a reassessment dialog similar to the Keystone Conference on pharmaceuticals among a “credible group of participants with broad-based interests” around care and services was raised, and Dr. O’Neill pledged \$20,000 to \$30,000 from HRSA to study the feasibility of such a meeting. This would include the issues around the PHS Guidelines and their implications on programs of all levels, disability and returning to work, Medicaid/Medicare, changing populations, new treatment regimes, support service systems, funding, vaccines, and collaborative opportunities. The goal would be to develop a broad policy consensus on these critical issues. A panel consisting of Dr. O’Neill, Mr. Levi, Dr. Goosby, and Abby Dilley, Vice President of the Keystone Center, spoke about the process with the Services Committee. They described it as “comfortable, informal, and off-the-record,” with a neutral mediator (Keystone). Panelists agreed that the current state of change in HIV/AIDS treatment is forcing the reexamination of populations,

paradigms, and definition of such terms as “early intervention.” Major questions asked by the Council concerned the public role in the changing systems and how to educate the HIV/AIDS populations about the new guidelines. The Council agreed that it should focus on the possibility of a Keystone Conference and to choose a delegation of two to three members to work with HRSA to determine scope and budget. Mr. Henderson, Dr. Bollman, Dr. Hitt, Mr. Levi, and Dr. O’Neill will meet to further discuss the possibilities.

Back-to-Work Issues/Medicaid Coverage: Rabbi Edelheit reported on a followup to the presentation by Susan Daniels of the Social Security Administration (SSA) at the last PACHA meeting. **Diana Fortuna**, Senior Policy Analyst, Domestic Policy Council, discussed with the Committee barriers to employment for people with disabilities and problems involved with Social Security Disability Insurance (SSDI) and Supplemental Security Income (SSI) eligibility. The Government, she said, has an “old-fashioned notion” of equating disability with inability to work; however, the SSA is trying to redefine the term. Currently, people with disabilities who become well enough to work part-time are in jeopardy of losing SSDI/SSI health care coverage. The President’s current budget request may help fill the gaps through State options on Medicaid, a proposed Medicare demonstration program allowing SSDI beneficiaries to return to work with 4 additional years of premium-free Part A coverage, and a pilot program that proposes expanded financial encouragement to rehabilitation providers to help SSDI and SSI beneficiaries return to work. At this point, all AIDS patients are facing reevaluation. Some have been given time eligibility and some are permanently eligible; substance abusers and alcoholics are no longer eligible under these programs. Ms. Fortuna said she would try to obtain statistics on how many people living with HIV/AIDS are affected. No funding exists to educate the public about the new programs, and Ms. Fortuna encouraged organizations like PACHA to spread the word. In Council discussions, Mr. Lew suggested that PACHA ask Ms. Daniels for names of other advocacy groups concerned with these issues so that HIV/AIDS organizations can join forces in dealing with them. There was a great deal of discussion of disability, with the conclusion that PACHA needs more input. Mr. Henderson said that the Keystone process could address the issues, and Dr. Hitt said that the Council will put together a presentation panel for the next meeting.

Prevention Committee

The Prevention Committee met April 5 and 6, with Mr. Robinson, Chair, and Mr. Anderson, Ms. Billings, Mr. Fogel, Ms. Fraser-Howze, Ms. Gerus, Dr. Hitt, Mr. Isbell, Mr. Johnson, Mr. Landau, Ms. Miramontes, Ms. Runions, Mr. Schatz, and Ms. Stokes present. The Committee received updates on needle exchange and substance abuse from outside panels and developed a long-term work plan. Mr. Robinson reported on major issues, including:

Needle Exchange: Much national attention is being focused in this area, with the most urgent needs being the lifting of bans on use of Federal funding for needle exchange programs and modification of State laws and regulations on sale and use of clean syringes. Speakers presenting an update to the Committee on these issues were:

- **Christine Lubinski**, Deputy Executive Director, AIDS Action Council (AAC).

- **Miguelina Maldonado**, National Minority AIDS Council (NMAC), who described the devastation caused by the twin epidemics of HIV and substance abuse in communities of color.
- **Jane Silver**, AmFAR, who covered Federal prohibitions in specific Acts; Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) reorganization; and the Departments of Labor and HHS.

Substance Abuse: Concerned that other substance abuse issues are not being sufficiently addressed at this time because of the current high level of interest in syringe exchange, the Committee called in speakers to present an update on various issues. The Prevention Committee is developing a panel presentation on all aspects of substance abuse to be given to the full Council at the next meeting. The major needs described are for more treatment slots and funds for every area of prevention and care. Panelists were:

- **T. Stephen Jones, M.D.**, Special Assistant for Substance Abuse and HIV Prevention, Division of HIV/AIDS Prevention-Intervention Research and Support at the National Center for HIV, STD, and TB Prevention at the CDC, who called for syringe exchange and educated primary care physicians who can help patients reduce HIV risk.
- **Beth Weinstein**, Connecticut Department of Health, who described the positive effects of a State law passed in 1992 allowing the sale of up to 10 syringes without a prescription and possession of 10 clean syringes without legal penalty. The Connecticut State action caused a drop in on-the-street syringe purchases from 71 percent to 28 percent and a decrease from 52 percent to 32 percent in injection drug users (IDUs) who reported sharing syringes, a “remarkable indicator of behavior change” from a program without Federal, State, or local funding.
- **Ellen Weber**, Legal Action Center, who discussed the inadequate funding in substance abuse prevention, including SAMHSA block grants.

CDC Briefing: Mr. Levi joined the Committee in planning the content and format for its briefing by CDC the week of July 21. A letter to Dr. Helene Gayle, head of the new, consolidated HIV/AIDS group at CDC, outlining areas for discussion was drafted and submitted to the Council for suggestions. Dr. Hitt will help formulate the final draft, which will address CDC’s overall HIV/AIDS strategy and the gaps that exist. The Committee believes that the prevention section is the weakest and does not constitute a true strategy. The Committee also will focus on working with the Administration and CDC to develop a mutual strategy and implementation plan.

Presidential Recommendations: These Recommendations were submitted to the Council (see New Council Recommendations, below) on the Coburn Bill, content of prevention materials, and needle exchange. Discussion of the Coburn Bill centered on whether the Recommendation should specifically ask the President to veto the bill. The Council agreed that this would be “micromanaging” and decided that it should alert the President to the need for a veto strategy.

Prison Subcommittee

The Subcommittee met on April 5, 6, and 7, with Mr. Landau, Chair, and Dr. Cade, Ms. Gerus, and Dr. Rankin present. Mr. Landau reported to the Council:

New Recommendations: Mr. Landau presented background on the issues of compassionate release, discharge planning, standards of care, protective barriers, and substance use in prisons (see New Council Recommendations, below).

Followup on Issues: Letters to Dr. Kenneth Moritsugu of the Federal Bureau of Prisons, Jeanne B. Fites, Deputy Under Secretary of Defense on HIV/AIDS programs in DOD correction facilities, and HHS Secretary Shalala regarding oversight language for discharge planning were submitted for PACHA and ONAP approval and coordination.

NORA: During a joint meeting with the NORA Working Group on Incarcerated Individuals on April 6, the Prison Subcommittee continued to gather background information on relevant issues. Guests included NORA participants Lin Hagood, CURE; J. Homar Perez and Tommy Reeder-Bey, National Association of People with AIDS (NAPWA); Cochise Robertson-El, Blind Faith; Jennifer Smith, Center for Women Policy Studies; Jonathan Smith, DC Prisoner's Legal Services Project; Marilyn Torres; and Jackie Walker, ACLU National Prisons Project.

International Subcommittee

The Subcommittee met April 5 and 6, with Mr. Fogel, Chair, and Mr. Lew, Ms. Miramontes, Ms. Runions, and Dr. Weniger present. Dr. Fogel provided responses given to international Recommendations from the Department of State and USAID.

Discrimination Subcommittee

The Subcommittee met on April 5 and 6, with Mr. Schatz, Chair, and Mr. Johnson, and Mr. Montoya present. Mr. Henderson, Ms. Gerus Mr. Schatz reviewed Subcommittee activities:

Recommendation Followup: Regarding Recommendation II.E.1 (elimination of discriminatory policies, including mandatory HIV testing, in Federal agencies), little has been done except by the Job Corps, which was the President's focus during presentation of the original Recommendation. Mr. Johnson noted that the DOD, Peace Corps, and USAID must follow State Department guidelines and that it will take very forceful, high-level leadership to change these practices. Mr. Fogel suggested omitting the military. Dr. Rankin said that the military actually does allow people with HIV to remain in service, but when they get out with a pension they must go into a test program. This represents a clear discriminatory practice. Rabbi Edelheit said that the policy inconsistency between this group of Federal entities and other agencies that do not have mandatory testing should be noted. Recommendation II.E.2. (review of HHS and CDC HIV/AIDS guidelines) is the "most egregiously ignored." HHS has not replied, and although CDC has made some commitment to bring its guidelines up to standards, nothing has happened. This problem should be revisited with Secretary Shalala and Dr. Gayle. A number of suggestions/recommendations sent to Secretary Shalala's office have not been answered or complied with, and Dr. Goosby said this was partially because of a reduction of HHS staff. He will help facilitate responses. On the issue of asylum, no response has been received from the Immigration and Naturalization Service (INS), and Mr. Montoya is drafting a followup letter.

Discrimination Letter: A letter to the President following up on Recommendation II.E.1, drafted by Mr. Schatz and Rabbi Edelheit, was approved unanimously. The letter will be circulated throughout the Administration, to Cabinet members, all of the listed agencies, and others concerned, such as Mr. Reed. (Dr. Hitt will provide the distribution list and any responses to members.) Mr. Henderson said that Mr. Reed was receptive to the idea of bringing the issue up at a Cabinet meeting or other such forum so that the President can stress its importance. The Council will follow up with Ms. Thurman every week until a written response comes from the President.

Communities of African and Latino Descent Subcommittee

The Subcommittee met April 6, with Ms. Fraser-Howze, Chair; Mr. Burgos, Rabbi Edelheit, Rev. Perez, and Dr. Goosby; and Mr. Montoya of ONAP present. A written report on the initial activities of the new Subcommittee was submitted to the Council, including its agenda (which will focus on disproportionately impacted populations.) A list of population-specific needs include, but are not limited to, AIDS orphans, women and children in communities of color, IDUs and drug abuse, immigrants, cultural and language barriers, inadequate health care and infrastructures, and minority CBOs. Other immediate process issues include the formation of a small advisory group and broadening the involvement of communities of color in the decision-making and information process of PACHA. Two issues of immediate concern are the requirement of military personnel with HIV/AIDS to participate as research subjects as a condition of their pension, which will be studied by Mr. Burgos, and the decision by individual physicians to withhold life-prolonging medications from patients determined to be noncompliant.

The Subcommittee discussed prioritization of the issues and limits to what can be covered adequately. The need for better demographic information on the epidemiology and the trends and impact on the communities requires immediate attention, as does the need for the President to demonstrate through action that he is aware of the changes in trends in the epidemic. Funding allocation commensurate with the areas of new infections is also advocated. A White House summit should be held to bring attention to the impact on and special needs of the targeted infected and affected populations. In addition, PACHA should be represented at the Presidential summit on Volunteerism in America, which will be held in Philadelphia. Dr. Goosby will explore these issues.

Dale Anthony, a community advocate from Long Island, attended the Subcommittee meeting to present concerns about the lack of support for the African-American community and discuss the difficulty in gaining access to lifesaving medications, the fear of discovering their serostatus that dominates this community, and the lack of will to comply with medical regimens.

Assignments for followup include information gathering on AIDS orphans, Mr. Fraser-Howze; medical determination and noncompliance and Presidential summits, Dr. Goosby; and compilation of names for an advisory group to the Subcommittee, Mr. Burgos and Rabbi Edelheit.

New Council Recommendations

New Recommendations to the Administration that were approved by the Council during the meeting are:

Medical Marijuana (Services Committee, with Prevention; passed unanimously)

Discussion by the Council included the fact that there is no mention of “physicians prescribing” marijuana for patients, an intentional omission.

Background: On November 5, 1996, voters in California and Arizona approved the use of marijuana for medical purposes. In 1994, Ohio approved the use of medical marijuana, though its legislature is currently considering reversing that stand. Virginia and Louisiana have decriminalized possession of marijuana in certain medical cases. Today, 26 States and the District of Columbia have existing laws and resolutions establishing therapeutic research programs, allowing doctors to prescribe marijuana, or asking the Federal Government to lift the ban on its medical use. In 10 States, similar laws have either been repealed or have expired.

Proponents of the use of medical marijuana cite anecdotal evidence of beneficial effects from its use, while opponents claim no convincing scientific evidence of such benefits and cite potential dangers. Research on the potential health benefits and/or risks associated with medical marijuana use is clearly needed.

- The President should direct appropriate agencies to take all steps necessary to encourage scientific research, including clinical trials, to gauge the potential benefits and/or risks of medical marijuana use (including smoked marijuana) on chronic pain, nausea, glaucoma, and other conditions due to illnesses such as HIV/AIDS, cancer, and other chronic diseases.

Further, the President should direct that, pending the results of such research, the Government refrain from any efforts to prosecute doctors who, in good faith, discuss the use of medical marijuana or recommend it for their patients.

Content of Prevention Materials (Prevention Committee; passed unanimously)

- The Secretary of Health and Human Services should eliminate all regulations and requirements for mandated reviews by citizen review panels of the content of HIV prevention materials. HIV prevention materials produced or distributed with Federal funding should be free of restrictions on content, subject to review only for scientific accuracy and cultural appropriateness for the targeted population. Grantees should be given great flexibility in utilizing the least burdensome methods of conducting these reviews.

Coburn Bill (Prevention Committee; passed, with one opposed)

- The President should forcefully oppose the HIV Prevention Act of 1997. Many provisions of this bill, including enforced mandates, interference with State and local control over health care policies, and the potential for institutional discrimination against people living

with HIV/AIDS, will undermine rather than enhance our Nation's HIV prevention strategy.

Needle Exchange (Prevention Committee; passed unanimously)

The PACHA commends the Secretary of Health and Human Services and the Department of Health and Human Services on the *Report to Congress on Appropriation for the Department of Labor, Health and Human Services Agencies: Needle Exchange Programs in America: Review of Published Studies and Ongoing Research*, which acknowledges the efficacy of syringe exchange programs to reduce the transmission of HIV.

WHEREAS, this report to the Congress confirms that syringe exchange programs reduce the rate of new HIV infections among injection drug users, and further confirms that such programs constitute a sound public health practice as part of an overall effort to reduce the incidence of new HIV; and

WHEREAS, the Secretary's report found no evidence that established that syringe exchange programs increase drug use; and

WHEREAS, a panel of nongovernmental public health experts convened by the National Institutes of Health found no scientific or medical evidence that syringe exchange programs increase drug use; and

WHEREAS, the President has set a goal of reducing the number of new infections each year until there are none; and

WHEREAS, the President has established a drug policy seeking to reduce the prevalence and incidence of drug abuse through prevention, counseling, and treatment; and

WHEREAS, syringe exchange programs and appropriate and effective substance abuse treatment and counseling efforts provide a unique opportunity to reduce the incidence of substance abuse and the number of injection drug users;

- **THEREFORE**, we strongly recommend that the President ensure that the Secretary of Health and Human Services take all necessary steps to promptly certify syringe exchange programs as effective in reducing the incidence of new HIV infections while not increasing substance abuse; thus, the use of Federal funds for syringe exchange and substance abuse counseling and treatment programs must be permitted in those communities that determine such programs to be appropriate.

Vaccine Development (Prevention Committee; passed unanimously)

Background: The following recommendations are the result of 2½ years of development by the Research Committee, with input from the entire Council and more than 50 other sources. The final critique came during the panel presentation (see AIDS Vaccine Panel Presentation, above) when a group of outside experts commented on the draft Recommendations.

Dr. Levine noted several changes that arose out of the panel presentation. The term “within a decade” remains in the first Recommendation, despite a consensus of the presentation panel that it is not appropriate to set a date for the vaccine development goal. Some Council members wanted to put a specific date; others believed that it was more appropriate to leave out even “decade” in deference to Dr. Baltimore’s request. A majority of members believed that “decade” should be maintained to highlight a sense of urgency without putting unrealistic aspirations forward, and most panelists had agreed that this was a realistic time frame. Other major changes included the addition of emphasis on an international perspective and recognition of the AVRC.

Preamble: Development of a successful HIV/AIDS vaccine is clearly feasible and should be considered of the highest priority by our Government. In order to succeed, we suggest the following recommendations:

1. The President must declare an urgent goal of developing a vaccine to prevent HIV/AIDS within a decade in order to mobilize public opinion, political will, and international collaboration, and to assign high priority to this effort within each of the governmental agencies involved in HIV/AIDS vaccine research and development. As the HIV/AIDS epidemic has no borders and a successful vaccine will require international collaboration, the President should work with the leaders of other nations in a global effort to achieve an HIV/AIDS vaccine for all nations.
2. A significant and sustained increase in funds must be made available for HIV/AIDS vaccine research and development. These funds must be derived from NEW sources from both Government and industry and must not be taken from existing programs aimed at prevention, research, care, services, and/or treatment for persons with HIV/AIDS. Innovative use of such funds is essential, as seed money to initiate new and creative hypotheses in vaccine research; to support product development; to expand the proportion of successfully funded grant applications; and to bring additional entities into the HIV/AIDS vaccine field.
3. Development of an effective HIV/AIDS vaccine will require expertise in many areas, including basic science, applied research, public health policy, and legal, ethical, industrial, and international issues. Dr. David Baltimore has recently been chosen to provide advice and leadership for the NIH HIV/AIDS vaccine effort, and the Council is highly supportive of this appointment. Additionally:
 - Participation by nongovernmental sectors and organizations is also essential to achieve the goal of expedited vaccine research, product development, and use. The Vice President should convene a public–private HIV/AIDS vaccine consultative forum, composed of senior representatives, to encourage communication between sectors, to address gaps in the field, and to speed progress toward the President’s goal. Participation on this HIV/AIDS vaccine forum should include representation from U.S. Government agencies, industry, the international community, academia, the World Bank and other funding agencies, the insurance industry, ethicists, and communities most affected by the epidemic.

- To achieve the goal of a more comprehensive vaccine development effort within the government, ALL relevant agencies within the U.S. Government—including NIH, CDC, DOD, DVA, FDA, USAID, and relevant offices within these agencies, especially those relating to minority and women’s health—must be substantively involved in the vaccine effort. The agencies must regularly communicate with one another and share information.

Prisons Recommendations (Prison Issues Subcommittee)

Following discussion and revisions, all Recommendations were passed: numbers 1 and 2 unanimously, number 3 with two abstentions, and number 4 with one abstention.

Background: Since the 1970s, when the war on crime became a war on drugs and drug users, the rate of incarceration has skyrocketed in this country. If we are seriously opposed to a war on drug users, then we also must stop this cycle where it does significant and far-reaching damage—in prisons among incarcerated persons.

If self-destructive behaviors are modified and prison clients are encouraged to adopt healthier, more productive lives, the rehabilitation process is enhanced, and thereby, the rate of recidivism among ex-offenders may be reduced.

Prisons are rehabilitary institutions. That the system is “broke” is neither the responsibility of inmates nor the justification for a punitive or inadequate health care delivery system within prisons. Health care is guaranteed to prisoners in the United States, and access to AIDS health care within prisons should be commensurate with the standards of care established for all Americans.

That the disproportionately high rate of HIV infection among African Americans and Latinos is discriminatory is reflected in the disproportionate number of African Americans and Latinos in the Nation’s prisons. It is impossible to separate access to care from institutional racism, and we must, therefore, be guided by a commitment to ensure the highest possible standards of care and access for all Americans, including prison inmates.

We therefore must place AIDS health care for inmates and ex-offenders in the context of national standards of care *and* prison reform, not in the context of judgments placed upon inmates, sentencing offenders, racism, classism, or anticipated recidivism. We must anticipate successful release of these individuals into a society where the mainstreaming of inmates works safely and effectively for all involved. The goal of no new infections and good health care among all of those previously infected must guide our activities within the discussion of AIDS among inmates and ex-offenders.

The issues facing inmates with AIDS are the same as the issues facing most Americans with AIDS. The risks of infection through injection drug use and sexual—consensual and forced—transmission may be even higher among incarcerated individuals than the general population as a result of the lack of adequate protection within this restricted living environment. The necessity

of effectively addressing this urgent need without prejudgment, therefore, cannot be underestimated.

1. **Compassionate Release:** The President should direct the Department of Justice and the Director of the Federal Bureau of Prisons to revise administrative and judicial standards of compassionate release for use in all Federal and federally funded prisons. Prisons will do this in accordance with American Bar Association (ABA) standards. Furthermore, equivalent compassionate release programs should be required in State and local prisons as a condition of these institutions receiving Federal funds. The Federal Bureau of Prisons also should be directed to maintain statistical and evaluative records concerning the compassionate release policy and file an annual report to the President, Secretary of Health and Human Services, and the Office of National AIDS Policy.
2. **Discharge Planning:** The President should direct the Secretary of Health and Human Services to develop standards of care to ensure that, prior to release, ex-offenders with HIV/AIDS are provided timely, thorough, and appropriate case management/discharge planning. These standards should address behavioral and social service needs; continuity of care; and appropriate linkages to local community services, medical services, social service benefits, appropriate case management, and housing assistance programs to ensure against homelessness.
3. **Standards of Care:** The President should direct the Federal Bureau of Prisons to incorporate the upcoming *Report from the HHS Panel on Clinical Practices for the Treatment of HIV Infections* in all correctional medical facilities. It should be required that care providers be adequately trained to implement these standards and all appropriate therapeutic options associated with the management of HIV disease be available.
4. **Protective Barriers:** The President shall direct the Attorney General to direct the Federal Bureau of Prisons to ensure that condoms and dental dams are made readily available for all prisoners within correctional facilities to prevent transmission of HIV/AIDS.
5. **Substance Use:** The President shall direct the Attorney General to direct the Federal Bureau of Prisons to investigate and report within 90 days on the feasibility of and various options for providing comprehensive substance abuse treatment for incarcerated individuals with a dual diagnosis of chemical dependency and HIV disease.

Process Issues

The Process Committee, consisting of all Committee and Subcommittee Chairs, will continue to meet by conference calls to discuss Council process issues and monitor Recommendations that need to be “pushed.” Process issues discussed during the meeting were:

Recommendations to the President: The strength of Administrative Recommendations can be weakened if they are not action-specific or are too lengthy. Council Recommendations should identify actions that can be taken by the President and/or Vice President and can be monitored by the Council. New Recommendations should follow the format of the original set—one or two

sentences that can stand alone—and be as succinct as possible for the purpose of alerting the Administration that there are new data available. If a Recommendation cannot stand alone, a brief explanation can be included. It is not PACHA’s role to provide background for the White House as to why a certain action should be taken, although members individually may draft background letters to the President. Broad language is sufficient until the Council knows the specifics of the issue, at which point Committees should convene by conference call to monitor and follow up with specifics to the Administration in letters or further Recommendations. Recommendations, responses, and followup should be coordinated through Dr. Hitt and the ONAP office. Another process suggestion is to trust Committees to develop effective Recommendations and thereby not spend so much time “wordsmithing” in full-Council meetings.

Letters to the Administration and Other Government Entities: Letters to the President, normally sent either as followup to Recommendations that have not been addressed or notification of new and pressing matters, should signify urgency and importance. Care must be taken to avoid sending too many messages, or by duplication diluting the strength of the letters. The process for sending letters to any Government entity is as follows: a Committee drafts a letter through conference calls, submits it to Dr. Hitt for suggestions and approval, and sends the final draft to Mr. Montoya, who will keep ONAP and other Council members informed, collect additional suggestions from ONAP, and give advance notification to the appropriate recipients. Committees should monitor responses and keep the Council and ONAP advised; the ONAP Director, in turn, can help in followup. Letters do not have to be approved by the whole Council, whereas Recommendations and resolutions do.

ONAP Authority over PACHA: Concern was expressed by Council members that ONAP should not have final say on PACHA letters and actions. Since the ONAP/PACHA relationship is not clearly defined, Rabbi Edleheit urged Dr. Hitt to discuss the limit of ONAP’s control at the next meeting. It was agreed that ONAP should not have veto power over PACHA letters or Recommendations, but that the Office, especially the Director, should be given opportunity for input before any message is sent to the White House.

Holding “Feet to the Fire”: Holding Government groups accountable should be a function of the Council as a whole, with assistance from Ms. Thurman at ONAP.

Committee/Subcommittee Meetings: Members noted that there are so many Committees and Subcommittees on the Council that major efforts may be diluted. Subcommittee meetings should start on time, times should be set so that they do not interfere with attendance at Committee sessions, and all meeting times should be announced to the full Council. Meetings also should start on time. Members should be notified of interim meetings and conference calls, through Mr. Montoya, and background information and agendas should be distributed to members at least 14 days in advance. More work, such as formulation of Recommendations, should be done through conference calls prior to full-Council meetings. It was suggested that members use e-mail more and make sure that Mr. Montoya has current contact information, including an emergency contact number.

New Business

Reevaluation of Recommendations: The process of reassessing responses to existing Recommendations was discussed, and the Assessment Committee formed to set up the process and conduct the evaluation. Assessment Committee membership, which represents all PACHA Committees and Subcommittees, includes Dr. Abel, Ms. Billings, Dr. Cade, Rabbi Edelheit, Mr. Henderson, Mr. Isbell, Mr. Johnson, Dr. Levine, Mr. Lew, Ms. Miramontes, Dr. Rankin, and Mr. Schatz. The previous evaluation included a request for agencies to respond to relevant recommendations, assessment of the responses in a written report, revision of the report by the full Council, and presentation of the report to appropriate agencies. It was agreed to shorten the process of assessment, without losing the input of the full Council. Dr. Hitt asked that Committees and Subcommittees keep this issue on their agenda for the next few months and that a report be given at the next meeting by the Assessment Committee.

Council Vacancies: With the resignation of Ms. Carole laFavor, two vacancies exist on the Council, with other openings possible in the near future. Ms. laFavor nominated her own replacement, and Dr. Hitt asked members to submit other suggestions as soon as possible. For a better balance on the Council, consideration should be given to ethnic descent (especially African and Native Americans); geographic factors (e.g., persons from Florida and rural areas); and experience in working with international issues, primary care, CBOs, and/or youth and HIV (or a young person).

The CDC Briefing in Atlanta: The Briefing (week of July 21) for the Prevention Committee may be extended to include a meeting of PACHA Committee and Subcommittee Chairs, if the budget allows, to cover interim Council business. A final date will be set as soon as possible.

Next Meeting and Closing

A date was not set, but the Council decided to hold a 4-day meeting in Washington, D.C., later this year, and members were to be polled for date preference. Three full-Council presentation panels covering disability and return-to-work issues, impacts on people of color, and substance abuse are proposed for the meeting. Dr. Hitt thanked Council Members, ONAP staff, and guests for their participation, and the sixth meeting of PACHA was adjourned at 2:00 p.m., April 8, 1997.