

Presidential Advisory Council on HIV/AIDS

December 7-8, 1995

Marriott at Metro Center
Washington, DC

MINUTES

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

December 7

Chairman Dr. R. Scott Hitt opened the meeting by thanking Ms. Patricia Fleming, Mr. Jeff Levi, Mr. Richard Sorian, and the other staff of the Office of National AIDS Policy (ONAP) for their work in organizing the first White House Conference on AIDS held the preceding day.

ONAP Director Ms. Fleming said she was almost speechless after the conference and was exceedingly grateful to President Clinton for his speech. She welcomed new members to the Council and advised them that they have a very important job ahead, particularly after the conference. She also announced the Food and Drug Administration's (FDA) approval of Sinequir, the first protease inhibitor, which was approved in the shortest period of time of any drug in FDA history, 90 days.

Council members then introduced themselves and discussed the implications of, and new opportunities presented by, the White House Conference the day before. Members echoed Dr. Hitt's thanks to ONAP staff in putting together the conference and acknowledged the Chair's work in organizing the meeting as well. Members uniformly praised the conference and President Clinton's commitment to HIV/AIDS but raised concerns about maintaining the momentum established at the conference, the need for an immediate focus on Black and Latino communities, discrimination, and what many saw as a lack of emphasis on prevention, particularly needle-exchange programs.

Dr. Hitt said he believed the conference accomplished its goals of raising awareness of both the President's commitment and AIDS as an issue. He said that the interaction of staff members and Cabinet level people with conference participants has helped increase faith in the Council. He said he was very impressed by the demographics of the Council members chosen by the Administration. Over one-third of members are living with HIV; one-third are people of color;

more than one-half are gay or lesbian; and almost one-half are women. Noting that he has also heard comments about what persons are missing from the Council, he said it is the Council's job to reach out twice as hard to communities and experts in fields that might not be represented on the Council, such as housing experts or high-level treatment advocates.

The Council then broke into meetings of its Services, Prevention, and Research Subcommittees (see attachments).

Alternative Medicine and HIV/AIDS

Dr. Wayne Jonas, Director of the National Institutes of Health (NIH) Office of Alternative Medicine (OAM), spoke before the Council about the Office's activities in alternative medicine and AIDS.

Dr. Jonas described the brief history of OAM, from its inception in 1992-93 at a budgetary level of \$2 million to its estimated \$5 million budget in FY 1995. The Office is mandated to facilitate the evaluation of alternative medical treatment modalities, investigate and validate the efficacy of alternative treatments, and support research training in alternative medical practices. It is also charged with establishing an information clearinghouse to exchange information with the public about alternative medicine.

OAM receives approximately 1,200 information requests each month, the vast majority of which (78 percent) are related to alternative therapies for cancer, Dr. Jonas said. Requests for information about AIDS come in a distant second at 7 percent, a figure that Dr. Jonas said he believes is relatively low because people with HIV infection and AIDS are accessing other resources for information about alternative therapies.

Clinical trials of conventional Western medical interventions outnumber those of alternative therapies 300 times. The issue of research in these areas is not one of quality, but of quantity, Dr. Jonas said. The lack of regulation and quality assurance for many alternative therapies leads to a higher risk that many treatments offered may be fraudulent.

The first grants awarded by OAM were for small exploratory studies of alternative therapies. Of 42 such pilot grants, 3 are related to HIV. Because the grants are funded at a level of \$30,000, however, many of the studies lack the number of patients and the statistical power necessary to answer the research questions posed. Small, simple studies such as one examining the effect of massage on weight and other health measures of HIV-exposed infants have been able to demonstrate positive results.

Another problem faced by OAM-supported investigators involves receiving Institutional Review Board (IRB) approval for studies when the participating institution has no IRB or any faculty on an IRB at another institution. Receiving FDA approval for Investigational New Drug (IND) use for formulations used in alternative medicine can prove costly and time-consuming. For example, in a study investigating acupuncture and a combination of 15 herbs with a long history of use in patients with chronic sinusitis, it was necessary for investigators to use a formula containing fewer herbs because of the high cost of chemistry, laboratory toxicology, and pharmacodynamic studies

required by the FDA. Even with the less complicated combination, the cost of the IND drug was three times more than the amount of the grant received to study the formulation.

In addition, many alternative therapies have been developed and are widely used in foreign countries, where the problems encountered in prospective analyses may be even more pronounced than in the United States. Dr. Jonas said one field investigation on chiropractic treatment found that diagnoses were recorded on only 24 percent of patient records. OAM does have a Research Development and Investigation Section, which pro-actively screens, prioritizes, and provides technical support to the most promising research opportunities from around the world.

Last year, OAM awarded 10 clinical research center grants, including 1 to Bastyr University in Seattle to study alternative therapies for AIDS and HIV infection and provide mechanisms for supporting collaborative research efforts in complementary and alternative medical practices. The Bastyr University center's \$920,000 grant will support an assessment and evaluation of research opportunities and the development of a prioritized research agenda.

Subjects of research proposals received by the Bastyr University center include glutamine treatment for overall improvement in AIDS, neuropathy and acupuncture, and the impact of therapeutic touch on the immune system.

Dr. Hitt commented that there is a feeling that Government is not doing enough research in this field. "Short of saying that we need to increase the budget by 200 percent or by 1,000 percent, what is it that we can we do to get the word back to the community that the Government is concerned about this, they are doing their best to get outreach about this?" He asked whether OAM's Advisory Council has provided AIDS-related advice to OAM.

Dr. Jonas said the Advisory Council has focused on a general discussion of the field, which has included AIDS, and that a report to Congress from experts in the field also contains information on AIDS. He said OAM hopes that its AIDS research center at Bastyr University will come up with an organized AIDS research agenda.

Members also discussed the difficulties in compiling a directory of alternative therapies for AIDS.

Dr. Hitt noted that an alternative therapies manifesto published by the Gay Men's Health Crisis provides a good review of alternative therapies. Government's outreach could include such a listing, he suggested.

Dr. Jonas said such an effort falls under OAM's agenda to develop an information clearinghouse, which may take the form of an online service, a directory, and/or an 800 number. (OAM already has an 800 number, but it has not yet advertised it.) The clearinghouse will have general information about, and descriptions of, therapies as well as reports of quality research. Dr. Jonas asked the Council what kinds of information it would like in such a directory. He said he hopes a full clearinghouse will be up and running in a year.

Council members said a year is too long to wait for a clearinghouse and asked what recommendations it can make to the HHS Secretary to help expedite the effort.

Dr. Jonas said OAM is developing an evaluation system for clearing information and its Database and Evaluation Section is starting to download existing online medical information and will try to develop bibliographies. OAM is also evaluating other information resources.

He also hopes to work with other Institutes at the NIH to fund more research in specific areas of alternative medicine.

Dr. Hitt asked whether there is an overall plan related to AIDS, and if so, whether it was developed with community input. Dr. Jonas said that next week he will have the first meeting with primary investigators from the OAM centers. Council members also discussed the need to develop such an AIDS plan with community input and to speed the establishment of an 800 number or information clearinghouse. Dr. Jonas said it would be very helpful for Council members to provide names of experts in the field.

Discussion of Services Subcommittee Recommendations

Council members began their discussion of recommendations from the Services Subcommittee with a proposed recommendation to "rescind mandatory testing and/or discriminatory policies currently in place in the U.S. Foreign Service, the Peace Corps, the Job Corps, the State Department, and the military."

Asked whether there is consensus in the military that there is no public health need to continue mandatory HIV testing, Mr. Benjamin Schatz said the primary concerns are related to autologous transfusions, expenses, and sending personnel overseas. Dr. Michael Rankin said that battlefield blood transfusions are probably the only legitimate public health concern.

Council members voted unanimously to endorse the recommendation with the addition of the phrase "where there is no compelling public health justification."

Members next discussed a proposed recommendation that the Centers for Disease Control and Prevention (CDC) review its guidelines for voluntary disclosure of HIV status by health professionals who perform "exposure-prone" procedures. Issued in July 1991, the guidelines have been used by courts to justify discrimination against a wide range of health care workers, which in turn makes it harder to recruit health care workers to work in the field of HIV, said Mr. Schatz.

The CDC has never defined "exposure-prone" procedures. The guidelines were issued when there was not much information on transmission from health care workers and were promulgated at a time of high emotion in the aftermath of reports of HIV transmission from a Florida dentist to some of his patients, Dr. Jerry Cade said.

The Council unanimously approved the recommendation that the President "instruct the U.S. Centers for Disease Control and Prevention (CDC) to review its guidelines that arbitrarily restrict HIV-infected health care workers and that lead to discrimination against them and to ensure that these guidelines are consistent with prevailing scientific and public health knowledge on the issue."

A further recommendation discussed and endorsed by the Council was that President Clinton "oppose any congressional efforts to require that otherwise qualified service personnel who test positive for HIV be discharged, including a veto of the Department of Defense Reauthorization Act if such a provision is included. In his veto message, we recommend that the President state that the veto is in part due to the inclusion of this provision."

Members next approved a recommendation that the President "Direct the CDC, Immigration and Naturalization Service (INS), and Department of State to monitor and coordinate the HIV testing of immigrants to ensure informed consent, pre- and posttest counseling, and appropriate legal and health referrals and to ensure that waivers of the HIV exclusion are granted on a priority basis when permitted by statute. Also, when permitted by statute, the INS and the Executive Office of Immigration Review (EOIR) should grant stays of deportation, suspension of deportations, extended voluntary departure, deferred action, and asylum based on the social group category of HIV-positive individuals."

The Council also approved four recommendations related to Medicaid and Medicare programs. The first calls for the President to "Continue to support and defend the entitlement status and funding for Medicaid and Medicare; and continue to oppose any efforts to restrict eligibility and services for people living with HIV/AIDS."

The second is to "Direct that any waivers granted to States under the Medicaid program ensure access to a comprehensive continuum of care for people living with HIV/AIDS. To implement this policy, you should direct the Health Care Financing Administration (HCFA) to establish national criteria by which to assess State waiver applications and to ensure that these criteria be consistent with current health care knowledge. These criteria also should be consistent with the provisions of the Americans with Disabilities Act (ADA), and State plans should be reviewed for this purpose by the Department of Health and Human Services (DHHS) Office of Civil Rights."

The third is that the President "Direct HCFA to ensure that State Medicaid programs cover HIV testing and counseling."

A fourth recommendation was discussed that would require HCFA to ensure that all FDA-approved drugs are covered under State plans, even when prescribed for "off-label" indications.

Noting that the FDA is holding hearings on this topic, Ms. Phyllis Greenberger said the issue may be too complicated for President Clinton to endorse a recommendation at this time. Members agreed with Mr. Nicholas Bollman's assertion that the refusal to reimburse for off-label uses of drugs is a medically inappropriate effort at cost containment. The problem is especially severe in pediatrics because 75 percent of drugs are not labeled for use in children, said Ms. Mary Boland.

Although Mr. Steve Lew pointed out that Medicaid can decide to reimburse for drugs in a specific compendium, other members said that the rapidly evolving standard of therapy for HIV/AIDS makes such a measure impractical.

Members voted to ask the President to "direct HCFA to report to the Council at its next meeting possible strategies to address the need to ensure that all Food and Drug Administration

(FDA)-approved drugs are covered under State plans, even when prescribed for off-label indications. These strategies should address both policies and vigorous enforcement mechanisms."

The impact of managed care on persons living with HIV/AIDS and the need for comprehensive HIV health care systems were also addressed. Although some members said that legislation is needed before services can be regulated, others said that, even if guidelines are developed by the Government, they could be used by States and private insurers to establish a minimum standard of services. Services Subcommittee Chair Mr. Edward Gould said the issue of managed care needs to be addressed and that the managed-care standard does not take into account that, in people with HIV disease, treatment tends to occur in hills and valleys. Mr. Bollman suggested that the Council at least identify the creation of standards for the provision of primary care for HIV-infected persons as an issue and ask HCFA to present its ideas on how to solve the problem.

Members agreed to table discussion on the recommendation until the Subcommittee returned with a rewritten version.

In a general discussion with ONAP staff about how best to direct its recommendations, Mr. Terje Anderson argued very strongly to maintain the recommendations directed to the President in the language of the report.

The Council then endorsed a recommendation that the President "Direct all appropriate agencies to support the investigation of the efficacy of complementary treatment therapies and provide increased financial support for this effort, and that therapies shown to have benefit should be reimbursed under Medicaid."

Specific directives to the NIH's OAM may be developed at a future meeting.

Members next discussed recommendations related to education and training. Noting that funding for AIDS Education and Training Centers (AETCs) was cut from \$16 million to \$0 and then increased back to \$8 million, Council member Dr. Stephen Abel said full funding should be reinstated. Although some problems existed in the program, the new centers will be working more closely with councils and primary care providers, he said. Because President Clinton recently wrote a letter to Congress requesting full funding for the centers, members agreed to be on record as stating the Council encourages full funding.

Members voted to recommend that the President "Continue to support full funding to a national network of AIDS Education and Training Centers (AETCs) and direct the Health Resources and Services Administration (HRSA) to ensure that the work of AETCs is coordinated with community providers and planning groups" and "direct HRSA to review and report to the Council at its next meeting the effectiveness of the Bureau of Health Professions' education activities specific to HIV/AIDS."

Members next discussed a draft letter to President Clinton thanking him for the White House conference and including the Council's recommendations as part of the letter.

CDC Public Service Announcements

Council members then heard from Ms. Melissa Shepherd of the CDC, who described and then showed videotapes of the agency's new public service announcements (PSAs) for HIV/AIDS. Introduced the previous week, the PSAs are part of a prevention campaign entitled "Respect Yourself, Protect Yourself." Their release retires the "America Responds to AIDS" campaign, an announcement that was greeted with applause from Council members.

The TV and radio spots were developed after multiple airing of a television program, "Smart Sex," and a phone survey of 500 viewers who identified the messages with the most resonance. Youth were then brought in for a 2-day meeting at which they viewed the messages and prioritized them. The youth also provided advice on music and graphics.

The resulting PSAs were tested in mall intercepts in Los Angeles, Seattle, Houston, and Atlanta. Following CDC approval, more testing, particularly of one video targeted to young gay men, was conducted among gay men in street intercepts in San Francisco and New York.

The PSAs range from 10 to 60 seconds in duration, with some available in both Spanish and English. Titles include "How Do You Know?" (about HIV status), "Buying Condoms," "Alcohol—Stay in Control," and "Abstinence."

Ms. Shepherd said the spots cost less than \$400,000 to develop and test and that within the first week the CDC had already recouped its investment through network broadcasts. When asked about the PSAs' exclusion of Asian and Native Americans, Ms. Shepherd said the CDC was aware of the need for greater representation but that the spots were made from existing video clips. She urged members to forward any footage that might be useful in future PSAs.

Asked about efforts to gain prime-time coverage, Ms. Shepherd said more than 30 percent of PSAs used in the 1994 campaign were aired during prime time and that some networks air the announcements during late-night talk shows popular with young audiences. The CDC has asked networks to air the PSAs during shows targeted at persons 18 to 24 years old.

Noting that in the past he has complained about the lack of PSAs showing men having sex with men, member Mr. Schatz said the new PSAs represent a very important step. He also applauded the announcements for their use of non-gender-specific language when discussing sex.

The Council then adjourned for the day, with ad hoc meetings of its three Subcommittees scheduled for the evening.

December 8

HHS Secretary Donna Shalala

HHS Secretary Donna Shalala addressed the Council and began by thanking Ms. Fleming for her leadership in organizing the White House conference. She told the Council that the Administration sees the conference "as part of a longer strategic effort in this area." She said that the President's budget announced December 7 protects spending priorities on AIDS and its

prevention investments. Although it is not a detailed budget, Secretary Shalala said, "Let me assure you that it repeats what the President said on Medicaid and our determination to stand firm on Medicaid. It actually, I believe, adds some resources on Ryan White, and the whole prevention package continues to be there."

Secretary Shalala did concede that decreases in the discretionary budget will affect many programs; nevertheless, the core of prevention, treatment, and research investments is protected as part of this overall budget, she added.

Next, Secretary Shalala, administering the oath, swore in the Council members as advisors to the President, and a group photo was taken.

Secretary Shalala continued to address members on the current budget debate with Congress. The only budget on the table now, she said, is the 7-year budget based on the Administration's assumptions. The Republicans have rejected that approach, arguing that the Administration must use the Congressional Budget Office (CBO) assumptions, she said. The Secretary then asserted that there were no CBO assumptions; they are still under development.

The Administration's decisions concerning what is left within the discretionary budget have not yet been determined, she said. She noted that priorities would need to be set with HHS but assured the Council that AIDS programs would be protected. She continued, however, that "obviously, this is a very tough budget, and we are in a very different era."

Asked whether prevention is an investment priority, Secretary Shalala said it has not traditionally been a priority, but the Administration will try to protect prevention investments.

Asked about Medicaid regulation of managed care by States and the possibility of exceptions for people with HIV/AIDS, Secretary Shalala said, "It has been our strategy all along to work with the States to develop those kinds of options." She stressed the "need to develop a set of managed care organizations and other kinds of alternatives to fee for service^{1/4} that have experience with AIDS patients and provide high quality of care." Whether or not HHS gives States more or less flexibility, she said, our focus will be "on the quality of care and the appropriateness of care and not simply on the nature of the organization and the delivery system."

Mr. Robert Fogel asked about block grants combining sexually transmitted disease (STD), TB, and HIV/AIDS funding as Performance Partnerships grants instead of providing direct funding. Secretary Shalala responded by stressing the attempt of HHS through Performance Partnerships to deal with outcomes rather than regulate the inputs. "We do not consider Performance Partnerships a traditional block grant," she said, "in which we turn over responsibility to the States as opposed to a partnership under which the Federal government and the States agree upon a set of outcomes" that can be regularly measured. The Administration, she continued, is attempting to develop a concept, a true partnership, in the Government's relationship with the States. In addition, the Secretary added, she herself is attempting to change HHS from being overly oriented toward tight regulation to actually measuring whether programs have an impact. She suggested that Dr. Philip Lee could meet with the Council at its next meeting to discuss in more detail what she is describing.

Asked about the receptiveness of the current Congress to the argument of the cost-effectiveness of prevention, Secretary Shalala said, "As far as I can tell, there are no substantive policy discussions taking place as part of these budget negotiations. Perhaps the term that was used in the session I did at the White House conference is most appropriate; that is, we are now sitting across the table from mad bookkeepers."

Prevention Subcommittee Recommendations

The general Council meeting resumed at 8:45 a.m. with a reading of the recommendations from the Prevention Subcommittee, followed by a discussion.

The recommendations begin with a statement, directed toward the President, that "We are delighted you have committed to set a goal of reducing the number of new infections every year until there are no more new infections."

It continues that "You should direct the Centers for Disease Control and Prevention (CDC) to develop a behavioral surveillance mechanism that will provide an analysis of patterns in risk-taking behavior. To assist in accomplishing this goal, we ask you to `Direct the CDC to join with the National Institute on Drug Abuse (NIDA) and other relevant agencies to institute surveillance methods for detecting patterns of risk-taking behaviors in populations that show a continuing disproportionate increase in AIDS cases."

Council members then voted to recommend that the President "Direct the Secretary of Health and Human Services (HHS) to coordinate the planning of an early warning system and ensure its ongoing use."

Members also discussed a proposal that the CDC issue an annual estimate of HIV incidence. Stating that the Subcommittee does not believe such efforts will require the collection of additional data, Mr. H. Alexander Robinson said, "What we don't get from the CDC is an analysis of the data. We get a lot of number reporting."

Although the information is necessary, testing and information collection could be intrusive, said Ms. Boland. Noting the previous discussions about managed care and capitation, Mr. Bollman said that without this kind of data, the level and range of services required for people living with HIV will likely be severely underestimated.

The Council agreed to postpone voting on the recommendations until a rewritten recommendation was prepared and presented.

The Council then discussed a series of recommendations intended to reduce the spread of HIV through injection and other drug use. Some Council members questioned the observation that at least 50 percent of new HIV infection is related to injection drug use. Subcommittee members said the figure is conservative and that at least five significant studies have corroborated the estimate. Members agreed that the recommendations should be broadened to include all substance abuse.

Members also discussed the need to revise the Department of Justice Model Drug Paraphernalia Act, which serves as a model for some 40 States. Developed in the 1970s, the law is outdated and does not reflect current knowledge about the effectiveness of access to sterile needles in reducing HIV transmission, they said.

While acknowledging that drug paraphernalia laws are within the purview of the States, Council members agreed that the model developed by the Justice Department should no longer be used and that its revision would send a message to States that they should consider revising their laws to reflect current knowledge about public health.

Echoing comments made earlier by Mr. Robinson, Mr. Anderson expressed concern about what he called mixed signals from HHS Secretary Shalala about needle exchange. "There is no question in the National Academy of Sciences report that needle exchange is effective and that needle exchange does not increase drug use in the community," he said. Needle exchange remains a controversial political issue, however, he acknowledged. "What we are asking the Secretary to do, what we are asking the Federal government to do, is to follow up to allow selected use of waivers, to allow Federal funds to be used in some circumstances when necessary to meet local conditions," he said. "We do not anticipate that this will lead to a general lifting of the ban. We wish we could go that far, but we are trying to provide a politically acceptable solution."

The Council unanimously approved the following statement and accompanying recommendations:

"The Administration should pursue a comprehensive strategy to decrease HIV transmission related to injection drug use, which accounts for at least 50 percent of new HIV infections. Additional infections occur through sexual contact with injection drug users. Injection drug use is directly or indirectly responsible for the overwhelming majority of HIV infections among women and infants. Strategies must explicitly address the sharing of injection drug paraphernalia as well as the high-risk sexual behavior associated with drug and/or alcohol use.

"We ask the Administration to do the following: Increase the access to effective substance abuse prevention and treatment research programs by opposing congressional efforts to cut Substance Abuse and Mental Health Services Administration (SAMHSA) and other Federal funding for drug abuse treatment and prevention programs in FY 1996 appropriations, restoring budget requests for SAMHSA and other Federal funding for drug abuse treatment and prevention programs to at least the FY 1995 levels, and supporting the continuation of specific funding for AIDS demonstration projects of the National Institute on Drug Abuse (NIDA).

"Revise the Department of Justice Model Drug Paraphernalia Act, which serves as a model for State drug paraphernalia laws, to make it consistent with current reports, studies, and data relating to the access to sterile syringes as an effective intervention to counter HIV transmission among injection drug users.

"Direct the Secretary of Health and Human Services to provide a recommendation (within 90 days) regarding the impact of needle-exchange programs on HIV infection and substance abuse. The recommendation should be based upon current reports, studies, and data on needle-exchange programs and should include specific recommendations for programs and demonstration

projects to implement needle exchange. The Secretary shall develop and execute a plan to carry out the recommendations and indicate what programs and demonstration projects will be started or expanded."

Discussion next moved to a recommendation that the Administration maintain independent HIV prevention programs and avoid consolidated grant programs, including Prevention Partnership grants and other block grants. Mr. Robinson expressed concern about the lack of evidence that the grants will improve services.

Mr. Levi outlined the Administration's view of the Prevention Partnership program. The Administration is trying to reaffirm its commitment to community planning, and the President has put out the performance measure of reducing the number of new infections each year, he said. The CDC and SAMHSA have agreed in writing to pursue development of the performance measures with input from the AIDS community, he added. Performance Partnership grants would bring together three funding streams with one community planning process and one set of performance measures, a proposal that has generated controversy, he acknowledged.

Mr. Robinson said that the Council did not object to the performance measures; rather, the objection lay in the combination of HIV, STD, and TB funding into one planning process. "There is no evidence that that will actually have a benefit in this area," he said.

Council members remained unconvinced by Mr. Levi's and Secretary Shalala's defense of the Prevention Partnership grants and voted to advise that the President "should reaffirm support for community-based planning for prevention activities. Your administration has begun to plan for the combining of HIV/STD and TB funding. The current proposal does not adequately safeguard the community planning process. This proposal does not take into consideration the need for measures that are relevant to communities of color, gay and bisexual men, substance users, youth, women, and/or other communities and groups that have not been captured by existing data."

The Council specifically recommended that the President "Direct the CDC to maintain HIV prevention programs independent of any consolidated grants programs including the currently proposed Performance Partnerships grants."

In its discussion of community-based planning and other activities, Council members voted to recommend that the President "Direct the CDC to continue direct funding to community-based organizations" and "Direct the CDC with the assistance of existing national minority organizations and other appropriate partners to structure its technical assistance programs to address the prevention program development and infrastructure needs of populations that are currently experiencing continued disproportionate increase in new infections."

Members also discussed a proposal calling for the Indian Health Service (IHS) to develop a comprehensive AIDS prevention and care program. Although some Council members expressed concern that the recommendation would exclude other populations, Mr. Jeremy Landau said there has been a significant negative change in IHS policy recently and that Native Americans are under purview separate from other population groups.

The Council endorsed a statement that "HIV/AIDS is established and growing throughout Indian Country and threatening a population already reduced to 1.4 million from war, disease, and poverty. Since the Indian Health Service (IHS) is the only health service provider for Native Americans on reservations, there is a need for prevention services specifically directed to Native Americans." The Council also recommended that the President "Direct the Director of the IHS to develop a comprehensive AIDS prevention and care plan for Indian Country within 90 days with the input of consumers of services."

The Council also approved a rewritten recommendation that the CDC conduct an annual estimate of HIV incidence based on geographic and demographic analysis. It voted to request that the CDC issue an annual estimate of HIV incidence based on seroprevalence studies that provides a geographic and demographic analysis of the populations where there is a continuing disproportionate increase in new HIV infections. This report will give the Public Health Service, the business community, and countless volunteer organizations the ability to focus on the most severely impacted HIV/AIDS populations. In addition, the Council requested that the President "Direct the Secretary of Health and Human Services to ensure that resources are allocated to accomplish the task stated above." The Council also recommended that the President "Ensure that funding is adequate and responsive to the epidemiological trends, needs, and prevention infrastructure of affected communities."

The Council then endorsed the following revised recommendations from the Services Subcommittee concerning the development by Government agencies of oversight guidelines for HIV managed-care programs:

"Direct those Federal agencies that either finance or administer health care services (including but not necessarily limited to the Health Care Financing Administration [HCFA], the Department of Veterans Affairs, the Department of Defense, and the Bureau of Prisons) to develop oversight guidelines for HIV managed-care programs. This will also require effective regulatory enforcement mechanisms.

"Direct the Health Resources and Services Administration (HRSA) to develop a coordinated agency-wide approach that provides effective education, training, and technical assistance to HIV/AIDS providers and AIDS service organizations on health care management issues. Such an approach should include active participation by the private sector."

Members also discussed the need for additional staffing for the Council. Mr. Robinson said the staffing should be from within ONAP. He also expressed concern that the Council has not provided in an effective manner for persons with AIDS.

Research Subcommittee Recommendations

Research Subcommittee Chair Dr. Alexandra Mary Levine said the first recommendations came from workshops held at the December 6 White House conference. One issue is the need for partnerships between the private sector, Government, advocates, and others in order to move forward in vaccine and other prevention research efforts. She noted that President Clinton had said Vice President Gore would be asked to organize these kinds of groups.

Council members unanimously approved background information stating that "A vaccine to prevent AIDS and an anti-HIV topical microbicide to prevent infection are feasible technologies that can be developed. Such technologies represent the most promising ultimate solutions for control of the global pandemic. These technologies will require the cooperation and collaboration of Government, community representatives, private industry, and academia, in the United States and other nations, to overcome current obstacles and to develop these products as rapidly as possible."

The Council approved the recommendation that the Vice President lead a Government initiative to promote partnerships: "The Vice President's leadership and technological expertise should be sought to bring together the resources and expertise of various Government agencies, the private sector, community groups, and other nations in the effort to develop HIV vaccines and microbicides, and to `reinvent' the Government's involvement in the development of these products."

Another set of recommendations related to the development of microbicides was developed after a workshop held by the Subcommittee with representatives from the National Institute of Child Health and Human Development (NICHD).

Dr. Levine began by describing microbicides as either spermicidal or nonspermicidal topical agents, in foam, gel, or suppository form, that a woman controls and can use to prevent HIV/STD infection.

Dr. Levine told the meeting that microbicial research is currently an extraordinarily small field—condoms and nonoxynol-9 have been the only methods for prevention of STDs for the last 25 years—but that production of an effective microbicide is both feasible and cheap. She also noted the importance of empowering women to prevent infection instead of relying on a sexual partner to use a condom, a practice that is not possible in many parts of the world and the United States. Development of an effective microbicide has tremendous implications for controlling the world epidemic, she said.

Important subissues in microbicial research include the vehicle in which the microbicide is dissolved, such as film or foam, and the safety of its use on the vaginal mucosa. Dr. Levine cited an uncontrolled study of the contraceptive sponge with nonoxynol-9. The study was poorly done and showed increased transmission. The disruption of normal vaginal tissue is another issue that must be studied, she said.

Proceeding as quickly as possible "to organize the appropriate science behind the microbicides" is another important issue, Dr. Levine said. Millions of women will continue to be infected until these products are available.

She added that other means, such as nonoxynol-9, other vehicles, such as diaphragms, and substances such as chlorhexidine that have potential as anti-HIV drugs have not been studied very well.

Clinicians need to be able to explain to a female patient her options for reducing her risk of infection, Dr. Levine said. She then asked for the Council's advice. The group recommended that the NIH hold a Consensus Development Conference.

Dr. Bruce Weniger noted that the recommendation intentionally calls for the development of a topical rather than a vaginal microbicide. Products should also be tested rectally so they can be used not only in vaginal intercourse but also in receptive anal intercourse. This product could be of great value to gay and bisexual men as well, he said.

Dr. Weniger compared the role of microbicides in a harm-reduction algorithm with that of drug use: that it is best not to use drugs; the next best thing is not to share a needle; if one is still going to share needles, bleach should be used to clean them; and if no bleach is available, they should be rinsed with water.

The Council then discussed whether it was appropriate for such a politically appointed body as the Council to make research recommendations. Concerning the issue of microbicides, Council members remarked that research is understaffed and that microbicides are probably the most cost-effective preventive measure.

The Council unanimously endorsed the following background statement: "Women infected heterosexually by HIV represent the fastest growing group diagnosed with AIDS in the United States and account for half of all cases in Africa and an increasing proportion of cases in Asia. Since women may not be able to demand the use of condoms by their partners, female-controlled methods such as anti-HIV topical microbicides to prevent sexual transmission of HIV are urgently needed."

The Council endorsed the recommendation that "The priority for funding by the OAR for microbicide research and development as well as funding within the CDC must be increased substantially, with a concomitant increase of FTEs allocated for this priority." The Council also recommended that "The Government should develop mechanisms to increase the pool of investigators in microbicide research and development, especially those involved in biomedical and behavioral aspects."

Members also approved the background statement that "While the results of ongoing microbicide research are awaited, it is urgent to promulgate public health recommendations for preventing sexual transmission of HIV by using existing, licensed pharmaceutical products for off-label indications, based on the best information currently available."

The Council approved the accompanying recommendation that "A public health policy consensus panel should be convened by the Public Health Service by the end of April 1996 to assess the possible efficacy of available spermicides (e.g., nonoxynol-9) and other licensed products (e.g., chlorhexidine, benzalkonium chloride, diaphragms) to be used in "harm reduction" algorithms to decrease sexual transmission of HIV. The panel should include senior public health policy officials (CDC, FDA, HHS Secretary's Office), research agencies (NIH), community groups (women's health research advocates, commercial sex workers, interested foundations), academia,

and industry. The meeting should also feature a review of the entire status of anti-HIV microbicide research."

The group also approved a recommendation that "The FDA comment by January 31, 1996, upon the proposed FDA regulations that require inclusion of women in all clinical trials of drugs for treatment of HIV/AIDS in which there is no known evidence of reproductive toxicity. When such toxicity has been documented, alternatives that allow the inclusion of women should be provided."

Another recommendation would require drug sponsors to provide whatever data they have on gender-specific toxicities, although concern was expressed that some clinical trials, such as one focused on Kaposi's sarcoma, do not include enough women to be statistically significant. Nevertheless, Dr. Levine argued for the provision of all current, relevant data, especially for gender-specific toxicity.

Members approved the recommendation that "The final version of the proposed regulations published in the *Federal Register*, Vol. 60, No. 174 at 46794, must require a sponsor to file gender accrual analysis in the annual Investigational New Drug (IND) report. In addition, for the New Drug Application (NDA) and the product licensing application (PLA), the regulations must require sponsors to analyze clinical data by gender and assess potential differences, including reporting on side effects between genders."

Another issue discussed was the current regulation that pregnant women must obtain consent from the father of the fetus in order to participate in clinical trials, regardless of individual circumstances. Council members approved a recommendation that "The Secretary of HHS should publish for public comment by March 1, 1996, the proposed regulations regarding participation of pregnant women in clinical trials, with the following revision: A pregnant woman's inability to obtain a written consent from the father of the fetus should not disqualify her from participation in a federally funded clinical trial. This fact should be so stated in the protocol consent form."

Council members then discussed a series of recommendations intended to ensure that therapies developed are acceptable to target populations and that advances in treatment are rapidly disseminated to the community. Noting that six drugs are now licensed for use in treatment of HIV infection, Dr. Levine said it is important to determine how to mandate postlicensing studies in order to ensure that combinations are studied.

Ms. Boland stressed the importance of ensuring that advances make it into the HIV service community, noting that it took 2 years to get out the message about ACTG 076, the study of AZT in pregnant women. Members also noted the difficulty in adapting drugs to formulations that are appropriate for pediatric populations, with Mr. Bollman saying that private industry is not developing pediatric formulations.

Members approved a statement that "Advances in HIV/AIDS therapies, vaccines, and microbicides require the dissemination, acceptance, and use of these products by the populations

that can benefit from them. Such applications of biomedical discoveries require the expertise of the social and behavioral sciences."

The Council voted to recommend that "In HIV/AIDS clinical research, the NIH must ensure the early and fundamental involvement of behavioral and social scientists in the process of initial study development, design, and implementation" and that "HHS should develop ongoing mechanisms to ensure the rapid translation of breakthrough research findings into clinical practice."

Leadership Recommendations

Members then discussed a set of recommendations in the area of leadership, asking that President Clinton discuss AIDS during his State of the Union Address and release the Administration's updated plan on AIDS.

Council members rejected the idea of setting a date by which the epidemic can be ended. Although all agreed that with proper prevention tools the epidemic can be ended even in the absence of a cure or a vaccine, Mr. Levi warned that setting a date by which it should be ended would be politically dangerous and reminded members of former HHS Secretary Margaret Heckler's overly optimistic setting of a date for a vaccine when the discovery of HIV was announced.

Mr. Robinson suggested the Council's commitment to the President's current goal, which is decreasing new infections every year, requires a numerical target. Without that, he said, prevention is not a priority.

The Council voted to approve the recommendation that President Clinton include the issue of AIDS in his State of the Union Address without establishing a date by which the epidemic can be ended. The approved recommendation states that "Much of America has lapsed into a complacency about AIDS even while the epidemic continues to expand its path of devastation. We would like to ask you during the State of the Union Address to renew your commitment to ending the AIDS epidemic and to committing our Nation's resources to preventing new infections, caring for people now living with HIV/AIDS, and finding a cure, vaccine, and effective treatments for HIV. Also during this address, announce the immediate release of an updated National Plan on AIDS."

The Council also approved a recommendation that "To accomplish further the goals outlined at the White House Conference on HIV/AIDS, the Administration should ensure that key Cabinet Secretaries initiate and maintain regular, face-to-face meetings with HIV service providers and advocates to ensure consistent and ongoing communication and partnership with community members on the frontlines of the AIDS epidemic."

Assistant to the President for Domestic Policy, Ms. Carol Rasco

Ms. Carol Rasco, Assistant to the President for Domestic Policy, met with the Council and expressed gratitude for its report and its recommendation to hold the White House Conference.

Ms. Debra Fraser-Howze said that the sustained and visible leadership of the President is very important and it will be mentioned frequently in the Council's recommendations. Ms. Rasco thanked the Council for its support and noted that it would be helpful if members could work with the Governors on Medicaid issues.

Mr. Gould suggested that there is a need to help educate and raise the awareness of corporate leaders. Ms. Rasco said Council members can help the Administration look for opportunities to reach out to the business community and others. Dr. Levine noted that she had spoken with a consortia of industry in Sao Paulo, Brazil, and that their knowledge of the number of persons with AIDS, the costs of the disease, and the need for AIDS programs far surpasses ours.

Ms. Rasco's response was that corporate America needs to be educated on the subjects of HIV infection and AIDS. She then related an anecdote concerning the manager of a Sunbeam plant in Louisiana whose insurance premiums had skyrocketed because of the increased numbers of female workers at the plant giving birth prematurely. After finding that the numbers of premature births could be decreased by simple measures such as directing the factory nurse to monitor pregnant women and providing healthy snacks and cots for naps, he became an advocate for simple, cost-effective health interventions.

Dr. Levine asked whether there was a way to increase staff support for the Council. She said her own secretary has been spending 2½ hours each day photocopying, collating, and mailing Council-related materials. Ms. Rasco, noting financial constraints, said she would see what she could do.

Mr. Schatz also called for increased support, saying that "we simply cannot carry out a meaningful national plan" without a significant increase in office support. Ms. Rasco suggested that foundations or other organizations may be able to provide volunteers to help in the office.

Finally, Mr. Richard W. Stafford suggested that the Administration encourage its most visible Cabinet officials to visit pediatric AIDS wards or group homes when they visit other cities. Such visits will reinforce the Administration's message on AIDS.

General Discussion of Council

Members then returned to a discussion of recommendations that had been previously tabled.

Ms. Fraser-Howze suggested the Council urge the President to hold a White House briefing and update with congressional Black, Latino, and Women's caucuses in order to solicit their support in the fight against AIDS. While supportive of the concept, Council members agreed it would be best to propose a detailed plan for ways to increase partnerships with congressional leaders.

In general Council business, members discussed the need for payment in advance for travel expenses of members, particularly those with HIV/AIDS who may be living on a limited income. Mr. Schatz asked that members improve their preparation for these meetings and suggested that deadlines be set for recommendations submitted to the Subcommittees. Mr. Landau added that members should prepare in advance for the meeting so as to avoid 12-hour days, which are stressful for persons living with HIV/AIDS.

Ms. Greenberger suggested the Subcommittees meet in person more often, perhaps using private funds for such efforts.

Members also discussed a number of process issues, such as the introduction of new recommendations, particularly leadership initiatives, that do not fall under the purview of a specific Subcommittee.

All agreed that a number of important issues raised at the White House conference should be addressed at future meetings. In addition, members suggested that outside persons should continue to be invited to meetings to provide information and make the process more inclusive. Members discussed how best to build on the momentum established at the conference. It was suggested that each participant at the conference be sent a document indicating the Council's previous recommendations and the Administration's responses as well as a copy of the Council's new recommendations.

Ms. Fraser-Howze suggested that a few members form a committee to meet with Dr. Hitt via conference call in order to develop recommendations on how best to work as a Council and that time be set aside at the next meeting for discussion. Members agreed that an ad hoc committee should be formed to develop mechanisms and guidelines for process as well as a set of strategic functions, strategic goals, and associated resources in AIDS.

Stating that he was concerned that it has not yet determined its role, Mr. Anderson suggested that the Council needs to develop a long-term vision, including what it wants to accomplish, and how.

Dr. Abel stressed the importance of reaching out to communities not at the meeting and suggested that the Council set aside time at its next meeting to discuss its long-term plans.

Dr. Hitt informed members that travel advances are available but must be requested 30 days in advance. He thanked ONAP staff for their hard work despite the Government shutdown. Noting that they did not have sufficient time to devote to the issue of housing, members voted to include a recommendation that "The Advisory Council recognizes the critical and growing need for housing services for persons living with HIV and AIDS. We also wish to acknowledge and thank Housing and Urban Development Secretary Henry Cisneros for his outstanding leadership and unprecedented willingness to work in collaboration with AIDS housing providers and advocates. In July 1995, the Council recommended to President Clinton that he make AIDS housing an investment priority in FY 1997. We underscore the importance of this earlier recommendation and commit to preparing a more detailed set of housing recommendations at our next Council meeting."

Members thanked ONAP and Social & Scientific Systems staff for their support for the meeting. Mr. Landau provided an outline suggesting how the meeting should be conducted and asked members for comment.

Presidential Advisory Council on HIV/AIDS

Services, Prevention and Research Committee Breakout Sessions

Breakout Session: Services Subcommittee

December 7, 1995

9:30 a.m. to 1:30 p.m.

Grand Ballroom Sections A/B, Marriott at Metro Center

MINUTES

Members Present: Mr. Edward Gould, Chair; Dr. Stephen Abel; Ms. Regina Aragon; Ms. Mary Boland; Mr. Nicholas Bollman; Mr. B. Thomas Henderson; Ms. Carole laFavor; Mr. Steve Lew; Dr. Michael Rankin; Mr. Benjamin Schatz; Mr. Richard W. Stafford.

Also present: Mr. Jeff Levi, Deputy Director, Office of National AIDS Policy (ONAP)

Recommendations on Discrimination

Mr. Benjamin Schatz read the Committee's November 28, 1995, draft of recommendations for discussion only. They included recommendations that the President should, by Executive Order, oppose mandatory testing currently in place in the U.S. Foreign Service, the Peace Corps, the Job Corps, the State Department, and the military and instruct the U.S. Centers for Disease Control and Prevention (CDC) to review its scientifically discredited guidelines that arbitrarily restrict HIV-infected health care workers and lead to discrimination against them and to make these guidelines consistent with the prevailing scientific and public health knowledge on the issue.

The Committee agreed that the President should veto the Department of Defense (DoD) Reauthorization Bill and state that the veto is in part a result of the inclusion in the Bill of a requirement that service personnel who test positive for HIV be immediately discharged. Mr. Edward Gould supported the recommendation because there is no place for mandatory testing. The Federal agencies included in the recommendation are the only agencies that now have mandatory testing.

Ms. Carole laFavor mentioned the opposition by the DoD, and Dr. Stephen Abel noted that currently people who are HIV positive are not allowed into the military. Those who test positive after joining the military are supposed to be granted all rights when under care and treatment; however, Ms. Mary Boland mentioned two friends in the military who were not legally discharged but were forced out after testing positive. Mr. Gould reiterated that the Committee recommends that the President veto the reauthorization bill because it requires service personnel who test positive for HIV to be immediately discharged.

The Committee discussed the language of the recommendation on discrimination and mandatory testing. Dr. Abel objected to the word "encourage" in the recommendation that the CDC review its guidelines because it denoted intention; it was changed to "leads to discrimination."

The Committee then discussed the degree to which the President can instruct the CDC to ensure its guidelines are in accordance with sound public health practices. The leadership should defer to the public health community on that, Mr. Jeff Levi said. He also cautioned that the guidelines should be consistent because a precedent of asking the President of the United States to determine what is sound public health policy should not be made.

Mr. Gould agreed that the President should state the above-mentioned reasons for the veto, eliminating the phrase "highly cynical." Mr. Levi added that background information or an explanation should be attached to the recommendations; for example, that DoD studies show that those with HIV are serving well and effectively or a statement that they should serve.

Medicare and Medicaid

The Committee next discussed action regarding Medicare and Medicaid. Mr. B. Thomas Henderson pointed out that because of the President's December 6 veto, the recommendation for the President to oppose the proposed changes for Medicare and Medicaid had been accomplished. Mr. Nicholas Bollman added that the Committee recommend that the President continue to support and defend entitlement status and funding for Medicare and Medicaid, to which recommendation Ms. Regina Aragon suggested adding that the President continue to oppose any efforts to restrict eligibility or services for persons living with HIV/AIDS. The Committee should establish a set of principles by which to judge the President's actions, Mr. Bollman said.

The Committee then examined the recommendation regarding State waivers. Mr. Gould said that the language should read that the President should direct that waivers sought or granted to States be consistent with or measured by Health Care Financing Administration (HCFA) criteria. Mr. Bollman added that these criteria should be consistent with the provisions of the Americans with Disabilities Act, should be reviewed for this purpose by the Department of Health and Human Services (HHS) Office of Civil Rights, and should be continually revised to reflect state-of-the-art scientific and health care knowledge. HCFA also should ensure that State Medicaid programs cover anonymous HIV counseling and testing and that all drugs approved by the Food and Drug Administration (FDA) for treatment of persons living with HIV/AIDS are covered under these State plans.

Mr. Henderson suggested that any waivers granted be consistent with appropriate standards. He said he wanted to ensure that any plan a State presents is not automatically deemed acceptable. There should be minimum standards that States must meet to qualify, and he emphasized that the Committee should ensure that at least minimal standards are in place for States to obtain a waiver. If the goal is to encourage optimum services, he said, there must be a minimum beyond which States cannot obtain a waiver and that ensures the floor is high enough to adequately protect those with HIV and AIDS.

Dr. Abel pointed out that in the New York City strategic plan a list of minimum services were designated as core HIV/AIDS services in programs and development. They include HIV testing and counseling, primary care, acute care, dental and oral care, pharmacy services, home care, adult day care, case-management services, nutrition and food services, alcohol and drug abuse services, and transportation assistance. Mr. Gould said that in New York many HMO-type plans did not allow for the fact that HIV tends to be a disease with alternating peaks of good and bad health.

Ms. Boland clarified the language in the provision to say that waivers granted to States under Medicaid ensure access to a comprehensive continuum of care for persons living with HIV. Mr. Gould said that at the minimum these waivers must ensure access to care.

The Committee then discussed the inclusion of "off label" drugs and agreed that HCFA should ensure that all drugs approved by the FDA are covered under the State plans, even if used for "off label" indications. Mr. Bollman suggested that within the recommendation, the language should include a comment that this policy will require HCFA's diligent enforcement.

Alternative Therapies

The Committee then discussed alternative therapies. Mr. Gould suggested that the Committee add more specific recommendations or kinds of alternative therapies at the next Council meeting. Dr. Abel asked the Committee how it would respond if asked how to investigate thoroughly the efficacy of alternative treatment. Ms. laFavor specifically mentioned HIV-related research in Seattle and Minneapolis. In Minneapolis, the research is in acupuncture and therapeutic massage. She thought that the Office of Alternative Medicine (OAM) has funded the research for \$850,000, and she was concerned about what she viewed as tokenism on the part of Government concerning alternative or holistic therapies because very little money is going into the research.

The Committee then discussed the language of the recommendation and agreed to use the words "review" instead of "research" and "complementary" instead of "alternative" therapies. Mr. Gould then read the revised provision: "Because complementary therapies are widely used and show benefit, the President should direct all appropriate agencies to support the investigation of the efficacy of complementary treatment therapies and provide increased financial support for this effort. Therapies shown to have benefit should be included as FDA-approved and reimbursed under Medicaid. The President should also direct the NIH Office of Alternative Medicine to review such therapies and compile and publish a resource directory and guide on alternative complementary forms of treatment for HIV/AIDs as well as all life-threatening illnesses."

Mr. Henderson asked that the phrase "all life-threatening illnesses" be removed, and the Committee agreed that the recommendations should specify HIV/AIDS.

Managed Care

Ms. Boland expressed concern that providers of medical care and community-based organizations that need to be included in the recommendation will be lost in the changes occurring in Medicaid and private health care.

Mr. Gould noted that the Committee must decide what is important, and Mr. Henderson suggested that the Committee deal with action items that can be dealt with in a relatively short time and then look at the broader issues. Mr. Gould suggested that, if the Committee wants to make managed care a priority, it must recognize that some other issues will be shortchanged.

Mr. Bollman then read the preamble to the Managed Care section, and Mr. Gould listed the issues the Committee would bring forward at the 3 p.m. meeting, such as discrimination, Medicaid, alternative or complementary therapies, managed care, and housing. Some of the discrimination recommendations, the housing recommendation, and the issue of substance abuse would be postponed. The Committee agreed to include the Bureau of Prisons as another agency that should be directed by the President to develop national oversight criteria for managed care.

Mr. Steve Lew said that the original intent of the recommendation on managed care was twofold: to prepare as much as possible the Ryan White CARE Act-funded community-based models for adapting to the changes in managed care and to clarify the objective of Health Resources and Services Administration (HRSA)-provided education—otherwise, the recommendation will be confused with the separate category of education and training. Mr. Bollman responded that, if the recommendation is seen as concerned only with community-based providers, there will be competition with other effective care models that are not community based. He suggested that the wording read "clinically effective care models."

Education and Training

Mr. Gould mentioned the need for public and private sector collaboration to ensure a knowledgeable work force. Ms. Aragon noted that community providers are not effectively linked to the communities and that there are no ties between planning councils or other bodies. She said that HRSA should ensure that the work of AIDS Education and Training Centers is coordinated with community providers and planning groups.

Housing and Substance Abuse

Ms. Aragon suggested that the President make AIDS housing a priority in the 1997 budget, including an increase in funding not only for HOPWA but also for the housing assistance grants, a section within the Housing and Urban Development Administration (HUD) that deals with HOPWA, and the McKinney Act. She said that certain issues, such as housing for people who are substance users or have a history of substance abuse, the difficulty of providing care, and regulations that have strict eligibility criteria for housing services, are more complicated and require further research.

Mr. Lew proposed that the Committee recognize that extra time would be needed for discussing the issues on housing and substance abuse and drafting the wording on the budget. Mr. Gould ended the meeting with a statement that the Committee had determined that substance abuse in connection with HIV is a significant issue that should be fully developed and that the Committee was not prepared to make a recommendation at this time.

Presidential Advisory Council on HIV/AIDS

Breakout Session: Prevention Subcommittee

December 7, 1995

10:30 a.m. to 2:30 p.m.

Washington Room, Marriott at Metro Center

MINUTES

Subcommittee members discussed how best to present its agenda in a dynamic and positive way and the importance of reminding the President and the American public that prevention works.

Its working draft report called for reinvigorating the fight against AIDS and "getting ahead" by aiming prevention efforts at the growing edge of the epidemic and focusing efforts on the most vulnerable communities. An annual report from the CDC could show where infection is increasing most rapidly, and that is where prevention efforts should be targeted.

Mr. Mario Solis, a health information specialist who helped the Subcommittee prepare its draft report, outlined key recommendations for a number of areas.

He noted that the Subcommittee had received a number of new recommendations within the previous 48 hours, including one that HHS should review all regulations to be certain that they do not restrict the content of prevention materials, and that the NIH and OAR should research sexual behavior and sexuality as indicators of high risk for HIV transmission—specifically, efforts to assess accurately the risk of oral sex.

Belief that prevention does not work is widespread, Mr. Solis said, despite evidence indicating that health prevention and promotion work. Also, we need to ensure that our goals are possible, that we do not have too many things on the list, and that we will have the desired impact, Mr. Solis said.

Mr. Anderson said he felt the draft report reflected the Subcommittee's discussion and is a good start. He was concerned, however, that the draft report did not focus enough on action and lacked a prevention plan on a national level. "The Federal government," he said, "does not have a coherent structured set of goals and objectives for bringing this epidemic to an end through prevention. I want to see us instruct the Federal government that they need to have a comprehensive, complete, working plan on bringing this epidemic to an end; that the efforts are united, coordinated, and collaborative."

Agreeing with Mr. Anderson, Mr. Schatz said he felt the Subcommittee should set aside time to examine the Administration's responses to specific recommendations, including instances in which the Council believes those responses have been inadequate.

There was discussion that inclusion of the word "plan" in any recommendation risked involving the Council in bureaucratic inertia. Mr. Anderson said he remained concerned about the lack of coherence in the national prevention effort. The Council's recommendations should impose on the various agencies "the obligation to work collaboratively; the obligation to think strategically about what they are doing."

Ms. Altagracia Perez stressed the need for the Government to make publicly available such information as the effectiveness of needle-exchange programs and the recent report on youth, and she endorsed the need for a "date certain" for ending the epidemic through prevention efforts.

Members then described their own priorities in the area of prevention.

Ms. Debbie Runions indicated that because 75 percent of new infections are drug related, her priorities are in prevention programs. She also cited a recommendation for joint efforts by the Secretaries of HHS and Education to address HIV education and prevention among youth. Such efforts are measurable and can be done quickly, she said.

Ms. Perez rated taking HIV prevention out of Prevention Performance Partnership grants as her first priority, followed by the need for national models for youth prevention programs and a revised model for State drug paraphernalia laws.

Mr. Landau indicated behavioral surveillance as his top priority, followed by needle exchange and a recommendation for development of an AIDS prevention and care plan by the Indian Health Service, which he said recently fired three of its AIDS coordinators and is not filling those positions.

Mr. Robinson said measures to reduce transmission related to injection drug use was his highest priority but that a comprehensive set of prevention applications "much larger than needle-exchange" programs is needed. His second priority was prevention for people with HIV, including early prevention and secondary prevention. The third would look at the Federal structure around prevention, especially as it relates to community planning.

Mr. Schatz proposed a new recommendation for research to assess accurately the risk of oral sex and said he wanted surveillance to be linked with funding. He listed limiting content restrictions as his third priority.

Mr. Fogel suggested that the group ask the President and appropriate agencies within HHS to report to the Council by January 1 about what the Administration is doing in specific areas of research. Needle exchange obviously "can dramatically affect the epidemic aspects of the disease," he said. Noting that the national networks still refuse to accept condom advertisements, he suggested the Subcommittee in the future consider recommending steps the Administration might undertake, such as a meeting with the Vice President in which network executives are encouraged to air condom advertisements that are tasteful, accurate, and educational.

Ms. Kathleen Gerus said she agreed with Ms. Runions' priorities of ending the epidemic among injection drug users and increasing efforts targeted to youth.

Ms. Denise Stokes called for education and prevention programs targeted to youth but suggested they be more specific and directed, particularly in their content. Her second priority was research and models for minority communities, followed by needle-exchange programs.

Mr. Robinson cited prevention education for youth as his highest priority and cited a point raised at the White House conference that the CDC provide technical assistance directly to school boards that are developing programs. He listed behavioral surveillance and a demographic and geographic survey as his second and third priorities.

Ms. Stokes again emphasized the need for research on successful models for encouraging behavior change in minority communities. Ms. Perez suggested that prevention strategies targeted toward minorities be specific to the communities being targeted and that information targeted to youth should be "explicit and honest." Other members suggested substituting the word "frank" or "comprehensive" for "explicit."

Because there is no Federal mandate for AIDS education, members discussed how best to encourage collaboration between the Federal government and States in school education efforts.

Mr. Anderson said the Federal government's primary involvement in school education is through the CDC's Division of Adolescent School Health (DASH), which provides HIV education and prevention. There are two model curricula, both of which have been tested and found fairly effective. Funds are given to departments of education, which are responsible for providing training and technical assistance to school boards, school districts, and individual schools on how to provide AIDS education.

Mr. Robinson said the draft education recommendation was intended to bring the Secretaries of HHS and Education together. Mr. Fogel suggested that the CDC needs to provide more information to boards of education about where the epidemic is occurring and the effectiveness of prevention measures.

Ms. Stokes recounted difficulties in addressing school boards even when armed with surveys about teenage sex. Mr. Fogel suggested the group ask for more information on current programs and then consider asking the CDC to be more aggressive in its prevention efforts targeted at youth. Mr. Robinson said that by the March meeting of the Council, there will be a presentation on current programs. Mr. Schatz suggested that the group ask Mr. Levi of ONAP to provide the information to the group by January.

In discussing the group's desire to lift the ban on Federal funding for needle-exchange programs, Mr. Landau pointed out that the conference committees of Congress can amend anything they want, such as Ryan White, so the Council should move with caution.

Members agreed that a scientific panel is not necessary to assess the effectiveness of needle-exchange programs because of the unequivocal nature of the recent National Academy of Sciences report.

Mr. Anderson stressed the need for needle-exchange programs to be conducted within the context of substance abuse treatment and other programs. He said that the recommendation would allow local and State governments to use Federal funds for needle-exchange programs and that the Federal government would not mandate such programs. The Government would need to establish a process to decide how to release funds for such programs.

Members agreed to ask the President to direct the HHS Secretary to provide a recommendation within 90 days regarding the efficacy of needle-exchange programs.

Discussion about the public's perception of needle-exchange programs continued. Ms. Perez said that until the general public realizes that such programs do not increase drug use, people will continue to oppose needle-exchange programs.

"At the very least, I want the Secretary to say that the evidence shows that this will not increase drug use, and that in fact there is some validity in it, and we are not going to do it anyway," said Mr. Robinson. "If that is the bottom line, that is what I want to know, that is what I want to be able to take back to the community and say we asked for it, here's an answer, here's where they are, they know the evidence, they reviewed it, and they are not going to do it.

"The Secretary said," Mr. Robinson continued, "when asked about this after the conference, that there is controversy over the research. It is not acceptable for the Secretary to continue to put forth that myth; that is not the science. There is controversy within communities about whether this is the right thing to do, but to say that there is controversy in the science is inaccurate," he said.

Ms. Perez, citing concerns in the Black community about genocide and the argument that AIDS was developed intentionally, said that nonetheless, condoms do prevent transmission. And while communities of color have legitimate concerns about drug use, she added, and may feel concerned that the measures will allow people to use drugs, needle-exchange programs do reduce transmission.

Needle exchange needs to be taken out of a moral context, agreed Mr. Landau, who suggested that the group preface its recommendation with language about how such efforts can reduce the epidemic by 50 percent.

Although needle-exchange programs are one of the tools we have for dealing with AIDS, Mr. Anderson said, they are probably not the most effective tool. The amendment of State drug paraphernalia laws will probably have a more extensive impact on the spread of this epidemic than anything else, he said.

Members agreed to work on the language of the recommendation and background information.

Presidential Advisory Council on HIV/AIDS

Breakout Session: Research Subcommittee

December 7, 1995

10:00 a.m. to 2:00 p.m.

Montreal Room, Marriott at Metro Center

MINUTES

Members Present: Dr. Alexandra M. Levine (Chair), Dr. Jerry Cade, Ms. Debra Fraser-Howze, Ms. Phyllis Greenberger, Dr. R. Scott Hitt, Ms. Helen Miramontes, Ms. Sandra Thurman, Dr. Bruce Weniger.

Presentation on the AIDS Drug Development Task Force

The meeting of the Research Subcommittee began with introductions by members of the Presidential Advisory Council on HIV/AIDS and the following members of the National Task Force on AIDS Drug Development: Dr. Arthur Ammann, Director of Research, Pediatric AIDS Foundation, and Ms. Theresa McGovern, Esq., Director of the HIV Law Project in New York City. Dr. Ammann referred to the document entitled "The National Task Force on AIDS Drug Development: A Status Report in Response to the Task Force Recommendations." He said that one recommendation was that the Task Force concept continue, but not in its current form, which must operate under Government regulations that require the meetings to be open to the public and that restrict sharing of confidential information. If the Task Force were set up as a working group that is a kind of think tank, information about drugs in the pipeline could be shared freely among representatives from industry, the AIDS community, the Federal Government, and research scientists. Such sharing could result in faster development of AIDS drugs, Dr. Ammann said. The Research Subcommittee suggested that the proposed working group be supported by private funds or that the Government be consulted to identify a specific legal structure to allow it to be free of some Government restrictions. The President could delegate Vice President Gore to implement this recommendation (former Vice President Dan Quayle's Competitive Council might serve as a model).

Dr. Ammann also noted that he had made 14 recommendations for drug development relative to pregnant women and infants. He said that four drugs to be approved within 6 months will not have safety and pharmacokinetics (PK) evaluation for infants and pregnant women, thus precluding them from being used to prevent perinatal transmission.

Dr. Levine read the Task Force's draft recommendation on this issue:

The President must mandate that all federally sponsored drug trials must enroll women in numbers sufficient for valid interpretation of results. While the FDA issued guidelines for such access in 1993, there was no assessment of the impact of these

guidelines or actual adherence to these guidelines. The President should mandate a review of the current status of women and infants in federally sponsored antiretroviral therapy trials.

Ms. McGovern noted that her agenda is to eliminate restrictions on women with life-threatening disease in early clinical trials and to ensure that drug side effects in women are studied. She said that she has developed recommendations that were approved by the Task Force at its January 1994 meeting, but these recommendations are on hold because of FDA opposition. She referred to the recommendation B.21 in the Task Force draft report:

DHHS must amend its Regulations Governing Human Subject Research which limits research on fetuses and pregnant women. In particular, DHHS must eliminate the requirement that the father of the fetus must consent before a woman may participate in a clinical trial.

The DHHS Office of Protection from Research Risks (OPRR) has forwarded a rule consistent with this recommendation to Assistant Secretary for Health Dr. Philip Lee, and the FDA has drafted a proposed rule responsive to this recommendation. The Council could make the following recommendation to the President:

The President should direct the Secretary, DHHS, to immediately release the review of the proposed recommendation by the OPRR so it can be published for comment in the *Federal Register*.

Ms. McGovern pointed out recommendation A.5.c in the Task Force report:

The FDA must amend the regulations defining circumstances under which it is appropriate to issue a clinical hold or terminate an IND to include instances where a trial sponsor imposes restrictions on the inclusion of women of childbearing potential in any phase of any clinical trial for life threatening illnesses where there is no evidence of reproductive toxicities....

A second recommendation to the President will be formulated to ensure that this recommendation is implemented. (Ms. McGovern will fax further input to Dr. Levine to allow drafting of this recommendation.)

An additional recommendation might be to ask the President to direct the NIH Director to evaluate each Institute's analyses conducted in response to FDA's 1993 guideline to assess gender differences related to drug effects. This might be broadened to recommend that the FDA review the gender analysis of all clinical trials (since FDA guidelines apply to more than NIH trials). The following two options for wording were suggested:

Direct the FDA to mandate side effect profiles of drug effects in women as part of safety and efficacy reporting. OR The FDA should ensure that applications for new drugs include data on all populations likely to use such drugs.

Other points made during the discussion included the following:

- Ms. Heidi [LeShan?](#) of NIH said that NIH research cannot be funded without a plan for including women and children in studies; if study sections find that this plan is inadequate, the study is not approved. She will find out how implementation of the plans are monitored.
- There has never been a lawsuit for harm caused by Phase I studies, so this should not be a deterrent to industry.
- The Subcommittee questioned why FDA is holding up implementation of the Task Force recommendations and why pregnant women must obtain the consent of the fetus' father to participate in trials.
- Dr. Levine noted that requiring gender analysis might hold up research while the large numbers of women needed to allow statistical analysis are recruited. Therefore, the recommendation might state that data on side effects and toxicity need not be statistically oriented.

Mr. Tim Westmoreland of Georgetown University Law School (who has worked with the Pediatric AIDS Foundation) reviewed issues related to drugs for pediatric patients, noting that 75 percent of drugs have no indications for pediatric use. Although the Foundation does not want to hold adult drugs hostage, it would like FDA to encourage manufacturers to develop oral formulations of adult HIV/AIDS drugs and to conduct simultaneous PK studies of these drugs in adults and children. It was noted that FDA Director Dr. David Kessler has identified this as a failure at the FDA level. The Council will press FDA on this issue and request more information from Dr. Kessler.

Mr. Westmoreland reviewed proposed legislation by Senator Nancy Kassebaum that would provide an incentive to industry by extending market exclusivity for 6 months against generic copies of the drug if a company conducts PK studies. He said that there is no obvious opposition to the bill; however, it was noted that the health care industry might object to increased drug costs that might ultimately result from such legislation.

The following recommendation was proposed:

The Administration should submit legislation to provide incentives to develop oral formulations of AIDS drugs for children and PK data. Other proposed legislation (e.g., involving tax credits) might also achieve this end.

Another issue raised was the recommendation involving conflict of interest disclosure for members of NIH study sections. Dr. Levine said that this is part of a large document ([Name of document? from ACT UP?](#)) that she will review.

Discussion of Other Issues

Dr. Levine then reviewed some of the issues that had been raised yesterday at the meeting of the Research and Treatment Subcommittee of the National Conference on AIDS. Some of these issues that the Research Subcommittee should consider are the following:

- The President should include mention of HIV/AIDS issues in his speeches on other topics.
- Presidential scholars in HIV research should be funded by NIH or through private donations.
- The President should direct DHHS to convene a consensus meeting to determine how to ensure Phase IV studies of drug combinations after drugs are licensed. (This might be part of the Vice President's role; Ms. Thurman will develop this point.)
- Ways of recruiting private investment in the drug development process should be explored. (This also might be part of the Vice President's mandate.)
- A national standard of care should be developed for the off-label use of drugs as standard of care, because many health maintenance organizations (HMOs) will not pay for off-label drugs. Feedback will be sought on the status of FDA guidelines being developed in this area.
- Ways of increasing the number of minority researchers should be explored. (Ms. Fraser-Howze will develop this point.)
- NIH funding mechanisms should be restructured to allow more creative research.

Dr. Weniger noted several messages from yesterday's meeting: (1) vaccines/microbicides for prevention are technically possible; (2) such products are highly cost-effective and justify the money invested in them; (3) a public/private partnership and international effort will be needed; Vice President Gore should oversee ways of energizing the private sector. Ms. Jane Sanville of the Office of National AIDS Policy said she will write up the notes from yesterday's meeting.

Before lunch, Dr. Levine reviewed two of the recommendations in the draft list "Important Issues in the Area of AIDS Research with Recommendations for Presidential Action (the third recommendation is found on page 2 of these minutes).

- 1. The Federal Government must make the development of an antimicrobial agent against HIV and other sexually transmitted diseases (STDs) an urgent research priority, with significant expansion and acceleration of the current federally funded research effort in this area.**
- 2. The President should veto any bill which weakens the budget authority of the Office of AIDS Research (OAR) at the NIH, or which fails to set a fixed funding level for AIDS research.**

These recommendations would be revised as necessary later during the Council's meeting. Dr. Weniger suggested adding a recommendation on behavioral research.

Panels on Microbicides

The afternoon session, led by Dr. Phyllis Greenberger, focused on presentations on the need to support research on microbicides. The first panel focused on public/private research efforts. To begin, Dr. Penny Hitchcock, Chief of the STD Branch, National Institute of Allergy and Infectious Diseases (NIAID), described NIAID's three parallel tracks in basic, applied, and clinical research. The basic science agenda includes studies of early steps of HIV infection; inactivation of pathogens; toxicity of spermicides/microbicides; and the ecology of the reproductive tract. Applied research includes *in vitro* assays of microbicides, studies in animal models, and studies of microbicide formulations. Clinical evaluations include Phase I to Phase III studies (a Phase III study of vaginal film containing nonoxynol-9 [N-9] is being conducted in Cameroon) as well as behavioral research on product acceptance and compliance. Dr. Hitchcock said that microbicides should be colorless, odorless, and tasteless so that women at greatest risk, who are often involved in nonconsensual sex, have control over the method. The products should also be cheap, safe, and stable. She mentioned other NIAID studies, including those of antimicrobial peptides called defensins, which may inactivate various pathogens.

Dr. Sharon Hillyer, an NIAID grantee at the University of Pittsburgh, noted that microbicide research is in its infancy—condoms and N-9 remain the only methods for preventing STDs in the last 25 years. She pointed out that heterosexual transmission of STDs occurs within the vaginal ecosystem and that any microbicide for use in the vagina must not disrupt or destroy the vaginal epithelium, kill beneficial vaginal bacteria that produce compounds that inhibit infectious agents (acidic conditions decrease STDs), or cause overgrowth of harmful organisms such as yeast or *E. coli*. She noted that a vaginal microbicide should be a woman-controlled method and that most effective microbicides will probably be "cocktails" of compounds with different activities. Dr. Hillyer's laboratory is testing three existing products: (1) chlorhexidine, a nontoxic agent effective against HIV and other STDs *in vitro*; (2) N-9, which is active against many STDs but somewhat toxic with repeated use; and (3) benzalkonium chloride, a spermicidal detergent-like compound active against many STD agents but toxic in the monkey model. The research is also developing two new products based on compounds found in a healthy vagina: (1) a lactobacillus suppository with myeloperoxidase that kills HIV *in vitro* (it will be tested in high-risk adolescents to determine whether it inhibits HIV transmission) and (2) a product based on synthetic milk lipids. Dr. Hillyer noted the limited resources for these studies and the need for a commitment from leadership to develop these important weapons against heterosexual transmission of HIV.

Dr. Pam Stratton, an obstetrician-gynecologist in the Contraceptive Branch of the National Institute of Child Health and Human Development (NICHD), described studies designed to evaluate spermicidal microbicides and to understand the effect of these products on the intravaginal system. Optimal characteristics of such products include activity against multiple viral targets; suitability for topical, vaginal, or rectal use; and being nonirritating with regular use. Dr. Stratton also reviewed the good and bad aspects of N-9, noting as its main drawback that multiple use (four times daily) is irritating and that daily use of the N-9 sponge leads to ulcers and

vulvitis, which may increase the risk of HIV infection. She stressed that new products must be compatible with condoms.

Ms. Anne-Marie Corner, President and CEO of Biosyn, a small biotechnology company concerned with AIDS and female health, described studies of the Prevecon suppository, a vaginal microbicide now in a Phase I trial in 20 women. This product is a synthetic organic molecule active against HIV and other STDs. Prevecon is spermicidal, active at pH 4 to 7.5, and will be available in several other formulations. The Investigational New Drug (IND) application was submitted in 1994, Phase II/III trials are planned for 1997, and the product is expected to be ready in 2000. NICHD has funded preclinical and Phase I trials, and the product has been tested in a NIAID program project grant for studies of STD prevention in animal models. The World Health Organization is expected to collaborate in the Phase III trial. Ms. Corner's recommendations for expediting the availability of microbicides include the following: (1) change product liability laws; (2) have a Presidential directive for increasing microbicide awareness; (3) have equal emphasis on contraceptive microbicides and HIV microbicides (to address the needs of different groups); (4) increase research support for the clinical development of products, and (5) speed up the Request for Proposal (RFP) process. In response to questions, Ms. Corner noted that about one-half of the women in the Phase I trial are members of minority groups; that all women in this trial are compensated for their time and child care expenses; and that the women are required to have had tubal ligation and be monogamous and free of STDs.

The second panel on microbicides consisted of Dr. Malcolm Potts of the University of California, Berkeley; Dr. Zena Stein [affiliation?](#); and Dr. Lori Heise of the Center for Women's Global Leadership at Rutgers University. Speaking from the perspective of his 30 years of work with contraceptives, Dr. Potts noted that microbicides are a low-tech solution not currently attractive to industry. He said that FDA must speed up the development of these preventive agents and that NIH must support the development of cheap and simple products by giving contracts to small, low-tech companies. The NIH should assemble a panel that would decide the requirements for products, which must kill virus *in vitro*, not harm the vagina, and slow the spread of HIV (the latter is harder to prove).

The need for a consensus conference to resolve practical and ethical issues was raised. Participants disagreed about whether microbicides should be promoted at this time or whether more research is needed. (N-9 is currently the only FDA-approved product.) Ms. Patricia Fleming noted that if people think a product will protect them, their risk of acquiring HIV infection might increase. Dr. Hitchcock added that *in vitro* data are not applicable to humans and that more research is needed before microbicides can be promoted; she believed that women should be given information on STD prevention. On the other hand, Dr. Potts countered that microbicides are better than nothing for high-risk women, such as sex workers or women who use crack. It was noted that a trial using the N-9 sponge in African women was not a success but that the study was uncontrolled and used a dose four times higher than normal.

Dr. Stein's handout discussed the need for research on the acceptability and effectiveness of various barrier methods, including the female condom, diaphragm plus N-9, and cervical cap. She noted the need for methods that are woman controlled and compatible with conception, and she called for research on the role of the cervix and the phase of the menstrual cycle in HIV

transmission and the role of sperm as vectors. She stated that the female condom is safe and reusable and allows women to use it without the knowledge of their partners. However, Dr. Hitchcock noted the lack of data on this product (Dr. Stein noted that there have been no studies of the male condom). Dr. Stein suggested that the President appoint a blue-ribbon panel to develop short-term recommendations and immediate steps to protect women using existing barrier products.

Dr. Heise summarized her written testimony, which stressed the need to increase funds for research to develop female-controlled methods of HIV/STD prevention, especially vaginal microbicides. She called for studies of multiple products, because many will "drop out" as testing proceeds, and for multicenter trials, with Phase III trials in developing countries. She noted that only \$15 million of the FY 1995 PHS \$2.7 billion budget for HIV prevention and care is devoted to female-controlled methods. Her recommendations included the following:

- Resources should be shifted to increase investment in studies of heterosexual transmission and vaginal physiology.
- The President should direct agencies to develop a network of clinical trial sites.
- The Government should test available methods as well as other methods, such as Germany's cervical cap and the N-9 contraceptive film being used in Cameroon.
- The OAR should sponsor a consensus conference to develop guidance for street-level prevention workers on how to counsel women using existing products such as N-9. The Government should consider promoting a hierarchical prevention message that takes into consideration that some method is better than no method.

During the discussion of microbicides, the following points were made:

- Approximately \$11.8 million is spent on microbicide research at NIAID. About 50 percent of STD research comes from AIDS funds. The Women's Interagency HIV Study (WIHS) involves a cohort of 3,000 women.
- Two types of microbicides must be developed: those that are spermicidal and those that are not (women must have the choice of getting pregnant without risk of infection).
- A public information campaign is needed to inform the public about microbicides. The scientific community also should be made aware that microbicides are not marginal products. Greater knowledge about microbicides would lead to increased private investment.
- An infrastructure is needed for testing microbicides. The infrastructure of the HIV Vaccine Efficacy Trials Network (HIVNET) could be used.
- The leaders who control the Federal funds (e.g., the Directors of the NIH, OAR, CDC) should be targeted.
- The NIH lacks the staff to oversee contracts.

Before the meeting ended, [Mr. Jeff Blum](#) of the Patients' Coalition (which includes representatives of people with AIDS, cancer, epilepsy and other serious illnesses) presented a handout listing the Coalition's Principles of FDA Reform: The Patients' Perspective. He asked meeting participants to endorse these principles by signing and returning the form on the first page of the handout. The Coalition's principles include support for special FDA treatment of drugs for serious and life-threatening diseases; pre-approval access to experimental drugs that show reasonable safety and efficacy; post-marketing approval of such drugs; validation of third-party reimbursement of off-label uses of drugs; FDA regulatory flexibility; FDA requirement of data for all populations likely to use new drugs; FDA responsiveness to public concerns; communication between FDA and industry; and incentives to encourage research.