PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

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MINUTES

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Meeting Report Prepared by:
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WELCOMING REMARKS

Louis Sullivan, M.D., Co-Chair

Dr. Sullivan thanked former members—Caya Lewis, John Perez, and Ingrid Duran—and introduced three new members:

- Dr. Edward C. Green, medical anthropologist and senior research scientist at Harvard School of Public Health;
- Dr. Franklin Judson, director, Public Health Department for the City of Denver, and president of the International Union against Sexually Transmitted Diseases; and
- Dr. Beny J. Primm, president, The Addiction Research and Treatment Corporation in New York (one of the largest minority substance abuse treatment programs).

Josephine Robinson, Acting Executive Director

This was the first PACHA meeting Ms. Robinson organized for the 34-member Council. She thanked everyone for the opportunity to serve, gave logistical directions, and announced the arrival of a program assistant for PACHA, Dana Ceasar.

Joseph O'Neill, M.D., Director, White House Office of National AIDS Policy

Three areas are the most important: domestic agenda, global agenda, and prognostications. Strides made in the last year have changed existing policy, namely, with the Food and Drug Administration (FDA)'s approval of the rapid test for HIV, and with the Centers for Disease Control and Prevention (CDC)'s new HIV testing guidelines, which incorporate HIV testing into the mainstream of medical care. To prevent losing ground in minority communities, the White House needs PACHA's ongoing guidance and thought.

On the domestic front, implementation and refinement of new testing approaches is a hugely important step for public health in this country. There is also a huge problem with access to medical treatment and pharmaceuticals, which will only get worse. But a number of changes are in motion in health care financing, all of which will be important to people living with AIDS (PLWAs). At the same time, tough structural issues need to be dealt with in a time of tough budget constraints (Joshua Bolton is in charge of budget), and every organization will have to determine what is less important. These decisions require PACHA's input. Ryan White reauthorization will come up, and this Administration will take strong policy positions. It is very important that this Council hear from a wide variety of people and issues. The President wants the best advice he can get and is not afraid of hearing things he disagrees with.

On the global front, Randy Tobias (Eli Lilly CEO) has been nominated to be the Global AIDS Ambassador and, to implement the new initiative, a skeleton crew is setting up an office at the State Department. For the President's Maternal–Child Transmission initiative, resources have been quickly deployed to 14 countries. This is also one of the first times an Administration is poised to release RFAs jointly from the Department of Health and Human Services (DHHS) and the U.S. Agency for International Development (USAID); this action will bring the development world and the health world together. The President has promised that the Global AIDS Program would have the money needed, and he wants to see results and accountability.

PREVENTION SUBCOMMITTEE—Anita Smith, Chair

This subcommittee tackled three topics: the new CDC guidelines, youth, and substance abuse and HIV. Each of the speakers had also spoken at the last subcommittee meeting.

Advancing HIV Prevention: New Strategies for a Changing Epidemic, U.S. 2003—Ronald O. Valdiserri, M.D., M.P.H. (CDC)

CDC and the Health Resources and Services Administration (HRSA) each had an advisory committee to look at HIV/AIDS; the two merged in September.

Dr. Valdiserri reviewed the epidemiological science behind the new initiative: Between 1981 and 2002 in the United States there were 859,000 cases of HIV/AIDS and 487,672 deaths. In the mid-1990s the incidence dropped because of better treatment, meaning that the period between infection and symptoms lengthened; deaths dropped a few years later but are beginning to level off. However, the number of PLWAs is steadily increasing, and consequently opportunities for transmission are also increasing.

For the third year in a row, diagnoses among men who have sex with men (MSM) have increased. Concurrently, there have been three outbreaks of syphilis among MSMs—in Miami, New York City, and Los Angeles. This is a matter of concern because of what it might imply about HIV/AIDS. Of the people who know they're HIV+, 40 percent engage in vaginal or anal intercourse but use condoms correctly; 27 percent abstain; 15 percent have sex with one HIV+ partner; and 14 percent have unprotected sex. We need to do a better job of delivering ongoing prevention messages among sexually active persons. Of the 850,000 to 950,000 PLWAs in the United States, an estimated 180,000 to 280,000 do not know they're infected. Too many get tested late in the infection when treatment won't be maximally effective. As for perinatal transmission, 300 babies are infected annually.

The goal of CDC's new initiative is to reduce HIV transmission by reducing barriers to testing, increasing access to and utilization of quality medical care and treatment, and continuing ongoing prevention services. These are not new policy issues.

At the end of 2002, the Institute of Medicine (IOM) advocated strengthening programs to help PLWAs, namely:

- Make voluntary HIV testing a routine part of medical care,
- Implement new models for diagnosing HIV infection outside medical settings,
- Prevent new infections by working with persons diagnosed with HIV and their partners, and
- Further decrease perinatal HIV transmission.

Health care delivery people need consultation with PLWAs to recognize the reality that they are sexually active and some have multiple partners.

In the perinatal component, HIV testing is now being offered to pregnant women with opt-out provision, the same way other tests are offered.

CDC has not clearly communicated what the guidelines are about. CDC will:

- continue to support efforts to keep HIV-negative people healthy;
- continue to fund community-based organizations (CBOs), especially those serving minorities;
- continue to rely on behavioral prevention approaches;
- continue to support community planning; and
- continue to support voluntary testing.

Several specific activities were mentioned. In mid-July, CDC published (with HRSA) *Incorporating HIV Prevention into the Medical Care of Persons Living with HIV*. Also in July, CDC hosted a meeting of medical and nursing associations. Health departments are required to make PLWAs their highest priority for prevention services. Demonstration projects were recently solicited. In August CDC plans a consultation with PLWAs, who are inadvertently stigmatized. The new OraQuick test kit provides diagnosis within 20 minutes; people are now being trained to use it. CDC also plans to monitor how well the initiative is working.

Discussion

Ms. Robinson: A breakdown of the budget will be available tomorrow.

Ms. Ivantic-Doucette: There are legal considerations. For example, in Milwaukee, a pregnant, HIV-positive woman went to a clinic for perinatal testing and did not consent to HIV testing. (She knew she was HIV-positive but didn't want her partner to know.) She was accidentally tested and sued the OB-GYN, who is closing his practice.

Dr. Valdiserri: The State can make laws about testing, and CDC is trying to become better informed to know what the State laws are. No one is suggesting that informed consent be done away with, but that an opt-out provision be available.

Mr. Sneed: Mr. Sneed has seen some past failures. Of the some 180,000 to 280,000 who don't know they're HIV-positive, how many are MSM and how many African

American? What about the 41 percent who were diagnosed late in the disease? What are ongoing prevention services?

Dr. Valdiserri: We can assume that racial and ethnic minorities are overrepresented and also that MSM are a significant component. The highest incidence occurs among young African American MSM. Ongoing prevention, for the private sector, means understanding what's happening with your patient's sexual behavior and it means screening for other sexually transmitted diseases (STDs). For nongovernmental organizations (NGOs), it may mean more in-depth counseling sessions. Studies have shown that stress reduction is helpful to PLWAs.

Mr. Sneed: Psychosocial support issues are important and will have to be incorporated.

Dr. Sweeney: She is concerned about testing without pre-test counseling, which gets into issues of telling partners.

Dr. Valdiserri: Once people learn they're HIV-positive, they increasingly engage in safer sex. Most people are very motivated not to spread the virus. Pre-test counseling is very important in the private sector, but CBOs have other issues such as quality assurance and privacy rights. In some settings, pre-test counseling was seen as a barrier to testing; post-test counseling could be effected by referral to resources in the community. This would address the time limitations. We need to develop models so other resources in the community can pick up the slack (as was done with prevention of smoking).

Ms. Rock: What about at-risk prevention in directly funded communities? Increased diagnosis will increase incidence, which will increase reliance on Ryan White CARE.

Dr. Valdiserri: Having CBOs apply directly to CDC for resources is under discussion. The initiative's focus is on counseling and testing, but a third domain focuses on ongoing prevention support to stay safe and to work with partners (especially if they are seronegative). The announcement will probably be published in November and will indicate dollar amounts for various activities. CDC and HRSA still think early diagnosis is important, but it is true that funding for care is an issue.

Dr. Reznik: People recently diagnosed will be coming into care in 2004 and 2005 in both the public and private sectors. What work is being done to translate these numbers of incidence into realistic budget projections for treatment and support?

Dr. Valdiserri: Some information we have; some we don't. Everyone identified will not seek care through Ryan White money. More resources will be needed, an issue PACHA might want to take up.

Dr. Primm: How will consultation with the HIV-positive community be done? At point-of-care testing, doctors must have a clear waiver. With rapid testing, the additional confirmatory test should also be done.

Dr. Valdiserri: CDC has a history of consulting with PLWAs and has rapport with NAPLWA. It would be a consultation with the HIV-positive community in Atlanta working closely with CBOs to get the information. Rapid testing is not The Answer (for one thing, it is much more expensive), but it is helpful. CDC intends to move slowly and with purpose and foresight. So, we need to find out how to work with the best public health community for the best outcome to patients.

Mr. Minor: Mandatory partner notification might keep people from being tested and it also has legal aspects. Many liaisons occur through the Internet. How aggressive is CDC in tracking people? How does community planning balance with prevention programs that have been cut or reduced?

Dr. Valdiserri: The Internet is a very important risk venue. CDC is involved in research activities to find how to best reach out to high-risk persons. Partner notification has been a required activity of State health departments since the early 1990s, but the reality is that some States do a better job than others. CDC would consider an appropriate level of tracking activity. To prevent criminalization and stigmatization, CDC will have to work more closely with PLWAs.

The Stop AIDS Program is still receiving CDC funds, but CDC sent the group a letter saying that some materials they had developed appeared to encourage sexual promiscuity. CDC will continue to work with sexually active people; their main concern is preventing transmission of STDs, and sex is the usual way they are transmitted.

Dr. Judson: CDC and HHS are getting together, but to really make progress, prevention has to go well beyond CDC's guidelines. It has to be a regular practice with its own funding mechanism. The obvious place is to have Ryan White incorporate HIV testing as a regular practice.

Dr. Valdiserri: Of the $35 million earmarked for AIDS, about $13 million is new funding; the rest is renewed. Developing infrastructure is expensive. With small health staff, it's about training and awareness of current developments in the field. Community planning involves looking at what is happening in the epidemic in your area, what's happening in treatment development, what's happening with PLWAs. Government alone cannot stop this epidemic. We have to do a better job of working with the private sector.

How Can We Become More Effective in Preventing HIV Infection among Young People?—Lloyd Kolbe, Ph.D. (CDC)

The number of 15- to 19-year-old females who engaged in sexual intercourse doubled in the 1980s and 1990s. The 13- to 24-year-old population is a 10-year age group, whereas all the other age groups span 20 years. These young people will age through the older cohorts, so being effective at age 13 implies being effective at the older ages. There were 3 million other newly diagnosed STDs/year. This age group suffers from other STD

epidemics, e.g., gonorrhea, chlamydia, and herpes. They also experienced nearly 1 million pregnancies.

Prevention programs can only be effective if they work with the social institutions that most influence young people, namely, parents, schools, etc.

CDC's goal is to decrease the incidence of HIV infection by 25 percent by 2005. To do this, they will work with CBOs and NGOs like the National Commission on Correctional Health Care, and they will implement school-based strategies. Now almost 90 percent of schools give HIV education; in 1991 few did. In that decade we have seen a major increase in abstinent young people, a major decrease in pregnancies, a major increase in condom use, and a decrease in multiple partners. However, as a Nation we need to do a better job of preventing high-school intercourse. Despite these improvements, the use of drugs and alcohol has increased (from 22 percent to 26 percent).

Gay, lesbian, and bisexual youth remain a concern. Some 20 percent missed school because they didn't feel safe; 36 percent had attempted suicide; 24 percent of the girls had been pregnant at least twice. Youth in high-risk situations are those who sell or barter sex; those who live in juvenile justice facilities or in runaway and homeless shelters; those who use STD clinics, mental health facilities, alcohol and drug abuse treatment; those who are members of gangs or are migrants.

Efforts to prevent HIV infection should be integrated with efforts to prevent other STDs and unintended pregnancy. Likewise, State education associations should integrate prevention activities with health departments.

Sex in the media has adverse effects and we need to learn how to reduce those effects. The new initiative is a major issue for young people. For instance, we need to understand the extent to which children receive age-appropriate counseling. Risk reduction should be integrated with youth development efforts. Clustering phenomena potentiates the opportunity. In order to focus adequate attention on young people, people with different perspectives must find the will and the means.

Discussion

Ms. Clements: How young should children be tested?

Dr. Kolbe: In the early elementary grades children need to understand the concept of infection. Toward the middle grades and high school grades we should provide more information about how HIV/AIDS is acquired. What they learn in school depends on their community.

Ms. Ivantic-Doucette: Values and attitudes begin developing by age 6; after that, it's a matter of refining them. The greatest influence is the family. What recommendations do you have for prevention?

Dr. Kolbe: We must help children to develop competence, confidence, caring, connections, contributions, and character. It's important to provide infrastructure and support to address HIV/AIDS and other epidemics, e.g., violence and substance abuse.

Dr. McIlhaney: Some would refer to peer-based education. Regardless, we need to give kids a vision of what life can be. We should deliver the STD risk message, incorporating a vision of possibilities.

Dr. Kolbe: We need to be honest with young people as to what we know and don't know about the efficacy of condoms. We must do a better job of helping them understand and of motivating them to use condoms. The HIV epidemic was responsible for building the adolescent and school health program at CDC; Congress provided the money. We need to deal with a wide range of other illnesses, so we should build infrastructure in a way to address other illnesses in addition to HIV/AIDS. We should give young people the opportunity to be risk-free and prepared for life.

Mr. Sneed: Many organizations are primarily for heterosexual youth. What about gay, lesbian, bisexual youth? They're prisoners of psychic isolation and have to learn on the street. Renaissance III (Mr. Sneed's organization) opened a center for gay, lesbian, bisexual youth, the first in Texas.

Dr. Kolbe: It's far more controversial to do the same things among these youth, although the data are very clear about the wide range of public health needs. The problems are further compounded when you cross these people with communities of color. We need specific focused attention to address these young people.

Ms. Shoemaker: What guidelines can we use when we speak in the schools in this age of budget decreases?

Dr. Kolbe: This Council can address the budget issue to recall our Nation's focus to the needs of young people. The controversy is not insignificant, but PACHA could call people together to ask them to state their concerns.

How Drug Use Exacerbates the Risk for HIV/AIDS—Donald Vereen, M.D. (NIDA)

Drug abuse is a huge but hidden problem. Drug use relates to AIDS in actual transmission of HIV and also in its direct effect on the progression of the disease. The disease is transmitted through shared needles, worsened by the poor decision-making of the drug-influenced mind. HIV incidence among MSM has increased as incidence from heterosexual contact has increased, while incidence among injecting drug users (IDUs) has remained the same. All three are related to drug use, which accounts for about half the cases of AIDS. Heterosexual male IDUs are most commonly implicated in disease transmission, followed by female IDUs, and then MSM IDUs. Since 1990 we have seen increases in the number of: children infected by their mother (from 4 percent to 17

percent); women infected by their husband (from 8 percent to 29 percent); men sharing needles (from 5 percent to 30 percent); and MSM (7–8 percent to 9 percent).

Drugs can interfere with judgment and reduce inhibitions, both of which are related to risk-taking behavior. Drug-addicted people often sell sex to obtain drugs. In addition, accumulating evidence indicates that some drugs (methadone or morphine, cocaine, methamphetamine) exacerbate AIDS progression by enhancing viral replication and infectivity. They also exacerbate changes in the brain relating to dementia. Lastly, drugs release dopamine, which gives the drug user excessive feelings of pleasure, so that users might substitute drugs for other pleasurable experiences.

Therefore, the most effective HIV/AIDS prevention strategy is drug abuse treatment. Any type of treatment slows seroconversion. This is science-based behavioral treatment. A national drug abuse treatment clinical trials network is underway.

Principles of Prevention (known as the "Red Book") and other information are available on the Web (<www.nida.gov>).

How Substance Abuse Exacerbates Risk Behaviors for HIV/AIDS—H. Westley Clark, M.D., J.D., M.P.H. (SAMHSA)

The Substance Abuse and Mental Health Services Administration (SAMHSA)'s mission is to build resilience and to facilitate recovery. SAMHSA's programs (e.g., co-occurring disorders, substance abuse treatment, HIV/AIDS and hepatitis, criminal justice) are all treated in light of crosscutting principles (e.g., data and evidence-based outcomes, collaboration with public and private partners, cultural competency, recovery, reducing stigma and barriers to service). Mr. Curry wants to focus on a few major programs rather than on many smaller ones.

IDUs represent the largest HIV-infected substance-using population in the United States. Sexual contact among IDUs is characterized by multiple partners, unprotected intercourse, and exchange of sex for drugs.

Of reported AIDS cases, IDU is involved in 57 percent of cases among women, 52 percent of reported pediatric AIDS cases, and 31 percent of all male AIDS cases. Treatment Improvement Protocol #37 outlines substance abuse treatment for persons with HIV/AIDS and includes medical assessment, mental health needs, counseling, integration of services, use of case managers, legal, ethical and privacy issues, and funding and policy considerations. Addiction is a treatable disease, but we must improve service delivery. Recovery Month (*see* <www.recoverymonth.gov>) was initiated to induce all levels of society to work toward enhancing addiction treatment access, availability, and quality.

For more information on SAMHSA's and the Center for Substance Abuse Treatment (CSAT)'s programs, see <www.samhsa.gov>.

Discussion

Mr. Sneed: In the South, care providers say crack cocaine is the #1 drug connected with HIV transmission. Is SAMHSA refocusing any of its programs? Have CBO contracts been audited?

Dr. Clark: Crack cocaine is associated with sexual activity, but in some areas there's no cocaine and the real question is sexual behavior fueled by psycho-active drugs. You must know the epidemiology of your community. SAMHSA has tried to work with the CDC to get the latest information. As for auditing, SAMHSA operates under a Government Performance Act that requires a task force to look at how money in block grants is being spent. Under set-asides, States are the responsible entities, so we work with them so they can spend the money wisely.

Dr. Vereen: A State-based household survey is emerging, but the Government hasn't started to compare States. States will be able to use the survey to customize their programs. The natural tendency is to develop programs geared to a specific drug, but we should intensify comprehensive anti-drug activities. For example, while public health people focused on treating heroine addiction, cocaine came in "the back door."

Ms. Ivantic-Doucette: At Marquette University they're trying to work with the positives around risk behavior. What about the drug-using population that is infected? Clinicians don't understand drug treatment or drug use—in studying the behavior of health care workers, they find that it takes 17 years to incorporate a new treatment method. An example is the finding that over time people with HIV/AIDS develop pain. Pain is poorly understood and treated, so these people return to a methodone program to take care of pain. If they can't manage their pain sufficiently, they return to the community and to substance abuse. The flip side is that if you reduce pain, you reduce substance abuse. Is anyone thinking about this? What about the linkages for the positives?

Dr. Vereen: The National Institutes of Health (NIH) are engaged in a number of exercises to re-tool to focus on real-world entities. At the National Institute on Drug Abuse (NIDA), often the kinds of issues you raise come from clinicians who are not involved in research. Researchers need to develop more on how knowledge gets transferred and translated. There is no national institute on pain; instead we have to organize five, six, or seven Institutes to deal with pain. The National Institute of Dental and Craniofacial Research works on pain more than any other Institute.

Dr. Primm: Both Dr. Clark and Dr. Vereen are psychiatrists, but neither talked about the mental health issues. The Office of AIDS Policy and the Office of National Drug Control Policy need to talk about this as well as about IDU and paraphernalia.

Dr. Vereen: It has been frustrating as the only physician in the Office of the National Drug Control Policy working on issues related to AIDS and also on other mental health

issues, e.g., co-occurring disorders. The top level isn't addressing mental health, but in Government agencies there's a lot of discussion under the top level.

Dr. Clark: We are dependent on groups like PACHA for input to be sure these issues aren't forgotten in times of limited resources.

Mr. Nickerson: Substance abuse treatment is effective in preventing HIV. Is this self-selecting? Sixty-one percent of people have never sought treatment—how can we reach them?

Dr. Vereen: The slide included people in coerced treatment (there was still a delaying effect with seroconversion). Some States don't spend all of their block grant money for treatment. Needle exchange, as part of a comprehensive drug program, acts like an outreach program. Increasing the number of relationships an addict has with other persons or institutions drives the treatment program.

Rev. Sanders: Do you use research from other institutions, specifically regarding the decline in IDU? To what degree have SAMHSA and NIDA looked at the new CDC initiative, and how does it relate to your own new initiatives?

Dr. Vereen: As a research agency, NIDA's approach would be to determine what research questions have to be asked to address the initiative. NIDA also works on the findings with the people in place to actually use the research results in new publication, for example.

Dr. Clark: SAMHSA is working with CDC, HRSA, and the National Institute of Mental Health (NIMH) to align SAMHSA's new efforts to translate them into service-driven, service-delivery systems. Part of our task is education. But there will be a lag time while we figure out the strategy. We use input from groups like PACHA.

PUBLIC COMMENT

Gene Copello—Florida AIDS Action/Southern AIDS Council

At the last PACHA meeting concerns for the southern region were distributed, namely, that the South is heavily affected (a third of PLWAs live there), but it is underfunded. Three policy positions will be presented in New Orleans this winter:

- All persons must have access to prevention.
- All PLWAs must have access to care.
- Support for all regions is needed, but the South must have support in proportion to its infected population.

Mr. Copello has not heard from PACHA or the Administration.

Murray Penner—NASTAD

NASTAD represents HIV/AIDS directors throughout the States and Territories. States intend to implement restrictions as shortfalls occur in ADAP, which serves more than 2 million people annually. NASTAD requests that PACHA request the President to request increased funding from Congress.

Jesse Milan, Jr.—CDC AIDS Advisory Committee

The CDC AIDS Advisory Committee recommends that PACHA and CDC/HRSA committees have mutual liaisons. Mr. Milan urges PACHA to act on that recommendation at this meeting. The CDC committee recommended the formation of a national plan.

Camron Craig—New York City AIDS Housing Network

Mr. Craig, infected since 1996, gave testimony to Congressman Velasquez and now he's giving testimony again. We know that education and prevention work and that abstinence hasn't worked since Adam and Eve. When the epidemic first occurred, faith-based organizations wanted nothing to do about it. Now the President wants to give these organizations money to do something they never wanted to be involved with in the first place!

Shirine Mohagheghpour—Planned Parenthood Federation of American

Combating the spread of HIV/AIDS is a national priority. Nevertheless, infection among some groups is increasing. Young people need sex education that will prevent STDs and unintended pregnancy. Despite the evidence, Congress has committed funds for abstinence-only programs and prevents groups from mentioning condoms, except to say they don't work. Federally funded programs continually discount the benefits of condoms. Abstinence must be included, but not at the expense of facts.

Lavern Holley—New York City AIDS Housing Network

Prevention works. Faith works only when combined with prevention. You can't tell kids not to have sex. This can be done only by CBOs, not faith-based organizations, because faith-based organizations only want to say "no."

Ronald Johnson—Public Affairs and Education Officer, National Minority AIDS Council

Gay PLWAs are continually confronted with stigmatization of being gay or having AIDS. Prejudice and stigma are prevalent in our community. Mr. Johnson is concerned about unintentional stigmatization that may result from CDC's new initiative. He asks PACHA to ask the Administration to form a broader study. New strategies should be subjected to rigorous peer review before they are implemented.

Shana Doucette—Senior Student at Santa Clara University

Ms. Doucette would like to underscore the importance of educating our youth. Because of normal cervical development, delaying sex by 1 year makes a difference in the likelihood of HIV transmission, but girls don't know this. They also don't know there is medication to prevent infection from date rape. Ms. Doucette has witnessed the impact this lack of education has had on her peers. Youth need information to be able to make informed decisions.

Mary Schmidt—Student at Marquette University

Ms. Schmidt strongly supports youth involvement in PACHA. Engaging children at a young age makes sense because children are often the experts in making plans for policies that affect them. Children and youth have a real need for information and support, and have something to offer in return.

Bonnie Marshall—Sisters for Life and the Global Initiative on AIDS

President Bush chose not to release a bundle of money on the AIDS bill right now. This was the right decision because there's no infrastructure for accountability. Secondly, black women have not been mentioned even though they are on the front lines. Abstinence works, so you can't say abstinence has no place. Ms. Marshall's challenge to PACHA is, why black women, who have the highest rate of AIDS, aren't on the agenda.

Jennifer Flynn—New York City AIDS Housing Network

Ms. Flynn spends hours finding housing, getting Medicaid "turned on," and other tasks. All of these other issues are intertwined with AIDS. Science says, "Programs that talk openly and frankly about AIDS in their community's language are the only ones that work." Condoms save lives. Ms. Flynn hopes programs that talk openly about sex and drugs will be funded.

TREATMENT AND CARE SUBCOMMITTEE—Brent Minor, Chair

The Treatment and Care Subcommittee dealt with two specific issues: hepatitis C and funding of HIV/AIDS care. The impact of co-infection is too dramatic to be ignored. In addition to Dr. Cargill, Jody Rich (Brown University) and Jules Levin (MCAP) also spoke at the Committee's meeting 3 weeks ago.

HIV and Hepatitis C Co-Infection–Victoria Cargill, M.D. (OAR)

HIV and HCV produce about the same number of virions per day. Of some 4 million people infected with HCV (30,000 new infections/year), about 10 percent are co-infected with HIV; of about 450,000 infected with HIV, half are co-infected with HCV. But Dr. Cargill's work in a Southeast D.C. clinic shows that its clients have gone from being half co-infected to 98 percent co-infected. At the Johns Hopkins University clinic, nearly 90

percent of IDUs are co-infected. People are living longer now, so they tend to die of end-stage liver disease. In 1998, a third of patients had to stop highly active antiretroviral therapy (HAART) because of liver toxicity.

HIV co-infection accelerates the progression of HCV fibrosis and causes death from liver disease while preventing the afflicted from taking HAART. HCV accelerates HIV disease progression and may blunt the CD4 response to HAART. As HIV progresses, so does HCV. There is a racial difference in HCV; type 1 most often affects African Americans. Sustained virological response in HCV type 1 is 50 to 60 percent; in type 2 it is 80 percent.

Discussion

Mr. Sneed: The material Mr. Sneed has read about HCV protease inhibitors makes them seem promising without side effects. Should we fast-track some of these medications, as we did with ARV?

Dr. Cargill: There are other drugs in clinical trials. Some data suggest significant toxicity. We know a lot about HIV, but there are a lot of questions about the HCV virion we can't answer. Some data suggest that even persons treated with drugs with side effects, on liver biopsy, show that change was made. You can't fast-track something you don't have. We do have prevention. It takes up to 18 months to get infected with HIV, but only about 2 to get infected with HCV.

Dr. McKinnell: Drug discovery to the marketplace is a 6- to 8-year process; if any drugs show promise, drug companies will go to the FDA to get them fast-tracked. Can we say early treatment with HCV will make a difference?

Dr. Cargill: There's no reason to suggest that early intervention would not make a difference. With HCV, people may think they have a cold or mild flu, so they don't get diagnosed.

Ms. Ivantic-Doucette: Who in the health care provider team will be managing the patients? From HIV studies we know that without a significant number of patients in your practice, you can do harm. What recommendations do you have about credentialing or competency?

Dr. Cargill: There's already a looming debate among those who care for HIV patients. HIV care is not something anyone takes on easily. The challenges are formidable because it requires a multidisciplinary staff—liver biopsies, psychological support, etc., in addition to pharmaceuticals and substance abuse treatment. There has been no clinical trial, but we may not need one. Dr. Cargill would recommend guidelines; but to require certification in areas like this—one that has 12 times the incidence as the national average, or a rural area that links with urban learning—could mean that those patients have no care at all.

Ms. Rock: When you have a 15-year-old who's pregnant and HIV-positive, it is the girl's right not to have the mother present, but the mother is responsible for her and whether she takes her treatment.

Dr. Cargill: There's no one-blanket solution. We have to trust that as human beings we'll make the right decision in these complex situations. Nothing in medical school prepared Dr. Cargill to deal with 14-year-olds having sex in alleys to avoid their mothers' boyfriends' advances.

Mr. Nickerson: What is your experience in treating people in conjunction with substance abuse?

Dr. Cargill: The Consensus Conference changed many policies; people used to have to abstain for 2 years. However, people who drink have active APC replication different from people who don't drink. It's not ethical to treat people who come to the office drunk or high because they can't understand the treatment. The clinician has to come to some kind of middle ground.

Ms. Clements: What about cost and treatment for poor people?

Dr. Cargill: Cost is not insignificant. There are some treatment slots if they're part of a protocol. Dr. Cargill's clinic provides transportation to ensure that people continue treatment. It requires creativity.

Dr. Primm: What is the efficacy of interferon in type 1 HCV?

Dr. Cargill: Pegasus is sustained much higher (to the 60th percentile), so they can stop over the weekend; the mental health side effects are not so severe. The longer you can get people through therapy, the longer you can stave off hepatocellular carcinoma.

Dr. Sweeney: She knew of a patient who was doing well on interferon but discontinued, because she was losing weight and didn't want people to think she had HIV.

Dr. Cargill: Weight loss is a side effect. You can try to adjust therapies, but you're working on a physiological goal.

Ms. McDonald: OUTREACH, Inc., has a staff of 20; 18 are HIV-positive and 16 are co-infected. They see about 1,000 clients a month. Ms. McDonald is afraid to start testing because they have no access to care.

Dr. Cargill: Women appear to have a great chance of clearing HCV infection. If we don't test, we miss an opportunity to counsel, we miss opportunities to intervene. The client's distress cannot dissuade us from giving the information we have.

An Assessment of the Ryan White CARE Act—Patricia Bass, R.N., M.A. (CAEAR Coalition)

The Ryan White CARE Act was authorized in 1990, reauthorized in 1995 and 2000, and will be considered for reauthorization in 2005. The CARE Act is flexible and responsive. It has evolved along with new technologies, is responsive to the changing epidemic, and will be able to address emerging trends through change, development, and refinement. Ryan White is working and is a safety net for the under- and uninsured. It helps us to move from a sick-care system to a health-care system by involving local control—essential and successful; by empowering and involving PLWAs in decision making; and by enabling community planning and collaboration among multiple agencies and providers.

Also important is its comprehensive range of services, which support the public health infrastructure and strengthen other systems of care including community-based programs. However, ADAP has become a crisis because there's now an 18-month waiting list; what will happen with the CDC initiative is unknown.

Issues for 2005 are: distribution of funds; local control and planning councils (which should include the homeless); support services (which mean that people will continue to take their HAART); funding for women, children and youth; quality; and early intervention. However, funding is for systems, not individuals, and shrinking Medicaid programs will leave gaps. Meanwhile, we need to talk about a continuum of care, not segmented services.

Discussion

Dr. McKinnell: Early treatment saves money in the long run. What about undocumented residents?

Ms. Bass: Accountability is very important. Certainly undocumented people are in Philadelphia's system, but we can't tell how many.

Ms. Rock: How can we invite other entities (e.g., the Department of Social Services) to close some of the gaps and provide a continuum of care?

Ms. Bass: Health care providers in the HIV-world are territorial. Nevertheless, we kept inviting the medical directors of all managed care organizations in Philadelphia to our meetings and finally we got them to join in helping to solve the problems.

Dr. Driscoll: Because new treatments emerge as the epidemic changes, ADAP is also changing. But, to have accountability, you have to prioritize.

Ms. Bass: We're seeing evolving core priorities. This is the importance of local control.

Ms. Clements: How can we be sure the dollars keep pace with the geographic flow (e.g., the difficulties in the South) across the United States?

Ms. Bass: The dollars follow the number of clients. But, we do need to address what's going on in the South.

Dr. Sweeney: There are people who get diagnosed and treated in New York, but go home to their family in the South, where they may not be able to get treated. There must be a way to do this better.

Dr. Judson: The best way would be to move forward with standards of care within Ryan White. Abstinence and drug use behavior can change, so this should include periodic assessment of the risk of transmitting to other patients. When the provider accepts a patient, s/he accepts responsibility to be sure their patient doesn't become the source of another case.

Ms. Bass: Our public health perspective should include primary, secondary, and tertiary care. It's not so much a matter of best practice—bringing people into care must be connected to keeping them in care.

Dr. Green: How is Title 1 funding determined from the EMA? We need credibility when we ask for more funding.

Ms. Bass: There's a 10-year band. It's based on a formula of the number of people living with AIDS, which is reviewed every 5 years.

Rev. Sanders: Our recommendation is faithful to making the formula follow the disease.

August 8, 2003

Condom Promotion for AIDS Prevention in the Developing World: Is It Working?—Norman G. Hearst, M.D. (University of California, San Francisco)

Efficacy is the theoretical effect of a treatment used under ideal conditions. We don't know the efficacy of condoms—no such study has ever been done and would be unethical. Effectiveness is what happens in actual practice. For condoms, this can be determined by following discordant couples and comparing over time. (Meta-analyses show 94 percent effectiveness.)

Condom use in Africa has increased to about 70 percent in some countries, but HIV prevalence has also risen (e.g., 35–40 percent in Botswana). However, these numbers don't tell what would have happened if people weren't using condoms.

Success stories are Thailand and Uganda. In Thailand, the main transmission involved the commercial sex industry; the health department focused on this and mandated that brothel owners require condom usage. They achieved about 95 percent condom use among

commercial sex workers, and with that increase, HIV incidence decreased. But, it wasn't just condoms: during this period, Thai men decreased use of brothels by about half.

In the mid to late 1980s, Uganda had one of the highest infection rates. They responded and brought down HIV prevalence from about 30 percent to about 5 percent. They did it by abstinence and an advertising campaign that encouraged remaining faithful to your partner(s). Condoms were not a big part of the message, but lately they've been a more important part of the campaign. There's an inherent conflict between a message that sex is safe as long as you use a condom; and the message that you can't have casual sex when you live in a country where 20 percent of the people are HIV-positive. Questions about condom use remain, e.g.: How consistent does condom use have to be? How high must rates of condom use be to protect the community? Can a generalized HIV epidemic be overcome primarily through condoms? How can condom promotion best be integrated into multifaceted prevention?

We know that:

- When condoms are used consistently, they are effective but not 100 percent effective.
- Condom promotion is proven effective in certain settings (commercial sex workers, MSM, etc.).
- Condom promotion for the general population has not yet produced the expected benefits.
- Sexual behavior change is possible and can make a big difference in the epidemic.

Condoms are an important part of any HIV/AIDS program and should be promoted. But, we can't look at outcomes in terms of condoms only. As for the ABC program, A and B worked in Uganda, but we don't know if it would work elsewhere; successful programs must be endogenous. We need to know how to do A and B and not discourage C; how to do C and not discourage A and B.

Discussion

Ms. Freeman: What ages were used in the control group?

Dr. Hearst: 18- to 25-year-old young men were the only people we looked at.

Dr Green: Two A and B programs have been promoted by USAID in Zambia.

As for condom use with a non-cohabiting partner, 57 percent means 57 percent of the 10 percent of the population that has a non-cohabiting partner. Most Ugandans don't have casual partners, but among those who do, condom use is high.

Dr. Judson: In the 1990s, Dr. Judson worked in Uganda with pregnant women and military recruits. The general knowledge about HIV infection has changed enormously, and this change can be attributed to the culture, religion, and common sense. Feeling at risk is also important; many of the women knew someone who was sick or had died.

Rates of gonorrhea serve as a surrogate. Before we knew what was causing HIV, rates had decreased by 50 percent between 1981 and 1982. By 1986, when government programs began, decreases were already occurring among gay men. The point is that any intervention must be accompanied by changes in exposure behavior, which Uganda illustrates.

Dr. Hearst: Knowing somebody with AIDS is a big part, and everybody in Uganda knows someone with AIDS. Stigma is also very important, and in Botswana no one talks about it.

Mr. Sneed: ABC programs might work in certain populations and situations in the United States. Information to clarify this might come from the STD transmission rates during the 1930s and 1950s, and experience with the A and B then.

Dr. Hearst: We can't assume that what works in the United States will work in Africa, nor vice versa.

Rev. Sanders: We can never talk about the data like that from Thailand and Uganda without talking about the leadership in those countries, and the psychosocial attitudes and response. Our message our President must be clear, and it must be grounded in science. There are also issues that arise from private conversation versus public and open conversation. With religious leaders, conversation flows easily when discussing A and B, but not C. The myths that continue to this day must also be dealt with (e.g., condoms are the ways the West is actively spreading AIDS in Africa; condoms are a way to take control from Africans). We need to give our leadership a voice that is sound scientifically.

INTERNATIONAL SUBCOMMITTEE—Abner Mason, Chair

We have three resolutions: sociopolitical assessment for the countries, the emerging epidemic in India and China, and improved AIDS drugs.

Socio-political Assessment of Emergency Plan for AIDS Relief (EPAR) Recipient Countries—George Ayittey, Ph.D. (American University, Free Africa Foundation)

Various initiatives have been started in Africa but got nowhere, and the reason had to do not with lack of U.S. political will, but with the type of government the United States was dealing with.

With a disease with no known cure, the emphasis is on making life for the victim more comfortable, and on prevention. Treating those already infected involves enormous costs, beyond the means of poor people. Modern health care infrastructure in Africa has collapsed in many countries—only 20 percent of the people have access to modern health care—so, we must also find a way of delivering the drugs. The vast majority of Africans

rely on traditional medicine and live in rural areas under the authority of traditional rulers (more than under the national rulers who live in the capital city). Therefore we must involve the traditional rulers and traditional healers, because if we don't involve them they can cause problems (e.g., one, by saying sex with a virgin would cure AIDS, set off an explosion of rapes in South Africa).

Leaders in Africa have shown no political will or commitment to confront the disease. They have been in denial. Senegal, Ghana, and Uganda have been the only countries that made credible efforts to educate their people. The others did not because they felt uncomfortable talking about condoms in public. South Africa (which has one of the highest rates of HIV infection) won a court battle to produce less expensive AIDS drugs; then it refused to distribute the drugs. Their priorities are skewed—they claim not to have money for AIDS drugs, but intended to spend money on weapons at a time when South Africa has no enemies.

Discussion

Dr. Hu: Without health care infrastructure and transportation, even if drugs are available, they are not accessible. The lack of political will is evident in other countries, not just in Africa. We also need to be sure patients can take the drugs correctly, e.g., with water and a meal. Without this, the drugs are useless.

Dr. Ayittey: Behavioral change depends on endogenous factors, and African leadership has not launched a public awareness campaign against AIDS. Many feel uncomfortable talking about sex in public. In Zimbabwe and Namibia, there is the bizarre belief that homosexuality caused AIDS, so they launched a vicious assault against homosexuals.

Dr. Driscoll: The President's initiative aims to put 2 million people into treatment in 14 countries. To do that we have to take advantage of the one country that has extensive infrastructure—South Africa. There seems to be no consensus about the reasons for Mr. Mbecki's behavior. How can we get the South African Government to change its policy? There's widespread support for a big change.

Dr. Ayittey: This is one of the tragic instances in AIDS. South Africans also have a relatively much higher income than residents of other African countries. South Africa has far better capacity, even than Uganda, to launch an effective campaign against AIDS, but Mr. Mbecki has not shown the leadership. People speculate about why—maybe to prevent a high-profile campaign that would focus on AIDS and deter foreign investment. It may also be a response to medical experiments during the days of apartheid. The dilemma is how you persuade recalcitrant African leaders to become more committed. This cannot be dictated from the outside; but traditional leadership might be useful. Also, the churches have been very effective. Since 1960, there have been more than 180 African heads of state; fewer than 20 stepped down voluntarily; fewer than 10 live in their own country. But in all the states that have collapsed, two institutions have always remained—national traditions and the churches. We need to involve both of these time-tested and durable institutions.

Dr. Reznik: Will traditional leaders and healers be able to overcome the lack of political will?

Dr. Ayittey: Previous initiatives were crafted in "partnership" with African governments, but Westerners have the naïve belief that there is a government as they know it in any African country. What exists is a Mafia-type group that holds the state hostage and doesn't care about the people. Therefore the people in the rural areas (most of the people) relate to the traditional chiefs. The formal (Western-type) governments lack legitimacy for the people who are infected with AIDS because the government is dysfunctional. However, it's diplomatically tricky to go into an African country and bypass the government in place and deal with other groups. For instance, if you provide food aid, the government will insist upon distributing the food and then distribute the food to their supporters only. Somehow we have to find a way to reach the people.

Dr. McIlhaney: How do you account for high usage rates of condoms in African countries? We could use the same means to encourage the A and B parts of the program.

Dr. Ayittey: Radio is the most effective means of reaching the African people. This means was used in Uganda and Senegal. But you can only get so far in changing attitudes about condoms. There has been a cultural resistance to using condoms. The African chief is the keeper of tradition, so if you want to change behavior you have to have the chief play a role (e.g., if an HIV-positive man dies, his brother inherits his wife—it's another means of transmission). The churches also could play an important role.

RESOLUTIONS

Prevention—Council Discussion

Local Involvement

Mr. Nickerson: The resolution should ask the Administration to project the number of people this initiative is likely to bring into care and to plan for that number.

Dr. McKinnell: We should not focus on the shortfall this year—it doesn't make sense to save a penny this year and pay a dollar next.

Mr. Sneed: The shortfall is disproportionate for people of color.

Ms. Ivantic-Doucette: Paragraph 3: "greater their risk of what"?

Rev. Sanders: A slide yesterday spoke to the concern that this CDC initiative does not exclude behavior modification that had been in place. Somehow the motion needs to reference that. Make it clear that this initiative is a part of what we have and is not excluding it.

Dr. Judson: Dr. Judson finds not helpful the term "people of color," "community of color," etc. It's a meaningless PC term (i.e., it offends nobody and communicates nothing). Are the others colorless? Indians and many Asians may be classed as people of color but are in the lowest risk group. In Colorado black communities have no larger incidence than whites in the same socioeconomic group. We should be focusing on socioeconomic group, not color group. The problem is where we're trying to direct funds.

Dr. Sullivan: Dr. Sullivan has no objection to changing it, but to what? This can be discussed in the Prevention Subcommittee; otherwise we'll never get to the end of our agenda.

Rev. Sanders: How we effectively identify people who are disproportionately impacted without stigmatizing them cuts across all of our committees.

Ms. Robinson: PACHA's language should be consistent with the guidelines this represents, and this is CDC's term.

Dr. Sweeney: The last paragraph sounds like the focus is being moved; we're broadening, not transitioning.

Ms. Clements & Mr. Sneed: Paragraph 6, last sentence: Could we add something about support services?

Mr. Sneed: Paragraph 7: add "and community leaders."

Dr. Sullivan: This is a resolution on prevention services; we have other resolutions, so this resolution doesn't have to cover everything. That will defeat our purpose and they won't be taken seriously.

Mr. Minor: It's important to include confidentiality and the integrity of public health information.

Dr. Green: Last paragraph: PLWA is not a change but an emphasis.

Dr. Reznik: Paragraph 6: change medical care to primary care.

Mr. Minor: We need to recognize that there is still a stigma attached to an HIV diagnosis.

Treatment and Support Services for Substance and Drug Users

Ms. Ivantic-Doucette: Add something about the impact of media.

Ms. Clements: The role of parents must be recognized, but many high-risk youth don't have parental associations.

Mr. Sneed: Last paragraph: include community.

Ms. Rock: Last paragraph: Ms. Rock suggested new language, which she will bring to the subcommittee meeting.

Prevention Subcommittee

Mr. Sneed: The SAMHSA representatives didn't answer his questions; maybe this will help.

Mr. Nickerson: Although supporting the gist of it, Mr. Nickerson worries about the 9 of 10 people not seeking treatment. Best practices should be recognized.

Rev. Sanders & Mr. Nickerson: Some of the science supports prevention initiatives that are so politically unpopular that we do not have a climate that allows them to be supported. Where can we find the language that at least recognizes the fact that we know the science is there.

Dr. McKinnell: We're missing an opportunity if we err on the side of political correctness and unpopularity. It's hard to criticize PACHA; we're the ideal forum to be blunt. Let's make sure we communicate clearly and break through these language issues; that's what's tying the hands of public health workers.

Ms. Smith: We aren't prepared as a committee to move forward on the language changes.

Dr. McIlhaney: If there is strong evidence that something doesn't work, we should get a scientist in here to discuss it.

Dr. Primm: We should all commit ourselves to being frank and honest. I saw two friends speak here yesterday who could not speak in the manner in which they would have liked. We need to ensure that those who come to us are not hog-tied.

Ms. Smith: Should we move forward on the motion on treatment, and consider the other separately?

Dr. Sweeney: We can't move forward until we have the science to support or not support our position. With the impact and number on IDU, an important part of our recommendation involves needle exchange if it works. We need to be conclusive about our recommendations.

Rev. Sanders: PACHA has a history, which we need to revisit. What we have seen in some of the decreases is caused by an initiative that is invisible and underground. We need to bring the Government to bear on what works. I support Dr. Sweeney in that IDU is so important, we must somehow address the issue. At least. we can give them some language to study it further.

Ms. Freeman, Dr. Primm, Mr. Sneed: We should not just ignore the "down low" issue even if all the data are not in. This is too important to African American women.

Dr. Reznik: Change the first to last word to: "all HIV treatment program." That would address the issue and allow us to discuss it later.

Treatment and Care—Council Discussion

Hepatitis C

Dr. McKinnell: This is a model for what we as a group should be doing. It's specific and far-reaching. We need to be more aggressive in what we're recommending.

Mr. Nickerson: Not a third, but half (as we saw yesterday) are co-infected. HCV infection is largely driven by IDU and we need to talk about substance abuse. Substance abuse should be one of the "whereases."

Dr. Driscoll: The motion is specific; it gives a standard by which we can measure and follow up. If we say something vague, we can't later determine whether we're being listened to.

Dr. Judson: Two important talks we heard yesterday dealt with our growing understanding of the psychoneurological basis of drug use, and with mental illness. And, we can't talk about HCV without talking about drug use and mental illness. We're getting closer to the mental effects. HCV treatments aren't that good, have serious side effects, and cost a lot. We can't say that if we treat everyone, everything will be fine.

Mr. Sneed: In addition to what Dr. Judson said, our effort would be better placed on research and development, and working with the pharmaceutical companies to develop more effective drugs. The third to last paragraph that requests an expanded effort on research doesn't satisfy because we have the cart before the horse: you can test, but there's no money to treat even if the treatments were good. So the emphasis should be on research to find good drugs.

Dr. McKinnell: The Treatment and Care Committee could undertake a project to think through how to do pharmaceutical research (classic high-risk, high-reward). Drug discovery is a very expensive, long-term project, which leads to FDA approval. Having to test a new drug against the best currently available is preventing a lot of research on HIV drugs.

Dr. Driscoll: Last paragraph in resolution: "add to the formularies." The best way to ensure new developments in drug research is to ensure the companies' incentive through reimbursement. The FDA seems to have picked up the idea that the "me too" drugs are worthless. But their profiles of efficacy, toxicity, and tolerance are also different, so a

person who cannot take a mainstream drug may be able to tolerate a "me too." Also, they are usually cheaper. We need the flexibility they offer.

Mr. Nickerson: Why would people want to be tested if they couldn't be treated? Co-infection with another hepatitis increases liver failure, although other factors go into determining the outcome, e.g., alcohol consumption. Testing should be encouraged.

Dr. Primm: Of drug abusers who go to the Addiction Research and Treatment Corporation, 65 percent are HCV-positive and about 20 percent are HIV-positive. While we have to do more research and development, some things can be done, e.g., ensuring good diet, exercise. We need to inform the public that these behavior changes will help.

AIDS Funding

Dr. McKinnell: We need to be high-reaching and specific and we need to facilitate a national discussion.

Mr. Sneed: National discussion is needed, but another discussion is also needed. How much do we at the Federal level spend on all HIV activities and programs? [Budget table completed and committees will have for discussion.] Is the money being spent as effectively as possible? You have to account for the money and make sure it's spent wisely before you ask for more.

Dr. Driscoll: Second to last paragraph: Consider changing to "future of AIDS funding priorities." We have to talk about priorities and maybe also accountability. We (PACHA) are the highest-level panel to discuss AIDS policy and we should be far-reaching and specific.

Ms. Smith: Can we call special meetings?

Dr. Sullivan: There's no restriction on what we can discuss; budget is the only restriction.

Ms. Robinson: The current budget doesn't allow for anything outside the Council meetings, but they're considering it. The purpose of the dialogue is to inform the President and the Secretary, so we need to be sure the vehicle will feed into a dialogue with them.

Rev. Sanders: What other ways can we achieve this conversation, perhaps with broader participation? For example, a few months ago, there was a 12-hour radio discussion about church matters, which is now being made into a video. This might not be immediately translatable, but it could inspire us.

Mr. Minor: We acknowledge Pat Ware for her previous work.

International--Council Discussion

Emerging Epidemic in China, India, and Other Countries

Dr. Sullivan: A task force was convened at the request of the Chinese Minister of Health who asked the United States for help in addressing the epidemic. The task force found that: Less than 50 percent of the Chinese population know there is an epidemic. There is great stigma against the disease, homosexuality, and sex workers. The infrastructure is weak to nonexistent. The Minister of Health sees the situation as a powder keg, but he doesn't have much support from provincial leaders in the government. He said it would help if our leadership encouraged their leadership to address this. They estimate that they have 1 million infected, but they have no data. Other countries face a similar situation, e.g., India, Pakistan, Russia. They are at the beginning of an epidemic. This resolution focuses on China, but acknowledges other countries and encourages our leadership to encourage their leadership to confront the epidemic at a time when the effect could prevent the situation we see in Africa.

Dr. Sharma: The problems in Africa are similar to those in many Asian countries—growing population, weak infrastructure, lack of access to medical care, and, most important, denial. The United States should take the lead and offer to go into these countries to offer assistance. Burma, which has been under a military dictatorship for years and which is denying an exploding epidemic, should be added

Dr. Hu: It is timely to include countries other than China. Actually India and Russia have received CDC and USAID assistance for years, and China has recently begun to receive such assistance. So we should include the technical support, because they already receive resources from the United States.

Dr. McIlhaney: We want to encourage programs that will result in the decline of HIV; other humanitarian concerns are commendable but we are here because we want HIV to decline.

Ms. Rock: In India they're becoming infected from unscreened blood transfusions.

Dr. Sullivan: Chinese peasants also sell blood and have become infected that way. But if we can get the leadership to focus, a number of these layers will come off.

Trade-Related Intellectual Property Agreement

Mr. Mason: PACHA thought it was important to go on record to achieve two objectives, namely, to balance commitment to access to drugs, with having worthy drugs. These drugs are life-saving and we have an obligation to make them available to as many people as possible. Almost half the people in the world who are infected live in the 14 countries the President targeted. Drug resistance is an increasing problem, so we need to continue developing new drugs. It's important to balance access and availability.

Mr. Sneed: The spirit of the motion is good, but the bulk addresses treatment and care issues as well as international issues and costs. In the future, if an issue relates to two committees, the committees should discuss the issue jointly.

Dr. Driscoll: In the early 1990s, drug companies had a "Manhattan Project" for AIDS. The private sector can deal with risk; the Government is risk-averse (or we throw them out). To develop drugs you have to be able to take risks and to be rewarded for that. People don't seem to understand that. We need risk-taking, incentives, and rewards or we will have no new drugs. Countries that remove incentives and rewards have developed no drugs. And the drug companies need protection of intellectual property.

Dr. Reznik: When you lose a partner, you lose a part of yourself; to prevent such sorrow, we must give pharmaceutical companies the freedom to discover drugs.

Rev. Sanders: Giving freedom to develop drugs is important, but so is having the political will to deliver these drugs wherever they are needed (e.g., drugs to prevent mother-child transmission). Even in the most remote areas, you can get a Coca Cola. We have to ensure that the will of Government, manifested by the proposed appropriation, is combined with the will of industry to distribute drugs as effectively as Coca Cola does. There must be a passionate commitment to extending life all over the globe. In some instances, there have been efforts to influence how these drugs are made available. It would be naïve of us not to realize that people infected with this disease will not use every means possible. We need to balance the interests of intellectual property rights against the will by dying people.

Dr. McKinnell: This discussion is like a group of people describing a coin. What you describe depends on which side you're looking at. Everything drug companies do to develop drugs isn't helpful if the drugs are never used. It's the tyranny of the "or"—it's not A or B; we need to do both. Within the World Trade Organization now, there is emerging consensus that may solve this dilemma. If the return on the investment can be earned from those who can afford to pay for the drugs, then the drugs can be offered nearly free because the greatest cost is in discovery; the cost of manufacturing is low. If we can get a consensus to do both, we can solve this problem.

Dr. Judson: The system of free enterprise requires international trade protection. Most of the costs of the development of these new drugs are being paid for by consumers in the developed countries. This will be a problem to come back to.

Rev. Sanders: The recommendation must speak to both sides of the coin.

Dr. Sullivan: When you get a Coke in a remote area, you only have to drink it. For HIV/AIDS drugs, you have to know what you're doing to take them so they will be effective. We have to stimulate development of health care delivery people.

Dr. Judson: Combination therapies are difficult even with a strong infrastructure with support services. A year after initiation, only half of the patients can continue because of

mental illness, the home situation, or compliance problems. Taking combination therapies is incredibly daunting at the village level. There's potential to throw away huge amounts of money on programs that do actual harm. We've seen this with food for the poor: We give food and people continue to starve.

Dr. McKinnell: NIH data from Uganda show that compliance in Africa is higher than here.

Dr. Judson: There's also the issue of theoretical efficacy versus effectiveness of actual use when you broaden an application.

Mr. Nickerson: Nevirapine may be administered in one dose, but it's not simple. We don't want to repeat the American experience where we used the weakest drugs until resistance developed (treat to fail). Even though Africans may not have modern buildings, they have infrastructure that can be developed and that we can work with.

DISCUSSION OF RESOLUTIONS

Subcommittees discussed their resolutions, then presented the revised draft to the whole committee to vote on (pages 31–41 below).

CONCLUDING REMARKS

Mr. Minor: The Council's draft letter to the President (distributed to the group) lays out some guiding principles that stay above politics.

Dr. McKinnell: The public comments are helpful, but it may be more useful to hold public comments to the end so the public will have a chance to react to the meeting discussions and presentations.

Dr. Driscoll: Some interested organizations were not represented. Should we publicize PACHA meetings more widely?

Ms. Robinson: Public comments are mandated, but they can be held at any point during the meeting. This meeting was posted on the PACHA and CDC Web sites.

Ms. McDonald: At CDC there was great interest in PACHA. Maybe we could get a listserv. Has someone been chosen to serve as liaison between PACHA and CDC?

Ms. Robinson: The process of setting up a listserv has been begun.

Dr. Sullivan: The letter suggesting PACHA–CDC liaison was just received, so we will think about it before we decide. Should there be interaction between the public and ourselves?

Dr. Driscoll: Last year we had trouble with the rapid testing resolution because the public had no information.

Ms. Robinson: All resolutions, once confirmed, will be posted on the PACHA Web site, so the public will have all the information used to make the decisions.

Minutes from PACHA's January meeting were approved.

Adjourned at 3:55.

COMMITTEE MEMBERS

Rosa M. Biaggi, M.P.H., M.P.A.
Jacqueline S. Clements
Thomas A. Coburn, M.D.
James P. Driscoll, Ph.D.
Mary Fisher
Vera Franklin
Mildred Freeman
John F. Galbraith
Katryna Gholston
Edward C. Green, Ph.D.
David Greer
Cheryl-Anne Hall
Jane Hu, Ph.D.
Karen Ivantic-Doucette, M.S.N., F.N.P., ACRN
Joseph Jennings
Rashida Jolley
Franklyn Judson, M.D.
Abner Mason
Sandra S. McDonald
Joe S. McIlhaney, M.D.
Hank McKinnell, Ph.D.
Brent Tucker Minor
Dandrick Moton
Nathan M. Nickerson, R.N., M.S.N.
Beny J. Primm, M.D.
David Reznik, D.D.S.
Debbie Rock
Reverend Edwin Sanders II
Prem Sharma, D.D.S., M.S.
Lisa Mai Shoemaker
Anita Smith
Don Sneed
Louis W. Sullivan, M.D.
M. Monica Sweeney, M.D., M.P.H.

AGENDA

Thursday, August 7, 2003

8:30 a.m.	**Continental Breakfast**
9:00 a.m.	**Welcome Remarks** Tom Coburn, M.D., Co-Chair Louis Sullivan, M.D., Co-Chair
9:10: a.m.	**Remarks** **Josephine Robinson,** Executive Director (Acting)
9:20 a.m.	**Remarks** **Speaker To Be Confirmed,** The White House
9:30 a.m.	**PREVENTION** Anita Smith, Chair, Prevention Committee, PACHA
9:35 a.m.	**Advancing HIV Prevention: New Strategies for a Changing Epidemic US 2003** **Ronald O. Valdiserri**, MD., Deputy Director, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC)
10:05 am	Questions and Council Discussion
10:50 am	**Break**
11:00 a.m.	**Targeting Prevention Messages to Youth** **Lloyd Kolbe** , Ph.D. Director, Division of Adolescent and School Health, Centers for Disease Control and Prevention (CDC).
12:00 noon	**LUNCH**
1:00 p.m.	**Substance Abuse and HIV Prevention: How Substance Abuse Exacerbates Risk Behavior for HIV/AIDS** **Donald Vereen, MD**, Medical Officer and Special Assistant for Medical Affairs, National Institute on Drug Abuse **H. Westley Clark**, M.D., J.D., M.P.H., Director, Center for Substance Abuse Treatment, SAMHSA
2:30 p.m.	**Public Comments**
3:30 p.m.	**TREATMENT AND CARE** **Brent Minor**, Chair, Treatment and Care Committee, PACHA
3:35 p.m.	**Hepatitis C Co-Infections** **Victoria Cargill**, **MD**., Director of Minority Research and Director of Clinical Research, Office of AIDS Research, NIH

4:20 p.m. **Break**

4:30 p.m. **Funding of HIV/AIDS Care**
Patricia Bass, R.N., M.A., Chair, CAEAR Coalition

5:30 p.m. **ADJOURN**

Friday, August 8, 2003

8:30 a.m. **Continental Breakfast**

8:50 am **Welcome Remarks**
Tom Coburn, M.D., Co-Chair
Louis Sullivan, M.D., Co-Chair

9:00 am **The ABC Model and Its Application to HIV/AIDS Prevention**
Norman G. Hearst, M.D., MPH, Professor, Family and Community Medicine, University of California, San Francisco

9:50 a.m. **INTERNATIONAL**
Abner Mason, Chair, International Committee, PACHA

9:55 a.m. **Socio-political Assessment of Emergency Plan for AIDS Relief (EPAR) Recipient Countries**
Speaker To Be Confirmed

10:50 a.m. **Break**

11:00 a.m. **Emerging Epidemic in China, India and Other Countries**
Council Discussion

11:30 a.m. **Trade-Related Intellectual Property Agreement**
Council Discussion

12:30 p.m. **Council Adjourns for Preparatory Work**

12:30 p.m. **WORKING LUNCH**

2:30 p.m. **Council Reconvenes for Motions and Voting**

4:00 p.m. **ADJOURN**

MATERIALS PRESENTED AT THE MEETING

Advancing HIV Prevention: New Strategies for a Changing Epidemic (Dr. Valdiserri, CDC)

Questions & Answers on CDC's New HIV Initiative, "Advancing HIV Prevention: New Strategies for a Changing Epidemic—United States" (CDC)

How Can We Become More Effective in Preventing HIV Infection among Young People (Dr. Kolbe, CDC)

Advancing HIV Prevention: New Strategies for a Changing Epidemic (NASTAD)

Reducing the Risk: Connections that Make a Difference in the Lives of Youth (NICHHD et al.)

How Drug Use Exacerbates the Risk for HIV/AIDS (Dr. Vereen, NIDA)

HIV and Hepatitis C Co-Infection—A Very Present and Growing Health Challenge (Dr. Cargill, OAR)

An Assessment of the Ryan White CARE Act of 2000 (Ms. Bass, CAEAR Coalition)

Overview of the Ryan White CARE Act AIDS Drug Assistance Program (ADAP)

AIDS Drug Assistance Programs: An Overview of Current and Future Issues (NASTAD)

Condoms for AIDS Prevention in the Developing World. A Review of the Scientific Literature

Leadership in the Campaign to Fight AIDS in Africa (Dr. Ayittey)

Averting a Full-blown HIV/AIDS Epidemic in China. A Report of the CSIS HIV/AIDS Delegation to China, January 13–17, 2003

The White House Initiative to Combat AIDS—Learning from Uganda (The Heritage Foundation)

Morbidity ad Mortality Weekly Report. Advancing HIV Prevention: New Strategies for a Changing Epidemic—United States, 2003 (CDC)

Public Comments; Murray Penner, National Alliance of State and Territorial AIDS Directors; To the Presidential Advisory Committee on HIV/AIDS (August 7, 2003)

2003 HIV/AIDS Resource Guide (Pfizer)

Presidential Advisory Committee on HIV/AIDS, Prevention Committee, draft resolutions

Presidential Advisory Committee on HIV/AIDS, Treatment and Care Committee, draft resolutions

Presidential Advisory Committee on HIV/AIDS, International Committee, draft resolutions