Presidential Advisory Council on HIV/AIDS
26th Meeting
Hubert Humphrey Building
200 Independence Avenue, S.W.
Room 800
Washington, DC 20201

February 7, 2005

Council Members—
Present
Louis Sullivan, M.D., Co-Chair
Anita Smith, Co-Chair
Abner Mason, Chair, International Subcommittee
David Reznik, D.D.S., Chair, Treatment and Care Subcommittee
M. Monica Sweeney, M.D., M.P.H., Chair, Prevention Subcommittee
Rosa M. Biaggi, M.P.H., M.P.A.
Cheryll Bowers-Stephens, M.D., M.B.A.
Jacqueline S. Clements
Mildred Freeman
John F. Galbraith
Edward C. Green, Ph.D.
Cheryl-Anne Hall
Karen Ivantic-Doucette, M.S.N., F.N.P., ACRN
Rashida Jolley
Franklyn N. Judson, M.D.
Sandra Singleton McDonald
Joe McIlhaney, M.D.
Henry McKinnell, Jr., Ph.D.
Brent Tucker Minor
Jose Montero, M.D., FACP
Dandrick Moton
Beny Primm, M.D.
Debbie Rock
Rev. Edwin Sanders
Lisa Mai Shoemaker
Ram Yogev, M.D.

Council Members—
Absent
David Greer
Jane Hu, Ph.D.
Prem Sharma, D.D.S., M.S.

Council Staff—
Present
Joseph Grogan, Esq., Executive Director
Dana Ceasar, U.S. Department of Health and Human Services (HHS)

DAY 1

MORNING SESSION

Welcome Remarks
Presidential Advisory Council on HIV/AIDS Co-Chair Dr. Louis Sullivan welcomed everyone to the first Council meeting of 2005. He noted the full agenda, including a number of presentations. He asked each Council member present briefly to identify themselves.

Dr. Sullivan began. He is President Emeritus of the Morehouse School of Medicine in Atlanta, Georgia.

Dr. M. Monica Sweeney is assistant clinical professor of preventive medicine, SUNY Health Science Center of Brooklyn, and is also affiliated with the Bedford-Stuyvesant Family Health Center, Inc., in Brooklyn, New York.

Lisa Mai Shoemaker is a motivational speaker about HIV/AIDS. She lives outside of Traverse City, Michigan.

Dr. Franklyn N. Judson has just retired as Director of the Denver, Colorado, Public Health Department, and is a professor of health science and policy at the University of Colorado.

Dandrick Moton is Director, Community and Youth Relations, for Choosing to Excel in Tempe, Arizona.

Rashida Jolley is from Washington, D.C.; she speaks to young people across the country about HIV/AIDS.

Debbie Rock is Executive Director of the Baltimore, Maryland, Pediatric HIV Program, Inc.

Mildred Freeman has just retired as Director, Health Education Division, National Association for Equal Opportunity in Higher Education in Silver Spring, Maryland.

Rosa M. Biaggi is Director of the Connecticut Department of Public Health in Hartford, Connecticut.

Dr. Ram Yogev is professor of pediatrics at Northwestern University's Medical School, Division of Infectious Diseases, and is also affiliated with Children's Memorial Hospital in Chicago, Illinois. He is looking forward to retiring.

Dr. Henry McKinnell, Jr., is Chairman and Chief Executive Officer of the largest pharmaceutical company in the world, Pfizer, Inc.

John F. Galbraith is President and Chief Executive Officer of the Catholic Medical Mission Board in New York City, New York.

Karen Ivantic-Doucette is an assistant professor at the Marquette University College of Nursing in Milwaukee, Wisconsin.

Dr. Edward C. Green is a senior research scientist at the Harvard Center for Population and Development Studies in Cambridge, Massachusetts.

Cheryl-Anne Hall is Director of the Caribbean American Health Center, Sunset Park Family Health Center Network, Lutheran Medical Center, Brooklyn, New York.

Rev. Edwin Sanders is senior servant of the Metropolitan Interdenominational Church and Executive Director of The First Response Center in Nashville, Tennessee.

Jacqueline S. Clements has been living with HIV for 20 years and is affiliated with the Lincoln Community Health Center in Durham, North Carolina.

Sandra Singleton McDonald is President and Founder of OUTREACH, Inc., in Atlanta, Georgia, and instigator of a series of public service announcements featuring NFL football players talking about the dangers of HIV/AIDS.

Dr. Jose Montero is a professor at the University of South Florida and practices medicine at the Infectious Disease Center of Tampa General Hospital in Tampa, Florida.

Dr. Beny Primm is, among many other medically related affiliations, Executive Director of The Addiction Research and Treatment Corp. in Brooklyn, New York.

Brent Tucker Minor is a long-time activist and person living with HIV/AIDS in Alexandria, Virginia.

Dr. David Reznik is the newly appointed Chair of the Council's Treatment and Care Subcommittee.

Abner Mason is the Chair of the Council's International Subcommittee.

Anita Smith is Vice President of the Children's AIDS Fund, based in Washington, D.C.

Joseph Grogan is Executive Director of the Council.

Announcements
Dr. Sullivan noted changes on the Council since the last Council meeting. Ms. Smith is now Co-Chair of the Council. Dr. Sweeney is replacing Ms. Smith as Chair of the Prevention Subcommittee. Dr. Reznik is the new Chair of the Treatment and Care Subcommittee. Dr. Sullivan thanked the former Treatment and Care Subcommittee Chair, Mr. Minor, for his continued leadership and contributions.

Dr. Sullivan also announced that Donald Sneed has completed his tenure on the Council, and he thanked him. He noted that Lt. Wanda Chestnut has returned to the National Institutes of Health after serving on the Council staff. He thanked her.

Public comment will begin tomorrow at 11 a.m. Before the end of today's meeting, an announcement will be made about where the Council will meet tomorrow. Subcommittee Chairs will conduct the portions of the meeting today and tomorrow that relate to their Subcommittees. Lunch will be available today, but only to members.

Co-Chair Smith thanked Dr. Sullivan and said it was a privilege to serve as Prevention Subcommittee Chair, and it is now an honor to serve as Co-Chair. She noted President Bush's statements in the State of the Union address regarding his support for reauthorization of the Ryan White CARE Act (RWCA) and support for reducing risk behaviors in youth. She noted that the Council has been active on both of those fronts.

Mr. Grogan thanked members for sending in advance materials for the meeting briefing book. He noted that today is National Black HIV/AIDS Awareness and Information Day, which will be addressed shortly by Christopher Bates, Acting Director of the Office of HIV/AIDS Policy. Mr. Bates is also the head of the Minority AIDS Initiative, HHS. Mr. Grogan noted that tomorrow's meeting will be held in Room 505A of the Humphrey Building.

Prevention Subcommittee Report
Dr. Sweeney thanked the Prevention Subcommittee members for communicating with her upon her new appointment. She is excited about the work that lies ahead, and she thanked Ms. Smith for her able leadership.

The Prevention Subcommittee has not met and doesn't have resolutions for this meeting. A large portion of the Council's June meeting (currently scheduled for June 20 and 21, 2005) will be devoted to prevention, so the Subcommittee will meet between now and then to draft motions. Dr. Sweeney noted the front-page story in The Washington Post today entitled "U.S. AIDS Cases Soaring Among Black Women." The Subcommittee hopes to address that tragedy. Dr. Sweeney said we will never be able to treat our way out of this epidemic. The Council needs to address where the epidemic is going, including among black women, men, and children.

We can change behaviors, Dr. Sweeney said. After the Vice Presidential debates last fall, she was very discouraged to hear that Vice President Richard Cheney was not aware of the epidemic. However, paraphrasing Margaret Mead, she said the Council should

remember never to underestimate the power of a few citizens to change the world. Indeed it is the only thing that ever has.

Dr. Sweeney announced that the Prevention Subcommittee would meet at lunchtime and also conduct a conference call on the first Friday of every month.

Dr. McKinnell suggested that the Council set a goal of zero new infections.

Dr. Sullivan noted Dr. McKinnell's suggestion and referred it to the Prevention Subcommittee for further discussion. He also urged all members to give thought to how to move forward with it.

Presentation

Dr. Sullivan welcomed Dr. Julie Louise Gerberding, Director of the Centers for Disease Control and Prevention (CDC), to give her presentation. He noted she is providing strong leadership at the CDC.

"CDC's HIV Prevention Efforts: Successes and Challenges," by Julie Louise Gerberding, M.D., M.P.H., Director, CDC

Dr. Gerberding said she is very sobered by what lies ahead of us. She heard Billie Jean King speak at a recent meeting. Ms. King said leadership is a privilege. She also said that champions adjust. What we do is doing some good in combating HIV/AIDS, but it's not good enough. She added she agrees with Dr. McKinnell's goal.

In her PowerPoint presentation, Dr. Gerberding noted successes in HIV prevention, including the steady decline in pediatric AIDS cases, reduced risk behaviors among youth, early diagnosis of HIV infection, stable HIV incidence with increasing prevalence, and implementation of the Advancing HIV Prevention initiative.

Dr. Gerberding provided data on each of these points. She characterized HIV reduction in children as an incomplete success, because "Every child born with HIV is a case of failure in the public health system. We have to start thinking about the system and where it is not working."

Data on sexual risk behaviors and pregnancy among youth show pregnancy trends are down, the proportion of youth who have ever had sex has declined, and the percentage of those who are sexually active and use condoms has gone up. While not dramatic, these data are promising, for they show that trends can be reversed and behavior modified.

Data from 25 States with confidential name-based reporting of HIV infection show more individuals were getting tested earlier in their illness in 2002 than in 1994, which gives us greater opportunity to treat them successfully and to help them protect their partners and others. Modeling shows that while HIV incidence has flattened, "to the best of our ability to model this trend, for we do not yet have data from all 50 States," HIV prevalence is increasing, which "is an issue for reauthorization of Ryan White and people's life stage

needs." This is a prevalence disease, and we should have a standard of elimination, Dr. Gerberding added.

In terms of awareness of serostatus among people with HIV and estimates of transmission, the CDC estimates that, of the 850,000–950,000 persons living with HIV/AIDS in the United States, about 25 percent are unaware of their infection, and they account for about 66 percent of all new infections. This is a strong argument for making people aware of their serostatus, Dr. Gerberding noted. And these estimates directly encouraged the CDC initiative "Advancing HIV Prevention: New Strategies for a Changing Epidemic."

CDC testing seems to be turning up significant numbers of positive tests, Dr. Gerberding said—1.3 percent of the number of tests conducted at CDC-funded sites in 2003. CDC is increasingly funding testing at new and various sites. The CDC's 2003–2005 rapid testing demonstration projects are being conducted not only routinely in medical settings but also through rapid testing in short-stay correctional settings, rapid testing in nonmedical settings, partner counseling and referral services (PCRS) with rapid testing, and through social networks.

Some suggest that by targeting populations, the CDC could do a better job, Dr. Gerberding added. But huge challenges lie ahead, including women at risk (especially black women), racial and ethnic disparities, the behaviors of men who have sex with men (MSM), and the confounding variable of crystal methamphetamine use. "I'm disappointed that after 20 years, we're not doing a better job of targeting," she added.

HIV risk factors for women include:

- Youth
- Lack of recognition of partner's risk
- Sexual inequality in relationships with men and domestic violence
- Biologic vulnerability and STDs
- Substance abuse
- Socioeconomic status.

Reporting on an important cluster study of HIV rates among women by age in North Carolina, 1998–2003, Dr. Gerberding noted profound disparities by race and age. Whereas rates among white women ages 18–40 were fairly flat, rates among black women ages 18–24 were rising, as were rates among black women ages 31–40. The most alarming increase is among black women ages 25–30.

The CDC's Sisters Informing Sisters on Topics about AIDS (SISTA) program offers:

- Five-session, group-level intervention
- Peer-led, social skills training intervention for African American women ages 18–29
- Culturally sensitive, gender-relevant HIV-risk reduction that builds social skills.

The CDC has received a number of requests for SISTA training across the United States. Dr. Gerberding is encouraged by the popularity of the program, but said it now needs to be scaled up and sped up.

CDC data from 2003 show that racial and ethnic disparities in AIDS annual rates persist, with African American rates at 74 per 100,000 against 27 for Hispanics and 8 for whites. "We need to expand our knowledge of this complex equation," Dr. Gerberding said. In 2003, 51 percent of HIV/AIDS diagnoses were among African Americans, and the 2004 picture is probably worse, she added.

A new focus for the CDC is to achieve health equity. The CDC's Office of Health Equity is helping the CDC set new goals and allocate resources to this effort. This includes reallocating funds and not just those specifically designated as disparity funds. Dr. Gerberding promised to report back to the Council in a year on the early results of this new effort.

Risky behaviors among MSM include:

- HIV/AIDS prevention fatigue among older gay men
- Fewer prevention efforts reaching marginalized MSM
- Popularity of bathhouses, sex clubs, and the Internet
- Substance abuse (e.g., methamphetamine)
- Viral load beliefs
- Internet chat rooms as a new venue to meet sexual partners
- Treatment optimism
- Lack of fear of acquiring HIV.

Focus group research studies are showing that MSM have delusions about the risks associated with their viral loads. There is also a change in the psychology. HIV/AIDS is no longer a death sentence, but it does remain a devastating illness. "We need to come to grips with people's false impressions," Dr. Gerberding said. In San Francisco in the early days of the epidemic, she saw firsthand the profound denial until people started dying. "We don't want to get to that level again. The biggest health threat is complacency. Where is the energy around HIV/AIDS in this country? I fear the disease is going underground."

Syphilis rates from 1981–2003 by gender and male-to-female rate ratios show "very ominous trends," with male rates and male-to-female rates rising.

The Internet also seems to be playing a large role in early syphilis cases. Dr. Gerberding noted that according to preliminary data gathered in urban centers across the United States, the percentage of MSM with early syphilis who met partners on the Internet was as high as 46 percent in San Francisco. Creative programs to use the Internet to combat this trend include offering:

- Online testing
- Partner notification via Internet chat rooms
- Online education, such as a Web site for Chicago residents that provides information about syphilis, testing locations, and how to notify a partner.

These are programs that "go where the customers are."

Dr. Gerberding noted methamphetamine use among MSM and HIV risk as a target for intervention, adding that through Project MIX, the CDC is conducting a randomized control trial to reduce HIV/STD risk behavior among substance-abusing MSM in New York City, Los Angeles, San Francisco, and Chicago.

CDC strategies for the future include:

- Estimate HIV incidence (we still can't do this well)
- Emphasize training and quality assurance and translate research into practice (new strategies are underway and now need evaluation)
- Continue to disseminate innovative testing strategies, including rapid testing (CDC needs to expand access to the system and will continue to work with the manufacturer on affordability)
- Incorporate prevention into treatment
- Invest in vaccine, microbicide, antiretroviral (ARV) prophylaxis, and behavioral research, the foundation for prevention in the future.

Dr. Gerberding stressed she needs the Council's help on HIV incidence estimates, that is, to have more States with confidential named reporting. CDC's goal by the end of the year is to have a reliable incidence estimate.

Recent HIV prevention developments include:

- Nonoccupational Post-exposure Prophylaxis (nPEP) Guidelines
- HIV Incidence Surveillance
- Bulk purchase and distribution of the OraQuick rapid test at a better price.

The nPEP Guidelines are now available. They:

- Are recommended in limited cases
- View postexposure treatment as a safety net
- Are not substitutes for safe behaviors.

The current status of HIV Incidence Surveillance is:

- To identify newly diagnosed patients through the current surveillance system
- To obtain aliquot of diagnostic specimen for STARHS procedure

- 33 areas funded (about 90 percent of all HIV cases) for 2005, with 14 currently collecting specimens
- To begin using the BED assay this summer (special U.S. Food and Drug Administration [FDA] labeling will not require consent for STARHS)
- National incidence data available late this year.

Dr. Gerberding concluded with a synopsis of CDC procurement and distribution of OraQuick:

- 522,775 tests kits shipped in 2003 and 2004 to 137 health departments and community-based organizations in 36 States
- Utilization between September 2003 and September 2004—173,003 persons tested; 1.6 percent HIV-positive; 17,266 devices used in training; 25, 296 devices used to run external controls
- Purchase of oral tests in FY 2005
- Working with the National Alliance of State and Territorial AIDS Directors to negotiate bulk purchase rates.

Question and Answer Period

Responding to Dr. Green, Dr. Gerberding said ultimately incidence data will come from a time when we have widespread testing so that we can determine seroconversion early.

Ms. Ivantic-Doucette asked whether the reported syphilis rates lump primary and secondary syphilis together; about mainstreaming versus targeting of prevention efforts; and what the CDC needs from the Council to help with incidence. Dr. Gerberding responded that the information she supplied about syphilis rates is not confounded by later syphilis rates. She said the CDC needs to do a better job of targeting. The rapid test has shown that you do end up with a net increase of people diagnosed and in treatment. "What we don't know is if intervention actually changes risk behavior." On the third question, Dr. Gerberding said, a resolution from the Council on the need for named reporting across all the States might be helpful. "I think we can do this in a science-based way. That has to be the basis on which the decision is made."

Dr. Yogev congratulated Dr. Gerberding for her leadership. He noted that in Chicago, the number of HIV-positive and pregnant African American women has doubled in 2 years. In the past 4 months, he has seen four infants born infected. Many of these women aren't seen until the last minute. He also said that SISTA needs to reach preteen girls. Dr. Gerberding said each of those four infants represents a failure of the system. We have to ask why the women came in so late. SISTA is in an early stage and needs to be evaluated, but Dr. Gerberding agreed that intervention at earlier ages and prior to exposure makes a lot of sense. The decision needs to be evidence-based. "We need to identify the programs that work."

Dr. Yogev asked if the rapid tests could be made available for individuals under the age of 13. The CDC will brief the Council on that on Day 2.

Dr. Judson noted the Council's frustration in getting all States on board with name-based reporting. He asked if there are any Federal barriers to this now, and Dr. Gerberding said no.

Dr. Primm called Dr. Gerberding's presentation excellent and expressed concern about a reduction in the CDC budget. Dr. Gerberding said the CDC budget is $9 billion. She noted the President's "very important statements" about RWCA reauthorization and the importance of HIV/AIDS' impact on African Americans. She said that the proposed new budget for the CDC will call for a total dollar amount less than was appropriated last year, but specifics are currently under embargo. She added she is not specifically aware of cuts to the CDC's AIDS budget. She added that the Council should think not only in terms of dollars but also leverage. There are ways to increase efficacy, including through the Centers for Medicare and Medicaid Services and quality improvement initiatives. Under the new HHS Secretary's leadership, she will be looking at how the CDC can combine resources and be more powerful as an agency.

Ms. Clements asked about the ability of the CDC and the Health Resources and Services Administration (HRSA) to work together toward a zero percent new infections goal. She mentioned that States and localities struggle about how to use the CDC's Prevention for Positives program. The CDC Director said from personal experience as a doctor at San Francisco General Hospital, she knows prevention counseling is important but difficult with a host of competing priorities, and HIV/AIDs counselors are rare. The CDC needs to evaluate programs currently funded. It's an area ripe for new approaches and new ideas, and she hopes HRSA will agree.

Dr. Reznik commented that at his institution in downtown Atlanta, where there are high prevalence rates, there are no protocols for rapid testing, and that's a significant problem. CDC templates are needed. He added that prophylaxis is good, but there needs to be more emphasis on rapid testing. Dr. Gerberding agreed that rapid tests cause anxiety, but they also help with risk behaviors. She added that the CDC wouldn't condition prophylaxis on testing because that's an access issue.

Rev. Sanders asked if despite the increase in rates of syphilis, there may be a shift away from funding services. Dr. Gerberding said she would verify what exactly is happening in terms of resources. The STD division at the CDC made a commitment to eliminate syphilis, and SWAT teams are still available. Rev. Sanders added that the President's State of the Union address reflected awareness of the need for resources, but now the Council needs to help him follow through.

Mr. Minor said he shares Dr. Gerberding's concern about complacency. He recalled that the Council had called for a domestic summit at the White House level in part because of that. He asked how the Council can advance the summit concept. Dr. Gerberding said she was aware of the resolution. Such a summit should take a big tent approach and avoid divisiveness. She agreed such a summit would show there is still energy to combat HIV/AIDS and that, politically, it is a live issue.

Commenting on The Washington Post story about HIV/AIDS rates among black women, Dr. Sullivan took issue with the concept that we won't make significant progress on that challenge until we make progress on such issues as poverty and education. Unfortunately, to make such significant progress would take decades. He noted that the article mentioned the black church as generally unsupportive of HIV-positive persons because, for example, of entanglement with what the church views as the issue of homosexuality. The question is, how can we change this dynamic? We've made progress on the scientific front but not on the social context of the disease, its stigma, and the sharing of test results.

Dr. Sweeney added, is there any way to address skepticism about the statistics in the black community?

Dr. Gerberding said these issues of trust need more discussion. Embedded in behavioral intervention is the need for trust. The other word is hope. We've seen hope emerge from ARVs. Those maintained on these drugs also need to have hope that they have a life ahead of them, that someone cares. HIV/AIDS interventions need to be presented in a way that allows people to believe there is value in the future.

She thanked the Council and asked for members to send her e-mail with new ideas, questions, or suggestions.

Presentation
Dr. Sweeney introduced Mr. Christopher Bates.

"National Black HIV/AIDS Awareness and Information Day and the Minority AIDS Initiative," by Christopher Bates, M.H.A., Acting Director, Office of HIV/AIDS Policy (OHAP), Office of Public Health and Science, HHS; and "HIV/AIDS Manual for Faith-Based Providers," by Vivian Berryhill, President, National Coalition of Pastors' Spouses

Mr. Bates said that as he travels the country, he realizes not enough people are talking about the domestic epidemic, not even those in the middle of it. Turning this around is a fundamental element of prevention strategy.

Mr. Bates said he is sad today because just this past week, he lost another friend to complications from HIV/AIDS, and he also learned that another friend, an HIV/AIDS health provider for 20 years, has just been diagnosed. He noted the heroism of the late Dr. Peter Singleton, Council member Ms. Singleton MacDonald's brother, who spoke about HIV when people didn't want to hear about it. He asked for a moment of silence for those who continue to die from the disease and for those who continue to live with the disease.

Much progress has been made, but The Washington Post story showed why our work is particularly difficult. There is a lack of trust, and it has to do with myths. We have to encourage all health care workers to advance the truth and dispel the myths.

Today is National Black HIV/AIDS Awareness and Information Day. It is timely. Several stories and reports have come out about the surge of HIV/AIDS in the black community, and how many African Americans either don't believe the statistics or believe this is some type of Tuskegee situation. The fact is, the front of the epidemic has rapidly shifted to minorities. And a lot of people can't afford even the medications. That remains a big part of our challenge.

National Black HIV/AIDS Awareness and Information Day, celebrated on February 7 and created by the Community Capacity Building Coalition (national organizations funded by the CDC), is one of several national HIV/AIDS observance days held each year. Others are HIV Vaccine Awareness Day, May 18; National HIV Testing Day, June 27; National Latino AIDS Awareness Day, October 15; and World AIDS Day, December 1. Additional HIV/AIDS observance days include the Asian/Pacific Islander HIV/AIDS Awareness Day, May 19, and a Women's HIV/AIDS Awareness Day to be announced.

The purpose of National Black HIV/AIDS Awareness and Information Day, as outlined in a four-color brochure provided to the Council, is to:

- Call attention to the devastating effects of HIV/AIDS on African Americans and communities across the country
- Help increase the capacity of community-based organizations (CBOs) and other organizations to get individuals tested for HIV, educated about the epidemic, and involved in prevention.

Awareness days also help HHS promote its policies, programs, and resources, as well as further its responsibilities to act as a broker for information and resources on HIV/AIDS for national, regional, and local health departments, as well as community and faith-based organizations. (See *www.omhrc.gov/hivaidsobservances.*)

Addressing the Minority AIDS Initiative through a PowerPoint presentation, Mr. Bates gave some history:

- The Minority AIDS Initiative (MAI) was enacted by Congress in 1999.
- The HHS Secretary targeted $50 million for the design and development of new and innovative projects and strategies to improve access to vital HIV/AIDS programs and services (a supplemental to the initiative).
- In FY 2003, Congress instructed HHS to report to the Appropriations Committee by October 15, 2003, details about how initiative funds were used and distributed.
- To date, more than $1.97 billion has been authorized.
- MAI is not a single initiative but many programs and activities that reflect the needs of highly diverse subpopulations among racial and ethnic minority communities.
- The care and treatment services provided by funded organizations must serve minority populations that are at disproportionate risk for HIV infection or who already have HIV infection or AIDS.

- The HHS Secretary established the Steering Committee on Implementation and Evaluation to coordinate and provide oversight of MAI activities supported through the MAI Fund.
- In FY 2005, OHAP hopes to lead an effort to assess and evaluate the impact of the MAI since its inception.

The allocation of direct-line appropriations for MAI, separate and apart from the Secretary's supplemental contribution, goes to CDC, HRSA, the Substance Abuse and Mental Health Services Administration (SAMHSA), the Office of Women's Health, the Office of Minority Health, the National Institutes of Health (NIH), and the Office of the Secretary.

Mr. Bates noted that NIH at one time tapped the supplemental from the Secretary's office but no longer does.

MAI funds received by the Office of the Secretary are also distributed to the above-mentioned agencies, with the exception of the NIH, plus the Indian Health Service, the Office of Population Affairs, and OHAP.

In the FY 1999–2002 period, the largest percentages of MAI spending were devoted to prevention (34 percent), care (32 percent), and training and capacity building (29 percent).

In FY 2004, the Office of Population Affairs Family Planning Clinics program funding was doubled. And SAMHSA asked for $6 million to provide counseling and testing. The agency is now working with the CDC on prevention and treatment.

In FY 2005, there was an increase in the supplemental fund, to $52.4 million from $49.5 million in FY 2004.

OHAP hopes to receive feedback soon from Congress on the MAI report submitted in 2003. An assessment and evaluation of the impact of MAI is also underway.

Question and Answer Period

Dr. Primm thanked Drs. Sweeney and Sullivan and Mr. Bates for acknowledging the contributions of several key Council members in the founding of the fund, but said he doubts that the funding is sufficient. Mr. Bates acknowledged there have been across-the-board budget cuts, but that the numbers he provided today are gospel.

Ms. Clements said she is disturbed by the recent RAND report that states students believe the HIV/AIDS crisis is a Government conspiracy. She is not sure how to change people's thinking. Mr. Bates said the spirit of the initiative was for it to be used for racial and ethnic minority groups that are disproportionately affected by the epidemic. The intent was to use indigenous organizations. At present, the Department looks at how to increase access and who at the local level is best qualified to do that. When we find that the

organization doesn't appropriately interface with the intended population, it doesn't get refunded.

Mr. Bates' Office also works with agencies to develop technical assistance in capacity building so that minority organizations that want to expand their opportunities or strengthen their work can. He added that HRSA has a particularly aggressive technical assistance and capacity building program.

Rev. Sanders, who, like Dr. Primm, was one of the Council members involved in founding the initiative, noted that the original intent was to get new funding and to allow local organizations to get past barriers that range from trust to cultural competency. The original idea was to have a national emergency declared, which would have mandated a broader response across the Government for supplying basic needs such as housing as well as treatment, care, and prevention. We need the full benefit of a bigger response. Mr. Bates responded that HHS will continue to focus on HIV/AIDS, but that focus is also part of larger effort to look at disparities.

Ms. Freeman noted that although she has retired, she is active in a new organization, the Health Education Network. The network works with young women. She has talked with 100 women recently about HIV/AIDS and no one mentioned a Government conspiracy. It is important to continue to work with students, but she finds funding for such efforts is lagging. Mr. Bates said MAI has had success with prevention among MSM and men of color through technology and science-based approaches, and while we are still seeing the number of MSM and men of color infected going up, this is in parts of the country where we haven't had many opportunities or targets for intervention. He added that in large urban areas, we are beginning to see a leveling off among these populations, and the number of cases going to AIDS from HIV has decreased significantly among MSM of color. His Office works with Native American communities, school systems, health care providers, and the Office of Women's Health, as well as mentoring programs inside and outside of prison. We weren't able to do that before. Because of these successes, we're doing an overall evaluation and assessment to show how the initiative has enhanced the base programs.

Ms. Freeman asked if more money was available now for women and minority women. Mr. Bates said he hopes this is true in base funds, but that he also hopes agencies would come to the Secretary's supplemental MAI fund if they were in need. In that regard, Dr. Reznik noted that two minority college graduates recently asked to work with his program in Atlanta but couldn't afford to due to college debt. Mr. Bates said he would make note of that kind of problem.

Mr. Bates introduced Mrs. Vivian Berryhill.

Mrs. Berryhill is the wife of Pastor Chester Berryhill, Jr. The National Coalition of Pastors' Spouses recently completed work on an HIV/AIDS manual for communities. Mrs. Berryhill thanked the Coalition's partners in this effort, including Mr. Bates' Office.

The manual's formal unveiling will be March 7, 2005, during the Black Church Week of Prayer for HIV/AIDS Healing.

Mrs. Berryhill said the Coalition, which is nonprofit, nonpartisan, and cross-denominational, is pleased to support the President and his efforts to quell the epidemic. The Coalition's efforts are realized through community churches and religious organizations.

The Coalition decided to create the manual because of its belief that one of the most effective ways to deal with problems is provide education in churches, which is where most African Americans turn in times of need. The Coalition believes that pastors' spouses can help empower patients, not only to become healthier but to develop and maintain healthy lifestyles. The manual is designed to help churches and pastors' wives promote that effort.

The manual consistently focuses on responsibility. This responsibility includes the need to know how you can get AIDS and how to protect yourself and those you love. The manual stresses doing the right thing, like getting tested and counseled and thereby helping to stem the continuation of the epidemic. The manual is also designed to educate communities, providing resources that communities can use to enable individuals to make informed decisions and to encourage individuals to get testing, followup care, and counseling.

The manual follows the ABC model "plus." The pluses are "D": Don't practice risky behaviors, and "E": Eliminate exposure. Mrs. Berryhill said she agrees with the President's call for a focus on the epidemic as it is affecting African American men and women. She also agrees with the President about the need to invest in young people. She said resources should now be invested in helping young people make responsible decisions, and she believes that the ABC model will have a major impact on African American youth and adults. It is important, she added, that use of the manual and its model can be customized for each setting and community. In addition, the manual includes a feedback mechanism so users can evaluate its effectiveness.

Mrs. Berryhill concluded by noting that the manual is designed to help "stop the myths and lies and stop the hate" that surround the epidemic. She said myths continue to make it difficult to work with this crisis in the African American communities, so the manual replaces myths with facts. It also calls for communities to stop hating and fearing people who are HIV-positive and, rather, to focus on the virus. Only when myths, hate, and fear are addressed will the numbers of infected individuals decrease in African American communities.

Question and Answer Period

Ms. Singleton McDonald expressed her appreciation for Mrs. Berryhill and her efforts, adding that Council members with CBOs now need to partner with the Coalition.

In response to a question from Dr. Primm, Mrs. Berryhill said in the 16 months that the Coalition has been together, it has become friendly with and networked with Dr. Debra Fraser-Howze, founding president and CEO of the National Black Leadership Commission on AIDS, and that the Coalition looks forward to working with all relevant organizations.

Ms. Clements remarked that the Coalition's manual is beautiful, easy to read, and seems comprehensive, and she looks forward to using it. Mrs. Berryhill said she wants everyone who goes to church to have the manual in their house next to their Bible.

Ms. Ivantic-Doucette asked if the manual discusses what to do with the "origins topic." Mrs. Berryhill explained that in an initial project meeting, the Coalition decided that too much emphasis is placed on blame and who didn't do what. "We decided we wanted to put our arms around the people who have HIV/AIDS and make the disease about people and helping them through their crisis. It's not about how you got it or who got it from you. We want to move people with HIV/AIDS away from guilt and denial."

Dr. Green thanked Mrs. Berryhill and the Coalition for adopting the ABC model.

In response to a request by Ms. Shoemaker that the Coalition sign up white churches, Mrs. Berryhill noted that three white pastors' spouses are members of the organization.

Dr. Sweeney turned the meeting back over to Dr. Sullivan, who called for a break.

Break

After the break, Ms. Ivantic-Doucette presented Council members with gifts made by women in Nairobi affiliated with the Marquette University AIDS in Africa project. Everyone thanked the makers of the gifts.

Dr. Sullivan then asked Mr. Mason to deliver the International Subcommittee report.

International Subcommittee Report and Draft Motions
Mr. Mason introduced the subjects of the Subcommittee's four resolutions:

1. Human trafficking,
2. Mother-to-child transmission (MTCT) and nevirapine,
3. Improving rates of MTCT globally, and
4. PEPFAR implementation of the ABC model.

The introduction was seconded. Mr. Mason asked for and received a show of hands to present the resolutions.

Presidential Advisory Council on HIV/AIDS
International Subcommittee

Draft Motion
Preventing AIDS and STDs by Curbing Human Trafficking

WHEREAS, human sex trafficking enslaves an estimated 600,000–800,000 human beings each year, with the majority of these being women and children;

WHEREAS, trafficked people involved in the sex trade have a high prevalence of infection of HIV and other STDs, regardless of condom use;

WHEREAS, there is evidence worldwide which suggests human trafficking, especially sex trafficking, has been and continues to be a major driver of the AIDS epidemic throughout the world;

WHEREAS, human trafficking ruthlessly exploits its victims and is a contemporary form of slavery and a fundamental violation of human rights;

WHEREAS, the goal of confronting the evil of trafficking is not to "clean up" trafficked individuals for the benefit of their clients;

WHEREAS, President George W. Bush has taken a strong stand against human trafficking, condemning it as "a special kind of evil in the abuse and exploitation of the most innocent and vulnerable" and that "we must combat this trafficking and protect and assist its victims both domestically and globally"; and

WHEREAS, the United States and other developed countries commit billions to AIDS treatment while efforts to curb one of the epidemic's main drivers, human trafficking and prostitution, lag;

BE IT THEREFORE RESOLVED that PACHA commends the President for his initiatives to curb the abhorrent practice of human trafficking and to further his efforts by adding to his recommendations the following elements:

Advocate and fund further research on the link between the sex trade and generalized epidemics of HIV;

Develop programs to abolish the sex trade, extending his advocacy of worldwide freedom for all;

Support further development and funding of programs and practices to rescue and rehabilitate those trapped in the sex trade, including training of health care workers in techniques tailored to address the special health needs of victims;

Combine programs enabling the most competent risk-reduction care (condom use and STD treatment, etc.) with rescue work so that health care professionals who treat trafficked individuals are not perpetuating the sex industry;

Continue vigorous investigation and prosecution of criminal offenses related to human trafficking.

Presidential Advisory Council on HIV/AIDS
International Subcommittee

Draft Motion
Improving Prevention of Mother-to-Child Transmission (PMTCT) Efforts while Preserving Current Treatment Options for Women of Childbearing Years

WHEREAS, increasing numbers of women in their childbearing years are being infected with HIV and AIDS, and

WHEREAS, transmission of HIV infection from mother to child decreased dramatically since prophylaxis of HIV-infected pregnant women with zidovudine was initiated in 1994 in the United States, and

WHEREAS, transmission of HIV infection from mother to child in resource-limited settings has been significantly reduced since prophylaxis with the single-dose nevirapine; and

WHEREAS, nevirapine prophylaxis has been proven to be simple, safe, and effective and tens of thousands of HIV-infected women already received this therapy without major problems, and

WHEREAS, recent allegations related to the study which proved the safety and efficacy of nevirapine in preventing MTCT was flawed, were shown to be unfounded by multiple subsequent reviews, and subsequent independent studies confirmed the results of the original study,

BE IT RESOLVED that the Presidential Advisory Council on HIV/AIDS (PACHA) recommends that the usage of single-dose nevirapine (with or without zidovudine) for prevention of MTCT is safe and effective and should continue to be recommended to HIV-infected pregnant women who have no other option for treatment such as with combinations of multiple ARV drugs.

BE IT FURTHER RESOLVED that PACHA recommends that nevirapine prophylaxis is an acceptable therapy until more effective antiviral therapy that does not induce drug resistance becomes available.

BE IT FURTHER RESOLVED that PACHA recommends that the Secretary of HHS take all necessary steps to expedite clinical trials on novel simple, effective, and affordable treatments to prevent MTCT during delivery.

Presidential Advisory Council on HIV/AIDS
International Subcommittee

Draft Motion
Improving Prevention of Mother-to-Child Transmission (PMTCT) Efforts Globally

WHEREAS, the President's Emergency Plan for AIDS Relief (PEPFAR), building on the significant work accomplished under the President's 2002 International Mother and Child HIV Prevention Initiative, calls for the rapid scaleup of PMTCT activities that promote improved access and efficacy of prevention efforts; and

WHEREAS, increasing numbers of women in their childbearing years are becoming HIV-infected, the majority living in communities without adequate access to prevention activities—such as those in the United States that have reduced pediatric infections from perinatal transmission to under 1 percent annually; and

WHEREAS, significant progress has been made in the global battle to reduce MTCT through strategies such as enhancing safe deliveries, breastfeeding avoidance, and short-course ARV therapy, it is recognized that treatment of the mother with highly active antiretroviral therapy (HAART) during pregnancy and the breastfeeding period will be required to achieve a reduction of transmission that resembles the U.S. success; and

WHEREAS, utilization of HAART reduces the viral burden in the mother thus reducing transmission to the infant and allows recovery of the immune system producing a healthier mother and more likely a healthier baby thereby reducing the number of orphaned or vulnerable children; and

WHEREAS, the President's Emergency Plan requires special attention be paid to mothers and children and the scaling up of ARV therapy;

BE IT RECOMMENDED that U.S. Government Departments and their implementing agencies involved in HIV/AIDS activities globally intensify their efforts to secure HAART for pregnant and breastfeeding women through the provision of effective medications, the training of nurses and midwives to manage medication therapies, and the monitoring and evaluation of the health of the mother, the child, and the prevention of new HIV infections.

Presidential Advisory Council on HIV/AIDS
International Subcommittee

Draft Motion
Call for Ensuring Broader Programs of AIDS Prevention in Implementing the President's Emergency Plan for AIDS Relief (PEPFAR)

WHEREAS, Uganda has achieved the greatest degree of HIV prevalence decline of any country and remains the only country with a generalized epidemic that has experienced significant HIV prevalence decline; and

WHEREAS, President Bush has heralded the Uganda ABC prevention model as the most effective model for prevention of sexually transmitted HIV in generalized epidemics (those of sub-Saharan Africa and the Caribbean) and has made it the centerpiece of the prevention component of PEPFAR; and

WHEREAS, recent research published in Science, British Medical Journal, The Lancet, and the Journal of International Development, among others, shows that the ABC model is indeed the best prevention strategy for generalized epidemics and that decline in casual sex (the B component of ABC) is the single most important factor accounting for success in Uganda;[1] and

WHEREAS, there is great institutional and bureaucratic resistance to conducting AIDS prevention in ways that differ from the programs of the past two decades; and

WHEREAS, the first two components of ABC are not being adequately supported by foreign donors, including USAID, in Uganda itself, as concluded by U.S. Senator Brownback, among others, after a recent trip to Uganda; and

WHEREAS, the National Strategic Framework for HIV/AIDS Activities in Uganda (2003/04–2005/06) and Uganda's current national Monitoring and Evaluation Draft Plan[2] contain no specific objectives or impact indicators related to the first two components of ABC, only to condoms, yet earlier plans were replete with these A and B objectives and indicators[3];

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[1] Stoneburner, Rand L. and Daniel Low-Beer, "Population Level HIV Declines and Behavioral Risk-Avoidance in Uganda." 30 April 2004 Vol 304 Science, pp 714-18; Shelton, James D., et al, "Partner reduction is crucial for balanced 'ABC' approach to HIV prevention." BMJ 328:10, 2004; Halperin, DC, et al.,"The Time Has Come for Common Ground on Preventing Sexual Transmission of HIV." The Lancet. 364, Nov. 27, 2004, pp 1913-1915; Tim Allen and Suzette Heald, "HIV/AIDS policy in Africa: what has worked in Uganda and what has failed in Botswana?" Journal of International Development. J. Int. Dev. 16, 1141-1154 (2004).

[2] Developed with support from USAID/Uganda.

[3] For example, AIDS Control in Uganda: The Multi-Sectoral Approach, Uganda AIDS Commission Secretariat, Kampala, February 1993; 2. Uganda National Operational Plan for HIV/AIDS/STD Prevention, Care and Support, 1994-1998; Uganda AIDS Commission Secretariat, Kampala, October 1993; 3. The National Strategic Framework for HIV/AIDS Activities in Uganda (1998-2002), by "Social Partners":

BE IT RESOLVED that PACHA use its influence to ensure that the Uganda ABC model be implanted just as the President and the Congress intended, as evidenced in the language of the bill and of the Smith and Pitts Amendments, which suggest equal balance between A, B, and C components in programmatic attention and in levels of resource allocation;

BE IT FURTHER RESOLVED that PACHA recommends to the President that basic program indicators be required of all PEPFAR-funded AIDS prevention projects and programs, indicators associated with all three intended components: abstinence, mutual faithfulness, and correct and consistent condom use. Indicators for condom use are already found in prevention programs. Those for the first two components should at a minimum include the following program indicators, recommended by PEPFAR:

For A: 1. Percentage of never-married young men and women aged 15–24 who have never had sex
2. Percentage of young never-married women and men aged 15–24 who have had sexual intercourse in the last 12 months, of all young never-married respondents surveyed

For B: 3. Percentage of women and men aged 15–49 who had sex with more than one partner in the last 12 months.[4]

Mr. Mason introduced the next presenter, Dr. Murray Lumpkin of the FDA. He congratulated the Council for having passed a visionary resolution requiring that PEPFAR purchase high-quality drugs for the PEPFAR program, one result of which is the fast-track approval process in place at FDA, which Dr. Lumpkin will now explain.

Presentation
"PEPFAR and FDA," by Murray M. Lumpkin, M.D., Acting Deputy Commissioner, FDA, HHS

Dr. Lumpkin noted that in the world market, there are many HIV/AIDS drug products, but the question is whether they should be purchased. These products include counterfeits, illegitimate knockoffs, and legitimate knockoffs. The challenges to FDA include how to ensure that products purchased under PEPFAR are quality products and at the same time to ensure that PEPFAR gets the best value for the dollar in drug-purchasing efforts to help treat the largest number of patients. In addition, there is the ethical issue of two standards, which was addressed by the PACHA resolution, i.e., how can we ask other countries to give their people drugs we don't use in the United States?

Government of Uganda, Uganda AIDS Commission, Joint United Nations Programme on AIDS, Other Partners in HIV/AIDS. December 1997.

[4] The President's Emergency Plan for AIDS Relief Indicators, Reporting Requirements, and Guidelines Revised based on FY 2005 Country Operation Plans (September 30, 2004)

FDA has initiated an expedited marketing application review process, which is more than just expedition. This process began in May 2004, when former HHS Secretary Tommy Thompson announced that FDA would implement a new, expedited review process for certain drugs to ensure that the United States could provide safe, effective quality drugs under the PEPFAR program.

Key elements of the expedited tentative approval are:

- FDA is not changing its standards. Efficacy, safety, and manufacturing quality, including inspections, are all intact.
- However, the process is newly and very explicitly open to all manufacturers, not just those in the United States. A tentative approval program has assisted the generic industry in the United States for years, allowing them to apply to manufacture and market generics before the U.S. patent on the drug they are "copying," in a bioequivalent way, has expired. In that way, they are positioned, the day the patent does expire, to "hit the market."
- In addition—another breakthrough—PEPFAR has told potential applicants that if they win tentative approval, they can have access to PEPFAR programs, and when the U.S. patents have expired, have access to the U.S. market as well.
- To help the process, FDA has provided guidance to the potential applicants, including the PEPFAR list of approved HIV/AIDS drugs. Most of these are single dose, but the guidance also says that if the applicants wish to apply to combine drugs and provide a fixed-dose combination (FDC), FDA will welcome the application and, further, will not require the applicant to prove that using previously approved drugs in combination is safe and effective because "FDA has seen enough data on this." However, bioequivalence must be shown.

FDA guidance for companies was posted on *www.fda.gov* on May 17, 2004. It outlines scenarios for review of different applications and provides a list of generics of the few fixed-dose drugs already available and of those not available in the United States. It also describes the components of a high-quality marketing application.

FDA's commitment to this program includes expedited review in approximately 8 weeks of completed marketing applications. Because such a process normally takes 6 months, this is "significant," Dr. Lumpkin noted, particularly since it includes inspections of manufacturing plants, many of which are expected to be located overseas.

Preapplication activities include spending time and effort up front to help potential manufacturers work through the complex nature of scientific and regulatory questions they will encounter. This will be particularly helpful to companies with little or no experience with the FDA.

FDA is also working with PEPFAR and drug regulatory authorities in the 15 focus countries to conduct train-the-trainer sessions and training about general marketing applications and the approval process, about assessment of current good manufacturing practices (CGMP) and current good clinical practices (CGCP), and about postmarket

adverse-event reporting. FDA is interested in postmarket adverse-event reporting because it wants to learn from new data on the safety and efficacy of drugs marketed under the fast-track program.

Planned for April is a large training program in the United States for regulatory authorities from the 15 focus countries. Dr. Lumpkin emphasized that even if FDA approves an application, local authorities will also need to approve the manufacturer's bid to market within their national borders. FDA will show other authorities how it handles marketing authorization and is also working on a confidentiality agreement that will allow FDA and signatory countries to share data and documentation.

Dr. Lumpkin said critical components of the program are FDA's plan to conduct preapproval and CGCP and CGMP inspections to ensure the integrity of the data in the marketing applications and of drug product quality during manufacturing. FDA is even prepared to conduct mock inspections to help manufacturers that have little or no experience with the agency.

Dr. Lumpkin confirmed that FDA has already received applications under the program and that they are under review. FDA cannot provide a list, but companies can make the fact of their applications public. In December, the U.S. generic company Barr received full approval for manufacture of didanosine delayed-release capsules. In January, tentative approvals were given to Aspen of South Africa to manufacture lamivudine (150 mg)/ziovudine (300 mg FDC), copackaged with nevirapine (200 mg). U.S. patents block the marketing of these generics in the United States. FDA inspectors have conducted a full inspection of Aspen facilities.

Question and Answer Period

Dr. Judson commented that the FDA fast-track approval program seems like a sensible and medically justified answer to those who would say we're using FDA to shield our own pharmaceutical industry. Has that issue been diffused? Dr. Lumpkin said getting angry comments is part of working at FDA. Press reports were mixed when the news about the Aspen approval broke, but many were favorable. Everything comes down to the fact that if U.S. dollars are being used in the program, they should be spent on drugs that meet high standards. The expedited process also opens high standards approval to more companies.

Dr. Yogev complimented FDA for a superb job and asked if we need to push interested companies into doing the right studies more quickly. Dr. Lumpkin noted that FDA is very proactive and open to meeting with and helping interested companies. For the PEPFAR fast-track program, the studies required are for bioequivalence. When companies submit clinical data, FDA will travel to the site to make sure the trial was real. Trials do not need to be conducted in the United States. He added that FDA worked very closely and quickly with Aspen. Approval was granted within 2 weeks of receipt of completed applications.

Mr. Mason also congratulated FDA. He noted that under PEPFAR, 155,000 people in 15 countries are in treatment. A remaining issue is the fact that FDA currently cannot discuss pending or failed applications. Dr. Lumpkin said the authorizing Act for FDA prevents this type of information sharing, for the most part, but FDA is exploring confidentiality agreements with counterpart agencies, including the World Health Organization. He added that the agency is very close to a confidentiality agreement with the South African Government. Without such agreements, a change in the FDA Act would be required.

Dr. Sullivan said once FDA review of an application has been completed, FDA should be able to release information about that application, particularly if it is denied. Should PACHA make such a recommendation? Dr. Lumpkin noted that FDA is permitted to do this under exemptions granted by Congress for pediatric drug applications. The Council could use this as an example. His concern is whether companies would be deterred from applying, although this hasn't seemed to be a problem for pediatric drug manufacturers.

Dr. Sullivan asked the International Subcommittee to review this issue and report back to the full Council. There was some discussion of whether generic companies would be deterred from making applications to the FDA. Dr. Sullivan said he believes the generic industry is not that fragile, and we shouldn't aid and abet the marketing of unsafe drugs anywhere.

Ms. Ivantic-Doucette expressed concern about PEPFAR's purchasing poor-quality malaria and tuberculosis (TB) drugs. Dr. Lumpkin said FDA is very willing to look at expedited approval for high-quality malaria and TB drugs as well.

Announcement

Mr. Grogan noted that PACHA is updating and improving its Web site and asked Council members to volunteer to review the progress made to date, at HHS, sometime in late February or early March. Interested members should provide their contact information to Mr. Grogan.

Lunch

AFTERNOON SESSION

Dr. Sullivan reconvened the Council meeting.

International Subcommittee Report, Continued
Mr. Mason introduced Dr. Lynn A. Paxton to give a presentation on tenofovir.

"CDC Safety and Efficacy Trials of Tenofovir for HIV Prophylaxis," by Lynn Paxton, M.D., M.P.H., Division of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, CDC

Dr. Paxton gave a PowerPoint slide presentation on:

- The rationale for HIV prophylaxis
- Tenofovir
- Tenofovir studies, including an extended safety trial on MSM in the United States and safety and efficacy trials in injecting drug users (IDUs) in Thailand and in heterosexuals in Botswana
- CDC/NIH consultations in December 2004.

The rationale for HIV prophylaxis:

- There is a need for biomedical interventions to complement existing HIV prevention strategies, given 14,000 new HIV infections each day globally and 40,000 new HIV infections annually in the United States.
- To date, we have no effective HIV vaccines or microbicides.
- Systemic HIV infection is not immediate, so prophylaxis could prevent or modify viral replication and spread.
- HIV prophylaxis could function as an "oral" vaccine or microbicide.
- Treatment medications are used as prophylaxis for bacteria, fungi, and the malaria parasite.
- HIV prophylaxis has been shown effective in reducing perinatal transmission (a 50 percent reduction in risk from single doses of nevirapine to mother and infant as well as use of combination drugs in the United States).
- Postexposure prophylaxis is recommended by HHS for occupational exposure (81 percent risk reduction from AZT) as well as for sexual and parenteral exposures (guidelines in press).

Dr. Paxton showed how studies in monkeys have demonstrated efficacy of tenofovir prophylaxis in at least these animal models. There are no human efficacy studies.

History of tenofovir (TDF):

- TDF is a highly potent ARV produced by Gilead and approved by FDA in 2001 for use in HIV-infected persons.

- TDF has been used in more than 15,000 patients in clinical trials and more than 200,000 patients in clinical settings.
- There is a low incidence of side effects.
- TDF can be given through once-a-day dosing with long serum half-life.
- Low levels of induced resistance (or a relatively high genetic barrier) have been seen.

Primary concerns regarding TDF prophylaxis include:

- Some evidence of behavioral disinhibition, although previous vaccine trials showed decreases in risk behaviors in MSM and IDUs.
- Toxicities in HIV-infected persons, including decreased renal function, decreased bone mineral density, and gastrointestinal episodes, although longer studies in humans have shown that these effects tend to level off over time and less than 1 percent of those studied stop taking TDF due to these side effects; in addition, these toxicities might be less in non-HIV-infected persons.
- Selection for resistant viruses in persons who do not become infected.

Dr. Paxton said CDC will closely monitor behaviors, toxicities, and resistance in upcoming trials.

Trials planned, underway, or suspended (possibly temporarily) include:

- The Gates Foundation's Family and Health International (FHI) efficacy trial in female sex workers in Cameroon (currently on hold), Nigeria, and Ghana, as well as a planned study of high-risk heterosexual men in Malawi
- An NIH-funded University of California at San Francisco/Gates-funded Australia efficacy trial in female sex workers in Cambodia, presently on hold
- A CDC nonhuman primate study in progress
- A CDC extended safety study in American MSM (just beginning)
- CDC safety and efficacy studies in IDUs in Thailand and heterosexuals in Botswana (to begin at the end of February 2005).

Dr. Paxton noted that the French equivalent of CBS' "60 Minutes" did an "inflammatory" show on the study in Cameroon, and the study is now on hold. Administrative irregularities have been found but no violations of consent or issues of safety. The Cameroon Minister of Health has come out strongly in support of the study.

Dr. Paxton also stated that a small but vocal HIV/AIDS advocacy movement led by ACT UP PARIS is against the trials in Cambodia and has made accusations that sex workers are too vulnerable to be involved. In addition, demands have been made for lifetime care of persons involved in the study. Dr. Paxton added there is division in the advocacy movement over what ACT UP PARIS has done.

The CDC's extended safety trial is being conducted at two sites: the AIDS Research Consortium of Atlanta (ARCA) and the San Francisco Department of Public Health

(SFDPH). The study objectives and design are to assess clinical, laboratory, and behavioral safety as well as adherence and acceptability through a randomized double-blind placebo-controlled Phase II extended safety study with 1:1 TDF/placebo over 24 months with safety committee review of data at 6, 12, and 18 months.

Study objectives, design, and status:

- Objective—to assess clinical, laboratory, and behavioral safety, as well as adherence and acceptability
- Design—400 HIV-negative MSM, 25 percent men of color; 9-month delay in enrollment of 200 men to assess behavioral changes once TDF prophylaxis has begun; close monitoring of seroconverters for resistance and clinical outcomes; adverse events and access to HIV care if infected, managed through physician referral
- Status—protocol is currently at the review board, with a start date in February 2005.

Dr. Paxton characterized the study as small, adding that CDC does not expect many seroconverters, and there is anecdotal evidence that prophylaxis lowers viral setpoint for subsequent infections.

What CDC TDF studies planned in Thailand and Botswana have in common:

- Both involve Phase II/III randomized double-blind placebo-controlled safety and efficacy trials with 1:1 TDF/placebo.
- Phase II safety trials (200 person-years followed by DSMB review [single DSMB for both studies]); if safety criteria met, will roll into Phase III efficacy trials.
- There will be screening, enrollment, and monthly and quarterly visits, including interviews, physical exams, labs, HIV testing, risk-reduction counseling, adherence assessments, and side effects monitoring.
- CDC will be looking at the following endpoints—HIV seroconversion, adverse events, risk behaviors, adherence, and altered viral load setpoint in seroconverters.
- For seroconverters, CDC will look at viral loads, CD4 counts, and ARV resistance.
- The planned start date is in February 2005.

Dr. Paxton outlined the differences between the two studies, noted critical components, and provided information about how the trials in Thailand are being coordinated with Global AIDS Program (GAP) activities and the trials in Botswana are being coordinated with PEPFAR/GAP activities.

A report is due out soon on the result of consultations between the CDC and the NIH on the implications of successful TDF prophylaxis trials. Dr. Paxton said the consultation involved:

- Impact of demonstrated efficacy in one trial on other trials
- HHS recommendations for TDF use in the United States, for acceptable efficacy level, differing transmission routes, and unstudied populations
- Monitoring for usage, increased risk behavior, HIV incidence, adverse events
- Impact on existing HIV prevention program, domestically and internationally
- Impact on future vaccine and microbicide trials
- Future HIV prophylaxis research with other ARVs, less frequent dosing schedules, and other delivery systems.

Within 18 months the CDC will have the results of efficacy trials. Dr. Paxton noted that some MSM are beginning to use TDF as part of a three-V-way party use of Viagra, Valium, and Viread (TDF). CDC is trying to get the word out that this is risky behavior.

In the ongoing process of considering the potential impact of TDF, the CDC has developed a communications strategy that includes factsheets; questions and answers; outreach and posting on the CDC Web site; identification and preparation of CDC, site-specific, and third-party spokespersons to respond to media inquiries; targeted outreach to key media and opinion leaders; and ongoing monitoring of and response to media coverage.

In conclusion, Dr. Paxton said the CDC strongly believes that assessment of TDF as an HIV prophylaxis is a rational next step in HIV prevention research; the CDC will be conducting complementary studies in the prevention of homosexual, parenteral, and heterosexual transmission; and HIV prophylaxis represents our best hope for an effective biomedical HIV prevention tool in the near future.

Dr. Paxton added that if TDF works as a prophylaxis, it will be a good weapon in the prevention arsenal. However, even if it is proven effective, not everyone will be able to use it. Therefore, we need to continue to try to develop a vaccine and microbicides. In addition, using protection such as condoms continues to be critical.

Question and Answer Period

Ms. Ivantic-Doucette noted she believes in TDF but feels cautious and thinks it is important to have high ethical considerations in working with vulnerable populations. Are there alternatives to using sex workers in such studies? She mentioned that in Kenya there are 30,000 nurses, 15 percent of whom are infected, and they would make a good study.

Dr. Paxton noted the Cambodia sex workers study is not a CDC study. She agreed that all studies need to be held to high ethical standards. The sex worker populations were chosen because they are the most affected. A basic tenet of research is that its modality is conducted in a community for that community's ultimate benefit. You do have to be ever vigilant. As scientists, we have to think about what is the best thing to do. Politics should not be our primary concern. She added that the idea of working with nurses in Kenya is interesting.

Dr. McKinnell asked about the real-world relevance of TDF prophylaxis, in terms of adherence, if we're successful. Would there be a problem with compliance? Dr. Paxton responded that a 50 percent reduction would translate into really large numbers, adding that TDF's long half-life might help, although that is not really known at this point.

Dr. Sweeney asked what percentage of people actually engages in prevention. She also asked about cost and resistance factors. Dr. Paxton said we do have better modalities, like the condom, that are available right now. She noted many people don't use them either. She thinks that the more choices we give people, the more likely we are to find a prevention method they will use. She said TDF's cost is falling, and is currently about 80 cents. While that may seem affordable to us, that is still out of reach of many in the developing world. In the trials it's inevitable that someone will become positive while using TDF. CDC hopes there won't be much resistance, but we don't know. That's why we're doing the studies.

Dr. Judson asked about the origins of the CDC's and other prophylaxis studies. Dr. Paxton said the Buenos Aires conference was the beginning, then TDF's manufacturer started thinking about it, as well as the Gates Foundation. She added she believes we will not be able to treat our way out of the epidemic, that TDF may provide secondary and tertiary prevention possibilities, and that she thinks there will be some disinhibition. "Those in greatest need are least likely to comply. They are also the least likely to be able to afford it."

Dr. Bowers-Stephens asked whether there will be a placebo in the U.S. safety trial. Dr. Paxton said no. Participants will be asked a number of questions including about the use of condoms.

Dr. Primm said the primate studies seem to indicate that route of exposure has an effect on effectiveness, and Dr. Paxton confirmed that the CDC studies will be looking at that.

Mr. Mason then introduced Ambassador John Miller to give a presentation on human trafficking and HIV/AIDS.

Presentation
"Human Trafficking," by Ambassador John Miller, Director, Office to Monitor and Combat Trafficking in Persons, U.S. Department of State

Ambassador Miller said he was here to share information and to ask for the Council's help. He was accompanied by Laura Lederer of the State Department's Global Affairs Office.

Most Americans would be surprised to find out that there is slavery in the 21st century, but in fact there is, with 800,000 men, women, and children trafficked every year into slavery over international borders. There is also domestic servitude.

The challenge to control global and domestic trafficking extends to every nation in the world. Trafficking for sex slavery is rampant and mostly affects girls. He has met many girls and young women who have suffered, and he knows their stories, such as the story of Katia from Czechoslovakia, who left her home with her 2-year-old after a failed marriage and went to work in Amsterdam. There, she was taken by traffickers who threatened her 2-year-old's life unless she became a sex worker.

Prostitution is drawing women all over the world into sex slavery. Patterns show transnational travel and implications for the HIV/AIDS epidemic worldwide. Ambassador Miller recalled one young female victim in Cambodia who was dying of AIDS. When she was younger, she had been taken from her village by a man who she thought would marry her, but it turned out that she had been sold. She was put to work as a sex worker to pay off her debts. The only way she became free of her slavery was to get sick.

Ambassador Miller said he needs the Council's help because of the tie-in between trafficking, sex slavery, and HIV/AIDS. Many in the sex trade want to leave their jobs. Many are in danger. He concluded that he is impressed by the human trafficking resolution before the Council because it attempts to link human trafficking and HIV/AIDS.

Dr. McIlhaney asked for permission to show a few slides of data relevant to the resolution.

Slide 1: Brothels and Core Transmitter Connection. "Asian countries with the highest HIV prevalence (2–3 percent of their 15–49-year-old population)…all have brothel-based female sex workers (FSW) as a dominant factor." (From the WHO HIV/AIDS in Asia and the Pacific Region 2001 report.)

Slide 2: HIV Transmission in Thailand: FSW to Client to General Population. "The noted success of Thailand, with its 100 percent condom program for all commercial and casual sex, has not had much effect on the slow but steady transmission of HIV from infected male clients of FSW to their regular sex partners (wives and girlfriends)." (From the same report cited above.)

Slide 3: Chart: HIV Prevalence in General Populations and FSW by Asian Country. An example was given of 2.8 percent prevalence in the general population of Cambodia but 38 percent among FSW, with 16–78 percent condom use by FSW.

Dr. McIlhaney concluded there is a direct relationship between sex workers and HIV prevalence. He thanked his coauthors of the resolution: Dr. Jane Hu, Dr. McKinnell, and Ms. Lederer. Ms. Lederer added that the heart of the resolution is that we want all the U.S. Government agencies to see the link and address it.

Question and Answer Period

Dr. Primm wondered about slavery in Saudi Arabia and East Africa. Ambassador Miller said his Office prepares an annual report on slavery around the world. The U.S. Justice Department also prepares a report on the United States. In Africa, there is a huge sex slavery tie between Nigeria and Italy. In the Middle East, there is quite a bit of domestic servitude slavery and some sex slavery. We need to focus more on demand and destination countries, like Italy and the United States. Next year we hope to do better.

Ms. Ivantic-Doucette noted the TDF prophylaxis studies that involve sex workers and asked if we do some things through research design or inadvertently that we shouldn't. Ambassador Miller said not every trafficking victim is an HIV/AIDS victim and vice versa.

Ms. Smith asked which is the lead agency on this issue and how are its efforts being coordinated with those of private organizations? Ambassador Miller said President Bush formed a Presidential Task Force on Trafficking Victims, and now he chairs an intergovernmental group on the subject with representation from all the major U.S. agencies. The positive news is that Governments around the world are waking up to the problem, and today there are more cases and more shelters than ever before. Nongovernmental organizations involved include the International Justice Mission, the Salvation Army, and Shared Hope.

Ms. Shoemaker asked what individuals can do to help. The Ambassador said media coverage of the issues has been helpful in increasing public awareness. Individuals can help by keeping their eyes and ears open and reporting to local law enforcement those they believe are involved in trafficking or are victims. More civic and religious groups need to get involved as well.

Dr. Green thanked the Ambassador for his passionate presentation. He asked how one goes about abolishing the sex trade, and how one identifies the sex trade in Africa, where there is "a lot of transactional sex." The Ambassador said there are no easy answers, but addressing causes, such as poverty, would help. He noted the Swedish success story, which began when the Government decided to arrest anyone procuring and trafficking. Although the problem of sexual slavery and prostitution hasn't been eliminated there, the number of victims going into Sweden has dropped dramatically. In Korea, 1 million women signed a petition against the sex trade, and then the Korean National Assembly passed legislation to provide job training and education to sex workers. In a short period of time many sex shops and brothels have been closed. In the United States, the Justice Department has tripled its prosecutions, and agencies now have foreign language programs to reach out to victims, including migrants. We are also setting up shelters in most major cities.

Dr. Sullivan said he needs to understand why this subject is being brought to this Council. He added that the resolution needs a lot of work. He objected to the resolution's language regarding health professionals. He asked that more information be provided on

the effect that curbing trafficking would have on reducing HIV/AIDS. He asked that the International Subcommittee respond.

Mr. Mason said Dr. McIlhaney of the International Subcommittee would work with the Prevention Subcommittee on the issues outlined by Dr. Sullivan, then bring the resolution back to the full Council.

Break

International Subcommittee Report, Continued
Mr. Mason then welcomed Dr. Anthony Fauci, noting that he had the pleasure of traveling to Africa with him in December of 2003. He noted Dr. Fauci's extraordinary career and dedication, and said if a cure for HIV/AIDS is ever found, it will be due in large measure to Dr. Fauci.

Presentation
"Presentation to PACHA on HIVNET 012," by Anthony Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases, NIH

Dr. Fauci said the focus of his talk today will be the HIVNET 012 clinical trial performed several years ago and subsequently published to show the safety and efficacy of nevirapine, as well as confusing news reports containing a series of allegations about the trial.

Using a PowerPoint presentation, Dr. Fauci reminded the Council of the epidemic's global numbers, including the fact that the highest concentration of infection and illness is in sub-Saharan Africa. He noted that about 2.2 million children are living with HIV/AIDS, that in 2004 there were about 640,000 new infections among children due primarily to infection during mothers' pregnancy, labor, and delivery or via breastfeeding, and that in 2004, there were 510,000 HIV/AIDS-related child deaths.

Dr. Fauci noted the targets for ARV drugs are reverse transcriptase inhibitors, protease inhibitors, integrase inhibitors, and fusion/entry inhibitors. He noted that state-of-the-art drugs in the developed world have had a major impact not only on newly diagnosed HIV/AIDS patients but on HIV/AIDS-related deaths.

In Africa, Dr. Fauci has seen firsthand the dichotomy between people who need drugs and those who are getting drugs. For example, in sub-Saharan Africa only 8 percent of people who need drugs get them. For mother-to-child transmission (MTCT), he added, the most effective strategy will be availability of potent, combination ARV therapy in the entire HIV-infected population. However, that is not feasible today in many countries in the developing world.

Dr. Fauci showed slides that contained important dates for key studies in understanding confusion that has arisen regarding nevirapine and MTCT. First, nevirapine was approved by the FDA for safety and efficacy in 1996—longer ago than many news

reports seem to indicate. It was the first in a new class of drugs—non-nucleoside reverse transcriptase inhibitors. Pediatric approval was granted in September of 1998.

Scientists saw that nevirapine might be a way to give a brief-course therapy to prevent MTCT through one dose to mother, one to baby. In 1997, the HIVNET 012 randomized study began. The trial took place in Uganda, and the results were published in The Lancet in 1999 as "Intrapartum and Neonatal Single-Dose Nevirapine Compared with Zidovudine for Prevention of Mother to Child Transmission of HIV-1 in Kampala, Uganda: HIVNET 012 Randomised Trial" (Laura A. Guay et al.).

In 2003, an 18-month followup study of the HIVNET 012 Randomised Trial (J. Brooks Jackson et al.) was published in The Lancet, showing that nevirapine blocked HIV transmission through breastfeeding. Earlier, the South African SAINT trial ("The SAINT Trial: Nevirapine versus ZDV +3TC in Prevention of Peripartum HIV Transmission," University of KwaZulu-Natal Medical School, Congella, South Africa) had preliminarily concluded that both nevirapine and ZDV + 3TC were effective, "with results comparable to those observed with NVP (nevirapine) in HIVNET 012 and with ZDV/3TC" in another study. No drug-related maternal or pediatric serious adverse events were reported.

A Thai study released soon after didn't address whether nevirapine alone was effective in blocking transmission, but it did add data to what was known about the safety of nevirapine in a single dose. Again, no serious adverse effects were found. Dr. Fauci emphasized that the safety of nevirapine in a single dose has been corroborated in multiple studies.

In 2004, G. Jourdain et al. published the results of their study in The New England Journal of Medicine ("Intrapartum Exposure to Nevirapine and Subsequent Maternal Responses to Nevirapine-Based Antiretroviral Therapy"). Dr. Fauci summarized the results of the study, emphasizing the finding of resistance mutations, but also noting the importance of clinical relevance:

- In an observational study in Thailand, immunocompromised women (CD4+ T-cell counts <250/mm to the third) received either intrapartum NVP (n+221) or no intrapartum NVP (n=48), and then began NVP-containing HAART.
- At day 10, 32 percent of mothers receiving intrapartum NVP had resistance mutations.
- At 6 months, mothers on NVP-containing HAART achieved maximal virologic suppression (<50 HIV RNA copies/ml) as follows—no intrapartum NVP (n=40), 68 percent; intrapartum NVP, no NVP resistance mutations (n=119), 52 percent; intrapartum NVP, NVP resistance mutations (n=61), 38 percent.
- The groups had similar clinical improvement and equivalent increases in CD4+ T-cell counts.

The key points here are that there was some resistance, but clinically the team didn't see any difference. The question was, is this genotypic resistance a show stopper? The researchers concluded it was not.

Later in 2004, Hoosen Coovadia, M.D., published an article in The New England Journal of Medicine entitled "Antiretroviral Agents—How Best to Protect Infants from HIV and Save Their Mothers from AIDS." Dr. Fauci emphasized Dr. Coovadia's conclusion that the Jourdain et al. study findings "are not a reason to abandon single-dose nevirapine for the prevention of MTCT. … Single-dose nevirapine is a regimen of striking simplicity, efficacy, and affordability."

Addressing the toxicity of nevirapine, Dr. Fauci quoted the FDA's January 19, 2005, advisory, which noted that while clinically symptomatic and asymptomatic liver toxicity has been observed with long-term use of nevirapine in combination with other HIV drugs, symptomatic liver toxicity has not been reported with the use of single doses of nevirapine to the mother and child.

Dr. Fauci showed two slides of critical chronological points in the HIVNET 012 study and related studies, as well as Boehringer Ingelheim's filing in 2001 with FDA for permission to expand use of nevirapine in the United States to MTCT. In 2002, site visits to Kampala turned up procedural issues with regard to a HIVNET 012 followup study. Later that year, Division of AIDS (DAIDS) staff unanimously concluded that the procedural issues identified had no bearing on the proven safety and efficacy of the single-dose nevirapine regimen. Plans were made and carried out for a series of DAIDS remonitorings. In 2003, DAIDS published an "Omnibus" report of its findings, and in 2004, allegations began to appear in the press, beginning with the Associated Press (AP), that U.S. officials knew of drug risks in the study, that the head of DAIDS, Dr. Edmund Tramont, had altered the study, and that a woman had died during the study. A firestorm of other stories and accusations followed, including in the African press. In addition, Rev. Jesse L. Jackson made a statement critical of the NIH.

Dr. Fauci emphasized that, with his approval, Dr. Tramont had reexamined everything regarding HIVNET 012. He noted that 2 years earlier, in 2002, the NIH had published a statement that "Although no evidence has been found that the conclusions of HIVNET 012 are invalid or that any trial participants were placed at an increased risk of harm, certain aspects of the collection of the primary data may not conform to FDA regulatory requirements." Dr. Fauci called these technical difficulties in the study that wouldn't pass FDA muster.

Dr. Fauci then examined four allegations about HIVNET 012 and provided facts.

Allegation 1: NIH officials were warned that research on nevirapine was flawed and may have underreported thousands of severe reactions including deaths.
Fact: This statement is absolutely false. Monitoring reports of HIVNET 012 found no additional serious adverse reactions related to nevirapine. The original published study and the multiple subsequent reviews of the HIVNET 012 trial found only a very small number of serious adverse reactions that potentially might be due to nevirapine.

Allegation 2: NIH officials chose not to inform the White House in the spring of 2002 about safety issues concerning nevirapine.
Fact: There is no truth to this allegation. No direct report to the White House was necessary because there were no new data that changed the conclusion of the initial HIVNET 012 report, that is, that single-dose nevirapine is a safe and effective regimen for blocking mother-to-infant HIV transmission.

Allegation 3: There has been scientific and administrative misconduct by staff within NIAID's DAIDS.
Fact: These allegations have been assessed by the NIH Office of the Director and have been found to be completely without merit. To address the issues of the scientific validity of the study, the NIH has contracted with the Institute of Medicine (IOM) to conduct an additional independent review of HIVNET 012.

Allegation 4: Dr. Tramont inappropriately "altered" a remonitoring report related to HIVNET 012.
Fact: These allegations are false. As Director of the NIAID DAIDS, Dr. Tramont had the overall responsibility for generating a remonitoring report of HIVNET 012. He edited several subreports (initially drafted by several DAIDS staff members) to make sure that the final omnibus report accurately reflected the entire remonitoring process.

Dr. Fauci concluded his presentation by showing Dr. Tramont's impressive vitae, adding that Dr. Tramont can't respond himself to these allegations due to an ongoing personnel dispute and the restrictions of the Privacy Act.

Question and Answer Period
Dr. McKinnell asked if there is any way to sensitize the news media. Dr. Fauci said his experience with this situation is very discouraging. The result has been terrible in sub-Saharan Africa, particularly in South Africa.

Ms. Clements asked Dr. Fauci how we can tackle the myths such as that the virus is manmade and is intentionally being used to destroy Africans and African Americans. Dr. Fauci said that, in general, many people don't know the history of how African Americans actually have been mistreated in the past. Continuing education and leadership is needed from black community leaders. The NIH has also tried to help, doing damage control by talking to various African Ambassadors. Also, the U.S. State Department has issued a misinformation bulletin on the imbroglio concerning nevirapine and the HIVNET 012 study.

Ms. Singleton McDonald said she is disturbed that Dr. Fauci has to spend time defending good work. She asked how the Council can help. On a personal level, she said some Council members would like to bring African American leaders to Dr. Fauci for a presentation on the matter. Dr. Fauci said a meeting would be fine. He suggested that PACHA could view the situation as an indirect attack on the President's $5 million program. He added that PEPFAR will be one of President Bush's great legacies because

he is responsible for saving thousands and thousands of African babies. That fact should come through loud and clear.

Ms. Rock noted that she works with 076 study moms and babies, and she agrees the Council needs to do something to help rectify misinformation about effective MTCT therapies here and abroad. She said one way to approach that is to wait for the IOM report. Dr. Yogev noted that a resolution on MTCT and nevirapine is already in front of the full Council and that it might help.

Dr. Primm commented that no one in the press talked about how nevirapine has saved many lives. That needs to be a main message in presentations to African American leaders and, subsequently, to the community at large. Dr. Fauci speculated that the press has not covered the drug's beneficial effects because it's not a story for them. He noted the whole matter was never reported in either The New York Times or The Washington Post.

Rev. Sanders noted that sometimes it is difficult to translate what you know into lay language, but this is something we must try to do in part to tackle mistrust.

Dr. Sullivan asked if Dr. Fauci had communicated with Rev. Jesse Jackson about his comments. Dr. Fauci said Rev. Jackson and an NIH official shared a spot on a National Public Radio show, and Rev. Jackson repeated his allegations. Dr. Sullivan said it's possible the Council could help. Dr. Judson commented that what will change Rev. Jackson's mind is if people he respects provide different information. Council members agreed to get back to Dr. Fauci on how they can help.

Treatment and Care Subcommittee Report and Resolutions

Treatment and Care Subcommittee Chair Dr. Reznik said the Subcommittee has a resolution regarding the President's State of the Union address. Other issues under Subcommittee consideration include the new Medicare prescription drug benefit, the RWCA, drug resistance, and the drug pipeline. Dr. Reznik thanked former Chair Brent Minor for his fabulous leadership.

Dr. Reznik introduced the State of the Union resolution.

Presidential Advisory Council on HIV/AIDS
Treatment and Care Subcommittee

Draft Motion
State of the Union Resolution

WHEREAS, the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, first signed into law by President George Herbert Walker Bush and subsequently reauthorized in 1996 and 2000, provides primary care, treatment, and essential support services to approximately 533,000 uninsured and underinsured people living with HIV/AIDS in the United States, and

WHEREAS, the care and treatment of persons living with HIV/AIDS is a high priority for this Administration and an important part of an effective national public health strategy,

BE IT RESOLVED that the Presidential Advisory Council on HIV/AIDS (PACHA) wishes to express our sincerest gratitude to the President of the United States of America, George W. Bush, for bringing national attention to the domestic HIV/AIDS epidemic and the disproportionate impact this disease has on African American men and women by calling for the reauthorization and modernization of the Ryan White CARE Act in the State of the Union address on February 2, 2005.

Dr. Reznik then introduced the last presenter of the day.

Presentation
"The New Medicare Prescription Drug Benefit: Impact on HIV/AIDS Care," by Christine Lubinski, Executive Director, HIV Medicine Association

Ms. Lubinksi said her goal is to give a snapshot of the new benefit and identify challenges and issues for people with AIDS who qualify.

Using PowerPoint slides, Ms. Lubinski provided Medicare 101. Medicare is:

- The Federal health insurance program for the disabled and elderly (65 years plus)
- Administered by the Centers for Medicare and Medicaid Services (CMS)
- A national standardized health plan with eligibility, benefits, and costs to beneficiaries
- An entitlement program, in which HIV/AIDS patients qualify primarily through disability.

Medicare and HIV/AIDS:

- There are about 60,000–80,000 Medicare beneficiaries with HIV/AIDS.
- They qualify for Medicare after approximately 2 years of disability, and currently there is no drug benefit; there is the AIDS Drug Assistance Program (ADAP).
- 70–85 percent of the beneficiaries also qualify for Medicaid as dual eligibles (getting full coverage from both programs), and Medicaid acts as a wraparound.

There are approximately 50,000 dual eligibles. They:

- Are disabled, poor, and in the end-stage of illness
- Rely on Medicaid for HIV medication
- Have varied benefits based on geography
- Sometimes use ADAP to supplement Medicaid medication limitations (for example, Texas covers four prescriptions per month; the rest are picked up by ADAP).

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 was signed into law on December 8, 2003. It is the biggest change to Medicare in 40 years. Primarily it adds a prescription drug benefit to Medicare.

The benefit starts January 1, 2006, but enrollment begins November 15, 2005 (earlier for dual eligibles).

The beneficiary chooses from a stand-alone prescription drug plan (PDP) or a managed care plan (Medicare Advantage) that includes a prescription drug plan (MA-PD), but this choice exists only if a Medicare Advantage plan is available where the patient lives.

The premium in 2006 is expected to be $35 per month, although this will vary by plan. All beneficiary costs and subsidy eligibility will be adjusted annually.

If a beneficiary is not subsidized, the plan will not cover the $250 deductible. It will cover 75 percent of the initial benefit from $251 to $2,250. It will then not cover what is called the donut hole, or annual expenses of between $2,251 and $5,100. After that, catastrophic coverage above $5,100 will be covered at 95 percent.

Generous low-income subsidies are available for beneficiaries with incomes below 135 percent of the Federal poverty level (FPL) in 2006. Those eligible for full subsidy for payment of deductibles or premiums are those who are:

- Dually eligible
- Receiving Supplemental Security Income (SSI)
- Earning below 135 percent of the FPL with asset limits of $6,000 if single and $9,000 if in a couple.

Low-income subsidies for beneficiaries with incomes between 135 and 150 percent of FPL (2006) are available for individuals with incomes below 150 percent of FPL and asset limits of $10,000 if single and $20,000 if in a couple. This subsidy provides for a sliding scale premium and a $50 deductible.

Dual eligibles need to know that:

- States will no longer receive Federal matching funds for Medicaid prescription drugs for duals.
- They must switch to Medicare for drug coverage.
- The impact will depend on the State's previous Medicaid plan and Medicare drug plans available in the area.
- Access is limited to the "average cost plan."
- They will be automatically enrolled in the drug plan in the fall of 2005 unless they choose another plan.
- They can maintain Medicaid coverage for other health care services.

Issues and challenges for beneficiaries include:

- Deciding whether to enroll if they have a choice. There are financial penalties for delayed enrollment.
- Enrolling in the low-income subsidy program: Will beneficiaries know they are eligible? Will they sign up?
- Comparing plans and deciding which to join when there could be wide variations in premiums, benefit design, formularies, and preferred drug lists each year.
- Facing the consequences of a bad decision, such as an annual lockin.
- Tracking total out-of-pocket pharmaceutical costs, which is important due to the benefit gap.
- Facing formulary changes with 60 days' notice.

Other issues include copays, which may discourage people from filling their prescriptions.

In terms of ADAP:

- It cannot provide "countable" wrap-around coverage to the new drug benefit.
- It will not count toward true out-of-pocket (TrOOP) costs, which trigger catastrophic coverage.
- ADAP may provide supplemental coverage in the form of subsidizing premiums or copays and covering nonformulary drugs, but coverage will be costly and ongoing for ADAPs, and persons will not reach the catastrophic coverage limit.

The problem is that the new program doesn't really help ADAP, Ms. Lubinski said. For example:

- Beneficiaries could experience an erosion of drug coverage as they transition from ADAP to the new benefit.
- Medicare beneficiaries with AIDS (including dual eligibles) may continue to need ADAP assistance to pay premiums and copays and to supplement inadequate formularies, if States are willing and able to do so.
- Financially strapped ADAPs will experience minimal fiscal relief and new challenges as a result of the new benefit.

Formulary requirements are a problem. For example:

- Plans are not required to cover all HIV antiviral drugs.
- Plans are encouraged but not required to comply with Federal guidelines for HIV/AIDS treatment.
- Plans are only required to cover two drugs in each therapeutic class, and the model formulary developed so far outlines four classes of HIV drugs—nucleosides, nonnucleosides, protease inhibitors, and others.

The good news is that CMS will review plan formularies to ensure they do not discriminate against certain groups of beneficiaries in their formularies or in their drug cost tiering structure.

Ms. Lubinski added she is hopeful CMS will provide proper oversight and not approve formularies that do not have all the ARV drugs, and she is hoping that the Council will support this.

In addition:

- Drug plan Pharmacy and Therapeutic Committees are required to have minimal physician representation, and there is no specific requirement about consultation with HIV medical experts in formulary development.
- Plans are required to send formulary information to beneficiaries in writing prior to enrollment.
- Plans are required to give beneficiaries 60 days' notice before removing a drug from the formulary. Physicians and beneficiaries may file for an exception based on medical necessity to continue receiving the drug.
- Plans are not required to cover drugs for off-label indications (and there are many used for HIV/AIDS patients), but CMS has indicated it will not allow plans to have a burdensome process for requesting this kind of coverage.

There is a procedure for grievances and appeals. Early drafts of CMS regulations on it were flawed. The current regulations are somewhat better due in part to advocacy intervention. The procedure currently:

- Allows an appeal for a drug not on a formulary only if the prescribing physician determines no other covered drug is as effective or there will be adverse effects.
- Allows a 72-hour time frame for coverage determination under a standard appeal.
- Allows an automatic expedited appeal if it is supported or initiated by a physician, and the response must be within 24 hours, initially.
- Does not require, in most instances, an emergency supply of medicine pending appeal.
- Permits appointed representatives, including physicians, to file an appeal on behalf of the beneficiary at all appeal levels.

Ms. Lubinski's organization will continue to advocate for a new drug benefit that:

- Ensures comprehensive coverage of HIV medications on plan formularies based on Federal HIV guidelines (at present, this is referenced in the CMS regulations but not required).
- Allows ADAP to supplement benefit and count expenditures as true out-of-pocket costs (at present, this is not allowed).
- Ensures coverage for off-label use of medications (at present, this is allowed but not required).

- Allows all medically necessary drugs to count toward the catastrophic limit (at present, this is not allowed).
- Allows dual eligibles the full range of health plans in their areas without additional premium costs, not just average cost plan (at present, this is not allowed).
- Does not deny dual eligibles medications for failure to pay cost-sharing (at present, this is denied).

In addition, Ms. Lubinski advocates changing the law to allow Medicaid to supplement Medicare coverage with Federal matching funds, at least through the transitional period, to ensure continuity of care.

What PACHA can do:

- Support an ADAP wraparound as countable toward out-of-pocket costs, which is an HHS policy decision.
- Support requiring that drug plans cover all HIV drugs.
- Support transitional Medicaid drug coverage for dual eligibles to ensure continuity of care.
- Request a CMS presentation on efforts to educate and enroll Medicare beneficiaries with AIDS (particularly dual eligibles).
- Monitor implementation after January 2006 by requesting ongoing reports and presentations from CMS on exceptions filed, coverage of HIV drugs, and other quality assurance measures.

Question and Answer Period
Dr. Primm noted that working with the addicted is his experience and specialty. Therefore, he is concerned about Medicare's not paying for treatment of IDUs who need to be maintained on an alternative. This problem will extend to about 60 of his daily patients. Ms. Lubinski responded that neither Medicare nor Medicaid handles addiction very well, but at least some States will continue to pay. Dr. Primm said CMS needs to address this and correct it.

Ms. Ivantic-Doucette wondered if the only gatekeepers are physicians, when most of the delivery of care and prescribing is falling to nurse practitioners and physician assistants. Ms. Lubinski said her organization primarily represents physicians, so that's why she referred to them when it comes to grievance and appeals. However, under the regulations, the gatekeeper can be anyone appointed by the patient. She will check the language. She added that it's unclear to how the freestanding drug plans and the new Medicare Advantage plans will interface with Medicare regional regulations.

Dr. Reznik said the Subcommittee would request that information.

Dr. Judson commented that this benefit has turned out to be something that only Americans can understand. We started out with a political demand for a drug benefit, Congress looked at what was politically bearable, and now we have a number of

regulations that are highly problematic. What is the process? Does CMS have full authority to change the regulations? Ms. Lubinksi noted that the draft regulations were subject to comment. Then final regulations were promulgated 10 days ago. CMS has said it will issue additional guidance in some areas. Now there is speculation that Congress will take another look at the law. A number of advocates are saying it should, for continuity purposes. Her opinion is Congress will take another look only if it has to and if it can narrowly control changes. PACHA can help by making sure that CMS conducts oversight and review of the drug formularies, and monitors the benefit.

Dr. Reznik said the Subcommittee is working on a motion that addresses these points and also how the benefit could free up ADAP. He asked for e-mail input from the full Council.

Ms. Shoemaker characterized the presentation as frightening, given that she is a single woman with AIDS who makes more than $6,000 per year with the help of Social Security. She gets food stamps and coverage for her Blue Cross/Blue Shield premiums. She owns her home and a car. She has no out-of-pocket money left. Now, as a survivor, she feels she is being penalized.

Ms. Clements said she is particularly concerned about the elderly. She asked if there is an upside to the new benefit. Ms. Lubinski responded that if you have no coverage at all now you'll get some, which could be very significant. If you have no coverage at all and high drug needs, the new benefit will be significant. However, 2 million people might lose other benefits. It remains to be seen. The devil is in the details. Will the benefit be generous enough and easy enough to access? We don't know right now. The law is very flawed. It was a sausage-making process by Congress.

Mr. Minor agreed that the new benefit as currently configured is very scary. He advocated that PACHA learn the financial implications. He advocated that PACHA make sure all the needed medications are part of the program, not just two per class. Public Health Service guidelines are needed here. It's a great role for PACHA to stand up and make sure that people continue to have access to needed medications.

Dr. Reznik promised the Council that the Subcommittee would return with a motion. He turned the meeting back over to Dr. Sullivan.

Dr. Sullivan called the day full and productive. He announced that Ms. Smith will chair Day 2.

Dr. Primm commented that he'd like to think President Bush's mention of the RWCA came from the urgings of this Council. Dr. Sullivan said he believes President Bush is paying attention to the information he receives from PACHA but that he has a number of important sources of advice.

Ms. Singleton McDonald asked when the Council will meet the new HHS Secretary as well as the President, again. Dr. Sullivan said the new HHS Secretary, Michael Leavitt, hopes to come to the Council's meeting tomorrow.

Dr. Sullivan then adjourned the meeting.

Adjournment

Presidential Advisory Council on HIV/AIDS
26th Meeting
Hubert Humphrey Building
200 Independence Avenue, S.W.
Room 800
Washington, DC 20201

February 8, 2005

Council Members—
Present
Louis Sullivan, M.D., Council Co-Chair
Anita Smith, Council Co-Chair
Abner Mason, Chair, International Subcommittee
David Reznik, D.D.S., Chair, Treatment and Care Subcommittee
M. Monica Sweeney, M.D., M.P.H., Chair, Prevention Subcommittee
Rosa M. Biaggi, M.P.H., M.P.A.
Cheryll Bowers-Stephens, M.D., M.B.A.
Jacqueline S. Clements
Mildred Freeman
John F. Galbraith
Edward C. Green, Ph.D.
Cheryl-Anne Hall
Jane Hu, Ph.D.
Karen Ivantic-Doucette, M.S.N., F.N.P., ACRN
Rashida Jolley
Franklyn N. Judson, M.D.
Sandra Singleton McDonald
Joe McIlhaney, M.D.
Henry McKinnell, Jr., Ph.D.
Brent Tucker Minor
Jose Montero, M.D., FACP
Dandrick Moton
Beny Primm, M.D.
Debbie Rock
Rev. Edwin Sanders
Lisa Mai Shoemaker

Ram Yogev, M.D.

Council Members—
Absent
David Greer
Prem Sharma, D.D.S., M.S.

Council Staff—
Present
Joseph Grogan, Esq., Executive Director
Dana Ceasar, U.S. Department of Health and Human Services (HHS)

DAY 2

MORNING SESSION

Welcome Remarks
Council Co-Chair Anita Smith welcomed everyone and asked that the meeting stay on schedule as much as possible, particularly so Subcommittees will have sufficient time at lunch to work on draft motions. The Council will also have presentations and a continued report by the Treatment and Care Subcommittee.

Dr. Louis Sullivan noted that the new HHS Secretary, Michael Leavitt, may come to the Council meeting around 1:45 p.m. If the Council meeting is over by then, would Council members be interested in staying to meet Mr. Leavitt? The majority of the Council indicated they would stay.

Ms. Smith then turned the meeting over to Treatment and Care Subcommittee Chair Dr. David Reznik.

Treatment and Care Subcommittee Report, Continued from Day 1
Dr. Reznik said the themes this morning would be drug research and drug resistance. Those of us who have been working on AIDS before AIDS drugs were available know how important these drugs are to their loved ones. Now we're stalled in new drug developments, and resistance is playing a role.

Dr. Reznik then introduced Dr. Henry (Hank) McKinnell, Jr., to present on drug research. Dr. Reznik recalled when he was sworn in as a PACHA member. He was a little overwhelmed. When he met Dr. McKinnell at that time, he wondered to himself what he could possibly have in common with the chief executive officer (CEO) of the world's largest pharmaceutical company. But he has seen Dr. McKinnell roll up his sleeves with PACHA and get very impassioned about an epidemic that has affected many of our lives.

Presentation
"HIV Medicines: Developing the Future," by Hank McKinnell, Chairman and CEO, Pfizer, Inc.

Dr. McKinnell thanked Dr. Reznik for his kind introduction. He is in his third and final year with PACHA. HIV/AIDS has become a manageable disease for those with access to HIV/AIDS drugs. But since the development of highly active antiretroviral therapy (HAART) in the mid 1990s, we've been locked in a race, trying to keep ahead of resistance by this insidious virus. Behind his presentation are thousands of his colleagues at Pfizer who very much want to bring to the battle the next generation of drugs. We must

realize the long lead times required—10–15 years. Pfizer constantly readjusts its forecasts and assumptions. Researching drugs is the most complex research process in modern society. Few researchers ever see a new medicine come out of their work. Pfizer spends $7.5 billion per year in developing new medicines. Because of the drug research industry's unique capabilities, "we are an indispensable partner" in the fight against HIV/AIDS.

Against that backdrop Dr. McKinnell discussed a number of issues, including access to drugs, the risks and costs of developing new drugs, and the need to always put the patient at the center of drug research and development efforts.

Since 2002, PACHA and its partners in the fight against HIV/AIDS have made good progress. Early testing and treatment are more accessible thanks in part to PACHA's call for rapid testing. Now testing should become routine and widespread. The goal of expanding Medicaid and Medicare coverage for those most in need has met with mixed success. While the new drug benefit is good, States are lowering their Medicaid funding. Reform and reauthorization of the Ryan White CARE Act (RWCA) is needed—it must continue—but we must now also stress prevention and early treatment.

Good strides have been made in increasing patient access to trained HIV/AIDS clinicians and in collaborations with nongovernmental organizations (NGOs) and patient support groups. Here, Pfizer has helped with its partnership in Kampala. Last, the large pharmaceutical companies have developed 9 of the 10 new medicines available to HIV/AIDS patients, but now we need to get these medicines to poorer nations at a lower cost.

Dr. McKinnell showed a slide of the worldwide pandemic, noting that the total number of adults and children living with HIV is 35 million to 42 million.

Dr. McKinnell ran down a list of the current U.S. Food and Drug Administration (FDA) approved medicines for HIV/AIDS—27 medicines in four classes. He said this number can increase significantly over the next 7 years. New therapies will be needed before waves of current medicines become resistant.

What does it take to discover and develop new HIV/AIDS medicines? Research-based pharmaceutical companies are the key. They have developed and brought to patients the four major classes available so far because of their unique capacity and expertise and the fact that they are the world's largest and best source of scientific research that leads to discovery and development of medicines. He noted that there is only so much the Government, academia, the biomedical industry, and publicly funded research can do because the development process can take so long, cost so much, and has a failure cap.

Dr. McKinnell showed a slide of the general process of biomedical research and development from discovery to approval. There are several discovery approaches for each target; Phase I, II, and III trials; and then the FDA review.

There has been great consolidation in the industry. In 1988, 42 companies were members of the Pharmaceutical Manufacturers Association (PMA). In 2003, 16 were left, including Pfizer. “This business is up or out. Each medicine comes with an expiration date. Either my company continues to compete or it will get absorbed by others who do it better. Is this bad? There is great pressure to innovate or be gone.”

Dr. McKinnell lauded the FDA’s expedited review of HIV/AIDS medicines through the preapproval access, fast-track approval, and a shortened testing and review process. But additional postmarketing safety and other requirements add significant costs, so despite expedited review, cost and development times for new medicines remain substantial. For example, it costs $492 million to develop an anti-infective medicine and some $800 million to develop a medicine for chronic problems, such as high blood pressure.

Challenges in research and development of new HIV medicines include:

- The complexity of the virus—the challenge of treating chronic viral disease and associated conditions
- The new challenges for innovation and production that come with each new class of drug
- Higher expectations—for simple treatments with fewer side effects and fixed-dose combinations (FDCs).

“This is the most complex virus we’ve ever seen. Eventually, it outsmarts all the medicines developed to date.” Each new class of drugs presents new challenges, including cost, which is mostly research and development with the exception of Fuzeon, which is also very difficult to produce, requiring 100 manufacturing steps.

Dr. McKinnell noted that even by conservative estimates of the total number of HIV patients in the United States, only 50 percent are on drug therapy, and 50 percent of those have reduced options for drug therapy. That’s not counting newly infected individuals, 10-25 percent of whom are never treated but are resistant to one drug class or another. Internationally, there is a lack of viable second-line options due to problems such as lack of health infrastructure, refrigeration, and expense. In addition, lessons learned about current regimens and resistance in the United States may not apply to developing nations. That necessitates research on all HIV subtypes. “Can you imagine 3 million people in developing nations failing treatment? It is a nightmare.”

Overall motivations for new treatment options include to:

- Improve quality of life through simpler, better tolerated regimens
- Improve tolerability and reduce short- and long-term toxicities
- Help people facing resistance
- Reduce the spread of HIV
- Improve access—domestically and internationally.

Dr. McKinnell called for expanded partnerships among stakeholders, including greater cooperation between the pharmaceutical companies. Greater cooperation would reduce costs and result in more FDCs. Expanded partnerships could also enhance vaccine research. Dr. McKinnell called for greater funding for vaccine research but added he is a skeptic. "We should behave," he added, "like we'll never have one."

His vision for the future is to:

- Continue to strive to overcome daunting challenges, such as rising HIV/AIDS rates in China, India, and Russia
- Enhance prevention and education
- Continue to research and develop new treatments with needed incentives.

Concluding, Dr. McKinnell said the large pharmaceutical companies are not part of the problem; rather, they're integral to the solution. He noted that while it's preferable to prevent HIV infection, "we need to keep in balance risk versus incentive for new drug development. Treatment saves lives, and early treatment saves money."

That is one reason why, he added, PACHA needs to do something about the new drug benefit's seemingly short-sighted formulary regulations.

Question and Answer Period

Rev. Sanders noted that we see major results from the private sector at the same time Government resources seem to be growing scarcer. Should we continue to expend large amounts of money on vaccine development, particularly when we might be able to succeed with behavioral modifications? Dr. McKinnell said adding all the money spent on HIV/AIDS from private and Government research across the board would total about $100 billion. You could ask how that might be better allocated, but you would gore some prized oxen along the way. In fact, we don't spend enough in prevention. We should also focus on what a reasonable timeframe for research is. If you believe a vaccine is 20 years away, as he does, more resources won't help. Scientific leads are needed. In terms of RWCA, we should put more money on rent subsidies or shortening waiting lists. More money is a cheap answer. Better allocation is an excellent project for PACHA.

Dr. Judson congratulated Dr. McKinnell for being a leader and an excellent spokesman for the industry. He asked what proportion of all money spent on HIV/AIDS medicines is coming from the Government. Dr. McKinnell responded that it must be 80 or 90 percent. Dr. Judson wondered how much the industry spends per year on marketing and on "me too" drugs. He added that it seems innovation has taken a back seat in the industry. Dr. McKinnell said of Pfizer's 15 percent of expenditures spent on marketing, about 3 percent is used to provide medicines free of charge and another 6-8 percent to pay bills. The balance is spent on marketing which, most often, is education of physicians and patients. He added that someone has to make the investment to make the new medicines, and that the large pharmaceutical companies have a system for doing that. For example, CCR5 represents a new class of HIV/AIDS drug therapy. It was developed in Pfizer labs. It will be available in a few years. When it is available, the company will need to recoup

its investment as well as make the drug affordable and accessible. Those who can't afford access should get it for free or at low cost. Those who can pay need to. If they don't, it won't be available for anyone else. The industry's new part of this bargain is to make them available.

Dr. McKinnell added that 5 years from now, the industry will look very different than it does today. Productivity declined in the 1990s. At same time, there were many new targets. The industry strove to develop drugs for these targets but struck out a lot. Today, however, the industry is on the edge of a boom in productivity. Pfizer alone will have filed for approval of 20 new medicines by the end of 2006, including some big ones, such as CCR5, and another drug that will help lower bad and increase good cholesterol.

Dr. Reznik commented that those who are multidrug-resistant are a smaller subset of the HIV/AIDS population and that, therefore, they are less profitable as a development target. He asked if there is anything PACHA can do to encourage further development, for example, on CXCR4. He also commented that Americans are irritated by having to pay so much for drugs against the fact of drug price controls in Europe and Canada and asked, how can we help?

The U.S. Government could help, Dr. McKinnell responded. The Government needs to negotiate with foreign governments. For example, the Canadian Government tells the U.S.-based companies what they can charge, which is 30-40 percent less than what they charge in the United States. "We've asked the U.S. Government to address this trade issue, including putting it on the G-8 agenda."

Dr. Reznik said PACHA could recommend that the issue be brought up at the G-8 meeting.

Dr. McIlhaney commented that he often defends the large pharmaceutical industry's independence and pricing, but drugs are only a holding effort until prevention works. We need to redouble our efforts in prevention. Dr. McKinnell characterized that as one of the elephants in the room. We should also track partners of those who are infected. If we were serious about zero new infections, we might think about calling for some new measures, but they might not be acceptable. He wouldn't, however, give up on the technology, because drug development advances are being made.

Ms. Rock supported the need for people to have access to medicines and the importance of adherence, but people also need help with meeting basic needs. If basic needs aren't met, it's difficult for patients to continue to go the doctor and stay on medications. Dr. McKinnell said his goal is to treat the disease early so people can stay at work, receiving an income and paying taxes. "We tend to think in terms of costs, but we need to think of the total system."

Dr. Sullivan commented that the industry takes risks and often loses, but when it wins, losses are offset. A lot of people have trouble with that. Why is it so difficult to get other developed nations to underwrite research? Also, is there discussion of trying another

model of development, such as having the Government underwrite the costs and contract with the pharmaceutical industry? Dr. McKinnell said he has considered that, but it's not a solution. For one thing, Governments aren't very good risk takers. Unfortunately, he said, "We've defined the problem in health care as its high cost. When you do that, you ration and control. If we defined the problem as the high cost of disease, everything would change. Investing in avoiding heart attacks and strokes is more rewarding than paying for heart attacks and strokes. The prevention model works." He noted Pfizer's partnership in prevention with Florida Medicaid that improved health outcomes by 50 percent or more as well as saved the State a lot of money.

Dr. McKinnell added that the U.S. Government needs to go to Australia, Canada, and other developed countries and say the game is over, that "You must pay your fair share. Some countries just take our technology through compulsory licensing and get a free ride."

Dr. Sullivan asked International Subcommittee Chair Abner Mason to consider a resolution on this issue.

Dr. Yogev commented that he disagrees with a gloomy assessment of a vaccine. There have been some breakthroughs. A vaccine would be a major prevention measure. Industry doesn't work on finding one as much as it works on other medicines because the money isn't there. However much they may be a minority group or subset, 20,000-plus kids in the United States still need a vaccine. Dr. McKinnell responded that the CCR5 development will apply to pediatrics. He added that the industry does need to do more pediatric work. He then gave a quick history of vaccines: 40 companies used to manufacture vaccines, but a combination of product liability and Government contracting practices pushed down prices and made vaccines unattractive. All but four companies have since left the vaccine industry, including Pfizer. Now the technology for human vaccines is frozen. However, Pfizer is number one in the world today in animal health vaccine research and development.

Dr. Green asked what PACHA needs to do to take up Dr. McKinnell's challenge to achieve zero new infections in the United States and abroad. Dr. McKinnell said routine and widespread testing would be his first recommendation. Dr. Reznik agreed, adding that it should take place in hospitals and other similar facilities. Ms. Cheryl-Anne Hall agreed, adding we also need early treatment.

Dr. Reznik introduced the next presenter, Dr. Richard D'Aquila, as a foremost expert in HIV/AIDS drug resistance.

Presentation

"Antiretroviral Drug Resistance," by Richard T. D'Aquila, M.D., Vanderbilt University Medical Center and the Vanderbilt Meharry Center for AIDS Research, Nashville, Tennessee

Dr. D'Aquila asked members to ask questions if he becomes too technical.

Dr. D'Aquila said the heart of his presentation is this: We're all worried for good reasons about antiretroviral (ARV) drug resistance, but has it reversed hard-fought gains in chemotherapy, is it a threat for the future, and what action is required?

HIV replication and chemotherapy is a sequential process. Current drugs tend to intervene in the process of viral entry, replication, and exit only at certain points in the sequence. What we need to do is interfere with the virus even earlier or render virions noninfectious.

The virus has many ways of getting around our defenses. It is teaching us a lot about evolution at warp speed. A great pool of variation is always present. The virus has great capacity to survive through the best variant. There is the phenomenon of escape mutants—that escape from immune pressures most common for that population. To acknowledge this could advance development of target vaccines—targeted for different immune responses.

Another important factor is the more a virus replicates on a drug, the greater the chance of resistance. This explains our historical problem with resistance: we have been using the same drugs for some time. It is critical to note, however, that mutants do get slowed down by available drugs; that is, resistance is relative, not absolute.

Does HIV resistance cause drug failure? In acyclovir-resistant herpes simplex virus (HSV), we learned the resistant virus was "fairly wimpy", i.e., HSV does not always cause drug failure. Some of the first studies to show clinical resistance to AZT, with which Dr. D'Aquila was involved, showed that a high level of resistance was associated with drug failure, but "we couldn't be sure lower levels of resistance harmed the AZT effect. Today, we can engineer a slightly better response if we identify mutations before choosing the next drug regimen for a patient."

In a relatively recent paper (Deems et al.), it was shown that, generally, CD4 count declines slowly during drug failure. The norm is some loss of drug suppression, but there is still some partial drop in viral load and some benefit. An even more recent study concluded that if viral load stays below 20,000 copies/ml, there was no worsened immunocompromise. If viral load went above that level, within months there was clinical evidence of worsening compromise.

At the Comprehensive Care Center in Nashville, "we have learned to use resistance testing and other information to help patients with failing drug therapy. Decisionmaking is driven by the degree of drug resistance observed, drug side effects, and the finding that failure does not occur suddenly but rather over the course of weeks."

Why do "failing" drugs sustain benefit? That is, why is resistance not absolute?
Dr. D'Aquila noted that:

- Drug activity against wild-type HIV results in the wild type staying suppressed.
- There is partial drug activity against resistant HIV.
- There is decreased replication capacity of resistant HIV.
- Immune response rises against antigens in the replicating resistant virus.
- There is decreased CD4 cell activation by resistant virus—statins inhibit HIV by decreasing cell proliferation.

Interestingly, in the evolution of resistant mutants for patients on drugs and patients off drugs:

- Patients on continued failing drugs experience a slow increase in both resistance and the mutant's replicative capacity.
- Patients off drugs experience a sudden change in CD4 count and viral load that is frequently associated with a shift to wild-type (or drug-susceptible) virus (a sharp increase in viral load and decrease in CD4 count leads to damage).

Dr. D'Aquila presented one case of acute HIV infection that he called unusual, in which the newly infected patient was found to be infected with not only one mutant but several. The choice was made not to treat him with drugs. Dr. D'Aquila speculates the better choice would have been to maintain pressure on the virus, with current drugs.

How common is resistant virus in North America?

- The best data come from Richman et al. who found that 50 percent of all patients studied and 87 percent of ARV-treated patients studied had detectable viremia, but they also had been on mono or dual therapies before the advent of HAART.
- In a more recent study, Harrigan et al. showed 25 percent of patients studied who had been on later drugs, including HAART, showed resistance.
- Today's standard is to start with more potent regimens, but no data are available yet on that.

Dr. D'Aquila said not all studies of newly infected patients in the United States and Europe show increases in resistance over time. One question is, is resistant virus less transmissible than wild-type? Some researchers think the answer is yes. However, we need to keep monitoring and to start drug therapy with triple combinations, always using the best available options to slow the spread of mutant virus.

Dr. D'Aquila said, "There's a clear trend we are doing better, and I think we will see less resistance prevalence."

Turning to the topic of adherence and resistance, Dr. D'Aquila showed the classic paradigm that indicates the greater the adherence the more complete the viral suppression. However, a recent paper showed that although better adherence is linear to viral suppression, it is not necessarily linear to the resistance trend. Apparently, different drugs make a difference in whether improved adherence equals better suppression as well as better resistance to drug-resistant virus.

Dr. D'Aquila showed a chart of adherence to HIV therapy in the industrialized North, with percentages of adherence as low as 53 percent in Hartford, Connecticut, and 57 percent in New York City. This has led to fears that adherence will be worse in poor areas and that more resistance will also be encountered. But a recent study of the prevalence of ARV resistance among the urban poor of San Francisco against the Nation as a whole indicated that resistance overall was lower among the urban poor with any ARV, PI, NNRTI, and RTI.

Now we are beginning to see small studies from Africa that show high adherence levels in patients on the common triple combination therapy of D4T/3TC/nevirapine (NVP).

Is average adherence enough? Dr. D'Aquila showed the results of a study in the United States (Bangsberg and Deeks) indicating that even with average adherence, HIV/AIDS drugs have had an enormous impact on morbidity and mortality. "Resistance has not yet destroyed this success."

In summary:

- Most resistance has occurred in highly adherent patients on partially suppressive regimens.
- Potent regimens reduce resistance at all levels of adherence.
- Poverty is not an international risk factor for incomplete adherence.
- Average adherence is sufficient to impact morbidity and mortality.

In conclusion, has ARV drug resistance reversed the hard-fought gains in ARV chemotherapy? Dr. D'Aquila thinks not. Is there a threat of the future? Yes, but we must make sure that the best drugs are available to everyone according to their individual needs. In addition, there must be more research and development of HIV drugs and diagnostics, and we must continue other current priorities, including HIV pathogenesis research, observational cohort research, monitoring for resistance, and clinician and patient education in expert management of resistance. Last, there is hope for better potency from new combinations, but new drugs are also needed, including those that target the virus at an earlier stage.

Dr. D'Aquila thanked Dr. David Bangsberg for his slides and recommended Dr. Bangsberg's 2004 Workshop on Disparities and the HIV Epidemic, available at *www.mc.vanderbilt.edu/root/vumc.php?site=Workshop&doc=4557*.

Question and Answer Period

In answer to questions by Dr. Judson, Dr. D'Aquila said there are ways in the lab that one could tackle replication by a nonintegrated virus. It has a short half-life. If it is not integrated in a week or 2, it's dead. He added that the rationale for monitoring in resource-poor settings is to monitor subpopulations for patterns of emerging resistance. "We need to be able to track those newly infected, too."

Dr. Sullivan asked for Dr. D'Aquila's assessment of HIV/AIDS vaccine development. Dr. D'Aquila said it holds promise. "We've learned immune responses are targeted by alleles and that epitopes of the virus presented to the immune system will be different in population A versus population B. This raises the possibility that what might be better than working with a single antigen would be working with all clades of the virus and all parts of the operative immune system. In short, it might be better to have a vaccine cocktail of different antigens that would be recognized in most people's immune systems."

Ms. Ivantic-Doucette noted that PACHA is considering a resolution regarding nevirapine, and there is concern about resistance patterns in single-dose nevirapine. PACHA is also considering a resolution about MTCT and triple combination therapy. Dr. D'Aquila responded that we need to balance what we see as risk today and the great good that has come from nevirapine prophylaxis. He does advocate triple combination for prophylaxis. "Ideally, we should be using triple combination regimes. If we had all the resources we need, I would argue vigorously for treating the mother so as not to orphan the child. While we can't eschew single-dose nevirapine right away, we should focus on developing better regimens, a combination, to minimize resistance to nevirapine."

Responding to Dr. Yogev, Dr. D'Aquila agreed that resistance is not unique to nevirapine. However, it has a very long half-life, and one dose is present at inhibitory levels for a very long time, maybe 1 or 2 weeks. In some people, it may be longer. "If you treated with nevirapine for a week or 2, you would see high levels of resistance." He noted a study on drug-treated patients in the United States that looked at response to a nonnucleoside-containing salvage regimen. It found that even with no evidence of resistance in the blood, responses were not good. In this study, researchers found mutant virus still present in low levels, and this was cause for compromise of the regimen.

Ms. Smith thanked all for the stimulating and engaging presentations and questions. She thanked the Treatment and Care Subcommittee.

Break

Ms. Smith reconvened the Council meeting. A Centers for Disease Control and Prevention (CDC) representative is available to answer questions stimulated by CDC Director Dr. Julie Louise Gerberding's presentation yesterday. Then the Council will open the Public Comment period.

CDC representative Ms. Eva Seiler noted that she is still trying to get answers about syphilis incidence in the United States and will send the answers later through Mr. Grogan. The HIV/AIDS rapid test is not available for those 12 years of age or younger, but it is available for those 13 years of age or older. The manufacturer cautions about the use of the test in persons under the age of 12 because data are lacking on safety and efficacy at those age levels. A representative from the manufacturer, OraQuick, will comment on this later. Finally, once the President's budget is released, it will show a

$4 million reduction in the proposed budget for HIV/AIDS, but CDC plans to make that up through changes in allocations to other internal programs.

Dr. Judson said he could try to answer the syphilis question. Ms. Ivantic-Doucette repeated her concern about whether both primary and secondary rates are shown in the increases in syphilis rates noted by Dr. Gerberding yesterday. Her concern is whether latent syphilis is showing up now. Dr. Judson said the United States is still seeing a decrease in syphilis in blacks, including in the high-rate rural areas. But for gay men, rates are increasing and in the infectious stages, primary and secondary, as well as early and late latent.

Dr. Primm reminded the Council that Dr. Gerberding had also mentioned bulk purchasing of the rapid test. Ms. Seiler said it is not clear how CDC will do this, but its goal is to make the test available at cost. She added that CDC doesn't have much experience in bulk purchasing. The goal is to make the greatest number of tests available at the best price possible.

Dr. Yogev asked whether PACHA could obtain an on-the-record statement that the CDC and FDA would allow the OraQuick test to be used in persons under the age of 12, and Ms. Seiler said that can be arranged.

Public Comment

Ms. Smith announced the opening of Public Comment. She noted each registered speaker will have 3 minutes to speak and will be reminded of their time left by timekeeper Lt. Wanda Chestnut.

Ms. Smith called Ms. Marsha Martin, Ms. Donna Crews, and Mr. Bill McColl. No speakers rose to the microphone. Ms. Smith called Ms. Jessica Tytel, Mr. Ronald Johnson, Mr. Tony Tran, and Mr. Nguru Karugu. No speakers rose to the microphone.

Ms. Smith asked if there was anyone in the audience who had signed up but who is not on the list of names she called.

Mr. David Oxley of OraQuick Technologies rose to the microphone. He said the OraQuick oral fluid test is now available. The company also has contacted CDC about bulk purchase of 211,000 tests for FY 2005. As of the end of January 2005, 55,000 tests have been deployed. He said OraQuick strongly supports the request for bulk purchasing. He noted that State health departments don't have access to U.S. General Services Administration (GSA) purchasing and that the company would violate GSA contract terms if it extended GSA terms directly to the States. As a consequence, the States have asked for the tests to be purchased through GSA. Now the company is waiting for further confirmation from CDC and Congress on available funding.

Dr. Samuel Jones from Nigeria then rose to the microphone. He said that up until 2 weeks ago, he was a medical officer monitoring MTCT in Africa. In Africa, pregnant women are usually first seen medically when they come to deliver. In short, the usual point of

contact with mothers and their babies is the day before delivery and perhaps 2 days after. Single-dose nevirapine as a prophylaxis for MTCT answers a need, in this context. He recalled when nevirapine was discovered. He noted that Ugandans who participated in the HIVNET 012 trials of nevirapine have written a letter to Rev. Jesse Jackson about how much it is needed.

Ms. Genevieve Grapman from the Health and Gender Equity Center rose to the microphone. Her Center worked with Congress on the writing of law supporting the President's Emergency Plan for AIDS Relief (PEPFAR). The Center was and remains specifically interested in comprehensive prevention, including but not limited to the ABC model. She stated that there is "no evidence that ABC is not being addressed in Uganda." She said the PEPFAR implementing plan, guidelines, and 2004 operational plan require reporting on A and B. In terms of C, in Uganda today there is a shortage of condoms. She added that in sub-Saharan Africa today, HIV/AIDS is growing rapidly among young women who were not sexually active before marriage and who have been monogamous during marriage. Her Center joins Mrs. Vivian Berryhill and the U.S. Congress in supporting ABC "plus," including addressing "D" for domestic violence.

Mr. William Arnold, CEO and Vice Chair of the Title II Community AIDS National Network and Director of the ADAP Working Group in Washington, DC, rose to the microphone. He summarized a written statement thanking the President for signaling the need for a $10 million increase in ADAP funding in the budget released February 7. However, he noted that the budget proposes only flat funding for the rest of RWCA and that, in FY 2006, ADAP will actually need an additional $250–$300 million. "Our commitment to fighting AIDS in the United States is not keeping up with either the facts of our epidemic here or the need to provide access to HIV/AIDS drugs, health care, and support." He noted that there are now between 100,000 and 200,000 more HIV-positive Americans than when the Act and ADAP were first implemented.

While the President's $20 million emergency funding for ADAP from FY 2005 was much appreciated, when it ends, those covered by this emergency funding will fall back into regular ADAP coverage. "How this can happen ethically in areas where ADAP programs are closed or capped, I cannot say. The present $10 million ADAP increase will not even guarantee drug coverage for the close to 2,000 folks we rescued temporarily last year from States with ADAP wait lists." He asked for PACHA's continued efforts and attention to the ADAP resource question, and to imagine what will happen in communities across the country when HIV-positive Americans discover their status only to also find that there is no available reliable source for providing them with the HIV/AIDS treatments that have cut AIDS death rates by more than 75 percent since 1996.

Mr. Murray Penner of the National Alliance of State and Territorial AIDS Directors (NASTAD) rose to the microphone briefly to address ADAP programs and the new Medicare drug benefit. He said NASTAD would release information February 9 about how ADAP waiting lists are beginning to grow again. This is an issue for reauthorization of the RWCA. He added that he supports Mr. Arnold's statements about the ADAP crisis.

Medicaid cuts and changes to drug benefits are coming January 1, 2006, and NASTAD is very concerned about the impact on the ADAP program. NASTAD is also concerned about limited formularies, dual eligibles, out-of-pocket expenditures, and the need for a great deal of education about enrollment under the new program. He urged PACHA to do everything it can to make sure that HIV/AIDS patients have access to the drugs they need.

Mr. Jim Driscoll rose to the microphone as a specialist in AIDS and health care expressing his personal views about human trafficking issues and proving the relationship between trafficking and HIV/AIDS. In the past 18 months, he has interviewed scores of individuals in Asia, including in Cambodia, Myanmar, and Vietnam. Many saw the tie between human trafficking, sex slaves, sex workers, and prostitution and HIV/AIDS as a major problem. He congratulated President Bush for acknowledging the need to crack down on human trafficking. He recalled when former San Francisco Mayor Dianne Feinstein closed bath houses in the city and was attacked for lack of proof of the connection between their operation and the spread of HIV. He called for locking up pimps as a key to addressing the spread of HIV/AIDS.

Ms. Marsha Martin from AIDS Action in Washington, DC, which works in collaboration with the Health Resources and Services Administration (HRSA), rose to the podium as the last speaker. She had two handouts, one with charts showing the size and populations of the HIV epidemic in the United States in general and the estimated number of individuals who are aware of their infection but are not in care (about 250,000). She called for creating a momentum of care whereby those who are aware but not in care get into care as well as those who are unaware but are most likely infected (about another 250,000 individuals). Without this momentum, new infections will and are occurring. In short, the greater the number of HIV-positive individuals in care, the fewer new infections. Care is key to prevention. She encouraged building alliances to bring about this change in the epidemic's dynamic. She encouraged PACHA to recognize the contributions of the FDA and of the pharmaceutical industry.

Ms. Smith announced the end of the Public Comment period.

Announcements, Breakout Sessions for Preparatory Work, Point of Order

Mr. Grogan provided instructions about where the Subcommittees would break out for lunch and preparatory work. Ms. Smith reminded the Subcommittees that they will be working on the draft motions that have been introduced. She invited members with issues or concerns about draft motions introduced by other Subcommittees to seek out the Chairs of those Subcommittees.

Mr. Mason asked as a point of order if motions not introduced on Day 1 can be introduced today.

Ms. Smith noted that, historically, PACHA has not done that.

Mr. Mason said that from the International Subcommittee's perspective, the goal would be to congratulate the President for his extraordinary commitment to combating the epidemic on a global scale.

Dr. Sullivan said that sounds like a followup to previous PACHA resolutions. He invited members to provide input on the idea. He said he does want to avoid debate in the full Council in order to complete the meeting in a timely fashion. He announced that Secretary Leavitt would join the Council at 1:45 p.m.

Ms. Smith adjourned the Council for its preparatory work.

Working Lunch

Break

Reconvened for Motions and Voting
Ms. Smith reconvened the Council. She said the goal will be to have completed work on all motions by Secretary Leavitt's visit at 1:45 p.m.

International Subcommittee Report
Mr. Mason said the International Subcommittee has decided to table two of the four draft resolutions it introduced on Day 1. These are the resolutions entitled **"Preventing AIDS and STDs by Curbing Human Trafficking"** and **"Call for Ensuring Broader Programs of AIDS Prevention in Implementing the President's Emergency Plan for AIDS Relief (PEPFAR)."** The Subcommittee will discuss these and report back to the full Council on next steps.

The Subcommittee is moving forward with the other two resolutions introduced on Day 1: "**Improving Prevention of Mother-to-Child Transmission (PMTCT) Efforts Globally,"** and "**Improving Prevention of Mother-to-Child Transmission (PMTCT) Efforts While Preserving Current Treatment Options for Women of Childbearing Years."**

New Draft Motion
Mr. Mason said the Subcommittee would also introduce today a new draft motion commending President Bush for his global AIDS budget. Initially, the Subcommittee thought to combine it with the Treatment and Care Subcommittee's motion commending the President and his State of the Union address, but the two may remain separate.

First PMTCT Draft Motion Changes and Discussion
On the first draft resolution on PMTCT before the Council, Mr. Mason said the Subcommittee had made one change in the language, in the second paragraph, to "2 percent" from "1 percent."

Dr. Montero, Ms. Ivantic-Doucette, and Dr. Reznik suggested language changes to the last paragraph. The last paragraph of the first draft resolution, on PMTCT, was altered to

read: “BE IT RECOMMENDED that U.S. Government Departments and their implementing agencies involved in HIV/AIDS activities globally intensify their efforts to secure HAART for pregnant and breastfeeding women through the development of infrastructure, such as the training of nurses, midwives, and other health care workers to manage medication therapies, and the monitoring and evaluation of the impact on the health of the mother, the child, and the prevention of new HIV infections.”

Mr. Mason asked if there was further discussion. There was none. Ms. Rock made a motion that the draft resolution be accepted. She was seconded.

Passage of First Resolution on PMTCT
Mr. Mason called for a vote by a show of hands. The first resolution passed.

Second PMTCT Draft Motion Changes and Discussion
Dr. Reznik asked to clean up the language in the fifth paragraph of the second PMTCT draft resolution. Dr. Reznik said he wants to make sure Dr. Fauci is supported, as well as the work that has been done on nevirapine.

Mr. Mason called for discussion. He commented that the studies done on nevirapine weren’t perfect, and PACHA needs to give a correct impression and interpretation.

Dr. Sweeney and Dr. Sullivan suggested changes. Ms. Clements suggested changes. Ms. Shoemaker and Dr. Reznik then suggested changes. The final change resulted in the fifth paragraph reading as follows: “WHEREAS, recent allegations related to the study which proved the safety and efficacy of nevirapine in preventing MTCT were shown to be unfounded by multiple subsequent reviews; and subsequent independent studies confirmed the results of the original study.”

Dr. Yogev also submitted changes to the draft resolution. In the third paragraph, he corrected the spelling of the word “transmission,” struck the word “the” and added the word “introduced” after “was.” In the fourth paragraph the word “major” was changed to “significant.” In the fifth paragraph, the words “as well as” were substituted for “; and subsequent.”

Mr. Mason asked if there was any further discussion. There being none he called for a vote.

Passage of the Second Resolution on PMTCT
By a show of hands, the Council passed the second resolution on PMTCT.

New Resolution
Mr. Mason read the Subcommittee’s new resolution, entitled **“Commending Presidential Leadership on Global AIDS.”**

"WHEREAS, the President's Emergency Plan for AIDS Relief is a 5-year, $15 billion U.S. Government initiative to provide treatment, prevention, education, and support to people infected and affected by HIV in 15 of the hardest hit countries in the world, and

"WHEREAS, the President's Emergency Plan has already started to show significant progress toward meeting its targeted goals for treatment with 155,000 people in treatment, and

"WHEREAS, the President's recently announced fiscal 2006 budget has recommended $3.2 billion for the President's Emergency Plan funding, one of the few discretionary line item increases in the President's budget;

"BE IT HEREBY RESOLVED that PACHA commends President Bush for his continued commitment to fund the President's Emergency Plan for AIDS Relief."

The motion was passed without discussion. Mr. Mason said this completes the report of the International Subcommittee.

General Discussion

Rev. Sanders asked to participate in International Subcommittee conference calls on the two tabled International Subcommittee resolutions. Mr. Grogan will notify all members of further discussion of these resolutions. In addition, all members will receive opportunities to participate in all future conference calls by any Subcommittee.

Treatment and Care Subcommittee Report

Subcommittee Chair Dr. Reznik stated that he could complete his report in the short time before the new Secretary arrives. He wanted to comment on the Federal poverty level, which had been discussed on the previous day. For one individual, in the 48 contiguous States and the District of Columbia, the FPL is $9,310; for a family of two, it is $12,490; for three, it is $15,670. These figures will change because they were released a year ago.

Dr. Reznik then read the Treatment and Care Subcommittee version of the State of the Union resolution.

"BE IT RESOLVED that the Presidential Advisory Council on HIV/AIDS wishes to express our sincerest gratitude to the President of the United States of America, George W. Bush, for bringing national attention to the domestic HIV/AIDS epidemic and the disproportionate impact this disease has on African American men and women by calling for a reauthorization and modernization of the Ryan White CARE Act in the State of the Union Address on February 2, 2005."

Discussion of Letter to Former HHS Secretary Tommy Thompson, Vote by Council

Ms. Smith suggested that the Council write a letter of thanks to former Secretary Thompson for his leadership.

The Council voted to approve such a letter.

Visit by HHS Officials
Dr. Sullivan introduced Christina Beato, M.D.

Dr. Beato thanked PACHA for all its hard work, including on the resolutions just passed. She noted that PACHA is here to have an impact on some of our most vulnerable populations. She asked that the focus always be prevention. Former Secretary Thompson will be pleased to receive the letter from PACHA. She has found the new Secretary to be just as warm, compassionate, and caring. He is very determined to fulfill the President's compassionate agenda.

Dr. Sullivan commented that the new Secretary may be the twentieth to head HHS since its founding in 1953 under President Dwight D. Eisenhower.

Visit by Secretary Michael Leavitt
As Secretary Leavitt entered the room, Council members stood and applauded.

Dr. Sullivan confirmed with the Secretary that he is the twentieth person to head the department since its founding. The Council very much appreciates his taking the time to meet. PACHA is a hard-working group and has had a good meeting.

Secretary Leavitt said he aspires to know more about each Council member and how they are connected to PACHA. He asked for each member to identify themselves, who they represent, and to provide a brief statement about their PACHA connection.

Dr. Sullivan introduced Mr. Grogan as PACHA's Executive Director who "works overtime for us."

Ms. Shoemaker introduced herself as a person with AIDS and a motivational speaker and educator who lives outside of Traverse City, Michigan. Answering the Secretary's question about what she teaches, she said grades 9-12, about HIV/AIDS and STDs. She added she was invited to be on the Council as a person living with AIDS.

Dr. McIlhaney introduced himself as a physician and gynecologist. His Austin, Texas, practice focuses on fertility. He became interested in HIV/AIDS and STDs when he began seeing a number of patients made sterile by sexually risky behaviors. He noted he is originally from Lubbock, Texas.

Mr. Dandrick Moton noted that for the past 6 years he has served as public relations director for a large nonprofit youth center. He lives in Arizona and is also a public speaking professor at the University of Arizona. Secretary Leavitt asked about the origins of Mr. Moton's first name. Mr. Moton said the base is Daniel, but his mother added to it, wanting it to be unique, like he was.

Ms. Jolley said she is a Washington, DC, native who speaks to middle and senior high school students all over the country about making healthy decisions. She is also a singer,

and she gave the Secretary a copy of her latest CD. She said she tries to make music that will help young people, especially young girls, make healthy decisions.

Ms. Rock said she is from Baltimore, Maryland, where she helps administer an HIV/AIDS program that provides many services to children. She said seniors and the risks they may take are of special interest, in part because her father has recently returned to the dating scene. Secretary Leavitt told a true story about an elderly couple he had met who had been married for 77 years. He told them that was inspirational, and they told him they were thinking of getting divorced but were waiting until the kids were dead.

Dr. Biaggi introduced herself and said she became interested in public health when she was hired by Catholic Charities to be a family therapist for HIV-positive people. Secretary Leavitt noted that people often find their passion through their work.

Dr. Yogev introduced himself as from Texas, south of Lubbock. He has lived in the United States for 30 years. He is a converted academician. After working with polio patients, he found his heart in the neglected area of pediatrics. His idol is Albert Schweitzer.

Dr. Jane Hu introduced herself as possibly the only Asian American in the group. She noted that in September, she started an AIDS treatment and training center in China with local Chinese doctors. She came to the Council as a politically active member of the Asian American community. She also campaigned for President Bush in 2000. She just returned from China and realizes that the United States is now her real home.

Secretary Leavitt commented that he has begun to feel the humanitarian and international outreach to the world represented by the Council and the President's policies. He said we have a very significant stake in the domestic manifestations of this disease but also how it is affecting people and nations abroad. He recalled that when he was in China a few years ago, he and his translator went for an informal walk and began talking to people on the street about their lives. They came upon a family singing Chinese opera to each other, accompanied by a tiny cellolike instrument with one string. Soon a crowd of people had gathered, curious about the visitors. It was a magical moment and one he always remembers about China.

Ms. Hall noted her affiliation with the Lutheran Medical Center in Brooklyn, which has a HRSA grant to develop an HIV/AIDS training program with Caribbean nations. She was born in Trinidad but emigrated 34 years ago, directly to Brooklyn.

Ms. Ivantic-Doucette introduced herself as from Marquette University. She has worked for 20 years on HIV/AIDS issues. She teaches and cares for clients, primarily African Americans in Milwaukee. She is involved with two training programs in Uganda. She has four boys, two in college. Secretary Leavitt said he grew up in a family of six boys, and he and his wife have four boys and one girl. And he just learned he is about to become a grandfather.

Dr. Green said he is originally from Washington, DC, and that he grew up in the Foreign Service. His grandfather was Ambassador to Iraq in the 1950s. He has been at Harvard's School of Public Health for 3 1/2 years. Before that, he was primarily a U.S. Agency for International Development consultant. He thinks of himself as an Africaans, and he has spent lot of time recently on the ABC strategy. Secretary Leavitt asked what Dr. Green wrote his dissertation on, and Dr. Green told him, escaped slaves living in Surinam.

Mr. Minor commended the Secretary for taking time to come meet and learn about the individual Council members. He is originally from North Carolina. Now he lives in Alexandria, Virginia. He started Food for Friends, delivering food to people with AIDS. He has also worked as the Chair of a Title Me council. He was diagnosed with HIV/AIDS in 1987. As a gay man, he finds his affiliation with PACHA to be very gratifying, on both philosophical and deeply personal levels. Secretary Leavitt asked if Mr. Minor lives in Old Town. Mr. Minor quipped that he doesn't get paid that much and that he lives in Arlandria. Secretary Leavitt said that although he made many trips to Washington as a Governor and has lived here now for a year, each time he leaves his house he gets lost.

Rev. Sanders introduced himself as a senior servant. He noted that his congregation has been involved in HIV/AIDS for 21 years, beginning with education. He works with HRSA, CDC, and the U.S. Justice Department. His church and its affiliated centers consider themselves to be models of faith-based participation because they are "of service." He told the Secretary he had witnessed a miracle today because brevity is not a hallmark of PACHA members.

Dr. Bowers-Stephens said she would like to mention first that she and her husband donate time and resources to the people of Zimbabwe. She was born in North Carolina, but moved to Louisiana with her family. Her father was a dental surgeon and native of New Orleans. Secretary Leavitt noted he has a younger brother by 22 years who is just now finishing his medical residency, yet also has six sons all under the age of 8. Secretary Leavitt has quipped to his brother that his motto must be, "If there's a harder way, I'll find it."

Ms. Clements introduced herself as a pre- and post-HIV test counselor and past chair of the North Carolina Governor's advisory council on HIV/AIDS. She was married in 1980, and then her husband developed swollen lymph nodes. He was finally diagnosed with HIV/AIDS in 1986 and died in 1988. Her daughter succumbed to the same disease in 1990, at the age of 4. As far as she knows, she has had the disease for 20 years. She comes to the Council as a person whom others shunned at one time. She turns 50 this year but never thought she would. Secretary Leavitt commented on Ms. Clements' compelling and moving story. He noted his wife's name is also Jacqueline. He asked where Ms. Clements got her name, and she responded from her aunt, but she knows no more than that. Secretary Leavitt shared that his father's first name is Dixie.

Ms. Singleton McDonald noted the Secretary's compassion and warmth, adding "we need you to lead our initiatives on health." She said she is a native of Atlanta who, in

1986, after leaving several jobs, decided to become self-employed, helping African Americans with AIDS. She then founded Outreach, Inc., the first and oldest agency in the country serving African Americans who have HIV/AIDS. Her youngest clients are 13-year-old twins; her oldest, an 80-year-old. She is a consultant to the National Football League, working with all the teams on a public service announcement campaign about HIV/AIDS. She asked the Secretary if he would like to get involved in that movement.

Dr. Montero characterized himself as a clinician and educator, primarily with hospital patients. He has also worked with HIV/AIDS care and treatment in the Caribbean and in India. He has been to India only once but that was enough to convince him that the nation needs his help, for the population is huge, the numbers of infected high, and the potential for the epidemic to explode great.

Dr. Primm characterized himself as a senior servant of PACHA. He is from New York City, where, among many things, he is involved in addiction research and treatment. He runs a large human services conglomerate that treats about 3,000 individuals in seven clinics. He also treats battered women and children. PACHA is his second Presidential commission appointment. He is founder and chairman of the board of the Minority AIDS Council, among many other positions. Secretary Leavitt commented: "What a great way to spend your life."

Dr. Sweeney said she is an internist with an M.S. in public health and also serves as Chair of PACHA's Prevention Subcommittee. She is here because long before HIV had a name, she was working with it. She helps run a multiservice center for the infected and affected in the heart of Brooklyn. She was originally from the eastern shore of Virginia. Dr. Sweeney invited Secretary Leavitt to come see her in Brooklyn, and he said he will.

Dr. Reznik said he started out as a community dentist in Atlanta, and then went into oral care for HIV/AIDS patients. He is now director of one of the most comprehensive centers for HIV/AIDS, where they treat 4,700 people living with HIV/AIDS. As of this meeting, he is Chair of PACHA's Treatment and Care Subcommittee. His mission is to ensure access to services and life-sustaining medications. Secretary Leavitt called that a remarkable mission. Dr. Reznik said he'll cut his hair when we have a cure.

Mr. Mason said he is from Los Angeles, where he runs a nonprofit. He noted that he is the Chair of PACHA's International Subcommittee. He grew up in Durham, North Carolina, but has spent most of his life in Massachusetts.

Ms. Smith said she is President of the Children's AIDS Fund, which she founded with her husband in 1988. Their organization is a PEPFAR grantee under Catholic Relief Services treatment grants. They work with close to 3,000 patients in several countries. Secretary Leavitt asked if she travels often, and Ms. Smith said, very often, and in fact she leaves tonight.

Secretary Leavitt said that President Bush's Administration commitment to the battle against HIV/AIDS is real, and the President's intent is for the Executive Branch and

advisory councils like PACHA to have a real impact. He noted that several PACHA members mentioned when they first became aware of AIDS. His first experience with it was in 1993. He had just been elected Governor, and he and his family were living in their own home, not the Governor's mansion, when a very close neighbor and friend, Larry, became ill with AIDS. One afternoon he received a call that Larry was going to die. He went to visit Larry and asked him to explain what this disease was about. Larry then began to teach the Secretary what PACHA members know now. Regrettably that was a time when being diagnosed was a death sentence. Lots of progress has since been made. However, this epidemic is still a remarkable challenge both domestically and internationally. Secretary Leavitt said he is committed to being as helpful as he knows how to be, adding that he is open to suggestions about how he can be more helpful.

A photograph was taken of the entire Council present and Secretary Leavitt.

Announcements and Adjournment

Ms. Smith announced that members' briefing books will be shipped to them and minutes will come shortly. She thanked Mr. Grogan and his staff. Mr. Grogan thanked Lt. Chestnut and Ms. Ceasar. He announced that there will be conference calls with the Chairs about Subcommittee and full Council meeting dates. He'll confirm the full Council meeting dates in June with the Secretary in coming weeks. Ms. Singleton McDonald thanked everyone, including the contractors and food provider, for an excellent job.