Presidential Advisory Council on HIV/AIDS (PACHA)
Thirty-fifth Council Meeting
Hubert Humphrey Building
200 Independence Avenue, S.W., Room 705A
Washington, DC 20201

March 25–26, 2008

Council Members Present
Raymond V. Gilmartin, B.S.E.E., M.B.A., PACHA Co-Chair
Marilyn A. Maxwell, M.D., PACHA Co-Chair
Carl Schmid II, B.A., M.B.A., Domestic Subcommittee Chair
Troy Benavidez
Robert C. Bollinger, Jr., M.D., M.P.H.
Freda McKissic Bush, M.D., FACOG
Shenequa Flucas
Robert Kabel, J.D., LL.M.
Robert M. Kaufman, B.A., M.A., J.D.
Rev. Herbert H. Lusk II, B.A., M.Div.
John C. Martin, Ph.D.
Jose A. Montero, M.D., FACP
Beny J. Primm, M.D.
Sharon Valenti, M.S.N., R.N., C.S., BC
Barbara Wise, B.S.
Ram Yogev, M.D.

Council Members Absent
Robert R. Redfield, M.D., International Subcommittee Chair
Cheryll Bowers-Stephens, M.D., M.B.A.
David J. Malebranche, M.D., M.P.H.
Zelalem Temesgen, M.D.
Eric G. Walsh, Jr., M.D., M.P.H.

Council Staff Present
Marty McGeein, M.B.A., R.N., Executive Director
Nancy Barnes, Committee Manager

Presenters
Kathryn Anastos, M.D., Professor of Medicine, Epidemiology, and Population Health, Division of General Internal Medicine, Department of Medicine, Montefiore Medical Center/Albert Einstein College of Medicine, New York City
H. Westley Clark, M.D., J.D., M.P.H., CAS, FASAM, Director, Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services (HHS)

Carl W. Dieffenbach, Ph.D., Director, Division of AIDS, National Institute of Allergy

and Infectious Diseases (NIAID), National Institutes of Health (NIH), HHS
Kevin Fenton, M.D., Ph.D., Director, National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Disease (STD), and Tuberculosis (TB) Prevention, Centers for Disease Control and Prevention (CDC), HHS
Joxel Garcia, M.D., M.B.A., Assistant Secretary for Health, HHS
William Steiger, Ph.D., Director, Office of Global Health Affairs, and Special Assistant to the Secretary for International Affairs, HHS
Ellen L. Stover, Ph.D., Director, Division of Mental Disorders, Behavioral Research, and AIDS; Director, Center for Mental Health Research on AIDS, National Institute of Mental Health (NIMH), NIH, HHS
Steven R. Young, M.S.P.H, Director, Division of Training and Technical Assistance, HIV/AIDS Bureau (HAB), Health Resources and Services Administration (HRSA), HHS

DAY 1

MORNING SESSION

Call to Order and Welcome

PACHA Co-Chair Marilyn Maxwell called the Council's 35th meeting to order at 8:40 a.m., welcoming members. She remarked that HIV/AIDS is a disease that has changed in many ways, including that while it is no longer necessarily a death sentence, for too many it is a chronic disease. PACHA too has changed over time and today welcomes new members. Dr. Maxwell noted that there will be conference calls and PACHA Subcommittee meetings to come for members old and new who could not be present today.

New Members Swearing-In Ceremony
Conducted by Joxel Garcia, M.D., M.B.A., Assistant Secretary for Health, HHS

Dr. Garcia swore into office, into the service of the President and of PACHA, new PACHA members Sharon Valenti, a nurse from the Detroit area, and Robert M. Kaufman, a lawyer from New York. Members were provided with their biographies.

Agenda and Rules/Housekeeping

Dr. Maxwell noted the full agenda for this meeting of the full Council and ground rules. A key ground rule is that presentations during the meeting are for the benefit of PACHA members; therefore, members of the public attending will not be permitted to ask presenters questions. Dr. Maxwell also asked PACHA members to turn on their microphones when speaking, as these meetings are recorded to ensure the accuracy of the meeting summary.

Introductions

Dr. Maxwell then asked members around the table to introduce themselves and to say a bit about their most passionate interest in HIV/AIDS. As members did so, it was clear that prevention, particularly among vulnerable populations here and abroad, is a

prevailing interest among both longstanding and new members, as are issues in treatment, including care setting and services transitions and access to mental health and substance abuse assistance.

Comments by Dr. Garcia
Dr. Maxwell invited Dr. Garcia to say a few words about his background and his vision for his new position, particularly pertaining to HIV/AIDS.

Dr. Garcia noted that he is an obstetrician-gynecologist who first began his involvement with HIV/AIDS while working as the Commissioner of Public Health for the State of Connecticut. There, he witnessed firsthand how the disease was affecting his community, particularly women and children in communities of color. People in the inner cities, Latinos, and immigrants from the West Indies were suffering, reminding him of his experiences as Deputy Director of the Pan American Health Organization (PAHO) and that what happens elsewhere also affects us in the United States. He looks forward to working with PACHA, whose responsibilities he is quite aware of. PACHA members are in a privileged position as community and national leaders who "can make a big difference for the Department, the President, and toward the goal of a generation free of the disease."

Further Comments
PACHA Executive Director Marty McGeein thanked PACHA for the priceless advice and recommendations the Council has provided to the President for more than 20 years. She noted that much of what the Council has advised should be done has been done, and much of what it has advised should not be done has not been done. She noted her first exposure to the disease as a nurse serving in the Reagan Administration who was asked by HHS to work on "this strange infectious disease for which they had no name, etiology, or treatment." She noted that in addition to serving as PACHA's Director, she also serves HHS as the Deputy Assistant Secretary for Disability, Aging, and Long-Term Care Policy.

Domestic Subcommittee Chair Carl Schmid II provided a brief report on Subcommittee discussions and identification of issues, some of which will be addressed by speakers today and tomorrow.

Puerto Rico—Mr. Schmid noted that at its last full Council meeting, PACHA adopted a resolution expressing its concern about the status of HIV/AIDS prevention and care and treatment in Puerto Rico and specifically the status of Ryan White CARE Act (RWCA) programs and CDC-funded prevention programs there. The Subcommittee then followed up at its February meeting, receiving an update from a representative of the Puerto Rican Government largely regarding technical assistance and training received from HRSA to help correct RWCA program problems. The Subcommittee will continue to monitor the situation.

District of Columbia—The Subcommittee also was briefed by the new HIV/AIDS Director for the District of Columbia, which has some of the highest prevalence rates in

the Nation. Shannon Lee Hader's presentation, outlining her department's plans, was preceded by a 2-day meeting on the epidemic at Howard University, Mr. Schmid noted.

Severity of Need Index—The Subcommittee also received a briefing on HRSA's Severity of Need Index (SONI), which the U.S. Congress has required as a way of possibly altering the distribution of some RWCA monies. The index, which has been revised and is still under review, addresses not only HIV/AIDS in a given locality but also levels of poverty and insurance, for example. In short, the SONI may be a way to ensure that RWCA funds go where the need is greatest.

Domestic PEPFAR Resolution—Finally, Mr. Schmid and Subcommittee member Beny Primm noted one of the two Subcommittee draft resolutions to be presented to the full Council tomorrow, which calls for a National AIDS Strategy for the United States. Mr. Schmid briefly noted that the resolution reflects the Subcommittee's concern about the lack of focus on the domestic epidemic, where we are experiencing 40,000 new infections each year, and "perhaps much more than that," as well as continuing testing and treatment and care issues, such as access and service delivery disparities.

Dr. Maxwell concluded discussion and introduced H.Westley Clark to provide an update on SAMHSA.

SAMHSA Update
Presentation by H. Westley Clark, M.D., J.D., M.P.H., CAS, FASAM, Director, CSAT, SAMHSA, HHS

Dr. Clark extended greetings from SAMHSA Administrator Terry L. Cline, noting that Dr. Cline is interested in HIV/AIDS as part of the SAMHSA agenda.

Quoting President Bush, Dr. Clark observed further that, in fact, interest in HIV/AIDS "cascades from the President throughout the Administration."

Dr. Clark showed slides of SAMHSA's organization and matrix of priorities, including the priority area of HIV/AIDS and hepatitis, and emphasized the agency's goals (see slide 5 for more):

- Accountability—Measure and report program performance
- Capacity—Increase service availability
- Effectiveness—Improve service quality.

A major challenge in the United States is that, based on SAMHSA's Household Survey, a large number of people meet criteria for needing treatment for illicit drug or alcohol abuse. Yet, according to 2006 data, 625,000 did not make an effort to get treatment, and 20.1 million perceived they did not need treatment. In short, in 2006, almost 21 million people were not receiving substance abuse treatment they need. This is an HIV/AIDS problem, in terms of injection drug use (IDU) in particular as well as responsible behavior in general. That the overwhelming majority of people who need treatment aren't getting it because they think they don't need it reflects "our society," Dr. Clark commented.

Dr. Clark provided additional specific information from the Household Survey in slides 7, 8, and 9, noting that prescription drug abuse, particularly of pain relievers, continues to be a "big problem." Methamphetamine use also continues to be an issue, associated, as cocaine in the past and present, with sexual activity among both heterosexuals and gay men.

Turning to injection drug use and HIV/AIDS, Dr. Clark noted that according to 2005 CDC data on adolescents and adults:

- About 20 percent of the reported new AIDS cases were related to injection drug use.
- 20 percent of males and 33 percent of females living with AIDS were exposed through injection drug use.
- Almost one-third of AIDS deaths were of adolescents and adults infected through injection drugs.

This is particularly a problem in the African American community domestically and continues to be a problem internationally, as does alcohol abuse.

In terms of HIV diagnoses by race/ethnicity, in 2005, according to the CDC, about one-half of individuals diagnosed with HIV/AIDS were African American (according to data from 33 States), including children (slide 11). Of some 960,000 AIDS cases reported to the CDC through 2005 (slide 12), African Americans accounted for:

- 40 percent of the total
- 60 percent of women
- 59 percent of heterosexual persons at high risk (contact with a person known to have or to be at high risk for HIV infection)
- 59 percent of children less than 13 years of age.

Slides 13, 14, and 15 showed how Hispanics accounted for a disproportionate share of AIDS cases in 2005; the estimated number of AIDS cases and rates for female adults and adolescents by race/ethnicity in 2005, based on data from 50 States and the District of Columbia; and that American Indians and Alaska Natives (AI/AN) have the third highest rate of AIDS diagnosis in the United States, despite having the smallest population, and are likely to be younger than non-AI/AN individuals with AIDS and to die more quickly after diagnosis.

Dr. Clark then turned to SAMHSA's HIV/AIDS and hepatitis activities through the Minority AIDS Initiative (MAI) (slide 17), with the goal:

- To increase access by racial and ethnic minority communities to HIV prevention, care, and treatment services;
- To implement strategies and activities specifically targeted to the highest risk and hardest to serve populations; and

- To establish collaborations, partnerships, or opportunities for programs and/or activities to be integrated, including through faith- and community-based organizations (FBOs and CBOs); research institutions; minority-serving colleges and universities; health care organizations; State and local health departments; and the criminal and juvenile justice systems.

In addition, SAMHSA is using some MAI funds to work with the President's Emergency Plan for AIDS Relief (PEPFAR) to address HIV/AIDS and IDU and alcohol use abroad.

Dr. Clark noted, however, that for the most part, SAMHSA's MAI funding has been and is estimated to remain essentially flat.

Dr. Clark then detailed HRSA's HIV/AIDS and hepatitis Targeted Capacity Expansion (TCE) grants administered by its three centers:

- For CSAT, the purpose of the grant program is to enhance and expand substance abuse treatment and/or outreach and pretreatment services in conjunction with HIV/AIDS services. Importantly, the grants require that, at minimum, 80 percent of all clients be tested for HIV/AIDS.
- For the Center for Substance Abuse Prevention (CSAP), the purpose of the grant program is to assist communities in expanding existing HIV/AIDS and substance abuse prevention services.
- For the Center for Mental Health Services (CMHS), the purpose of the grant program is to increase capacity to provide culturally competent mental health treatment services to individuals living with HIV/AIDS (PLWA).

SAMHSA projects to meet MAI objectives (slides 21 and 22) include most particularly a Rapid HIV Testing Initiative (RHTI). From fiscal year (FY) 2005 to FY 2007, more than 400,000 rapid testing kits were distributed to CSAT and CSAP grantees to promote "knowing status" efforts among minority populations possibly at greater risk for acquiring or transmitting HIV associated with substance abuse and/or a mental health disorder and to ensure that facilities were trained to facilitate use of the tests.

SAMHSA's RHTI goals include not only incorporating the rapid test methodology into qualified program sites as a strategic intervention but also:

- Increasing referrals to sustained quality counseling, treatment, and other supportive care services for those diagnosed;
- Providing effective counseling to persons who previously tested negative to decrease their risk of acquiring HIV; and
- Identifying an increased number of evidence-based prevention and treatment programs and practices in the area of HIV/AIDS association with substance abuse and/or mental health issues.

SAMHSA also provided access to training to eligible service providers.

Importantly, SAMHSA is currently working with the CDC to be able to collect information on the number of those tested and the results. "Because the CDC compiles most of these data, working with it will facilitate success here," Dr. Clark commented, noting that next month, Dr. Cline will lead a delegation of SAMHSA officials to meet with CDC Director Julie Gerberding to continue this data-exchange dialogue.

Dr. Clark then turned to hepatitis A and B vaccination and hepatitis C testing. Prevention strategies here include:

- Providing an early diagnosis of hepatitis infection in drug users involved in treatment programs, and referring HIV-positive clients to care and recovery support services;
- Providing testing for hepatitis C infection in HIV-positive clients in substance abuse treatment programs; and
- Vaccinating for hepatitis A and B infections with the Twinrix vaccine, followed by referral to hepatitis care for those who test positive for hepatitis C infection to reduce the risk of progressive liver disease.

In addition:

- CDC-recommended immunizations are occurring as a "one-stop" patient care service so that patients are effectively immunized against hepatitis A and B virus that could otherwise result in significant disability or death.
- Forty thousand hepatitis C test kits have been procured and distributed, allowing for testing of 800 individuals at each of 50 testing sites.

Dr. Clark then expanded on CSAT and CDC collaborations:

- SAMHSA is actively engaged in collaborating with the CDC regarding HIV initiatives and data. Outcomes from a February meeting between the agencies included that SAMHSA will identify points of contact for collaboration in data collection and implementation guidance for testing; SAMHSA is actively engaged with the CDC in implementing HIV testing guidelines.

In terms of CSAT and HIV/AIDS and hepatitis activities, Dr. Clark showed a map of where the HHS/SAMHSA CSAT MAI activities are occurring (slide 29), noting that:

- MAI grants are awarded to CBOs with 2 or more years of experience in delivering substance abuse treatment and related HIV/AIDS services.
- Programs target African American, Latino/Hispanic, and other racial or ethnic communities highly affected by substance abuse and HIV/AIDS.
- HIV outreach grants have served nearly 23,000 clients, and TCE/HIV grants have served some 18,000 clients, for a combined total of nearly 41,000 clients.

Dr. Clark reported TCE/HIV evidence of success (slide 31), noting in particular substance abuse declines at 6-month followup and changes in risk behaviors among

clients reporting IDU (slide 32). He noted that clients reporting having had unprotected sex decreased 10.4 percent, adding that that figure concerns him, and he wants to figure out how to improve it (slide 33). Dr. Clark reported additional changes in risk behaviors in slides 34-36.

Dr. Clark reported that in terms of the HHS Minority AIDS Initiative:

- Last April, SAMHSA received $3 million to increase or enhance services to AI/AN at risk for substance use and HIV/AIDS.
- Areas of activity include rapid testing and training, education, prevention, outreach, and capacity building, as well as implementation through partnerships with a number of entities, including the Indian Health Service (IHS) and the CDC.
- Current plans are to purchase and distribute 50,000 test kits to tribes, tribal organizations, and urban Indian health clinics that have the capacity to provide rapid testing, and to host two CDC testing trainings and a CDC "train the trainer" session.

Dr. Clark then outlined a number of challenges to SAMHSA's goals (slide 41), including:

- Stigma in facilities and communities,
- Concern for confidentiality,
- Jurisdiction in situations at the State level,
- Lack of consensus on what/how to educate,
- Lack of human resources with local expertise,
- Appropriate but competing funding priorities,
- Complacency and perception that HIV is rare,
- Complexities in gathering data, and
- A reactive paradigm.

Dr. Clark detailed the Targeted Capacity Expansion program for substance abuse treatment and HIV/AIDS services (TCE/HIV) for FY 2008 (slide 42) and reiterated the HIV testing requirements in the FY 2008 TCE/HIV Request for Award (RFA) (slide 43), including that grantees must justify an HIV testing rate below 80 percent and that CSAT will consider any failure to provide an adequate justification when making annual determinations to continue a grant and the amount of any continuation award. In short, the reason SAMHSA is taking a more assertive position is that "if you don't know status in 2008, it is difficult to do interventions. This coincides with the CDC position of knowing status. We understand the issues, including feasibility and confidentiality, but we want programs to be able to explain the importance of testing to prospective clients and to get them to understand that, if they are drug or alcohol abusers, it is important to know their status."

Dr. Clark then detailed the CSAT Substance Abuse Prevention and Treatment (SAPT) Block Grant Set-Aside program (slides 44 and 45), emphasizing that designated States with an AIDS case rate of 10 or more per 100,000 individuals are to set aside a certain percentage of the SAPT block grant to establish one or more projects for early

intervention services for HIV. In FY 2008, there were 21 States so designated, as well as Puerto Rico and the U.S. Virgin Islands. Early intervention projects include counseling, testing, and referral services, and States are being encouraged to use part of their HIV set-aside (currently at $56.77 million) to purchase rapid test kits. Dr. Clark emphasized that States are gradually over the course of multiyear contracts recognizing the importance of CDC recommendations for testing.

Dr. Clark then provided multiple examples of MAI grantee activities (slides 47 and 48), noting that through these examples, he wanted to show the effort to reach a wide range of individuals at risk for HIV/AIDS in many different contexts.

Dr. Clark then detailed CMHS HIV/AIDS and hepatitis activities, including the Mental Health HIV Services Collaborative (MHHSC) Program, designed to support the provision of culturally competent HIV/AIDS-related mental health treatment and case management services to persons in minority communities (slides 50-57). Dr. Clark also detailed CSAP HIV/AIDS and hepatitis activities, linked to a new strategic prevention framework (slides 59-70).

Concluding, Dr. Clark noted that SAMHSA has one staff person funded by PEPFAR to help translate information developed in the United States for other countries and another staff person funded by the State Department to help Vietnam establish methadone programs, which are expected to go online shortly. SAMHSA is also consulting with PEPFAR on brief alcohol interventions in Botswana. Future meetings are planned to discuss further tie-ins between methamphetamine and HIV/AIDS.

Discussion

Drug Use Versus Sex Behaviors Impact

Dr. Maxwell asked Dr. Clark to comment on why TCE/HIV evidence of success points to greater programmatic impact related to drug use than to sex behaviors, to which Dr. Clark responded that these kinds of performance findings will allow SAMHSA to reflect on what it is doing. He noted that the agency has greater expertise in addressing substance abuse and that the performance data alluded to come from a period of time when testing was an option, not a requirement, for grantees. The knowing your status effort is a starting point for the agency to do new performance evaluations, although it has limited resources for research and evaluation. The agency is reflecting on what it is trying to treat, but one thing is clear, when people are high, it is hard to constrain behavior. Now the question is what the agency can reasonably do with the resources at hand and how those resources can be titrated to address both substance abuse and risky behavior. Substance abuse is a complex phenomenon, and when it comes to HIV/AIDS and changing risky behaviors, it is one thing to tell people what they need to know when they are sober as opposed to drunk or high on drugs such as methamphetamine. The central question is, can we achieve reduction in substance abuse and high-risk behavior? Before the agency collected data on performance, it didn't know the magnitude of the challenge per se, but now that data are in hand, it will be asking grantees to come up with solutions. That is key.

Criminal Justice System Issues
Dr. Primm complimented Dr. Clark on the wonderful job he is doing and on his complete report, adding that he has a few observations. First, in terms of the challenge of 21 million people needing but not receiving treatment for illicit drug or alcohol abuse, it has been argued in reports out of Harvard University that substance abuse is a contagious disease. It could thus be argued that those not in treatment are infectious to others and, therefore, there should be a greater focus on making those people less contagious. That should be an agency goal. Second, Dr. Primm said he is concerned about the criminal justice system and SAMHSA's intentions to deal with the high number of drug users coming out of the system, of whom some 5-10 percent are infected with HIV/AIDS. He asked Dr. Clark specifically to address what is being done in the prison system to address these individuals, adding that they might be receptive to messages received while in prison. Last, Dr. Primm asked what the Office of National Drug Control Policy is doing in this area, concluding on his previous point that perhaps substance abuse should be viewed as an infectious disease and focused on like any other infectious disease.

Dr. Clark responded that in regard to the first observation that the some 20 million people who do not feel they need treatment are not going to specialty treatment centers. They are not being turned away; they are simply not presenting. So, the agency has funded screening on more than 600,000 individuals for brief treatment and referral to treatment, and the agency also has an initiative to expand the effort to reach others, including those who are using and abusing, by training practitioners through a grant program that is still open but may be closing soon. Here, the agency is asking universities and hospitals to apply for a small number of grants to educate medical residents as to the holistic nature of substance abuse. When someone presents at alternative sites, screening will be promoted at those alternative sites, and as that is being accomplished, it will become easier to incorporate HIV/AIDS screening as well. Dr. Clark added that the President has asked for twice as much money for FY 2009 to screen more of the general population.

Addressing the criminal justice system, Dr. Clark noted he recently attended a meeting on corrections health that will help address the need there. Part of the criminal justice situation is when those who were incarcerated return to their communities. Here, the agency has a number of programs that target reentry; in short, these programs are not inside prisons but rather extend outside the walls to the community. In addition, in collaboration with the Department of Justice, the agency works to promote working with inmates 6 months prior to release. The proposed FY 2009 budget also addresses this, increasing "substantially" the amount of money for work with the drug courts. In summary, the agency can't do all it wants to with its limited resources, but it has broadened its portfolio. In addition, the Office of Management and Budget (OMB) is looking at the drug courts, and the agency is also collecting performance data "in that context." Incarcerated and released populations "are very important," Dr. Clark concluded.

Methamphetamine, the Set-Aside Program, and Coordination with RWCA
Mr. Schmid commented that the crystal methamphetamine epidemic is fueling the HIV/AIDS epidemic, particularly among gay men in the larger cities, and asked what the

agency is doing to address this, specifically with how many grants and with what funding amounts. He also asked how the agency is coordinating with the NIH on research and the CDC on prevention. Second, he commented that the 5 percent set-aside is an important program, but he would like to know what the agency requires in terms of grantees' working with the RWCA mental health and substance abuse programs in the relevant States and cities.

Dr. Clark responded that the agency will be meeting with the CDC in December, he believes, to review the state of affairs in terms of methamphetamine and also specifically to discuss educating authorities at many jurisdictional levels about strategies to address the problem, for which SAMHSA has produced a treatment protocol. In the meantime, the agency does have grants addressing this, and Dr. Clark will forward the specifics to staff for PACHA members. Thanks to the President's initiative, the agency has targeted a minimum of $25 million to work on methamphetamine issues, including with the District of Columbia. In conjunction with this, the agency is working with the CDC and the gay community as well as the heterosexual community and American Indians, Hispanics, and whites to address the issues. In short, dealing with methamphetamine abuse is "a priority, resources are being devoted to it, and we are working with the community and tying it to HIV/AIDS." Concluding on this point, Dr. Clark said he came from San Francisco, which had a methamphetamine problem, so he is very much aware of the spectrum and hazards of abuse of this drug. The agency has not relented in interventions or in making education available to a number of localities that are very concerned about the problem, as is the U.S. Congress and the Office of National Drug Control Policy.

Addressing Mr. Schmid's question about the set-aside program, Dr. Clark said the agency's clout here "is limited to moral suasion." That is, "we can't compel people to do things, but the agency does have a working relationship with HRSA and has an ongoing battle to resolve issues relative to RWCA and effective use of funds." In terms of the block grant and set-aside program, a smaller jurisdiction may have only $30,000 to work with, a big State much more than that. It would be good to explore with localities what they are doing in terms of testing and treatment but also whether they are tying into substance abuse. It would be good to explore RWCA compliance and maintenance involving HIV/AIDS as well as hepatitis and the effect that a drug like methadone has on antiretroviral therapy and vice versa. The agency wants to address many of these issues in a more aggressive way, "but these are conservative times financially."

Overwhelmed Medical System

Ram Yogev expressed concern about a medical system that is already overwhelmed and underpaid yet potentially faces a great number of new clients with enormous needs for medical care. He observed that a number of professionals are already leaving the HIV/AIDS field because they are overwhelmed. Dr. Clark responded that access to health care is a systemic issue SAMHSA can work on only in partnership with other Federal agencies. Dr. Cline has acknowledged that the agency fits into the larger public health paradigm. As such, "we are hoping, with early intervention, that we will be paying less down the road for complex care. We are hoping early detection will avoid additional cases." Specifically, SAMHSA is working in partnership with Federal agencies and the

larger community to make sure that substance abuse and those who are at risk are addressed, for great economic benefits can be achieved from that approach. In summary, the issues Dr. Yogev raised are part of a holistic situation that involves partnerships and a complex public health picture. "SAMHSA is trying to do our part."

Cross-Medications Problems

Dr. Yogev asked Dr. Clark to note the "almost total ignorance in the mental health system about the interaction of antiretrovirals with psychiatric drugs." Dr. Yogev himself has had experienced patients given psychotherapeutics, yet this was discovered only after the patients had failed their HIV/AIDS drug regimens. In short, he hopes SAMHSA will "educate mental health personnel to learn to communicate with other medical personnel when working with HIV/AIDS patients and check before prescribing" certain medications. Dr. Clark responded that this was a "wonderful recommendation" which he will bring to the attention of appropriate SAMHSA officials so that work can be done with the National Institute on Drug Abuse (NIDA) and the U.S. Food and Drug Administration (FDA) to produce materials that capture the dynamic of the key issues involving HIV/AIDS medications and psychotherapeutics, as well as methadone and possibly other medication interaction problems that loom as the American population ages. He also seemed to accept Dr. Yogev's suggestion that the medical community be involved.

Counseling and Followup/Stigma Challenge

Freda McKissic Bush asked about: what kinds of counseling and followup have been available through the agency's Rapid HIV Testing Initiative with individuals who previously tested negative; whether following up with those released from the prison system would be a good opportunity to capture data "on what a difference 6 months makes"; and what is being done to address the several challenges listed on slide 41, beginning with "stigma," which seem to be common challenges in terms not only of substance abuse but also of HIV/AIDS.

Responding, Dr. Clark said various counseling and followup strategies have been pursued in partnership with communities and grantees. The desire is to recognize those strategies with best practices that evolve. More data will help the agency titrate the types of interventions it can promote, which is the way the agency is working with the criminal justice system as well. In terms of challenges, "various challenges will continue to tax our imagination. That is why we list them. We will work with the community on them, dealing with what the community is observing." Dr. Clark added that SAMHSA is a services-based agency and when PACHA is briefed on the FY 2009 budget, members will learn more about its priority for services over infrastructure.

SAMHSA/CDC Coordination on Data

John C. Martin asked Dr. Clark to expand on SAMHSA's effort to receive effective data from the CDC regarding HIV testing initiatives, to which Dr. Clark responded that his agency and the CDC currently have an open dialogue on the issues involved, which both parties "are moving very quickly to resolve." What specifically needs to be done is being hammered out. Dr. Clark anticipates that the CDC will have relevant data in October, and

his agency is working to resolve outstanding issues before then so it can report on its part of the data stream and also reflect on how well it is doing in reaching the appropriate populations. "Without data streams, you can't make course corrections. As Dr. Bush pointed out, we can make observations, but it takes time to incorporate them in the new portfolio." Dr. Clark added that, for the time being, he is "happy with the CDC's commitment. In October, it will be a fair question" to ask again about status.

Difficult-To-Reach Populations?

Noting that 68.9 percent of clients in the TCE/HIV program reported having unprotected sex at intake, which decreased 10.4 percent at 6-month followup, Ms. McGeein expressed disappointment at the figures and asked whether the clients involved are difficult-to-reach people, perhaps sex workers. Dr. Clark responded that the data involved a wide range of categories of people, yet he is optimistic about the potential for behavioral changes. As a physician, he said he believes he needs to work with his patients on how best to get from point A to point B. While he can't make sure a patient will do anything differently, the question is how do I, as a physician, get that patient to change his or her behavior? While there is a wealth of strategies and literature, "at the end of the day, what we're discussing has to do with your working relationship with your clients so that they alter their behavior over time." Ms. McGeein responded that the two nurses sitting at the table share that perspective.

Discussion Conclusion

At the conclusion of discussion, Dr. Primm noted his recent discussions with women in the New Orleans prison system about the need to be tested. Of the 50-some women involved, several stepped up to be tested. Although the women involved included IDUs and sex workers, most tested negative. This reminded him that when he was head of CSAT, a criminal justice program was in place.

Break

Upon reconvening the Council, Dr. Maxwell announced that Igor V. Timofeyev, Esq., Director of Immigration Policy and Special Advisor for Refugee and Asylum Affairs, Policy Directorate, U.S. Department of Homeland Security, would be unable to present an update on the HIV visa waiver issue this morning for reasons beyond his control. Dr. Maxwell expressed the hope that Mr. Timofeyev would be able to present at the next full Council meeting in October.

Dr. Maxwell then introduced Kevin Fenton to provide a presentation on the domestic AIDS epidemic.

HIV/AIDS in the United States: An Update
Presentation by Kevin Fenton, M.D., Ph.D., Director, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), CDC, HHS

Dr. Fenton apologized for the time that has passed since he last addressed the Council due to problems with timing and other conflicts. He noted that he had just been at the White House with sub-Saharan African colleagues employed as part of PEPFAR's program for a meeting with White House staffers that "underscored the importance of our work, internationally and domestically, in prevention."

Dr. Fenton said that today, he would provide an overview of the NCHHSTP mission and priorities; the HIV/AIDS epidemic in the United States; HIV prevention—challenges, priorities, and opportunities; and a summary.

NCHHSTP:

- Was established as the NCHSTP in 1995, with viral hepatitis added to its portfolio in 2006.
- Is one of the larger centers at the CDC, employing more than 900 domestic FTEs (full-time-equivalent employees) and nearly 300 field staff operating in more than 45 countries.
- Supports both domestic and global activities.
- Was rated "effective" by OMB's Program Assessment Rating Tool (PART).

NCHHSTP's mission is to maximize public health and safety nationally and internationally through the elimination, prevention, and control of disease, disability, and death caused by HIV/AIDS, non-HIV retroviruses, viral hepatitis, other STDs, TB, and nontuberculosis mycobacteria. The Center is part of the CDC's Coordinating Center for Infectious Diseases.

Key Center priorities are:

- Program collaboration and service integration (PCSI) through holistic approaches that look at synergies and opportunities for collaboration within the CDC as well as at the State, local, and community level
- Reducing health disparities (Dr. Fenton said his Center has been at the forefront of this and, furthermore, this is a personal priority of his, observing that stark disparities exist, and the Center can provide leadership to address them.)
- Maximizing global synergies (how PEPFAR and CDC staff working in more than 45 countries can maximize their efforts).

Dr. Fenton noted a series of workgroups formed within the NCHHSTP across Center departments and disciplines, ranging from surveillance and strategic information to corrections, and intended to look for opportunities for guidelines, recommendations, and policies that will make the Center's activities more holistic.

FY 2008 priorities for the Center (slide 9) range from publishing a PCSI white paper and research priorities to publishing a green paper for research on tracking social determinants to strengthening external communications with partners, heightening meta-leadership, identifying opportunities for strategic partnerships for prevention, and

completing a 2020 strategic plan for the Center to "visualize the shape and form of our prevention activities over the next 20 years." The last strategic plan was crafted in 1995.

Turning to HIV/AIDS in the United States, Dr. Fenton provided macro- and then micro-level information, reporting that the number of prevalent HIV infections is now more than a million, yet the number of individuals unaware of their HIV infection is running somewhere between 250,000 and 310,000. This prevalence is not randomly distributed. While the overall prevalence is 0.47 percent, there are marked differences by race, ethnicity, age, and gender (slide 12), with non-Hispanic African Americans and males in the leading percentages, population-wide. Dr. Fenton also noted that while the death rate from AIDS has been falling slightly in recent years, "we are still seeing people dying from HIV. We are not yet ahead of the curve. More needs to be done in health impact" (slide 14).

In terms of estimated AIDS prevalence from 1985 to 2006, there has been a "radically sustained increase in the number of people diagnosed in the United States, and we have seen a doubling of people living with AIDS (PLWA) in the past 10 years" (1996-2006).

In terms of AIDS cases by race/ethnicity and year of diagnosis, the latest data available track 1985-2006. Here one sees sustained increases in AIDS cases among African Americans to the point where 48 percent of cases in this time period were found in non-Hispanic African Americans. The data indicate an increase in Hispanic cases and also in AI/AN cases. There are increases in cases in men who have sex with men (MSM): in the data's time period, this is the origin of 43 percent of new AIDS cases. New AIDS cases due to heterosexual contact are on the rise—32 percent. There have been slight though consistent declines in cases due to IDU (slides 15 and 16).

Reported AIDS cases and population by race/ethnicity in 2006 show that while African Americans are 13 percent of the American population, they represent 49 percent of reported AIDS cases (slide 17).

Dr. Fenton then reported on the basis of data from 33 States on transmission modes for adults and adolescents, broken out by gender, noting that for females, 80 percent of cases are from heterosexual contact, and for males, 67 percent are from MSM contact (slide 18).

Focusing on estimated AIDS cases in males through 2006, Dr. Fenton noted the need to ensure culturally competent prevention intervention given the following:

- Eighty-one percent of the some 973,000 cases of AIDS in adults and adolescents diagnosed through 2006 were males, with 4 percent of those cases among males aged 13-24 years, and 64 percent in males aged 13-24 attributed to male-to-male sexual contact.
- In 2006, 43 percent of adult and adolescent AIDS cases were in MSM.

Looking at the proportion of AIDS cases among male adults and adolescents, 2002-2006, it is clear that for all racial and ethnic groups, MSM dominates as the transmission mode, but there is variation, including high rates for whites and Asians and Pacific Islanders. Dr. Fenton called slide 20 a potent reminder of the need for prevention intervention to be culturally competent, as "no one size fits all." Slide 21 shows how "we are not getting ahead of the curve in reducing the number of AIDS cases occurring among MSM."

Moving on to MSM AIDS cases by region and race/ethnicity, 2006 (slide 22), Dr. Fenton noted that the majority of new cases are occurring in the South, primarily among African Americans and whites. The purpose of the slide is to show that variations exist not only across racial and ethnic groups but also across regions. In addition, cases among MSM by age group from 33 States show the most marked increases among MSM aged 13-24, particularly among African Americans (slides 23 and 24).

Finally, in terms of estimated HIV/AIDS cases among MSM aged 13-24 from 33 States, again, while African American estimates dominate, high percentages are also shown for whites and Hispanics (slide 25).

Dr. Fenton then began to focus on women. Slide 26 shows the rates of estimated HIV/AIDS cases per 100,000 population from 33 States by racial and ethnic groups and by gender. Here, cases among African American males weigh in at 119 percent, and among African American females at 56 percent, far outstripping all other groups. AIDS cases among female adults and adolescents, 2002-2006 (slide 27), "show tremendous variation across racial and ethnic groups," with AI/AN leading in the category of IDU.

Zeroing in on HIV/AIDS in adolescents, 13-19 years, 2006 (slide 28), Dr. Fenton noted that focusing on the pattern of the epidemic among the young "gives us a sense of the epidemic's evolutions." Again, the data are "stark," particularly for African Americans, with tremendous geographic variations (slide 29). As the epidemic is evolving, "many of the new cases are occurring in the Southeast corner of the United States, from Virginia to Florida and then Texas and California. This has extreme implications for us in rural, suburban, and city settings. We are seeing a greater involvement in rural areas, where there are many health care delivery challenges." Dr. Fenton also called particular attention to the prevalence rate for the District of Columbia, which at 2,016.5 per 100,000 population, "rivals other parts of the world and generalized population epidemics."

Dr. Fenton then showed estimated perinatally acquired AIDS cases, 1985-2006 (slide 31), noting that this represents "another prevention success story." Now we are at the stage, he added, where "we should be setting and identifying bolder targets such as elimination." One could note, he went on, that such bold language has been heard in other countries. He then asked whether elimination in the United States is feasible or worth pursuing. Here, one must ask what the drivers are of the continued domestic epidemic. This is "not to draw our attention away from other clear areas of [domestic] need, but, rather, on how we can build on successes."

Turning to challenges and opportunities, Dr. Fenton outlined epidemic drivers among MSM and African Americans (slide 33). Some suggest that among MSM safer sex fatigue may be a driver, as well as optimism about treatment. It is also important here to tackle substance abuse, for both MSM and African Americans. One must also take into account changing demographic characteristics and growth in MSM and sexually active MSM, fueled in part by social networks such as the Internet. For African Americans, drivers include higher rates of other STDs, substance abuse, incarceration, which facilitates novel networks, and structural factors, such as poverty, racism, and discrimination, and stigma and homophobia. Dr. Fenton noted that he recently spoke at Pastor Eddie Long's church in Atlanta, in part to break the silence around HIV/AIDS, but also to look at outreach opportunities. "Faith-based organizations will be important in tackling this epidemic."

Domestic HIV/AIDS prevention challenges include the following:

- One-quarter of those with HIV infection are undiagnosed.
- MSM remain at increased HIV risk.
- African Americans and other communities of color are at increased HIV risk.
- The availability of effective treatments has led to complacency about risk.
- Stigma persists.
- There are changing patterns in distribution of substances of abuse such as methamphetamines and crack cocaine.
- The Internet facilitates meeting new partners but also could serve in interventions.

Dr. Fenton noted in particular that he is working with CDC colleagues and others to consider what a national initiative around stigma "would look like."

Domestic HIV/AIDS prevention priorities for the CDC include:

- Increasing knowledge of HIV infection through testing,
- Identifying effective interventions for at-risk and HIV-infected persons and increasing use of these interventions,
- Ensuring cost-effective allocation of prevention resources to match the changing profile of the epidemic, and
- Implementing surveillance systems to better monitor HIV epidemic, risk behavior, and prevention programs. ("If we are not measuring correctly, we need to invest in new surveillance systems.")

Recent accomplishments include:

- Decreased HIV/AIDS cases among IDUs
- Decreased HIV/AIDS cases among women, including African American women
- Increased numbers of persons tested for HIV
- Decreased pediatric AIDS cases (to 37 in 2006)

- Refocused HIV prevention efforts—
    - More than 3,600 agencies trained on effective behavioral interventions
    - New programs for young MSM of color and transgender persons
    - New research on biomedical prevention strategies (with the NIH)
    - Launch of the Heightened National Response to HIV/AIDS Among African Americans campaign
    - 2007 HIV Testing initiative
    - Early diagnosis screening program
- Improved surveillance, monitoring, and evaluation—
    - Confidential, name-based HIV reporting adopted in 48 States
    - New HIV incidence and behavioral surveillance systems
    - Program Evaluation and Monitoring System (PEMS) (which over time should facilitate better understanding of who is accessing programs and how better to tailor access)
    - Medical Monitoring Project (As this project matures, it is assisting a look at the character of those in care, their social and medical needs, and what kinds of support these individuals need.)

Dr. Fenton thanked PACHA for having been a "real leader" in moving us toward confidential, name-based reporting, adding that he is looking forward to total national coverage on this in the near future. He also noted the Council's abiding interest in new incidence data and thanked members for their interest.

Dr. Fenton then addressed the CDC major initiatives.

First, advancing the CDC 2006 Testing Recommendations has worked well, Dr. Fenton said (slide 41). It has been less than 2 years since these recommendations were advanced, but since then, major citywide testing initiatives have been launched, numerous emergency departments have made HIV screening routine, 38 professional organizations have issued supportive policies, and some States have harmonized their laws to remove barriers to testing, with others moving toward that goal—all in all a "tremendous success." Next year, Dr. Fenton added, the CDC will be looking to "codify this."

Moving onto the FY 2007 HIV Testing Initiative (slide 42), Dr. Fenton emphasized that as the CDC moves forward with this initiative, it is "important that we build capacity and infrastructure to support it" and to scale it up. Dr. Fenton then showed a map of Testing Initiative awardees that "perfectly overlays" his earlier map showing prevalence rates in certain regions of the country (slide 42).

Dr. Fenton then highlighted the CDC's Heightened National Response campaign launched a year ago, the key pillars of which are:

- To expand the reach of prevention services,
- To increase opportunities for diagnosing and treating HIV/AIDS,
- To develop new, effective prevention interventions for African Americans, and
- To mobilize broader community action.

Dr. Fenton then provided several examples of Heightened National Response activities, including "key" involvement by historically black colleges and universities. He noted that the more than 80 community leaders initially involved in the response pledged to take action, and that the past year has "seen commitments realized." In May, the CDC will hold a large meeting to discuss how to take the campaign "to the next level."

Dr. Fenton also noted the "Take Charge, Take the Test" evidence-based social marketing campaign targeting single African American women ages 18-34 who make less than $30,000/year, have some college education or less, live in specific areas of Philadelphia and Cleveland based on AIDS data, and are having unprotected sex with men. Dr. Fenton said the campaign has been "amazingly successful," and that he hopes to share data on that with the Council later this year.

Summarizing, Dr. Fenton noted:

- HIV/AIDS continues to evolve with marked geographic heterogeneity and a high burden among African Americans and MSM.
- Stigma, homophobia, prevention workforce issues, and the Internet are major challenges. ("We need to be thinking about the structural factors driving the epidemic here, such as the Internet as well as high rates of incarceration.")
- Renewed commitment to increased partnerships, testing, and integration of services is essential.

Discussion

Structural Factors Initiatives

Noting Dr. Fenton's passion about structural factors such as stigma, Dr. Maxwell asked him to comment further on initiatives in the area, to which Dr. Fenton responded that "stigma has not been tackled head-on in the past by Federal agencies. Yet there are a number of ways we tackle it today." First, there is stigma around the disease itself, "so we tackle that through education and social marketing campaigns." Second, there is stigma related to testing—many don't want to get tested—so the CDC is tackling this through its initiatives, revised recommendations, and social marketing on testing. Finally, there is stigma attached to behaviors that would lead to transmission, and "this is where we haven't done as much work on tackling homophobia and racism, for example."

Coordination of Programs

Mr. Martin asked how the CDC is helping to bring about integration and coordination in programs and among partners, to which Dr. Fenton responded that the CDC has been working to strengthen partnerships over the past few years. Usually, this starts at a personal level, colleague to colleague, but because that is not sustainable, engraining structures need to be created, such as the internal workgroups mentioned earlier in his as well as in Dr. Clark's presentation. Leadership also needs to play a role, which has helped lead to regular meetings between the CDC, HRSA, and SAMHSA, for example, where collaboration is encouraged. Dr. Fenton added that he has been conducting site visits recently to various Federal agencies to communicate "our vision, what we are doing,

what we are doing together, and future opportunities" for coordination and collaboration. Dr. Fenton noted that of course "collaboration has to be planned and paid for—money and time are necessary—to have shared vision."

Prevention, Including More Targeted Prevention

Mr. Schmid noted that prevention is the Domestic Subcommittee's top issue, and he has heard that when the new incidence numbers are released, the number of new infections will be much higher than 40,000, although "whatever the number is, it is too high." Speaking personally, his guess is that "we will need a lot more money to bring down that number in the United States." Mr. Schmid noted that Dr. Fenton had talked about effective allocation of resources, yet such allocation may not be in effect for MSM if the infection rate is almost 50 percent in the MSM community and only 21 percent of CDC funds allocated to the States are being spent on MSM interventions. In addition, of the 49 approved interventions just released by the CDC, 37 are geared toward minorities but "none are geared toward black and Latino MSM." So, he asked, how can we do a better job specifically in those communities?

Dr. Fenton responded that Mr. Schmid has touched on why investment in research is so important, and why "there's a danger in lagging behind the epidemic." The key thing "is not thinking about how the CDC does everything but, rather, how we can partner with and leverage the resources of other agencies, such as the NIH." Dr. Fenton went on to note that last year, the CDC had a joint research consultation with the NIH and HRSA and the result "fed back into priority setting for the NIH, the CDC, and HRSA."

More importantly, Dr. Fenton added, Mr. Schmid's question highlights "pipeline difficulties" for development of needed studies. First, "we need researchers from the risk groups so that we can develop culturally competent interventions. The real challenge is with African American researchers. While we have more today, there is still a dirth, particularly in terms of MSM researchers. And this has affected the range of strategies available." Another aspect is that interventions take years to develop. The CDC has other interventions in the pipeline, "but it is quite a process, so we are looking at ways to accelerate it." As we think about effective interventions, "we're hoping in 3-5 years to have more of them." In addition, "we shouldn't be thinking only of using DEBIs (Diffusion of Evidence-based Interventions) because in any given year, given the magnitude of this epidemic, we need to look at other tools, such as social marketing and educational campaigns." The "Take Charge, Take the Test" campaign and the testing initiatives "give us broad, population-based approaches. DEBIs are part of the strategy."

Expanding Testing Recommendations and Countering Conspiracy Theories

Dr. Primm suggested that, given the data Dr. Fenton provided about prevalence in key age groups, the CDC expand the current age range of 13-64 in its testing recommendations, to encompass younger ages but also older, as people over 64 are not "chopped liver." He also noted recent media activity over what the Reverend Jeremiah Wright, Jr., has said about HIV's being a Government conspiracy to murder African Americans and how prevalent that view actually is in the community. He then asked Dr. Fenton what the CDC is doing to counter the universal negative messages that continue

"to fuel this conspiracy nonsense." He also asked how the CDC plans to measure the efficacy of its testing intervention, particularly when stories are circulating about blood tests not being handled correctly in terms of spoilage in the Southeast, for example.

Dr. Fenton responded that the CDC is particularly concerned about the Southeast and that he will be conducting site visits there as well as in the Southwest. "We want to understand the context of intervention in those areas, particularly the rural areas. It's a completely different world, and we need totally new models." Meanwhile, with limited funds, his colleagues are doing research on how to measure the effectiveness of these testing interventions, and when new monies are released, there will be a push for monitoring and evaluation of "these investments." Dr. Fenton added that he wants to be able to tell stories about the successes in part to be able to clearly articulate that investments in testing save lives. Number of tests done, number of newly diagnosed, and "time of testing to progress" are "all indicators that can give us a sense of getting people earlier and show that we're having impact." But other factors are also being examined. For example, "as we move outside of STD clinics, we want to know about our outreach and what the positives are" on the basis of data collected from partners to be collated by the agency.

As to the conspiracy theory, Dr. Fenton added, he manages the Tuskegee program at the CDC and thinks that feelings of mistrust still persist. Therefore, the CDC's approach is to make sure that messages are coming not just from the Government but from members of the community as well. That is, shifting the discourse and responsibility for intervention from Government to the communities "is a key strategy for changing discourse on this epidemic." Dr. Fenton noted that he is often asked why the African American community doesn't take to the streets like white gay men have done. He feels this doesn't happen because of different trajectories and time periods. Meanwhile, using community-based approaches "is the way forward."

Last, in terms of the testing recommendation for ages 13-64 years, Dr. Fenton said the CDC is hoping it will pick up clients before age 64. "We know that with limited funds, we need to invest where we can get bang for buck, and the data show that focusing on the age group identified is most cost-effective."

The Heterosexual Epidemic

Robert C. Bollinger, Jr., asked two questions "to help us interpret some of the data," specifically, first, about relations between the heterosexual epidemic and the IV-using epidemic, adding that in his experience in Baltimore, many presenting women represent heterosexual contact with high-risk men who are IV drug users. He thinks that the impact of this is underestimated and that there is a need to prioritize interventions to reduce such drug use, but he would like to learn more from Dr. Fenton about this and what is being done about it. Second, Dr. Bollinger said he is "a little confused looking at data on prevalence and AIDS cases and at other times HIV/AIDS cases because in understanding how to target cost-effective interventions, the decline in AIDS cases in IV drug users is very important." When one thinks about how to reduce cases of AIDS, "some of the decline could be access to effective treatment, as in earlier diagnoses and earlier access to

care." Therefore, when looking at the Southeast and increases in HIV/AIDS cases there, he is interested in finding out how much this has to do with access to care.

Dr. Fenton said that in terms of the first question around using HIV/AIDS cases, in a macro presentation such as this, he uses data from many sources. While he could have focused on HIV/AIDS, each of the indicators he presented shows slightly different things. In the end, however, HIV incidence data are "the Holy Grail," and he looks forward to release of the latest data on that later this year. In terms of the second question, regarding IDU, "it's not only that people are living longer and healthier lives, but we're actually seeing fewer diagnoses over time, consistent across all four regions. The driver for this is comprehensive approaches to IDU, including education, targeted services, and needle exchange, so that's consistent, and we believe it." In the Southeast, Dr. Bollinger's point about access to care is very well taken, as "it could easily be that individuals there are getting into care late." The incidence data "will give us a true sense of this." At present, "we have every reason to think that late care may be a situation there, as we also see higher rates of STDs there, issues in terms of access, and issues in terms of health care quality."

Dr. Bollinger commented that "it's important to have effective interventions identified…and it's important to know what you're intervening." He then asked about the heterosexual and IDU connection. On the one hand, women are getting infected through heterosexual contact with male IDUs, but on the other hand we also know about women who are being infected who are IDUs themselves. Then there is the possibility that a smaller proportion of women are getting infected through partners due to their partners' homosexual behavior. The bottom line is that when looking at such data, "it's important to ask how to unpack the overlap. What is a high risk for women, and how do we capture increased risk due to partners?"

Latino and Hispanic Interventions

Troy Benavidez commented that culturally relevant interventions in the Hispanic community require understanding of the population, such as immigrant status. Dr. Fenton responded that he is particularly pleased with the CDC's work with the Hispanic community over the past few years and that he has worked with Hispanic populations much of his life. At present, the CDC is "unable to unpack ethnic subcategories at the national level. If this is done, it is at State and local levels." However, he is aware of the great diversity in Latino populations depending on the region, and the CDC has been working over the past few years with a number of Hispanic partners to develop and refine approaches to HIV/AIDS among Latinos and Hispanics. In fact, there is a Latino Executive Group that brings together colleagues specifically focused on that. He has met with a number of representatives of the Latino community as partners, and this year, the CDC will host the first Latino/CDC consultation. Essentially, the epidemic there is located primarily among MSM, "so no matter what we do, we need to focus on them and the ways in which homosexuality is being expressed across Latino cultures." In addition to aforementioned activities, there is a "CDC en Espanol" to provide information to the Latino community in the Spanish language. And in December of last year, the CDC introduced many new initiatives to engage Latinos who prefer Spanish, to create a

dialogue with that community, and these are "making good strides." Dr. Fenton added that he would welcome other suggestions.

Followup on Social Marketing

Referring to the "Take Charge, Take the Test" campaign, Dr. Bush asked about mechanisms for followup with those who took the test. Specifically, she is interested in referral systems for those who might have wanted then to limit their partners, given that the most effective intervention occurs when a total package is involved in clinical settings, including helping to move individuals to abstinence.

Dr. Fenton responded that for those diagnosed positive, the CDC works with local health departments, which were prepared before the campaign began with monitoring tools. As a result, "we were able to capture good data." Part of counseling with newly diagnosed persons is around risk behaviors and what can be done to mitigate risk behaviors, as well as followup. The CDC relied on locally available services, in short, and therefore built on what was already available. In the clinical setting, he added, one-to-one discourse allows exploration of various avenues for risk behaviors, but when working at the community level, "the packaging is different." Here one sees use not only of ABC and D and E but also community-level approaches. Part of the packaging here is "community resiliency—what can this community do to protect itself?"

Bigger Problem Than We Think?

Dr. Yogev observed that the number of AIDS cases under President Reagan was about 800,000. Now the number of PLWA is about 450,000, and "we've been stuck" on the figure of about 1 million infected for the past 5 years. He asked Dr. Fenton to explain the difference, wondering if it is possible we have a bigger problem than we think? Dr. Fenton responded that the number of PLWA is a figure "that has been available for some time and used by the CDC." With the availability of new incidence data, we will "have the most robust estimate we have" of that level of prevalence in the United States. He pointed to the health statistic of overall HIV prevalence of 0.47 and noted that if that is applied to the general population, one gets about the same number as about 1 million prevalent HIV infections. He also stated that the Household Survey probably underestimates MSM HIV infections. He stated the hope that "we will be ready with new prevalence data so that we can focus on the true challenges in the United States today."

Conspiracy, Inmates, and Activism

Dr. Primm made two comments, the first about the National Ministerial Conclave that is making an impact that could counter statements by individuals such as the Reverend Wright. In addition, a University of North Carolina study on the impact of prisoners' being released to counties in North Carolina indicated that inmates are not being "hooked up" to continuity of care, including for substance abuse, a subject he is very familiar with. He advocated an expansion of testing and education in all drug treatment programs to further reduce infection. While African Americans are not engaged in the same kinds of actions as gay white men, perhaps the community needs to begin to demonstrate.

Dr. Fenton responded that Dr. Primm touched on issues he too is passionate about. He said Dr. Primm was correct that what we know about IDU abuse underscores the importance of testing, and "that's why we are committed to moving forward with testing. It's not just testing, but also leading IDUs to effective treatment, including counseling. The moment the community says this is what we must do, we will have a sea change." In terms of the conclave, he has heard many stories from pastors about how they should have been involved in the fight against HIV/AIDS earlier. But the important thing is that they are getting involved now. Dr. Fenton said that at one time, he didn't realize how important the faith community is to the African American community, but in the United States, "it's a very strong link, and it would be foolhardy to circumvent such a major cultural pipeline." Thankfully, great leadership has been exercised by pastors, the word is spreading, and "we now need to think about how to accelerate that." Addressing prisons and the incarcerated, Dr. Fenton said "we're in the middle of a structural crisis there that has an impact on many health issues in addition to HIV/AIDS." Here, too, "we need to think about how to address this crisis at a structural level, and while the CDC is committed to moving beyond boundaries, jurisdiction here does lie with some other departments."

Discussion Conclusion
Concluding discussion, Dr. Maxwell asked Dr. Fenton to return to present to the Council, and Dr. Fenton noted that he had brought copies of his Center's first annual report.

Dr. Maxwell then asked members to break for a working lunch and to reconvene at 1:15 p.m.

Working Lunch

AFTERNOON SESSION

Reconvening and Presentation
Dr. Maxwell reconvened the Council and introduced Steven R. Young to make a presentation on the Ryan White CARE Act (RWCA), substituting for HRSA HIV/AIDS Bureau (HAB) Associate Administrator (Director) Deborah Parham Hopson, who was unable to present due to duties on Capitol Hill. Dr. Maxwell noted Mr. Young's biography and that he is well versed in RWCA and its implementation by HRSA.

Implementing the New Ryan White HIV/AIDS Program
Presentation by Steven R. Young, M.S.P.H, Director, Division of Training and Technical Assistance, HAB, HRSA, HHS

Mr. Young said he would be providing current information on the implementation of the new RWCA, adding that he has worked with RWCA for the past 17 years.

The "new" RWCA, which passed in December 2006, has a new name—Ryan White HIV/AIDS Treatment Modernization Act of 2006—and new basic characteristics:

- It has parts, not titles.
- Its authorization is for 3 years, not 5 as in the past.
- It sunsets on September 30, 2009, which "means we all have work to do to plan for the future."

Mr. Young explained that the new Act maintains many components of the old but also codifies the MAI, with specific requirements. Its critically important goals are:

- To serve the neediest first,
- To focus on life-saving and life-extending services,
- To increase prevention efforts,
- To increase accountability, and
- To increase flexibility.

Mr. Young elucidated these goals. HRSA's data indicate that, at present, HRSA is on the mark in serving those it is supposed to—the most needy, including those who are uninsured, underinsured, and lacking financial resources. Second, the Act has an increased focus on life-saving and life-extending services, and core medical services are now in place to address a number of things, including drug therapies, issues of comorbid conditions, and hepatitis B and C. Third, in terms of prevention, a large focus of this PACHA meeting, HRSA is working with the care and treatment community on prevention. Fourth, increased accountability means that HRSA has increased the levels of reports and financial requirements at the service provider, grantee, and Federal Government levels. And last, increased flexibility means ensuring that "every dollar follows the epidemic."

The challenge of all these goals, Mr. Young commented, is that they contain many interwoven and moving parts. For example, there are changes in the formula for Part A metropolitan area programs "to follow the epidemic more closely, yet at the same time, eligibility requirements here have changed." As more metropolitan areas are eligible, there is "more competition for available funds, yet there is not necessarily enough money to go around." And some of the Act's interchangeable parts may "conflict with one another." For example, "with increased flexibility, there is some constriction in eligibility criteria."

HRSA's reauthorization implementation approach is as follows, although a number of things are "still in process":

- Inform grantees about the changes in the law. (Only two programs—both dental—traversed the switch to the new laws without changes.)
- Develop a new portfolio of application guidances based on new requirements.
- Issue funding as quickly as possible to meet grant start dates despite significant timing issues.
- Communicate implementation changes to the agency, the Department, the U.S. Congress, and other interested parties.

- Conduct conference calls to all grantees about the new changes, using transparent and open communication processes and strategies.
- Formulate question-and-answer documents for each of the programs.
- Provide more formal letters to all grantees—
    - To Part A grantees on Transitional Grant Area (TGA) definition and status, new membership requirements for Planning Councils, new requirements for administrative costs, and new requirements for unobligated balances;
    - To Part B grantees on the AIDS Drug Assistance Program (ADAP) and requirements to maintain drugs in six classes, which may in the future be eight, and on unobligated balances;
    - To Part C grantees on budget categories and services; and
    - To Part A, B, and C grantees on Interim Waiver Requirements on Core Services, which were implemented in 2007 but will be formalized for 2008.
- Revise all implementation manuals, an ongoing process. (At present, these are available only electronically, and the Web site is still being updated.)

Additional implementation activities include:

- Revised and released guidances
    - For Part A Transitional Areas (those with 9,000 to 999,000 cases),
    - For Parts A and B MAI, now a competitive grant, and
    - For Part B ADAP Supplemental Drug Treatment Grant Program;
- Implementation of a process for Public Health Emergency and Priority Funding (for Part A); and
- Development of talking points placed on the Web site.

Mr. Young commented that in terms of unobligated balances, HRSA is asking grantees to report these, which can have implications for future awards. Therefore, the agency is providing a great deal of guidance on this and also mounting technical assistance (TA) efforts onsite and to ensure tracking by grantees. At this point, HRSA "is a little behind the curve on this, and what happened in 2007 will impact 2009 grants. For example, if a Part A grantee shows greater than a 2 percent balance, this will make the grantee ineligible for supplemental funds in 2009. The money is not lost, however. It is to be reappropriated the following year to those who need it most."

Continuing with implementation, Mr. Young noted that:

- Many briefings have been conducted for Congress, HHS, HRSA senior staff, community groups, and other organizations.
- HAB has formally responded to more than 400 inquiries from Congress, grantees, advocacy groups, and individuals at the same time it was providing ongoing TA to States and territories, Eligible Metropolitan Areas (EMAs), TGAs, and other grantees.

- All FY 2007 grants were awarded under new guidelines and on time, with the exception of smaller EMA grants.

Mr. Young then noted grants awarded in FY 2007 (slide 8), commenting that the total grant case load between EMAs and TGAs went up from 51 to 56; that the Part B ADAP Supplemental was not triggered in 2007 or 2008 due to lack of receipt of additional funding; that HRSA now has authority to fund demonstration projects to help clients get ready for client-based reporting; and that "a number of States are still sending in code-based data. Here, Congress told us to reduce their allocation by 5 percent."

Mr. Young noted that nearly all FY 2008 grant processes "are out the door" and that HAB is seeing shifts in Part A and Part B funding, "as Congress intended." HAB continues to develop core medical service requirement procedures for 2008 and 2009; the client-level data reporting structure now includes clinical outcomes, with a report due to Congress in 2009; and another report is due to Congress later this year on the Severity of Need Index (SONI).

Mr. Young reported on progress in core medical services:

- In March 2007, Part A/B/C grantees were informed by letter that 75 percent of their funding after administrative and quality management allocations are taken out would need to be spent on core medical services.
- In July 2007, interim core medical services waiver application requirements were published in the *Federal Register.* (Grantees must ask for a waiver if they "don't like the new restrictions.")
- Five Part A and three Part B grantees submitted waiver requests in 2007, all of which were approved.
- FY 2008 grant applications instructed grantees to request a waiver at time of application. Five Part A waiver requests and no Part B waiver requests have been received.
- At present, HRSA is in the process of providing a permanent waiver process, and a final rule is expected in the near future. At present, grantees must certify that there are no current ADAP waiting lists in their jurisdictions, and that all RW services are available within 30 days and linked to public process. In the future, Mr. Young said, "it will be difficult for grantees to get waivers."
- HRSA has revised data collection systems to provide a mechanism to monitor allocations and expenditures of RW program funds under core medical services provisions.

Reporting on progress in client-level data (service visits and utilization), Mr. Young noted:

- From October 2007 through the end of March 2008, HRSA has been vetting a client-level system with grantees, Federal partners, and HAB external partners.

- Through April 2008, a contractor will be working with HRSA to develop Unique Patient ID number algorithm and encryption methods to help Part A and Part B grantees.
- It is anticipated that the client-level data collection system will be implemented in November 2009. HAB staff will receive a briefing on status in the near future, and based on critiques of the draft to date, "there may be a phase-in" of this system.

Mr. Young then briefed members on the SONI, which is discussed in greater detail at http://hab.hrsa.gov/severityofneed/. (See also slide 13.) Mr. Young called the SONI in progress "a seminal piece of work." The draft SONI was hypothetically applied to relevant FY 2007 grants, and "the effect would have been in the direction that Congress intended." A SONI report is due to Congress in September. Implementation will not occur for FY 2009. Within the Bureau, there are significant operational considerations. That is, "we're concerned we have sufficient personnel with sufficient expertise" to work with the SONI, Mr. Young said.

Issues and the Future

Mr. Young went on to detail how the Bureau is thinking about the future even as it implements the Act in the present. The future is "not a general epidemic, but it is one with lots of disparities," so discussions are taking place about that and the purpose of the Act. For example, the Bureau has had a planning discussion about emerging care and treatment issues that "we feel are having an impact on the effect of our program." These include the shortage of HIV clinicians and staff. "We're losing our best and brightest for many reasons," Mr. Young stated, noting that at all grantee meetings in 2006, virtually everyone attending was "new staff—we are training and conducting TA with new staff."

Another factor is the wide range of clinical issues. Mr. Young noted the new law's increased focus on hepatitis B and C as well as the need to monitor for resistance, sensitivity tests for certain drugs, and increasingly complex care and costs. Also on the clinical side, HRSA is "pushing hard on clinical quality measures. We just rolled out five measures. This is not 'Judgment Day'; rather, it's taking where you are now and improving it." Mr. Young went on to observe that "we've seen the most dramatic improvement by those who started in the middle but came up in quality once they understood what was going on and made changes." HRSA will be rolling out more quality measures in the future, including on ADAP.

Continuing to outline other issues that affect HRSA, Mr. Young identified retention as another big one. "Outreach used to be a big issue for us, but we're doing a good job there. Now the issue is keeping folks in care. There are many lost to followup, so this causes the need to ask what we need to have in place in terms of models of care." (Mr. Young also noted that HRSA and the CDC have an interagency agreement, whereby the CDC helps support testing training that has reached about 50,000 providers.) Mr. Young also noted concern about "the fiscal viability of our grantees and providers." Grantees and providers will need to diversify their funding streams, he said, and "not depend mostly on Federal dollars." Therefore, it will be important that these entities have the organizational capacity needed to seek other grant opportunities, for example." Another issue is State

health reform. HRSA has been watching how changes in Medicaid and larger reforms "are affecting HIV/AIDS. Importantly, HRSA currently has a study out in six States to try to uncover from a broad range of stakeholders "what is happening to living cases who have Medicaid—regarding changes in their lives and coverages—and how that will affect Ryan White."

Mr. Young said some legislative fixes will need to be made to the new Act, possibly including one that would address the last few States with code-based data. It may be that the unobligated balances situation should be revisited in the next authorization as well. "We encourage States to seek rebates. If they do a great job of getting those, if it goes into their Part B, it increases their unobligated balance. So we're talking with OMB on how to handle that. We have a number of TGAs in danger of falling off the list," so HRSA is interested in "how we can prevent loss of care if TGAs lose status and funding."

Mr. Young concluded by noting that HRSA has a diverse and experienced staff that is engaging in shared discussions every 2 weeks during which "we focus on a State and ask any relevant staff to come in…and try to identify some of the emerging care and treatment issues that might have to be addressed across the silos." These have been informative, as have discussions looking across the States. Last, Mr. Young reminded PACHA members that the RWCA grantees meeting would be held in August of this year in the District of Columbia and that many of the issues he outlined today would be discussed further there.

Discussion

Mental Health Retention and Adherence

Dr. Yogev asked about mental health retention and adherence under the new law, to which Mr. Young responded that this has been identified as a core medical service. Within broad Federal guidance, however, "it is really the States and cities that make decisions" about allocations among competing medical services. While he agrees that mental health is a critical issue, "we need additional funding for it, we need to look at models of multidisciplinary care, and we need to look at means of retention."

Prevention Efforts and Client-Level Data Collection

Dr. Bush noted that increasing prevention efforts is one of the goals under the new Act and asked what is required of grantees. She also applauded the client-level data collection effort.

Responding, Mr. Young said one of HRSA's mantras is that "we try to support good quality data collection with multiple purposes, so in part grantees can eventually own program efforts and also know where they stand and can improve," assuring Dr. Bush that the process is thoughtful and includes engagement with grantees and others. As to prevention, just as Dr. Primm referred earlier to preachers' carrying scripture, Mr. Young has his own "Bible," which is a red-lined version of the reauthorization showing everything that has been deleted or inserted. He would have to consult with that in order to answer Dr. Bush's prevention question. However, there is emphasis on earlier identification and testing in clinical care settings and identification of positives. "We

clearly have expectations of service providers' engaging with positives. We have collaborative activities at the Federal level and also at the grantee level, which we are coordinating and trying to make sure proper linkages are in place. We also have linkages requirements for a number of our grantees as points of access to the HIV/AIDS care and delivery system and vice versa." Mr. Young added that he will get back to PACHA staff with more information on prevention, including increased efforts.

Growing Numbers of Clients, Fewer Dollars

Mr. Schmid commented that while the RW program is not growing very fast dollarwise, the number of people needing services is, not only for medications but also for health care. Therefore, he asked, how are we going to take care of all these people? Mr. Young responded that was a good question, and he will expand upon the problem of increasing numbers of people in need. What the Bureau hears all the time from grantees is that people in need are coming in the front door and the side door because what they've had they've lost. And now, some Part C grantees are thinking of instituting waiting lists for primary care. While these don't exist at the moment, "this is not to say they won't in the future because in a number of areas, providers are at their capacity in terms of who they can care for." While "more money would be great," HRSA has been looking at making inroads through community health programs that serve populations affected by HIV/AIDS, even programs not funded by RW, "because at least they are stepping up to the plate." The bottom line, however, is that "we face the prospect of being squeezed, no question about that."

Discussion Conclusion/Next Presenter

Concluding discussion, Dr. Maxwell then introduced the next speaker, Ellen Stover, whose Division at the National Institute of Mental Health (NIMH) has an annual budget of approximately $180 million.

NIMH HIV Prevention Research
Presentation by Ellen L. Stover, Ph.D., Director, Division of Mental Disorders, Behavioral Research, and AIDS, and Director, Center for Mental Health Research on AIDS, NIMH, NIH, HHS

Dr. Stover noted that this is the first time she has addressed the Council and that she is accompanied by staff members Drs. Andrew Forsyth and Christopher Gordon.

Dr. Stover said she will address the following topics:

- The NIMH mission,
- Taking HIV prevention science to practice through the CDC or HRSA,
- Interagency collaborations, and
- Current and future initiatives.

NIMH has been involved in the HIV/AIDS risk-reduction arena since 1983. The agenda it carries forth is very broad, but today, Dr. Stover will address behavioral research—how

to get people to reduce risky behaviors or increase or adopt healthier ones, which was recognized as critical "very early on."

The behavioral research priorities for the Center for Mental Health Research on AIDS are as follows:

- Support for innovative, multidisciplinary HIV prevention research,
- Clarification of the impact of new biomedical strategies,
- Development of multilevel prevention strategies for HIV, and
- Improvement of the efficacy of mental health services for people living with HIV and mental illness.

Dr. Stover noted the phases of behavioral prevention research (slide 4), which are modeled along the lines of drug research.

Dr. Stover noted different levels of effective prevention approaches, as follows:

- NIMH Multisite HIV Prevention Trials (which target individuals and are "costly")
- African American Serodiscordant Couples (which target couples and have complicated protocols)
- Family-based interventions (the program "CHAMP")
- Popular Opinion Leaders (At the community level, this has provided landmark data on changing community norms, similar in concept to the Tipping Point.)
- HIV Testing Policy Change (which targets Government/policy).

Dr. Stover then turned to how interventions must be targeted and tailored to particular populations, stating that in more than 50 percent of the research she supports, more than 75 percent of the studied populations are minorities, which extends to the researchers as well. In addition, in MSM and racial and ethnic health interventions research, NIH in general is able to recruit and retain.

In terms of moving science to practice, current primary HIV prevention research priorities are:

- To identify patterns of risk for HIV transmission
- To develop and test new interventions to reduce risk
- To have multilevel interventions
- To ensure long-term maintenance of change (For example, research grants are 3, 4, and 5 years in length, and it is "difficult to follow change in people when one has to keep getting grants renewed.")
- Increasingly, to examine behavioral aspects of biomedical strategies to prevent HIV infections.

In terms of translation of science to practice from NIMH to the CDC:

- The CDC disseminates evidence-based interventions through the Diffusion of Evidence-Based Intervention (DEBI) program.
- Of the 15 most rigorous interventions included in DEBI, 8 were developed and tested by NIMH grantees (more than all other NIH Center contributions combined).
- The CDC has conducted trainings for more than 3,000 agencies through the DEBI process.

In terms of science to practice and intervention for women living with HIV, Dr. Stover briefly noted the Women Involved in Life Learning from Other Women (WiLLOW) program and a randomized controlled trial to reduce HIV transmission risk behaviors and STDs among women living with HIV (slide 11). The key finding here is that the WiLLOW program lowered incidence of risky sex over a 12-month period among participants.

Dr. Stover also noted Project LIGHT, a 1998 randomized clinical trial involving more than 3,500 participants (Hispanic, African American, and nearly 60 percent female) and seven-session cognitive behavioral interventions in 37 inner-city community-based clinics in five U.S. cities (slide 12). The results here were fewer unprotected acts and a higher rate of condom use over 12 months; for men, gonorrhea incidence was reduced by 50 percent. These results have since been packaged to be made available to clinics, Dr. Stover added.

Moving on, Dr. Stover noted the Popular Opinion Leader (POL) Intervention (slide 14), which has been picked up throughout the country and across the world. The original studies were in gay bars, with "very efficacious results."

Asking the question of whether investment in prevention has paid off, Dr. Stover showed slide 15 and the estimated annual numbers of HIV infections in the presence or absence of evidence-based HIV prevention services. On the one hand, Dr. Stover said, prevention has been successful, but on the other, the numbers of infected may have increased. In the end, however, prevention may have, according to a model shown on slide 16, prevented, in the best case, about 1.6 million infections between 1985 and 2000, and in the worst case, 204,000.

Other policy-relevant NIMH research has included:

- Modeling studies to estimate cost-effectiveness of HIV testing (which informed the CDC's recommendation for routine HIV testing for American adults),
- A study to examine social networks of young African American MSM following a 2002 HIV outbreak in North Carolina, and
- Rapid oral HIV testing in urban emergency rooms (which has yielded lower positive predictive values than anticipated).

In 1997, behavioral study data were considered sufficiently strong to hold a consensus conference on Interventions To Prevent HIV Risk Behaviors. It was the only NIH-

sponsored conference held to date to emphasize behavioral research, and a key finding was that prevention for positives still needs work

With increasing awareness that HIV is becoming a chronic disease, NIMH has moved into a "robust" secondary program. NIMH has concluded that a comprehensive HIV prevention strategy for the United States requires secondary HIV prevention, meaning that secondary prevention equals prevention and care targeted to HIV-positive individuals, that behavior interventions targeting this group should complement primary prevention interventions, and that promotion of engagement in medical care and improvement of medication adherence is needed.

Collaboration within NIH includes:

- Developing prevention messages for emerging biomedical prevention strategies,
- Examining facilitators and barriers to microbicides use (such as partners, context of use),
- Examining brief, feasible interventions for persons with acute HIV infection (HPTN), and
- Age-appropriate interventions for adolescents (ATN, PHACS, IMPAACT).

Dr. Stover then showed a Venn diagram (slide 22) of multiple comorbidities in HIV infection, where HIV/AIDS, substance abuse, and mental disorder all intersect. This highlights the point that HIV/AIDS infection "does not occur in isolation," Dr. Stover said, adding that this fact "requires integrated effort."

Dr. Stover also addressed comorbidity with HIV and hepatitis among persons with severe mental illness (slide 23), noting that the high percentages of HIV-positive individuals with severe mental illness, hepatitis B, and/or hepatitis C "are very serious." In short, "mental illness must be addressed."

Dr. Stover then turned to prevention for adolescents, stating that a large percentage of adults became infected in their teens. She noted different outcomes, including delayed onset, which is a component of "many of our interventions"; reduction in the number of older partners—a specific target of intervention; and perceived invulnerability/impact of disease. She commented that perceived invulnerability among adolescents is "typical," so age-appropriate information and education "is important." That is why specific venues and approaches have been developed to address this, including the family, schools, clubs, and through new technology and media (such as the Internet and cell phones).

Moving on to interagency collaborations, Dr. Stover highlighted the HRSA Special Programs of National Significance (SPNS) Initiative (2005-2007), originally funded by NIMH. During this initiative, HRSA funded 15 clinical sites across the United States to implement OPTIONS. Evaluation is in progress. The OPTIONS project was designed to be a very brief collaborative discussion between clinicians and patients with the following goals:

- To assess the patient's risk behavior,
- To address any ambivalence about change,
- To elicit strategies from the patient for moving toward change, and
- To negotiate a behavior change goal or plan of action.

Data to date (slide 28) indicate that OPTIONS intervention reduces risk behavior among patients in HIV care. The intervention is, in short, "effective."

Dr. Stover noted CDC and NIMH collaboration in research on technology transfer and intervention dissemination. NIMH and the CDC share common interests: both seek to study and improve the process of dissemination, adoption, and implementation. NIMH recently developed a Funding Opportunity Announcement (FOA) with the CDC that will be released shortly in the *NIH Guide* to encourage more research on effective dissemination strategies.

Current and future initiatives are seen in FOAs at NIMH (slide 31). These include announcements in line with the CDC's strategic plan involving men's heterosexual behavior and HIV infection—"an emerging area"; prevention research with HIV-positive individuals; and the effect of racial/ethnic discrimination and bias on health care delivery.

Sample initiatives within the National Institute of Allergy and Infectious Diseases (NIAID) HIV Prevention Trials Network (HPTN) include NIMH staff work with protocol teams on two new intervention efforts: a multilevel intervention for African American MSM in six to eight cities and a feasibility study to determine rates of HIV incidence among women at high risk in 10 geographic areas.

Concluding her presentation, Dr. Stover observed that "there have been disappointments in biomedical strategies, and although these efforts will continue," she would like to "underscore the importance of behavioral intervention to HIV/AIDS."

Discussion

Followups

Dr. Yogev asked about followups to interventions in terms of time intervals. Dr. Stover responded that, on rare occasions, the interval is 18 or 24 months. Dr. Yogev noted a study he was involved in with young mothers. After 6 months, many were doing well, but many were not. In short, "one has to be careful about short sessions and no booster over time." Responding to Dr. Yogev's followup question about the effect of having no booster, Dr. Stover said NIMH does have studies involving boosters, but to build that in, "you need a longer term grant." Dr. Yogev asked Dr. Stover to share the results of those studies. She agreed. She also noted that these studies "are more costly." Concluding, Dr. Stover pledged to send studies involving boosters as well as information about other effective interventions she did not mention in her presentation today.

NIH and MSM Research

Mr. Schmid noted PACHA's great interest in NIH, given that "we know a lot of answers can come from your Division." He indicated his concern as previously stated to Dr.

Fenton about the lack of approved effective interventions for the MSM community, particularly African Americans and Latinos. He asked whether Dr. Stover has or plans to release announcements geared to those populations. Dr. Stover responded that she would provide more data on the Center's current portfolio, noting that, at present, of 54 grants in the portfolio, 14 target MSM. In secondary prevention, of 25 grants, 50 percent target MSM. Dr. Stover and her staff mentioned several other studies, all of which are currently funded but for which no results are yet available. Dr. Stover went on to explain that her priority is to make data available as soon as possible, even short of publication. Yet it takes years to do the work and analyze the data. The long process involved and how the data get out "would be good issues to grapple with."

One of Dr. Stover's staff, Dr. Gordon, said the Center is already working on trying to shorten the time period between grant application, acceptance, and issuance of data. "Applications take a long time. Once efficacy has been demonstrated, it is important to understand how to get the results out as quickly as possible, including how effective they are among front-line providers." Dr. Stover noted a key question to be considered, i.e., "how much do you want to alter interventions under rigorous scientific standards? An issue in the DEBI process is how much the research can be altered or tailored to meet a community's needs."

OPTIONS Findings

Dr. Bush asked for further explanation of the OPTIONS findings on slide 28, specifically why the control group and the intervention group started out at two different levels of estimated risky sexual events. Dr. Gordon responded that that was part of a quasi-experimental design, whereby the OPTIONS intervention was conducted in one clinic, and the control in another. The standards of care were different in each clinic, but they were in similar locations and serve similar populations. In short, this was not a randomized trial.

Dr. Bush expressed interest in more dissemination of OPTIONS, to which Dr. Gordon responded that "we think it will snowball" after evaluations in progress are completed. He mentioned a New York State demonstration project and that, "as more evidence accrues, we could speak with stakeholders like the American Medical Association." Dr. Stover added that because physicians and health care providers "aren't comfortable with these discussions, a prompt they can reference would be effective. We could also look at OPTIONS in terms of adolescents."

MSM

Ms. Flucas said that her organization in Beaumont, Texas, has tried many of the interventions Dr. Stover mentioned, but asked how one addresses MSM "who don't identify." Discussion ensued about the Popular Opinion Leader (POL) intervention. One of Dr. Stover's staff members, Dr. Forsyth, said NIMH has at least one research project addressing MSM who don't self-identify, funded last January, that takes a more individual approach than POL. In addition, there is at least one other related research project "making its way through the pipeline."

Peer Review
Dr. Stover returned to the peer review process, noting that back when behavioral research was "not seen on par with biomedical," she wanted to make sure NIMH had "rigorous review." Therefore, what she has presented today in terms of findings is "solid science," much of it backed by publication in peer-reviewed journals. Dr. Forsyth added that NIMH is "grappling with reaching out to communities of color but also reaching out to researchers to develop applications in areas we know are important." In fact, work is underway at present on a public health article that addresses developmental issues in the field, including the need to have "a more robust pipeline of researchers."

Research Translation and Community Capacity
Dr. Bollinger commented that the two most important things being presented and discussed are the need to take research to practice and the need to help build research capacity in the communities that need to do the research. Following up on Dr. Yogev's earlier question about the sustainability of effectiveness in behavioral change, Dr. Bollinger asked Dr. Stover how she is defining effectiveness. There are several ways to report behavior changes, he added, and definition of effectiveness is "important for program implementation."

Dr. Stover responded that NIH is trying hard to make the link between research findings and program implementation, but, at present, "we're not set up in a way that requires investigators to give us a plan for how they will make sure their interventions are disseminated. We just haven't gone that far. However, we do have the prerogative to make requirements." Dr. Stover added that interventions used to be longer, but now they are getting briefer, and that cost is a factor. The POL intervention is "cheap," and even before we had data on it, "China wanted to move it out because it is intuitively doable and feasible." Dr. Stover's staff also reiterated that the NIMH portfolio includes research into measurement and effectiveness in behavioral science studies.

CHAMP
Dr. Primm asked about HIV/AIDS empowerment interventions in the Community HIV/AIDS Mobilization Project (CHAMP). Dr. Stover responded that she would get back to PACHA staff on that, adding that the program is a good example of one that involves the community and that it could be "part of the domestic PEPFAR agenda." She noted that Roberta Berkoff did a study that involved role playing, where her intervention made it easier for young boys to engage in safer behavior as they got older, adding that "an intervention like that could be easily scaled up for any community."

Current Face of the Epidemic
Dr. Primm asked Dr. Stover to say more about the current face of the epidemic, adding "we've got the problem here." Dr. Stover responded that back at its beginning, the epidemic was in the gay white community, and it took a long time, "because of denial and stigma," for people in the African American and Latino communities and others to want to address or grapple with what was going on there. NIMH funded research in those communities, but later than research in the gay white community. "Part of what we need to do," she added, "is break down barriers to actually addressing the problems. We deal

with very sensitive behaviors, and that's a difficult issue to overcome." However, the decision made years ago to mandate teaching about HIV/AIDS in the public school system is helping to break stigma. "An educational process is needed to bring people, particularly adolescents, to the point where they can talk about HIV/AIDS."

Research Translation Regarding Psychotherapeutics
Dr. Primm asked how often NIH talks to HHS about bringing the bench to the trenches. Dr. Stover responded that she has not received applications on the problem that exists in cross-prescriptions of psychotherapeutics and antiretrovirals. Dr. Primm replied, "You have to tell other organizations what to do."

Dr. Yogev noted that having a domestic PEPFAR is important for many reasons, including the need to address an experience he knows about in which a researcher was asked to change an application to NIH because it mentioned MSM; there was concern about adverse congressional reaction. Dr. Stover responded that she tells people that it is "her job to get the data. Eventually data will get to the people who can use them, when the country is ready. We have tons of data. I just showed you the tip of the iceberg today."

Adjournment
Concluding discussion, Dr. Maxwell adjourned Day 1 of the full Council meeting at 3:33 p.m.

DAY 2

MORNING SESSION

Welcome
PACHA Co-Chair Raymond V. Gilmartin welcomed members back and called the second day of the 35th meeting of the Council to order at 8:33 a.m. He noted that the meeting is being filmed this morning by the BBC and reminded the public that speakers appearing today before the full Council present for the benefit of Council members and, therefore, speakers would not take questions from the public. Mr. Gilmartin also reminded members that they would break out into their Subcommittees for a working lunch today.

Mr. Gilmartin then introduced Carl Dieffenbach to give a presentation on HIV research at NIH and some of the disappointing results to date that have received press attention, including an article this morning ("AIDS Vaccine Testing at Crossroads," by David Brown, *The Washington Post,* March 26, 2008).

Future Directions in Prevention Research
Presentation by Carl W. Dieffenbach, Ph.D., Director, Division of AIDS, NIAID, NIH, HHS

Dr. Dieffenbach began his presentation by noting that this is a "very interesting time in prevention research. There are wonderful successes such as in circumcision and mother-to-child transmission (MTCT) to discuss as well as strategic areas, in addition to vaccine research, where there are issues." He also noted the writeup in today's *Washington Post* about the NIH summit on prevention research, calling it "a reasonable report" on the meeting, to which he will refer in more detail later.

Dr. Dieffenbach then targeted how HIV is different as a disease:

- The natural immune system to HIV is inadequate.
- HIV hides from the immune system.
- HIV targets and destroys the brain of the immune system, CD-4 cells.
- HIV mutates rapidly in every step of its life cycle—a "slippery foe."

Dr. Dieffenbach then noted the history of NIH funding from 1984 to 2008. NIH's 5 level years of funding were discussed at the recently concluded NIH summit, in large part in the context of how to undergo midcourse corrections in HIV research "when you have virtually no flexibility."

Dr. Dieffenbach then noted nine approaches to HIV prevention (slide 5), the first four being:

- Education and behavior modification,
- Condoms and other barrier methods,
- Treatment/prevention of drug/alcohol abuse, and
- Clean syringes (i.e., needle exchange programs).

In the next five approaches, research continues on:

- Interruption of MTCT,
- Preexposure prophylaxis,
- Topical microbicides,
- Circumcision, and
- Vaccination.

Dr. Dieffenbach noted that suppression of herpes is now on the last list, due to the showing that acyclovir "has no impact on HIV/AIDS transmission."

Dr. Dieffenbach said that both basic and clinical research are important to AIDS prevention, treatment, and care, noting the iterative cycle between basic and clinical research that is at the heart and soul of pharmaceuticals in this country. He then quoted Dr. Peter Piot, Executive Director of the Joint United Nations Programme on HIV/AIDS (UNAIDS), as stating in May 2007 that "Treatment is not going to stop this epidemic. In

2005, there were six new infections for every person put into treatment. That is not sustainable. That means we are losing the battle." We cannot treat our way out of this epidemic, so "we must have prevention," Dr. Dieffenbach stressed.

Guiding principles for HIV prevention research are as follows:

- Multiple strategies are needed to assemble a well-rounded "prevention toolkit" (see toolkit at top of slide 8).
- No one prevention strategy will be 100 percent effective, appropriate to or accepted by everyone.
- Multiple prevention strategies must be evaluated in different populations, domestically and globally, to determine the best combinations for a given population.

Discussing slide 9, on the percentage of individuals at risk with access to HIV prevention, Dr. Dieffenbach stressed that if we have the six valid approaches that make a difference as shown on the slide, "one has to ask about the level of their availability to individuals at risk." He noted that data collected by UNAIDS and published in 2007 indicate that only 11 percent of those who should have received single-dose nevirapine to prevent MTCT received it. This is a relatively straightforward biomedical method for MTCT, so one must observe that the ability of Governments to make this kind of straightforward method available in their countries "could have a profound impact, in addition to research." He added that NIH "has a mission to be able to deliver proven modalities."

Dr. Dieffenbach went on to observe that "female-controlled prevention methods are needed, because social and economic disempowerment frequently prevents women from insisting on condom use." In short, "it is absolutely essential that future prevention methods be validated as female-controlled. So much of the epidemic around the world is heterosexual, and women need to be able to have tools to protect themselves. Condoms are not sufficient."

Focusing on MTCT, Dr. Dieffenbach commented that using a drug to block transmission is, in many ways, "a simple form of prophylaxis…for which we have, essentially, proof of concept." Yet there are two MTCT epidemics, one worldwide and mostly in developing countries, in which 420,000 children under age 15 were infected in 2007, and the other in the United States, where 142 infants were newly infected in 2006. The existence of these two epidemics "gets back to availability of modalities—primarily, single-dose nevirapine." Dr. Dieffenbach went on to show the preliminary results of a study involving PACHA member Dr. Bollinger that showed that the incidence of HIV among breastfed infants can be significantly reduced by extending antiretroviral drugs for much longer periods, up to 6 months.

Dr. Dieffenbach then turned to the need for topical microbicides because:

- Most HIV infections are spread by unprotected sex.
- Current methods are male-controlled and contraceptive.

- Women have no means to protect themselves if their partners do not use male condoms or allow the use of female condoms (which are not widely used or distributed).
- Abstinence and being faithful are not likely to protect married women or those who are sexually abused.

Dr. Dieffenbach emphasized in his "areas to explore" slide (15) that it is very important to take into account behavioral aspects of microbicide use. "You either have to de-link products from sex or come up with a robust method for daily use, which will get us into a question of pharmacology, where if someone misses a dose, they will still be protected." In addition, many of the microbicides we are looking at need to be used in combination. "We know that highly active antiretroviral therapy (HAART) works…so we absolutely need to work on combination microbicides in research and also eliminate…the strong behavior component by having long-acting methods of delivery."

Addressing the role of preexposure chemoprophylaxis for HIV infection (slide 16), Dr. Dieffenbach explained that this is about use of a single agent—tenovofir or Truvada. While many studies are being conducted in this area, and there is evidence that pre-exposure chemoprophylaxis can work, the question remains whether a single pill daily can prevent acquisition because of behavioral factors, such as adherence.

Dr. Dieffenbach then addressed the timeframe for ongoing and planned biomedical prevention trials (slide 17), noting that NIH has had a series of meetings with the CDC on how best to coordinate this agenda. He noted the number of studies involving tenofovir or Truvada and that there had been many discussions with FDA and other agencies on how to make these licensed drugs available should the studies succeed. He noted particularly the excitement around the Microbicide Trials Network (MTN)-003/VOICE (Vaginal and Oral Interventions to Control the Epidemic) study to be launched later this year, as it will compare topical versus oral tenofovir or Truvada preexposure prophylaxis (PrEP) (microbicides and PrEP).

Looking ahead, "NIH isn't the only game in town," Dr. Dieffenbach said, noting specific studies in slide 18 with other, collaborative groups.

Next, Dr.Dieffenbach addressed circumcision research, noting, first, that *Time* magazine had declared the finding that circumcision can prevent HIV as the top medical breakthrough of 2007. Because he was very involved in that research, Dr. Dieffenbach joked that, "as an encore, I'm going to get a vaccine."

Noting the positive findings of three separate circumcision trials focused on the heterosexual general epidemic (slide 20), Dr. Dieffenbach quickly turned to a U.S. study involving African American and Latino MSM, where there was "no evidence of protection" (slide 21), noting that the CDC has a paper in press that concludes this as well. In addition, there is "good biological plausibility to assume this is correct." Dr. Dieffenbach also noted another study of HIV-positive males and circumcision that

showed “no protection” to females because ejaculate is the source of infection in that case” (slide 22).

Turning to vaccines, Dr. Dieffenbach noted that the HIV Vaccine Trials Network (HVTN) 502 and 503 trials have been stopped, and that the PAVE 100 trial out of the NIH Vaccine Center has been suspended “for the time being” (slides 23 and 24). All three used or were to have used a DNA/Ad5 vaccine. Meanwhile, however, the RV 144 trial in Thailand is still “humming along.”

“We were in a position, earlier, where we thought we understood something,” Dr. Dieffenbach said. “We thought that after getting the vaccine [involved in the two stopped trials], participants with high viral loads would have significantly lowered viral loads, which would have a significant public health benefit, including in terms of the virus’ ability to spread. In addition, those with lower viral loads live longer.” However, what the trials uncovered was “a trend toward harm.” Now it is essential that “we pause, take stock, and undergo a midcourse correction.”

Dr. Dieffenbach turned to the study results from the HVTN 502 or STEP trial (slide 26). Results were that:

- The vaccine did not protect against infection.
- The vaccine did not lower the viral “set point.”
- There were more infections in vaccine than placebo recipients, and this trend was more pronounced in participants with high baseline Ad5 titers.
- Therefore, next steps and future directions in HIV vaccine clinical trials include NIH evaluation of the DNA/Ad5 vaccine.

Before addressing PAVE, Dr. Dieffenbach paused to emphasize that NIH “needs to define a new direction.” Part of this effort is “taking stock of currently funded research…an assessment that has been underway since September.” Aware that “we have invested very heavily in the T-cell-based concept, we need now to go back and broaden our portfolio.” Other ideas “out there” include how to introduce a “broad…antibody,” yet “we don’t know how to make an immunogene that will produce this antibody, so new approaches are needed as well as others [that] we haven’t thought about yet.”

What we do know about the disease, Dr. Dieffenbach added, is that “there are people who are resistant to infection, who have had a deletion of the delta 32 mutation.” Can one mimic that in a vaccine, though, he asked, then noted that “it’s difficult to target a human protein through a vaccine.” This is a challenge and a problem that requires “the best minds to come forward. NIH does its best to support research, and we will solicit this and other new and novel ideas to become the cornerstone of what we move forward with in the future.”

Dr. Dieffenbach then detailed what PAVE is, its goal, and why it is needed:

- PAVE stands for Partnership for AIDS Vaccine Evaluation. It is a voluntary consortium of U. S. Government (USG) agencies (the CDC, NIH, the U.S. Military HIV Research Program, and others) and key USG-funded organizations involved in the conduct of HIV vaccine clinical trials.
- PAVE's goal is to provide a forum and clearinghouse to achieve better harmony, increased efficiencies, and increased cost-effectiveness in the conduct of HIV/AIDS preventive HIV vaccine trials, especially Phase III trials.
- PAVE is needed because no one entity or institution will accomplish the goal of identifying a safe and effective HIV vaccine. Speed is critical, and different expertise and sectors are required. Unnecessary duplication also needs to be avoided and/or eliminated. The bottom line is that there is an urgent need to increase efficiency and improve effectiveness.
- PAVE 100 is the first trial developed by this collaboration. Dr. Dieffenbach noted that this trial was originally budgeted at $20 million/year. But now the question concerns what we do "in light of the STEP data." One problem is that, given the STEP data, "if we went to Africa, we would have to run the trial in circumcised men who had little or no prior exposure to Ad5 or the adno virus. That's a small number, so the trial isn't necessarily generalizable."

Dr. Dieffenbach then noted the decisionmaking process involving the PAVE 100 trial (slide 28), summarizing that much important discussion is needed now and that "a decision" about the trial's future has not yet been made.

Dr. Dieffenbach's last slide addressed the purpose and selected goals of the NIH HIV Vaccine Summit (held March 25), as follows:

- The Summit is an important step in ongoing efforts to examine the current direction of HIV vaccine research and is part of an iterative process.
- NIAID is seeking input on the entire HIV research endeavor, including but not limited to—
    - The optimal balance between vaccine discovery and development,
    - Nonhuman primate (NHP) model development, optimization, and utilization, and
    - Integration of clinical research with discovery.
- Based on input and feedback, NIAID will make adjustments to existing efforts to attract and support novel, high-priority science.

Discussion

Prevention Access and Abstinence

Dr. Bush noted slide 9 addressing access to various forms of prevention and asked about the seeming lack of mention of behavioral change in terms of abstinence or limiting partners. Dr. Dieffenbach responded that the data are from the Global Prevention Working Group and the World Health Organization (WHO)/UNAIDS/UNICEF and that "it is possible they didn't look specifically at that as an intervention and therefore data on it were not captured." He added that PEPFAR has made the ABC strategy part of its agenda.

Dr. Bush then asked if Dr. Dieffenbach had indicated that being faithful is not appropriate, to which he responded that on slide 14 dealing with the need for topical microbicides, he had addressed conditions where a woman is married or sexually abused. Under these conditions, a woman "often doesn't have the opportunity to remain abstinent, so female control is needed." Following up, Dr. Bush observed that under a condition of sexual abuse, a woman may not even be able to negotiate condom use, and then asked about the effect of condom use even absent sexual abuse. That is, not only what is the effect of condom use, but "is it enough to prevent the disease and what percentage of reduction would you expect over time if a condom was used for every act of intercourse?" Dr. Dieffenbach responded that the incidence of HIV/AIDS from sexual transmission would be zero in perfect use of condoms in a perfect world. However, there is a whole other set of issues to consider, such as drug use and that condom use requires behavior. "Consistent condom use is very useful, but like other inventions, exhaustion occurs when it is not used," he added, to which Dr. Bush responded that her understanding is that condom use efficacy is more like 87 percent, "so there will always be need for avoidance." Dr. Dieffenbach said he was emphasizing an idealized world and that in the real world, "87 percent would be pretty high."

NIH Funding

Dr. Yogev noted that PACHA has been addressing the need for a "domestic PEPFAR" to get more domestic policy structure and funding around the domestic epidemic, which is why he is so concerned about NIH funding. He asked Dr. Dieffenbach to spell out his dream of how much funding would be needed to do appropriate levels of research, on both domestic and international fronts. Dr. Dieffenbach responded that 80 percent of the research being proposed is not moving forward, wasting incalculable researcher time and energy. His simple answer is, however, that a sustained 10-15 percent funding increase per year "would get us back on the right track."

IDU Harm Reduction

Dr. Primm asked Dr. Dieffenbach what his concept of harm reduction for IDU is. Dr. Dieffenbach said behavioral counseling and the availability of methadone or a methadone-like agent, as well as needle exchange. He called needle exchange part of "the full package of what we consider is needed for drug use reduction," such as is being pursued in the Netherlands and New York City. Dr. Primm responded that when discussing harm reduction, it is important "not to hide any more" about methods appropriate for the United States.

Moving the Research Agenda Forward

Dr. Bollinger asked Dr. Dieffenbach to list the top three things needed to move the research agenda forward, observing that he was certain more funding would be at the top of the list, followed by the challenges that lack of funding poses to getting grants through, particularly innovative grants for, for example, new approaches to vaccines. But, in addition to funding, are there structural changes that Dr. Dieffenbach would like to see, in addition to the midcourse correction on the vaccine program—additional course corrections on which PACHA could help facilitate discussion? Dr. Bollinger then

expressed particular concern about NIH resources' being primarily focused on networks and about the lack of funding focus on innovation grants.

Dr. Dieffenbach responded that within the Division of AIDS, a new program has been formed to focus specifically on prevention, which "is a big step forward"; within that structure the Division will work with prevention and microbicides networks. In addition, within NIH, there is a "trans-NIH Workgroup on the need for a domestic prevention agenda," which is "the biggest gap we face at NIAID." He applauded Dr. Stover's efforts and studies being launched under her aegis, yet "we are short of funds for those studies. As they grow in terms of evidence-based ways of looking at interventions for African American MSM and women of color at risk, these studies will evolve into larger studies." Concluding, Dr. Dieffenbach noted that he likes the domestic PEPFAR concept. He also noted that because the District of Columbia's epidemic today "is as bad an epidemic as anywhere in the world," NIH has started a "D.C. initiative." Last, while "the networks are a source of great price and work, they are also sometimes a waste. They need to undergo adjustments." Specifically, more flexibility is needed, and "we need to redirect pre-clinical and clinical funds."

Discussion Conclusion

Concluding discussion, Mr. Gilmartin then introduced Kathryn Anastos to give a presentation about HIV and women's empowerment.

Women's Empowerment and Containing the HIV Epidemic
Presentation by Kathryn Anastos, M.D., Professor of Medicine, Epidemiology, and Population Health, Montefiore Medical Center/Albert Einstein College of Medicine, and Executive Director, Women's Equity in Access to Care and Treatment (WE-ACTx)

Dr. Anastos began her presentation by noting that she has spent a lifetime working with AIDS in the South Bronx and now in Africa. In Africa, "altering this epidemic and preventing its spread lies with the women of Africa and their communities and their countries." Dr. Anastos also noted that while she is currently Executive Director of WE-ACTx, which was formed 4 years ago at the request of Rwandan women who were victims of genocidal rape, she hopes to be retiring from that position soon, as the organization does not need a doctor as its Director. She is also conducting research on the effect of antiretrovirals in African women, specifically examining who does well and who does not, with ancestry and biology as driving factors.

Dr. Anastos then noted that "In all countries, many/most women are responsible for:

- All childcare,
- All care of others in the family, community, and of orphans,
- Food preparation,
- Health care, and
- Agriculture."

Yet, increasingly the HIV-infected in the world are women. At least 50 percent of the infected worldwide are women. The only situation where women aren't drivers of the epidemic is in use of intravenous drugs. In that case, IDU men get infected and then infect the women. In the United States, well over 70 percent of those infected have been infected heterosexually. In Africa, it is 100 percent.

In sub-Saharan African countries (according to data through 2005), "women and girls are 50 to 300 percent more likely to be infected" than men and boys (slide 10). This "has a lot to do with lack of control," Dr. Anastos said, and the fact that infection is easily transmitted from men to women "and especially from men to girls."

Dr. Anastos then noted that "In all countries, many/most/some women cannot control their and their children's:

- Risk of HIV infection,
- Access to care,
- Economic stability, family finances, and food security,
- Fertility, and
- Physical safety."

Discussing trends in annual death rates among persons ages 25-44 in the United States from 1987 to 2001 (slides 11, 12, 13, and 14), Dr. Anastos noted that the steep decline in death from HIV/AIDS in that time period "is a public health achievement we almost never see." As a general internist, there is nothing she does that is as successful as this. Yet even in the United States, there are differences between infection growth levels and declines in death between white men, African American men, and African American women. Of particular note is that deaths due to HIV/AIDS have declined by only 50 percent among African American women. "That is not access, because women access health care. Something is going on here beyond access," Dr. Anastos said.

In Africa, HIV infection in women is:

- Overwhelmingly heterosexually transmitted,
- More likely at higher incomes,
- Highly likely to be transmitted by husbands,
- Transmitted to young women by older men,
- Transmitted to children by pregnancy, delivery, and breastfeeding, and
- 99 percent preventable.

Addressing the recent disappointing news on the prevention front, Dr. Anastos noted:

- Circumcision does not prevent women from HIV infection (although it does provide some protection from other sexually transmitted diseases [STDs]).
- Suppressing herpes simplex infection does not decrease HIV transmission (although it does decrease ulcers).
- Microbicides need new safety assessments.

- Vaccines are not protective.

Therefore, other forms of prevention are critical:

- Barrier protection is essential. (Dr. Anastos always stresses condoms.)
- Abstinence "is not achievable for women without control in the bedroom."
- In terms of being faithful, "man needs to be faithful also; none of us knows for certain that our partners are faithful."
- Women "can't prevent HIV infection until they can control their risk, and the sex behavior of men changes."

Dr. Anastos then went on to address the scale-up of antiretroviral therapy (ART) worldwide at ART-LINC sites (slide 18); time trends in the number of patients initiating ART by site (slide 19); and the proportion of women among patients initiating ART (slide 20). The last side indicates that the proportion of women among patients initiating ART in sub-Saharan Africa rose in 2003 and 2004 and then began to decline in 2005 and 2006. Dr. Anastos said that, worldwide, women are more likely to access care for themselves and their children—in all groups of equal socioeconomic status—but, worldwide, women also experience the same degree of barriers to care.

Dr. Anastos stressed the lack of women's control: over their ability to earn money; over the activities of the men in their families, including alcohol abuse; and over the fact that many families in the world and particularly in Africa are hungry. Yet, she added, "this does not impair women's adherence." Importantly, women's ability to earn income immediately changes the family dynamic, shifting the balance of power. When a woman has the ability to earn money, she becomes a source of hope for the community and the family; women and girls become more valuable; and downstream social effects can be realized—daughters see a different scope of opportunity for themselves and sons come to see women differently as well as their own roles.

Dr. Anastos briefly touched on an example of developing world women's entrepreneurial successes thanks to a nonprofit program called Business for Peace (Bpeace—www.bpeace.org), stressing that entrepreneurship and small business have been the fuel for economic development in every successful economy in the world. To foster this, talent must be discovered and nurtured through:

- Access to capital (micro and not so micro credit) and
- Training and development in specific skills, such as in choosing a product to make and/or sell according to available markets.

Addressing women's control of fertility, Dr. Anastos made the following observations:

- Fewer children spaced farther apart decreases maternal and infant and child mortality and improves family circumstances and health.

- Control of fertility is important for communities and Nations, not only for individuals and families, because overpopulation extends poverty, especially in limited-resource settings.

Therefore, family planning services:

- Need to have a broad reach,
- Are more effective if highly community-based,
- Should be brought to patients whenever possible,
- Can be a community value, and
- Should make all methods available—hormonal, IDU, and barrier protection, which also prevents HIV infection.

Women can be better protected and treated for HIV, Dr. Anastos stressed, with:

- A change in the paradigm of care,
- Community-based primary care—mobile teams providing HIV counseling and testing, care, and PMTCT, family planning, and cervical cancer screening and prevention,
- Leverage of information technology, and
- Cost-effective services.

In terms of women's physical safety, "in all countries," Dr. Anastos said:

- Violence from men is tolerated to a greater or lesser degree.
- Women are at risk of violence within the family and the community and from strangers.

Dr. Anastos then detailed domestic and sexual violence research findings from Rwanda and the United States (slide 32), as follows:

- In Rwanda, the prevalence of any history of domestic violence is about 20 percent in both HIV-positive and -negative women, and the prevalence of sexual violence is about 5 percent.
- In the United States, according to the Women's Interagency HIV Study, the prevalence of any history of domestic violence is 72 percent in both HIV-positive and -negative women, and the prevalence of sexual violence is 35 percent.

Dr. Anastos then quoted former U.N. Ambassador for AIDS in Africa Stephen Lewis as saying, "We must zero in on the inappropriate male behavior and put [these men] in jail for long periods when they engage in rape and sexual violence and change the laws that give them free run of the land. There just has to be very firm dealing with the men who are making such a dreadful hash of gender equality."

Dr. Anastos observed that:

- Equality can be legislated, and then quantum leaps occur generationally.
- Key parameters include ensuring property and inheritance rights, rights to children (upon divorce, for example), and fertility control.
- In Rwanda, there was a paradigm shift for women after the genocide that is embedded in the Nation's Constitution.
- This shift is part of the Nation's attitude that the Rwandan genocide must never happen again.
- In Rwanda, women who were previously considered property are now in positions of power nearly everywhere but for the military.
- Rwanda has a very successful PEPFAR program, perhaps the best in the world.

Dr. Anastos then highlighted the recent (January) evaluation of the Rwanda PEPFAR program (slide 36):

- 92 percent of adults and 93 percent of children are being retained in care at 12 months.
- Of those not retained, 2.6 percent of children and 4.4 percent of adults were known dead.
- Because it is estimated that from one-third to one-half of the remainder have in fact died, Rwanda has very low lost-to-followup rates.
- Rwanda has a goal of zero transmission, which requires prevention with positives.

Based in part on her experiences in Rwanda, Dr. Anastos advocated development and assessment of models for primary care services that (slide 37):

- Are community/village-based and family-centered,
- Are mobile, bringing services closer to patients, and
- Combine services that utilize the same infrastructure and have high impact on leading causes of death, such as services for HIV counseling, testing, and care; PMTCT, family planning, and prenatal care; and cervical cancer screening and prevention, including vaccination.

Beginning her conclusion, Dr. Anastos reiterated that the HIV epidemic is fueled by women's lack of control of:

- Risk of infection,
- Access to care,
- Economic stability, family finances, and food security,
- Fertility, and
- Physical safety.

Yet, Dr. Anastos stressed, for each of these, there are "clear and achievable solutions," many of which she presented today.

Discussion

How To Treat Men/Planned Parenthood

Herbert H. Lusk II thanked Dr. Anastos for her presentation and "passion." He noted that he traveled to Rwanda with the First Lady. He added that in all of his African experiences, he has come into contact with "many powerful and brilliant African males." He mentioned that his organization, People for People, Inc., is funding programs in five countries there, and "the idea that the solution to the problem is just put them in jail" represents a "terrible travesty." What is needed is education of males, "getting young men early and educating them on the issues and how to better treat a woman, rather than imprisonment." He observed that in the United States today, "there are many more African American males in prison than in college."

Moving on to planned parenthood, Pastor Lusk commented that, "in Africa, that could be great or that could be trouble." In the United States, "planned parenthood in the African American community has reduced the population." In short, he is "very concerned about planned parenthood, as we need strong African American men and women," to which Dr. Anastos responded that she "completely agrees" with much of what Pastor Lusk said, adding that the issue of jail is for men committing criminal behavior, specifically sexual assault. And part of the educational process is to show that "sexual assault will not be tolerated." She added that the United States "has a particular legacy of racism that is, in some ways, very peculiar to us. And it does not always translate to Africa. Issues of fertility and abortion grow out of that [legacy], in part." In terms of fertility and control, "the community should control the issue, not us. But that has to include that women have control…including around sexual risk both from pregnancy and from infectious disease."

Dr. Anastos added that "the men in Africa who are inspiring are as inspiring as the women. They remember that it's not about them and that it's about making things better." In conferences she has attended in Rwanda, for example, the Government representative always talks to the group at the end about why we are here. "And why we are here is because too many Rwandans are dying from HIV, and our intention is to prevent that and to treat them." Dr. Anastos noted that Rwandan President Paul Kagame is "a particularly inspiring man who has been described as noncorruptible. That's one of the reasons Rwanda is so successful." Also, there, "it's all about reconciliation and justice. They get rid of waste. They do everything as cost-effectively as possible." One of the things Dr. Anastos learned almost immediately in Rwanda is "we really are all the same. The concepts we have about Africa are not correct. Some people—more people there—are less well educated, but there is a sophistication of thought and an ability to solve problems that in many ways seems more effective than what you find in either academic or business medicine. They're about achieving a result." Identify the outcome you want and find the ways to get there—"that's what I see in Africa over and over again."

Projects To Fund in Villages and Bush Country

Pastor Lusk asked Dr. Anastos what his organization could most effectively fund in villages and bush country. Dr. Anastos responded that the two most important things to fund are local economic development and certain pieces of health care. In terms of the former, "Bpeace does that very effectively," and in terms of the latter, "without changing

the burden of disease and death in the community, we will fail, so the solution lies with solution sites in the community. For example, there are clear community leaders, sometimes identified and sometimes not. You can link the public health system to those people." In addition, she noted that her organization, WE-ACTx, acts entirely through grassroots organizations. "All the care we give is in coordination with grassroots organizations. We serve as the TA." In short, the answer lies in the community.

Botswana

Mr. Gilmartin noted that he has been impressed by the courage, sophistication, and commitment in Botswana by its people and its President to fighting HIV/AIDS, where progress has been made despite a disease that infects 48 percent of the country and threatens to destroy it. He noted in particular opt-out testing and the availability of antiretrovirals. In Rwanda and in Botswana, a great deal of innovation is occurring, "including the whole idea of community-based organizations' taking the lead and making a difference."

Access to Care for Men through Women

Dr. Bollinger said he agrees that the solution is family-centered care with women's access to the system. He agreed also that many countries have dedicated men who are focused on this issue. He returned to Dr. Anastos' point about women and their access to services and care not just for themselves but for their families as well. This is critical. In India, he wants to find ways to get more men to recognize the value of this perspective. Dr. Bollinger then cited two studies. In one, of the women studied coming into seven clinics (a large study), those who were sex workers experienced a significant decline in their risk and incidence of HIV/AIDS and other STDs, whereas the incidence level for married, monogamous women "didn't change at all." The behavioral difference was that men's condom use with sex workers went from 10 percent to 90 percent in 10 years, while with their wives their condom use stayed at 10 percent. In the second study, in the same community, an antiretroviral program was started, and compliance among women was very high; however, more careful examination revealed that the women weren't getting healthier because they were giving their medications to their husbands and children. What this comes down to is that many men are accessing care only when they are very sick. Women are accessing care earlier and can benefit from HAART. So how can we convince men that their wives should be the access to care at an earlier point?

Dr. Anastos responded that access to care for men through their wives "would be a good thing to look at." Dr. Bollinger asked if Dr. Anastos knew of any supportive data from Rwanda, to which Dr. Anastos responded that identifying everyone and treating everyone is the answer. "This can be tested and should be in Rwanda through mobile teams to provide care that hits the biggest killers." But, she added, "male health care workers are key players." Also, "we define the family to include anyone you want to bring to care. You need the community. The definition of family needs to be broad." Last, she observed that in terms of access to care for the family, including the men, resting on women's access when they are pregnant is not a complete concept, as "not all women are pregnant all the time."

Dr. Bollinger said that if Dr. Anastos had access to data that showed men who come in with wives have better outcomes than men who come in on their own and are sicker, "you would get the attention of men in the community." Dr. Anastos said she thinks she may be able to find those data. She went on to observe that African American men in the United States come in late, and wondered whether some of the reasons include late access or choice. But "some of it is racism." She recalled her work in the South Bronx for 20 years and the lack of access or the ability to receive care that she has witnessed. She advocated making care available close to men and women and preventing economic barriers. "Economic barriers and distance are the two biggest problems in Africa," she added.

Natural Family Planning

Dr. Bush noted that in terms of family planning services, she did not see Dr. Anastos list "natural family planning," which requires some abstinence, adding that while it is very labor-intensive to teach this in the United States, "it is an option." Dr. Anastos said that she doesn't have enough experience to know a great deal about this option, adding that her experience with family planning is her organization's current effort in Africa, as it moves from being an HIV/AIDS provider to looking for funding to implement a model of community-based primary care that extends beyond HIV and includes family planning. She did observe that, to engage in natural family planning, "you have to know when you're ovulating, and you can prevent pregnancy, if you are careful." Because the Rwandan Minister of Health is very committed to population control and encourages couples not to have more than three children, "what that Ministry is putting forth is a new, longer acting version of Norplant and IUD at the time of delivery." Basically, Dr. Anastos concluded, "everyone should be educated by everyone in all the tools available."

Microbicides

Ms. Flucas thanked Dr. Anastos for her perspectives, particularly as relates to nonoxynol-9, which has been discussed in the "Sistah!" program, including some complaints.

ART Before PEPFAR?

Ms. McGeein asked whether there were a significant number of women on ART prior to PEPFAR, to which Dr. Anastos responded that slide 20 shows the proportion of women among those initiating ART during that cycle (2001-2005/2006). Prior to PEPFAR and The Global Fund, "there was virtually no access, and the infrastructure wasn't there. That's why developing community-based infrastructure is so important. Rwanda, for example, can procure the drugs, but the question is how to get a system that delivers them. It's the same problem as in the South Bronx."

Rwanda's PEPFAR Program

Mr. Gilmartin noted that the Council would be hearing more later about PEPFAR, but, meanwhile, he asked Dr. Anastos why she thought Rwanda's PEPFAR program was particularly successful. Dr. Anastos responded that "it is because the Government there knows its mission, knows there is an evidence-based way to get there, and doesn't allow the donors to control what happens." The Rwandan Government "wants care distribution across the country, and for the money to be used in the most effective way for the short

and long term, so care distribution goes through the public health system, where the infrastructure is being upgraded." In addition, the Government "is mission-driven and not corrupt. It is very careful to examine the way the money gets spent." In Rwanda, for example, providers no longer test liver function before providing antiretrovirals. The Government said it wasn't necessary. In addition, there is good cooperation among the donors. In abstracts she has been reviewing for an international AIDS meeting, she has found some highly inflammatory statements about "care not reaching the people and how donors are cherry-picking and how donors should control that." However, ultimately, Dr. Anastos said, "the control is in the country itself."

Break

Schedule Switch
Mr. Gilmartin reconvened the Council and announced that Dr. Steiger would address the Council at 2 p.m. instead of 11:30 a.m. Therefore, the Council has an opportunity to reflect on what it has heard, and then Dr. Primm will provide reflections on his many years as a Council member on this, the last day of his appointment.

Open Discussion
Domestic Subcommittee Resolutions
Mr. Schmid noted that the Domestic Subcommittee is working on two draft resolutions, which have been placed in everyone's packet. Subcommittee members will discuss these resolutions in their working lunch today. Mr. Schmid asked International Subcommittee members also to review the resolutions and, if possible, discuss any concerns with him before formal Council consideration after the working lunch.

Young Men
Barbara Wise said she was encouraged by Dr. Anastos' report on Rwanda, adding that what she has observed in working with young people is that a number of young men want to be protectors. "We should encourage that…as it is a piece in prevention that would strengthen all the other pieces," she added.

The Future
Mr. Schmid said he feels the Council could talk all day about what it has heard and that the Domestic Subcommittee will certainly discuss relevant points later, but he advocated that the Council talk now in general about the future, before its next meeting in October. For example, he would like to hear more about how well or not HIV testing is going. While Dr. Fenton "discussed this somewhat, I would like to hear more." Mr. Schmid noted that he heard Dr. Fenton say a progress report is coming, but he has "a feeling" that the impact of the testing recommendation "has slowed down."

Mr. Schmid also observed that the Council has heard mostly from Government representatives and that it is important to hear from the "real world, on the ground—about problems as well as success stories." He indicated that his comment pertains to testing as well as RWCA implementation. Specifically, he is interested in "what is happening on the ground in certain clinics where they are working with the same level of

funding but more people." He is also interested in hearing how changes in the RWCA are affecting patients on the ground.

In addition, Mr. Schmid noted the lack of focus on the budgets of each of the agencies that has presented during this meeting. While the CDC budget was discussed, it was discussed in the context of HIV prevention, and not in the context of the CDC's many other activities, such as surveillance, testing and counseling, and some research. His goal is for all programs to do more, and "do better," so he wants to know more about how money is being spent before asking for more. This includes NIH, he stated, although there he is fairly convinced that the Institutes need more money for interventions and research, as key programs there "have been pretty flat for several years."

Testing and Reimbursement/Clinician Education

Addressing Mr. Schmid's comment about testing, Sharon Valenti said one problem on the basis of her experience working with providers is that when they did the rapid test, they had a grant; generally, however, from the provider standpoint, "testing is not reimbursable, and these tests are expensive." Therefore, "could we look into pushing insurance companies to understand that even if this is a screening, reimbursement is the only way you're going to get a lot of providers on board?" In addition, while she is unsure how much money is being spent on education, "what we've found in the clinics, and in the ER, are clinicians who are biased. They have their own clinic patients, and they would never ask them about HIV/AIDS, so some education is needed of primary care physicians as well as residents, for example." Evaluations of the testing program she has been involved in turned up interesting statements from physicians about why they were not participating. The most frequent statements about why they wouldn't ask their patients to take the test were: (1) they didn't think their patients would be positive; and (2) they were concerned about what they would say if their patients were positive.

Mr. Schmid agreed that reimbursement is "a big issue," and the Council has been investigating it. He recalled that at the last full Council meeting, representatives from several insurance companies and the Centers for Medicare & Medicaid Services (CMS) responded to questions about testing reimbursement, "but I can't say we were completely happy with those answers. We have to probe a little more, even with those who maintain they would cover testing." It was commented that reimbursement may have to do with proper coding by practitioners, to which Mr. Schmid responded that "while testing has been a success story in the past few years, we have to keep an eye on it."

Adolescents

Dr. Yogev said one issue he feels is not being addressed is adolescents. Given data about MSM ages 13-24 in Africa becoming infected, as well as young women even as young as 12, Dr. Yogev said he would like to know more about the adolescent agenda, including in the United States. Domestically, when you turn 18, unless you are handicapped, you no longer receive Medicaid. This means that some young people are "thrown out of the system without work or insurance." If they are infected, "they often get the medication anyway but not other treatment," Dr. Yogev maintained, adding that "the only time I go to funerals now are to the funerals of adolescents."

Mr. Gilmartin responded that Dr. Yogev's points are well taken.

Innovative Research Funding

Robert M. Kaufman said he is very concerned by the indication that innovative types of research are not being funded where it is absolutely necessary. It is one thing to suggest that innovative grant applications go to the foundations, "but we should address how they should go to NIH. The message should be that whether it is in research or treatment, innovation is what we're looking for."

It was noted that Drs. Bollinger and Yogev are trying to raise interest in a resolution on this point. Dr. Bollinger thanked Mr. Kaufman for bringing the subject up and that he agrees there is a problem. He characterized what he understands the current situation to be in part, which is that after 5 years of flat funding at NIH, a smaller slice of the pie is being allocated to innovative programs because of innovative programs still in the pipeline to which resources have been committed. He noted that he has written many grants and can report that it is getting harder to write them; "you find yourself being more conservative," adding that he "would love to see more high-risk, high-impact proposals get funded."

Dr. Stover noted a number of new NIH mechanisms for easing the situation somewhat, such as the "Pioneer Award" and the "R56." She said her Center has used these mechanisms successfully to provide funding for researchers to take an additional year to gather data. She also noted the NIH Director's Series, which provides a forum for discussion about innovation.

Dr. Bollinger thanked Dr. Stover and said that while these mechanisms are great to hear about and important to do, they may not be sufficient to get the "traction we're talking about." Not only is innovation involved; it's also "getting young investigators to stay in this business. We must find a way to incentivize the system." And while NIH has special programs to address this, simply "there is not enough money." Dr. Stover responded by relating a short anecdote about a grant that recently came to her Center for review. Her Center gave it a low rating, but when it reached the AIDS Committee, the Committee gave the grant its highest score. In short, "they're giving us a message also."

Mr. Gilmartin observed that "the innovation for pharmaceutical and drug discovery has been combination of efforts" and "that research may or may not lead to a drug." He noted that companies track new knowledge and then have venture capital to follow through, and this whole network fuels pharmaceuticals in this country, such as the development by Merck of three antiretrovirals and a cervical vaccine. He too has heard, from all sides, that grants are more conservative. He also has heard that the peer review process "seems to crowd out innovative proposals." He then proposed a fundamental look at how grants are selected.

Continuing on this point, Mr. Gilmartin said the significance of this discussion could be derived from Dr. Dieffenbach's presentation this morning, where one "could make the

case that HIV is winning or set up to win because all the therapies that have been so effective are being resisted, and the number of targets available for therapy are diminishing and, in fact, may already have been exhausted." In addition, in terms of an HIV vaccine, "it is not clear where to go next. Basic science needs to be done." While "we have had specific successes," what is happening now "is far too little for the size of the epidemic, both here and abroad." Science "will ultimately answer…but now we're looking at 20 years."

Mr. Kaufman commented that in the grantmaking foundations with which he is involved, grants are given grades at 2 years and "we complain if there isn't a failure once in awhile because that means risk isn't being taken." By contrast, one of the Government's grantmaking failures is that occasional failure "is a blot on the record of the grantee." You have to "let researchers try some things" and not have the occasional failure go against their records.

Dr. Yogev brought discussion back to the concept of a Council resolution on the need for "a different system for innovative research." Specifically, he called for a resolution directed toward NIH specifically addressing the need for funding at a certain percentage per year of investigator-oriented, investigator-initiated research. Dr. Bollinger responded that he would support something like that, adding that he is not sure the Council needs to recommend a change in the system first because "the bottom line is the flat funding. [With more resources], I think you would see more grants being funded that would fail but also more successes as well."

Innovations Needed Abroad

Pastor Lusk noted the need for innovation and more funding of innovation in HIV/AIDS initiatives abroad as well, adding that while the President did create a New Partners Initiative, "more needs to be done."

Abstinence and Behavior Research

Dr. Bush said that given Dr. Stover's observation that "behavior is the next AIDS vaccine," and Mr. Schmid's notation that "we still haven't found a solution," she wants to raise the strategy of abstinence. She said it is "cost-effective," and she doesn't understand "why we're overlooking that as a potential real hammer or resource in this fight." Neither condom use nor abstinence comes naturally per se, "yet we put more dollars into condom marketing and promotion." Her observation is that she believes in people's ability to practice behavior if they believe in it. Perhaps NIH should look at this factor more closely as it pertains to abstinence and get the strategy published in a peer-reviewed journal so that it will be considered more viable, as opposed to being marginalized and dismissed almost summarily. Therefore, her recommendation is that behavior research look more closely at abstinence.

Ms. McGeein responded that HHS has conducted abstinence evaluation, and abstinence education and information are available. If one looks specifically for abstinence in HIV/AIDS prevention literature, efficacy does show up for youth and children. In addition, she believes that Dr. Stover's group may already be doing abstinence research.

Speaking for Dr. Stover, Dr. Forsyth said that the Center for Mental Health Research on AIDS has been involved most recently in looking at abstinence as part of an approach to reducing risk behavior in adolescents in Maryland, and, in fact, the Center "has supported research in this area for many years." Many of the programs he is aware of use abstinence as a prevention tool, "yet many of the studies that have been conducted have not yielded results that demonstrate the efficacy of this." Also, there have been several meta-analyses "that raise real questions about the rigor of abstinence-based programs." Over all, "the science is beginning to point to the conclusion that while abstinence may be one important component" of prevention, "the evidence isn't as strong as the field had hoped." Dr. Stover added that "we have data showing you can get adolescents to delay sex [through abstinence], but if they are not also provided with instruction on safe sex, they engage in riskier behavior later." She want on to say that data not published but discussed in a meeting that looked at abstinence programs a few years ago indicated that if parents allow a boy and girl to go upstairs and sit in bed and watch TV, "they begin to think about boy-girl interaction" and "if you don't allow them to do this, they won't develop the idea, and that in itself could cause delay."

Dr. Bush said she was not sure she understood Dr. Stover's last comment, but she does want to comment "on the mathematical study recently published that did not show that abstinence was all we had hoped for." In that study, the programs examined were "limited and immature." Even so, the study "showed that the students, if they did become sexually active…were not harmed" by their exposure to an abstinence program. Her point is that she "would like to see us spend as much effort on that as we do on other methods besides abstinence, and I hope that we could find a research methodology to allow a sensible approach that would benefit those who choose abstinence."

It was commented that this is a very important discussion to have, "but the problem with the word abstinence being used today is that there have been abstinence-only programs…that close your mind to the fact that there will be [sexual] activity." Pastor Lusk added that "when you teach abstinence, you teach why." In terms of "abstinence being dangerous," he is "just an old country preacher" and he "respectfully disagrees."

Discussion Conclusion

Concluding discussion, Mr. Gilmartin summarized that the Council seems to be interested in looking for new approaches and innovation in HIV/AIDS prevention and, here, investment is needed and perhaps new approaches in the behavioral sciences as well. He said it is clear that both Subcommittees will have ample material to work with on these and other issues in the future.

Mr. Gilmartin then asked Dr. Primm to provide reflections on his long tenure with the Council, lamenting that PACHA is about to lose the benefits of his insights and wisdom.

Reflections

Dr. Primm began by saying that PACHA is his extended family. He marvels every morning when the Council meets how members will look out for one another as they get

on the bus, making sure everyone is there and, most importantly, that everyone is all right. That the Council is his extended family has been a "very important" part of his experience as a member.

Dr. Primm reflected that he has a number of things to share, now, about events in his life that have influenced his cognition and how he feels about life. In 1983, he was diagnosed with cancer of the lung, which resulted in the removal of part of his right lung. He "knew" he was going to die. When he was released from Sloan-Kettering, he made changes in his life, which up to that point had included studying medicine in Switzerland and becoming fluent in French and meeting Robert Gallo, who would influence his interest and work in HIV/AIDS. The year he beat his cancer, he was appointed to a Presidential Commission, where he first met Ms. McGeein. In 1988, he helped write a seminal report and, in this time period, he became the first CSAT Director at SAMHSA, where, at long last, "they are now doing much of what I suggested" needed to be done. He also founded several organizations reflecting his renewed commitment, when he was ill, to help substance abusers.

Dr. Primm said he hoped he did not sound "egomaniacal" when talking about HIV/AIDS issues. He simply wants to share with his family a bit more about himself so that his family can better understand his perspectives and why he has said some of the things he has said in the Council. His "greatest moment" came in 2003, after Secretary Louis Sullivan asked him to serve on the Council. Then Joe O'Neill invited him to the White House to talk about PEPFAR with President Bush himself. Others at the meeting included HHS Secretary Tommy Thompson, Colin Powell, and Condoleezza Rice. The meeting was very productive. During it, he suggested to the President that he expand PEPFAR to include more Nations in the Caribbean. Dr. Primm noted that in New York City, which is where he lives and serves, he has observed constant traffic to and from the Caribbean and a "high incidence of HIV/AIDS" among this transient population. And now, after many years, he hears that PEPFAR will be expanded in the Caribbean, for which he is grateful. He will never forget how, when he advocated to President Bush that this happen, the President gave him "the thumbs up." A crowning moment in his life was to be able to meet with the President personally, "and for him to promise to do that."

Disappointing to Dr. Primm, however, is the lack of an AIDS czar, "someone who could have direct communication with the President besides the Secretaries we've had." Once the Council lost contact with representatives from the Domestic Policy Council, "it has had no direct relationship with the White House." For PACHA designation to be as important as it sounds, "it would be better to have more contact with the Executive Branch. We're the Presidential Advisory Council, but, except for me, we have never seen the President."

Other outstanding issues include the need to connect prisoners to treatment as they leave incarceration—those who are substance abusers as well as those with HIV/AIDS. The Council should also get behind the $600 million proposed for the MAI in FY 2009 and "build the infrastructure as initially intended by President Clinton." MAI "has been

funded rather nicely over the years," but "that funding needs to be directed to benefit some of the service organizations that need a shoring up of infrastructure."

As Dr. Primm has often said to himself and to his family, "you should sing all the songs you can sing, whether it is solo or, best still, in duet, so that you don't die with your music in you. You should try to help everyone you can when you are alive," adding that he hates to leave everyone and most particularly Ms. Wise and Ms. Flucas, "who, in the past, have asked me to ask questions for them." He pledged to still "be there for you, wherever I am."

Former PACHA Executive Director
Noting that former PACHA Executive Director Joseph Grogan was present, Ms. McGeein said she would miss Dr. Primm terribly, but her guess was that Mr. Grogan would miss him more.

Mr. Grogan apologized to Dr. Primm for being "a discordant note" after his beautiful message, then thanked Dr. Primm for how much he had learned from him. He quotes Dr. Primm and refers to him a great deal, and not just for his work in substance abuse and HIV/AIDS. He recounted a few anecdotes, including one from his first days as PACHA's Director, when he attended a small Treatment and Care Subcommittee meeting. Dr. Primm was there. Everything seemed to be going well, until one of the members asked Mr. Grogan a question, and Dr. Primm said, "Don't ask him. He won't know. He's only a lawyer." Mr. Grogan concluded by saying it was an absolute joy to work with Dr. Primm, and that he will always remember his association with PACHA and Dr. Primm as one of the most precious times in his career.

Presentation
Ms. McGeein and Mr. Grogan then presented parting gifts to Dr. Primm.

Adjournment for Working Lunch
Mr. Gilmartin then adjourned the meeting for a working lunch for the Domestic and International Subcommittees.

Working Lunch

AFTERNOON SESSION

Council Reconvenes for Motions and Voting
Mr. Gilmartin reconvened the full Council at 2 p.m. While waiting for Dr. Steiger, the last presenter of the day, Mr. Gilmartin asked that the Council take up draft resolutions from its Subcommittees, beginning with the Domestic Subcommittee.

Domestic Subcommittee Resolutions
Domestic Subcommittee Chair Mr. Schmid introduced the Subcommittee's two draft resolutions, which Subcommittee members had approved at lunch today, the first

commending HRSA's HIV/AIDS Bureau (HAB) and the second calling for formulation of a "Domestic President's Emergency Plan for AIDS Relief (PEPFAR)."

Domestic PEPFAR Resolution

Mr. Schmid asked that the Council consider the second resolution first, explaining the few changes made by Subcommittee members during their lunch meeting. The resolution follows with changes highlighted:

Presidential Advisory Council on HIV/AIDS
Domestic Subcommittee

Draft Motion

WHEREAS, HIV/AIDS continues to be a critical health care crisis in the United States with over 1 million people believed to be infected with HIV;

WHEREAS, the Centers for Disease Control and Prevention and State and local health departments have recently announced higher rates of HIV infections in some communities in the United States;

WHEREAS, HIV/AIDS disproportionately affects certain populations, particularly the poor, African Americans, men who have sex with men, Latinos, Native Americans, substance users, and the incarcerated;

WHEREAS, certain populations such as women, the young, and heterosexuals are also vulnerable to HIV/AIDS;

WHEREAS, the Presidential Advisory Council on HIV/AIDS has previously gone on record in support of reducing and eliminating new HIV infections in the United States in its December 2005 white paper, "Achieving an HIV-Free Generation";

WHEREAS, quality health care and drug treatment are essential for people with HIV/AIDS, particularly the poor, to remain healthy and reduce the likelihood of further spread of the epidemic;

WHEREAS, there are numerous Federal agencies and programs, State and local governments, and public and private organizations that currently address the various aspects of [the] domestic HIV/AIDS epidemic but do not coordinate their efforts to maximize results;

THEREFORE BE IT RESOLVED the Presidential Advisory Council on HIV/AIDS urges the President to develop a comprehensive National HIV/AIDS Strategy, a "Domestic President's Emergency Plan for AIDS Relief (PEPFAR)," in order to create an HIV-free generation in the United States and to ensure the proper coordination of the necessary health care and treatment to those with HIV/AIDS who are in need;

BE IT FURTHER RESOLVED that such a strategy utilize the recommendations of "Achieving an HIV-Free Generation";

BE IT FURTHER RESOLVED [that] the President appoint a National HIV/AIDS Coordinator to oversee the development and implementation of the Strategy for the Federal Government, who has the authority to identify and manage the resources, policies, and research in order to accomplish the Strategy's goals;

BE IT FURTHER RESOLVED [that] the Strategy includes [sic] measurable goals and outcomes and its work shall be periodically evaluated and monitored;

BE IT FURTHER RESOLVED [that] the Strategy address the racial and other groups disproportionately affected by HIV/AIDS, including African Americans, men who have sex with men, Latinos, Native Americans, substance users, and the incarcerated, as well as address the special needs of women, youth, and heterosexuals; and

BE IT FURTHER RESOLVED [that] the Strategy in its development and implementation include all relevant Federal Government agencies and be coordinated with and involve State and local governments, [and] affected and interested communities and businesses.

Discussion
Mr. Schmid briefly outlined the Subcommittee's thinking behind the resolution, which was originally drafted by Dr. Primm. Members have been disappointed in the level of effort on the domestic front, he explained, not just in prevention but also in care and treatment. Therefore, "we are asking the President to adopt a national AIDS strategy that is monitored against measurable outcomes and that resources be identified to carry out the strategy to achieve an HIV-free generation." A beginning point for the strategy is coordination, and this is why the resolution refers to a "Domestic PEPFAR."

Vote
Mr. Gilmartin asked if changes forwarded to the Domestic Subcommittee by the International Subcommittee had been made in the resolution, to which Mr. Schmid responded in the affirmative. Mr. Gilmartin then asked for a motion to approve the resolution and a second, and upon receiving a motion and a second, asked members to vote. By verbal vote, the resolution passed unanimously.

Switch to PEPFAR Update
Mr. Gilmartin announced that William Steiger was now present, and suspended until after his presentation further discussion of Subcommittee resolutions. He noted that Dr. Steiger's short bio is in members' packets.

PEPFAR Update
Presentation by William Steiger, Ph.D., Director, Office of Global Health Affairs, and Special Assistant to the Secretary for International Affairs, HHS; Alternate U.S. Member, Board of Directors, The Global Fund

Dr. Steiger said that the U.S. House of Representatives may take up the House Foreign Affairs Committee's approved version of a PEPFAR reauthorization bill as early as April 2. It is a "major achievement" that the bill is bipartisan. It reflects with very few exceptions what the President wanted. On the U.S. Senate side, a companion bill co-sponsored by Sens. Joseph Biden (D-DE), Richard Lugar (R-IN), Edward Kennedy (D-MA), and John E. Sununu (R-NH) was recently approved by the Senate Foreign Affairs Committee. This bill "retains the parameters of the emergency plan," and Dr. Steiger's hope is for Senate floor action on that bill before Congress' May recess. The most optimistic scenario is that both bills could be in conference committee and sent to the President before Memorial Day.

Key notes on what the bills contain include that both authorize but do not appropriate $50 billion over the next 5 years for international HIV/AIDS and related relief, whereas the President had asked for $30 billion. The bills contain provisions for $41 billion to be spent on HIV/AIDS and within that amount, "depending on the math and The Global Fund portion," the bilateral portion of the plan would total in the upper ranges of $30 billion. The Administration is currently stating that it prefers a lower total funding level closer to the President's request and is working with appropriations committees to effect that.

Current goals are to preserve the President's original focus on a quantifiable approach to supporting treatment, care, and prevention to meet specific targets, which Dr. Steiger said he expects could be met in 2008 and 2009. It is "important to note the 3 million in treatment goal, which would cover two-thirds of the people in poorer countries in need of treatment by clinical criteria." The Office of the Global AIDS Coordinator (OGAC) is working on raising this goal to 4.5 million, "not including wealthier people in the West."

Both bills maintain balanced funding for the ABC prevention strategy. "It is noteworthy" that for FY 2008, a provision was taken out of current law requiring that programs target abstinence before marriage. In short, for FY 2008, there are no targets for abstinence and being faithful programs, but "the current bill restores a certain version of that target." Both bills make a distinction between sexual prevention and other preventions. Both bills preserve current law in terms of legalization of prostitution and sex trafficking and preserve requirements that funding recipients have policies opposing legalization of prostitution and sex trafficking. In terms of The Global Fund, the Senate bill maintains a ceiling on U.S. contributions, "in effect leveraging our contribution." The Senate bill also has "new benchmarks for transparency, accountability, and adherence to principles by The Global Fund." The bottom line on both bills is that both are bipartisan, and while Dr. Steiger expects "a few bumps down the road between now and final passage" of reauthorization legislation, "the President's core principles and numerical targets carry over into the reauthorization."

Last, The Global Fund "has grown considerably since last time we spoke." While U.S. funds going into 2008 have not yet been committed, The Fund has disbursed or has plans to disburse $5 billion in more than 130 countries. The next Fund Board meeting will take

place in Geneva at the end of April. It launched its eighth round of funding earlier this month, and that will close early in summer.

Discussion

HIV/AIDS Admissibility into the United States

Mr. Schmid asked about a provision in the Senate bill that amends the Immigration and Naturalization Act to "no longer make HIV-positive individuals admissible for entry into the United States." He commented that only a few Nations around the world have such a blanket policy that puts HIV positivity in the same category as engaging, for example, in child smuggling, human trafficking, or tax evasion. Responding, Dr. Steiger said this provision is only in the Senate version of the bill, and he referred back to the President's request last December for the State and Homeland Security Departments to work on regulations and a formal, permanent waiver process for short-term visitors to the United States who have HIV. He added that he expects proposed regulations to go out shortly, then to be put into effect "very shortly, in weeks, possibly before the bill passes." Meanwhile, the Administration is studying the bill's provision, looking at its potential impact, and has no specific comment at this time.

Ceiling on U.S. Contributions to The Global Fund

Dr. Bush asked about how the ceiling on U.S. contributions to The Global Fund works. Dr. Steiger responded that, on July 31 each year, the Administration takes a snapshot of what all other donors have contributed over time, and if at that time, "our contribution would carry us over one-third of the aggregate amount, we would reduce our contribution back down to one-third." This has never happened, he added. There was a time, when The Fund first began, when the U.S. contribution was running about 40 percent of The Fund's total, but "since that time, other donors have stepped up."

MTCT Plans

Dr. Yogev asked where PEPFAR stands in increasing the percentage of women and children receiving MTCT prevention and treatment and also in its work with countries and pharmaceutical companies to provide pediatric treatment formulations for children. Dr. Steiger responded that in terms of pediatric formulations, he is unaware of specific provisions in the reauthorization bill that discuss pediatric treatment formulations, but it does emphasize treating children and also emphasizes MTCT. In addition, "where we stand in encouraging cooperation on pediatric formulations is that the First Lady encouraged that cooperation a few years ago, and we are also seeing increased applications for generic formulations to the FDA." Major barriers include the failure of developing countries to provide rapid approval of medications and "bureaucratic slowness," specifically in PEPFAR focus countries. Dr. Steiger said he would provide specific data on this.

In terms of PEPFAR and the status of MTCT now, Dr. Steiger's sense is that in the transition between the President's original MTCT program and PEPFAR, while the MTCT network model transferred to PEPFAR, MTCT "lost emphasis." He noted that the President's original 2002 MTCT goals have not been met, "but after 2008 and 2009, we will be back on the path to those goals." The good news about the reauthorization bill's

separate provisions for MTCT is that this "will lessen the competition" MTCT has faced in the past with other program areas.

Discussion Conclusion
Concluding discussion, Mr. Gilmartin thanked Dr. Steiger, and Dr. Steiger promised to keep members updated on the progress of the reauthorization legislation through Ms. McGeein. In addition, his Office will brief members fully "when the final package comes together."

Council Motions and Voting Continued
Mr. Gilmartin asked members to continue considering the Domestic Subcommittee's resolutions.

HAB Resolution Introduction and Discussion
Mr. Schmid introduced the Subcommittee's second and last resolution—a commendation to HRSA's HAB. Specifically, the resolution commends staff and leadership for all the work they have done, in particular, in implementing the new RWCA under difficult circumstances so quickly; for related work on a RWCA Severity of Need Index (SONI); and for providing ongoing TA to Puerto Rico. Mr. Schmid acknowledged that while sometimes PACHA is critical of its Government friends, in this case it should commend them "for a job well done." Dr. Maxwell added that because PACHA is often encouraging action to be taken, "it is good to commend when good action has been taken."

The draft resolution as provided to members without changes reads as follows:

Presidential Advisory Council on HIV/AIDS
Domestic Subcommittee

Draft Motion

WHEREAS, the President signed into law the Ryan White HIV/AIDS Treatment Modernization Act on December 9, 2006, that considerably alters the manner in which Ryan White funds are distributed and utilized;

WHEREAS, the HIV/AIDS Bureau (HAB) of the Health Resources and Services Administration, Department of Health and Human Services, successfully implemented the law with its many new features and requirements in a timely and professional manner that required a great deal of staff time and leadership;

WHEREAS, the Ryan White HIV/AIDS Treatment Modernization Act requires the development of a Severity of Need Index that seeks to improve the distribution of Ryan White HIV/AIDS program funds in such a way that could help improve the health care and well-being of more low-income people living with HIV/AIDS;

WHEREAS, the HAB has overseen the development of a comprehensive Severity of Need Index with the assistance and input of outside affected parties, which is now available for public comment; and

WHEREAS, the HAB has been providing valuable technical assistance to the Commonwealth of Puerto Rico so that it can address the ongoing challenges of implementing the Ryan White HIV/AIDS program in Puerto Rico;

BE IT RESOLVED, the Presidential Advisory Council on HIV/AIDS commends the staff and leaders of the HIV/AIDS Bureau (HAB) of the Health Resources and Services Administration, Department of Health and Human Services, for its exemplary work and dedication over the past year. In particular, the Council commends HAB for: (1) expeditiously and diligently implementing the Ryan White HIV/AIDS Treatment Modernization Act; (2) developing a Severity of Need Index that seeks to distribute Ryan White HIV/AIDS program funds to those areas where the need is greatest; and (3) providing technical assistance to the Commonwealth of Puerto Rico as it seeks to improve in the delivery of Ryan White HIV/AIDS program services.

Vote
Without further discussion, full Council members made a motion to approve, it was seconded, and by verbal, unanimous vote, members approved the resolution.

International Subcommittee
Dr. Yogev said the International Subcommittee had a short draft resolution "suggestion" that needs to be copied for members. He read the text of the short draft, as follows: "Be it resolved that PACHA recommends that additional funding be provided to the National Institutes of Health to support new, investigator-initiated HIV research with particular emphasis on HIV infection in minority communities in the United States, men who have sex with men, and at-risk women."

Dr. Yogev made clear that today, he was simply raising the issues addressed in the resolution and that if the full Council agrees with the concept, the International Subcommittee will continue to develop a more formal resolution to any needed deadline. He noted that he had already discussed further work on the draft with Dr. Bollinger and Pastor Lusk.

Ms. McGeein and Dr. Yogev briefly discussed process on continued work on the draft resolution, with Ms. McGeein noting that the next Subcommittee meetings are scheduled for September 9 and September 16 for Domestic and International, respectively, and that the next full Council meeting is scheduled for October 21 and 22, with the next budget proposal due to the White House November 10. This provides time in a timely fashion for the International Subcommittee to draft a budget-oriented resolution, the Domestic Subcommittee to review it, and the full Council to vote.

Mr. Schmid noted that the Domestic Subcommittee had discussed passing a budget-related resolution not only for NIH but also for RWCA and CDC programs, to which Dr.

Yogev responded that "we put only NIH in there because of the need for more basic research."

Mr. Gilmartin commented that this matter is "very important," and it is well to continue work on it as Ms. McGeein suggested. Mr. Martin suggested that Dr. Yogev could be in e-mail contact to share iterations with Mr. Schmid. Mr. Martin asked Dr. Yogev if he was thinking about being specific about adherence in this resolution. Dr. Yogev responded that this can be discussed, but his initial observation is that he would support a more specific statement not about adherence but about behavioral changes, not about the virus but, rather, human behavior versus the disease.

Mr. Gilmartin congratulated everyone involved in this new effort, observed that good progress was underway, and that the full Council's agenda was now concluded.

Public Comments

Dr. Maxwell assumed the chair to preside over Public Comments, noting that each individual speaker would be held to 3 minutes.

Suzanne Miller, Public Policy Associate, The AIDS Institute:

"Today we would like to comment on the lack of targeted HIV prevention efforts for numerous populations as evidenced in the CDC's Compendium of Evidence-Based Interventions. The Compendium, which includes 49 Best-Evidence and Promising-Evidence Interventions to be implemented in community-based prevention settings, was recently updated for the first time in 6 years. The original compendium included 24 interventions, 12 of which were not included in the updated compendium because they were not proven to be effective.

"The AIDS Institute is pleased that the CDC has added 37 new interventions and that 38 of the 49 specifically or predominately target minority populations, who account for 69 percent of all AIDS cases. In addition, the Compendium recognizes the growing epidemic among women, particularly minority women. Twenty-one of the 49 interventions are specifically targeted to women, who currently account for 26 percent of all HIV/AIDS cases. Of these 21 interventions, 10 are targeted specifically to African American women and 4 for Latino women. African American women account for 66 percent of all HIV/AIDS cases among women, and Latino women account for 15 percent. In addition, we are pleased that the Compendium includes two interventions specifically targeting the incarcerated population. In 2004, the Department of Justice reported that HIV/AIDS prevalence among U.S. prisoners was three times that of the general population.

"However, we are disappointed that the Compendium fails to include targeted interventions for numerous populations and intervention settings. Although men who have sex with men (MSM) account for 53 percent of all new HIV/AIDS cases, only 4 out of 49 interventions specifically target them. Furthermore, there is not a single intervention targeted specifically to either African American or Latino MSM. In 2005, African American MSM accounted for 36 percent of all MSM with HIV/AIDS,

and Latinos accounted for 19 percent. Earlier this month, the CDC reported that HIV cases among young African American MSM increased by 80 percent from 2001 to 2005. Given the overwhelmingly disproportionate burden of this disease on these populations, it is simply unacceptable that there are no interventions that target these populations.

"In addition to MSM, the updated Compendium fails to address other subpopulations at high risk of HIV infection, including sex workers, transgendered individuals, persons over age 50, and veterans. In 2005, the CDC reported that persons over age 50 constituted 15 percent of new HIV/AIDS diagnoses, and the rates of HIV among this population were 12 times higher for African Americans than for whites. In addition, research suggests that veterans, who are at high risk for homelessness and substance abuse, including IDU, are also at high risk for HIV infection. There is also a strong need for more diversity in regard to intervention settings. For example, there are no interventions for faith-based and rural settings.

"While we respect the rigorous scientific process of developing effective interventions, we strongly believe that prevention research efforts must be guided by priorities. The CDC's Compendium of Evidence-Based Interventions does not adequately reflect the realities of this epidemic and needs to better focus on the populations that are greatest affected, and at greatest risk for this disease."

Larry Brian, Housing Works:
Mr. Brian noted the discussion yesterday on the lack of—or perceived lack of—community involvement by people of color affected by HIV/AIDS. When one looks at the history of HIV/AIDS activism and advocacy, such as ACT UP/ New York and ACT UP/ Philly, much of that kind of activism ended in 1991/1992. When African American infections rose and white infections decreased, the prevailing perception, particularly in terms of services being rendered, was that a large portion of the infected population had medications and housing and that the epidemic was over, when, in fact, for the African American community, it was just beginning. Mr. Brian noted that he has been HIV-positive for 22 years, that he is straight, college-educated, and not drug-addicted, but back then and today, he is not necessarily part of the CDC's Compendium. "We know from Dr. Anastos," he added,"that addressing heterosexual transmission to women—and to men—is needed." Mr. Brian thanked PACHA for its domestic PEPFAR resolution and expressed the hope that it will result in "a fully developed plan."

Nancy Bernstine, Executive Director, National AIDS Housing Coalition:
Ms. Bernstine commented on HRSA housing policy, first noting that her Coalition and its 23-member board have been working since 1994 to assert the right of all people living with HIV/AIDS to decent, safe, and affordable housing and supportive services.

Ms. Bernstine said she wished to protest HRSA's recent, final notice of revisions to its housing policy. Specifically, the Coalition is alarmed by proposed imposition of a

cumulative 24-month lifetime cap on use of RWCA dollars for short-term and emergency housing. The Coalition has formally asked HHS Secretary Mike Leavitt to withdraw that unprecedented policy, which is slated to take effect tomorrow. Not only does the policy impose a cap, but it also fails to contain a waiver for medical conditions and fails to allow communities with multiple funding streams to partner their diverse resources with RWCA resources to meet housing resources needs.

Ms. Bernstine observed that lack of affordable housing has reached crisis proportions nationwide, affecting some 3 million families. She advocated that RWCA dollars not used for core services be used for housing. However, this remains a local decision, and in many communities, very few resources are devoted to housing, given the competing supportive service needs localities face. Yet in those jurisdictions that use RWCA funding for housing, this funding is meeting a critical need.

Ms. Bernstein concluded by observing that housing stability is central to improved individual and community health outcomes and that the new HRSA housing policy poses a direct threat to the RWCA goal of stabilizing people with HIV and improving their health status.

Dr. Maxwell called out a number of additional names of individuals who had signed up to speak, and none responded. This concluded Public Comments.

Last Comments Before Adjournment
Ms. McGeein told Dr. Primm that he would be very much missed but that, hopefully, he would visit.

Housekeeping
Ms. McGeein reminded participants to be sure to turn in their red security badges. She also noted that C-SPAN would be airing portions of the meeting over the next few days and referred to the C-SPAN Web site: www.c-spanvideo.org (204529-1 is the program number). She noted that the next conference call is scheduled for April 3, to which Mr. Schmid responded that the Domestic Subcommittee had cancelled its call. She also reminded members of the next scheduled Subcommittee meetings: September 9 for the Domestic Subcommittee and September 16 for the International Subcommittee. In addition, the full Council next meets October 21 and 22.

Adjournment
Mr. Gilmartin then adjourned the full Council meeting at 2:50 p.m.