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

June 12–13, 2007

Council Members Present
Marilyn A. Maxwell, M.D., PACHA Chair
Troy Benavidez
Cheryll Bowers-Stephens, M.D., M.B.A.
Freda McKissic Bush, M.D., FACOG
Shenequa Flucas
Raymond V. Gilmartin, M.B.A.
Edward C. Green, Ph.D.
Franklyn N. Judson, M.D., M.P.H.
Robert Kabel, J.D.
David J. Malebranche, M.D., M.P.H.
John C. Martin, Ph.D.
Jose A. Montero, M.D., FACP
Beny J. Primm, M.D.
Robert R. Redfield, M.D.
Carl Schmid II
Barbara Wise, B.S.
Ram Yogev, M.D.

Council Staff Present
Marty McGeein, M.B.A., B.S.N., R.N.C., R.N., Executive Director, PACHA
Nancy Barnes, Program Assistant

Guest Speakers
John O. Agwunobi, M.D., M.P.H., M.B.A., Assistant Secretary of Health, U.S. Department of Health and Human Services
Timothy P. Condon, Ph.D., Deputy Director, National Institute on Drug Abuse, National Institutes of Health, U.S. Department of Health and Human Services
Capt. Hilda Douglas, M.P.H., Deputy Director, Division of Service Systems, HIV/AIDS Bureau, Health Resources and Services Administration, U.S. Department of Health and Human Services
Hon. Mark R. Dybul, Ambassador, U.S. Global AIDS Coordinator
Timothy H. Holtz, M.D., M.P.H., FACP, Commander, U.S. Public Health Service, International Research and Programs Branch, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services
Miguel Gomez, Director, The Leadership Campaign on AIDS, Office of HIV/AIDS Policy, U.S. Department of Health and Human Services

DAY ONE

Welcome Remarks and Introductions

Council Chair Marilyn Maxwell welcomed the members and guests and officially opened the thirty-third meeting of the Presidential Advisory Council on HIV/AIDS (PACHA).

Dr. Maxwell introduced Marty McGeein, the Executive Director of PACHA, and Nancy Barnes, a PACHA staff member. Ms. McGeein offered information about her background and thanked the members for their service to the public. "I am here as a human being, a woman, a nurse, an entrepreneur, a grandmother, and interested in the very vulnerable. My motto is to leave it better than you found it." Ms. McGeein said she anticipated that the years ahead would be the most successful period in PACHA's history.

Dr. Maxwell asked the members to introduce themselves and to briefly explain their passion and interests in the field of HIV/AIDS.

Cheryll Bowers-Stephens, M.D., is a child and adolescent psychiatrist in New Orleans, Louisiana. Her interests are in the role that mental health plays in the epidemic, particularly with regard to medication adherence and disease continuation.

Freda McKissic Bush, M.D., practices obstetrics and gynecology in Jackson, Mississippi. Her passion is to help women raise awareness of their own sexual behavior, to obtain jobs, and to take care of their families.

Shenequa Flucas lives with HIV, is an outreach educator, and is a mother of three from Port Arthur, Texas. Her passion is making more people become aware of the risks of contracting HIV. She encourages other individuals living with HIV to live positive lives despite their infection and to prevent others from contracting HIV.

Raymond Gilmartin, M.B.A., is Professor of Management Practices at Harvard Business School, in Boston, Massachusetts, and former Chairman and Chief Executive Officer of Merck & Co. His passion is developing new medicines and vaccines to treat HIV and AIDS.

Edward Green, Ph.D., is a Senior Research Scientist at the Harvard Center for Population and Development Studies, in Cambridge, Massachusetts. His passion is promoting primary behavior change, which includes fidelity, partner reduction, and delay in sexual debut to prevent HIV infection, particularly in Africa and the Caribbean.

Franklyn Judson, M.D., practices medicine at the University of Colorado in Denver, where his work entails examining the biology and behavior of sexually transmitted diseases. His passion is to thoroughly understand the behavioral determinants of HIV in the United States and in developing countries.

Robert Kabel, J.D., is of counsel with Baker & Daniels, LLP, in Washington, D.C. Mr. Kabel was Board Chairman of Log Cabin Republicans and currently serves as Chairman of Liberty Education Forum. His passion is to promote HIV prevention issues both domestically and internationally.

David Malebranche, M.D., practices internal medicine at Emory University in Atlanta, Georgia. He is interested in how the HIV epidemic affects black men.

John Martin, M.D., is President and Chief Executive Officer of Gilead Sciences, in Foster City, California. His passion is to devise new drug treatment options for treating HIV and to ensure that people living with HIV have access to antiretroviral medications and medical care.

Marilyn Maxwell, M.D., is Professor of Internal Medicine & Pediatrics at St. Louis University, in St. Louis, Missouri. Her passions are educating and empowering teenagers to make the right decisions, and to ensure that African American women and men and incarcerated individuals are not disproportionately affected by the epidemic.

Jose Montero, M.D., is Associate Professor of Medicine at the University of South Florida, in Tampa. His passion is to ensure that all people have access to routine tests and that incarcerated individuals or those living with mental illness are not disenfranchised.

Beny Primm, M.D., is the Executive Director of the Addiction Research and Treatment Corporation in Brooklyn, New York. His interests are making sure that HIV stays on the public's radar screen and to mitigate the devastating effects that HIV/AIDS is having in the African American community.

Carl Schmid II is Director of Federal Affairs at The AIDS Institute, in Washington, D.C. His passion is to promote HIV prevention, particularly among the gay and African American communities in the United States.

Robert Redfield, M.D., has worked as a clinician at the University of Maryland in Baltimore since 1983. He is committed to promoting prevention and treatment options for individuals. One of his passions is to ensure that everyone has access to HIV treatment; another is exploring novel targets to exploit the host-cell pathway and to reduce infectivity levels.

Barbara Wise lives with HIV. She cofounded WiseChoices, in Littleton, Colorado. Her interests are in showing people the reality of living with HIV/AIDS and demonstrating that a person's outcome in life depends on the choices he or she makes.

Ram Yogev, M.D., is Professor of Pediatrics at Northwestern University Medical School in Chicago, Illinois. His passion is to ensure that children affected by the HIV/AIDS epidemic receive care, treatment, and compassion.

International Issues: Robert Redfield, M.D., Chair of the International Subcommittee

Dr. Redfield spoke of President Bush's commitment to seek reauthorization of the President's Emergency Plan for AIDS Relief (PEPFAR), noting that the President has asked Congress to approve $30 billion for the next phase of PEPFAR, and that the Group of Eight (G-8) leaders have also committed approximately $30 billion in new international AIDS funding. "Clearly, the United States is taking the lead to invest resources in malaria, tuberculosis, and AIDS." Dr. Redfield noted that he has been informed that strong bipartisan support exists in the Congress to reauthorize PEPFAR and spoke of the program's successes thus far: more than 1 million patients are receiving antiretroviral therapy (ART) (from an initial baseline of 52,000 patients), nearly 102,000 infant infections have been averted, and more than 2 million orphans and vulnerable children are receiving care. Dr. Redfield expressed great confidence in the program, but also some concern: "In 5–10 years, ARTs will be different, and we need a long-term strategy. We haven't addressed a sustainable, long-term plan to work with the pharmaceutical firms to develop new drugs, especially for pediatric populations. If new pharmaceuticals are developed, we will need new [care] models."

Remarks and Swearing-in Ceremony: John Agwunobi, M.D., M.P.H., M.B.A., Assistant Secretary for Health, U.S. Department of Health and Human Services

Dr. Agwunobi was appointed Assistant Secretary of Health in the U.S. Public Health Service in 2005, and serves as the Department of Health and Human Services representative to the World Health Organization.

Dr. Agwunobi thanked the panel members for their service and noted that PACHA is one of the President's most important advisory councils, adding that the Council has more work ahead of it than behind. "The epidemic is still a scourge. Your work is probably more important than mine. I have a job description. You, on the other hand, can go wherever you think you're needed and say whatever you think needs to be said. Your job is to lead, and I look forward to hearing the results of your work in the future. I serve you." Dr. Agwunobi thanked Ms. McGeein for agreeing to serve as the PACHA Executive Director, noting her extensive experience in fighting the HIV/AIDS epidemic.

Dr. Agwunobi swore in the Council's two newest members, Mr. Gilmartin and Mr. Schmid.

Questions and Comments Addressed to Dr. Agwunobi:

- Dr. Primm expressed great concern that domestic spending on HIV/AIDS is not keeping up with international spending. "It concerns me and the community greatly that the domestic focus seems to be waning. It's bad for the African American community, because HIV is still spreading." He asked Dr. Agwunobi to comment. Dr. Agwunobi said he took Dr. Primm's comments with great respect and understanding and asked the Council members to recognize that the United States had committed itself to being a global leader in the fight against HIV/AIDS. He said the epidemic should not be an Us/Them dilemma, that the global epidemic is the United States' epidemic. "The larger fight is our fight. That we've declared our international interest does not diminish our domestic fight." Dr. Agwunobi acknowledged that the spread of HIV is beginning to insidiously undermine the African American community. "I'm heartened that African American leaders are taking this on; I'm confident we can take on both global and domestic [aspects of the epidemic]."
- Dr. Judson asked what Dr. Agwunobi saw as important changes and priorities that might be expected or might not occur in the next 18 months in light of the 2008 Presidential election. Dr. Agwunobi urged the Council members not to be distracted by the political pundits and opinion makers and assured them the President is committed to the epidemic. "We aren't coasting; we have a lot to do, and we intend to do it in the time that is left. I do know that what we've committed to do, we will do, [regardless of] whether it's PEPFAR, Ryan White funding, or testing."
- Dr. Redfield commented that nearly 40 percent of the persons with HIV in his program are uninsured, 40 percent are underinsured. And, in Maryland, about 30 percent of those living with HIV are undiagnosed. He noted there is reluctance in urban areas, the rural south, and in disaffected African American communities to expand case loads by 30 to 50 percent when resources appear to be restricted. "We should not have undiagnosed HIV infections, but we need dollars [to care for] noninsured and underinsured individuals." He asked what discussions have occurred to ensure that HIV diagnosis occurs early and becomes routine. Dr. Agwunobi responded that no one's health care needs should be unmet because a patient or a care provider is worried about not being able to meet patients' needs. "Testing is not just about treatment, it's also about prevention. We know that those who know their status change their behavior. . . . [Testing] is one strategy to start slowing the spread of HIV." He expressed his confidence that if a large segment of the population is identified as needing care and treatment, it will become a compelling reason to find the means to provide these services.

National HIV Testing Day: Miguel Gomez, Director, The Leadership Campaign on AIDS, Office of HIV/AIDS Policy, U.S. Department of Health and Human Services

Mr. Gomez spoke to the Council about National HIV Testing Days (NHTDs). He said there are now nine HIV/AIDS Observance Days, such as Caribbean American HIV/AIDS Awareness Day, HIV Vaccine Awareness Day, and World AIDS Day. Mr. Gomez spoke at length about Caribbean American HIV/AIDS Awareness Day, in part to use it as an example of how to promote successful awareness and testing options. He noted that his Office encourages organizations to not just declare an awareness day, but to devise a sustainable plan that involves fact sheets, posters, event locations, and involvement by local officials such as a mayor, an imam, or the head of a local health department. Mr. Gomez's Office encourages those who run testing days to compile personal stories and to get the event publicized in the local press. "We must advertise what the message is and why it is important that people learn about the epidemic, take the test, and learn about care." Mr. Gomez spoke of the importance of those being tested having a support network, such as friends, siblings, or a parent. He spoke of new recommendations that were compiled recently by the Centers for Disease Control and Prevention (CDC) (i.e., HIV tests should be a routine part of medical care, patients should have the choice to opt out of testing, those at high risk for contracting HIV infection should seek annual screening, and all pregnant women should be screened for HIV) and new posters that were being endorsed by the National Association of People with AIDS (NAPWA), which has as its slogan "Take the Test, Take Control." Mr. Gomez said that in previous years, HIV/AIDS used to be among the top 5 news stories, but now the issue is rarely considered to be among the top10.

Mr. Gomez explained that the Department of Health and Human Services (DHHS) is committed to promoting NHTDs because it gives the Department the opportunity to promote HIV testing; to educate the public about the change in HIV testing recommendations; to promote domestic HIV/AIDS policies, programs, and resources; and to have senior DHHS officials publicly support HIV testing. Mr. Gomez noted that DHHS has 67,000 employees, many of whom have not been tested. "If we're not committed to employee testing, how can we ask the public to do it?" He provided extensive details on how DHHS works internally and with groups around the United States to promote NHTDs.

Mr. Gomez spoke of various Web and other mass media activities to promote the 2007 NHTD, and showed a video that First Lady Laura Bush made to promote NHTDs via podcast media. Mr. Gomez explained in detail the importance of using podcasts to reach young people (particularly those aged 13–24 years), many of whom prefer to receive their news and general information through the Internet and other new media. Mr. Gomez displayed the new DHHS National Testing Day Web site (www.HIVtest.org) and explained its new features to the Council members. He also introduced the www.aids.gov Web site and explained its goals to Council members.

Questions and Comments Addressed to Mr. Gomez:

- Dr. Malebranche noted that an inherent barrier in promoting HIV testing is that many medical providers will not seek an HIV test unless the patient is homosexual or a woman planning a pregnancy. He pointed out the paternalism inherent in health care providers

promoting HIV testing: "Do as I say, not as I do," and noted the powerful image that was evident when the Reverend Jesse Jackson agreed to be tested at a church.

- Mr. Schmid asked why the testing that HHS is doing for its employees takes an hour. He noted that many people may be put off if it takes that much time.
- Dr. Green noted how the Internet has been implicated as a risk factor in HIV transmission in recent years and noted that it is good to see it being used for prevention purposes rather than for purposes of promoting sexual encounters.
- Dr. Maxwell noted a sample, one-page promotional advertisement that had been included in Council members' meeting packets about NHTDs and encouraged her colleagues to share it with local media outlets. [Ms. McGeein said the document is in the public domain and could be used as Council members saw fit as long as they removed or modified the sentence in the first paragraph of the handout that reads "As a member of the Presidential Advisory Council on HIV/AIDS (PACHA), I encourage you to adopt that motto and take an HIV test."]
- Dr. Yogev noted that pretest and posttest counseling is a barrier to people seeking HIV tests, adding that one can receive test results in 20 minutes, but that counseling adds thousands of hours and labor to the process. He also discussed the absence of adolescents in the media samples that Mr. Gomez displayed and asked whether DHHS is making any attempt to find a teenage idol to serve as the U.S. HIV testing ambassador.

Implementation Update on the Ryan White HIV/AIDS Treatment Modernization Act of 2006: Capt. Hilda Douglas, M.P.H., Deputy Director, Division of Service Systems, HIV/AIDS Bureau, Health Resources and Services Administration, U.S. Department of Health and Human Services

Capt. Hilda P. Douglas offered a brief overview of the current status of procedures for implementing the Ryan White HIV/AIDS Treatment Modernization Act of 2006. The Act became effective in December 2006.

Capt. Douglas noted that her Office had until March 2007 to review the new law and to devise new application guidelines for awarding Part A (the part of the Act that provides emergency assistance to localities disproportionately affected by the HIV/AIDS epidemic) grants by March 1, 2007, and to communicate those implementation changes to other Departments within DHHS and to the Congress. Her staff held several conference calls with grantees to notify them of changes that would occur in the application and grant process. The Bureau staff learned that several communities (Baton Rouge, Charlotte, and Indianapolis among others) that used to be considered Part B (the part of the Act that provides grants to States and territories for primary health care [including the AIDS Drug Assistance Program] and support services that enhance access to care for people living with HIV and their families) grantees are now eligible for Part A funding.

Capt. Douglas said that her staff was given the responsibility of interpreting the new Act and, as a result, they had answers to some questions but not all questions. Bureau project officers gathered questions, created a question-and-answer document, and posted the document on the Bureau Web site so that everyone would have access to clear and concise answers.

The Bureau staff wrote letters to all grantees providing definitions of status and interpretations of the new requirements. Letters to Part A grantees provided a definition and status of a Transitional Grant Area (TGA), an outline of acceptable administrative costs, and new requirements for serving on the planning council. Letters to Part B grantees provided new guidance for the AIDS Drug Assistance Program (ADAP) and new classes of drugs. Letters to Part C grantees delineated budget categories and services. Letters to all Part A, B, and C grantees explained interim waiver requirements for core services. Under the new Part B regulations, all drugs approved by the Food and Drug Administration for the treatment of HIV and AIDS were placed in the ADAP formulary. Previously, States could decide on their own which drugs they would provide to patients on the basis of how much the State could afford to pay.

Grant awards were issued January 1 and April 1, 2007, to Part C grantees for early intervention services. The formula for calculating Eligible Metropolitan Area (EMA) grants and new TGAs (i.e., those that were formerly considered EMAs) was issued March 1, 2007. The formula for calculating Part B ADAP funds was issued April 1, 2007. On April 4, 2007, the HIV/AIDS Bureau released its formula for calculating new TGA grants. Part A supplemental funds were issued May 23, 2007.

Part C grantees did not have to provide significant paperwork other than recalculating their budgets.

Capt. Douglas noted that 60 reviewers are currently screening Part A and Part B applications in anticipation of awarding Part B ADAP supplemental funds on July 29, 2007, and Parts A and B Minority AIDS Initiative funds by August 1, 2007.

Capt. Douglas told the Council members that the Act was passed without a management statement, and the DHHS General Counsel was engaged to interpret the law and to provide legal opinions on new definitions for EMAs, TGAs, emerging communities, grandfathering, and other issues. She noted that the profile of the 20 project officers has changed; previously, project officers managed specific issues of the Act. Now, project officers are assigned to manage specific geographical areas.

Questions and Comments Addressed to Capt. Douglas:

- Mr. Schmid: Some jurisdictions that were previously considered EMAs are now reclassified as TGAs, and several communities took a financial cut more than 5 percent. How were the awards calculated? How much money did your Office hold back for emergencies, and how will it be distributed? [Capt. Douglas: Previous funding formulae depended on estimates of HIV/AIDS case data, whereas new formulae used actual case data. She noted the HIV/AIDS Bureau has retained $1 million for emergency needs.]
- Dr. Judson: What is the year-per-year dollar increase and the dollar percentage increase for the new authorization versus the prior appropriation? What is the maximum amount by which any EMA would have had its funding reduced? [Capt. Douglas said she would need to review data to respond to Dr. Judson's first question. She said that funding for ADAP remained flat, at $2.9 billion.]
- Dr. Martin: Are the new TGAs [that were previously considered EMAs] not required to have planning councils? [Capt. Douglas: My Office invited health officials from those

areas to Washington for a 4-day consultation to help them understand how Parts A and B differ.]

- Dr. Redfield: Without Ryan White funding it would be impossible to practice AIDS medicine in Baltimore. Has the Health Resources and Services Administration held meetings to calculate what the funding implications are from [previously] estimated case data to now using actual HIV data? If we encourage national HIV testing and find that an estimated 25–50 percent of HIV cases are truly undiagnosed, how will we find the significant resources that will be required to provide care and treatment to those individuals? Dr. Redfield also asked Capt. Douglas to examine the discrepancy between $2.9 billion for domestic HIV funding versus a proposed $30 billion for international expenditures. [Capt. Douglas responded that the needs of all patients living with HIV/AIDS are probably unmet. She also noted that Ryan White funding is not the definitive or only program that provides care and treatment to people living with HIV/AIDS. "The Medicare and Medicaid programs contribute a large percentage of AIDS care."]
- Dr. Maxwell noted that States that chose not to report names of individuals who had tested positive for HIV are now at a financial disadvantage. She said those States had blatantly ignored Federal law, and although they were not being punished, they were being "disincentivized."
- Dr. Malebranche said he understands that names-based reporting is an incentive for receiving more Federal money, but that flat-line funding means dead funding. For patients with a diagnosis of AIDS, and with more patients seeking an HIV test, he asked whether Capt. Douglas was planning to take the same pot of money and shift it accordingly. [Capt. Douglas responded that it was up to individuals affected by HIV/AIDS and their care providers to seek greater funding from elected representatives if they believe that funding is insufficient.]

Open Discussion

PACHA members held a 2-hour open forum. The first questions and comments were directed to Mr. Miguel Gomez.

- Dr. Martin: For testing to be routine, it must not cost a fortune. People in South Carolina who were diagnosed with having HIV had four intersections with the health care system before they were tested. How can we ensure that testing is adequately reimbursed or covered by health insurance providers? [Mr. Gomez: I would reemphasize what Dr. Agwunobi said this morning, that resources should be available for testing. Behavioral studies have shown that when individuals learn they are HIV-positive, they change their behavior. The Centers for Medicare & Medicaid Services provides the largest reimbursement for National Testing Day.]
- Dr. Judson: Once we achieve a certain standard-of-care status in this country, it will be paid for. Whether or not it benefits society, it'll be paid for. If this works the way we hope it will (people seek testing) and we don't have the funds to pay for tests, we will go to city councils, to the States, to the Federal Government, and say we have people with HIV for whom we do not have the budget resources to provide treatment. There are extremely few places in the United States where someone cannot receive treatment. I like one of your mottos ("Take Control, Get Tested") but not the other ("Love Is Fleeting, Knowledge Lasts"). In most countries love is enduring; knowledge is something we often

forget, or it changes. I'd propose that sex or making love is fleeting; love lasts and knowledge is fleeting. [Mr. Gomez: That comes from a public relations firm in Boulder, Colorado, and from the Kaiser Family Foundation. I'm not familiar with flash mob behavior. I'll ask what the focus groups thought of it. I'll review the research and bring it to Marty's attention so that she can distribute it.]

- Dr. Judson: In 1987, at the Stockholm conference, I started promoting the wider use of HIV testing. I insisted this was one of the best HIV tests we had, and to not use it widely was unethical. Everyone in my department was tested. There's no stigma. It's become such a normal, common thing to do for what has become a treatable disease. Every new case that we wouldn't have known about previously can be quickly moved upstream to the source and downstream to potential spreaders through partner notification. Then begins the covenant between the health care provider and the patient: HIV stops with me and with my patients. Ryan White and CDC funding will encourage States to use epidemiological data to test for earlier, undiscovered infections, and thus promote better prevention efforts.
- Mr. Schmid: I suggest that we have CDC here for our next meeting to determine how testing is going. For reimbursement, you could bring in some large insurance companies. I think the reimbursement issue is so important.
- Ms. McGeein: When CDC first announced this, we put representatives of CDC and the Centers for Medicare & Medicaid Services (CMS) in a room together and suggested how CMS would pay for it. I was assured by CDC that it was successful. But apparently, the policy is not in place.
- Mr. Schmid: It is my understanding that the group that is critical for reimbursement did not issue a positive opinion on whether or not routine medical testing should occur.
- Dr. Martin: We should ask the companies that supply the tests what their policy should be.
- Dr. Yogev: You're talking about reimbursement for underinsured people, but a much higher proportion of those infected are unofficial immigrants. Medicaid will not pay for testing in Illinois. There's no reimbursement. You have to offer tests from the kindness of your heart. An interesting [testing gap] exists in the adolescent population. How do emergency rooms do it? We need a safety net. [Mr. Gomez: I appreciate the recommendation that John [Martin] made. We need an update from emergency rooms and one from CDC. What's happening with the promotion of more HIV testing in emergency departments? I don't have those data yet.]
- Dr. Judson: CDC has no responsibility for medical care payment. The agency recommends guidelines, but CDC has no control over how people should follow or pay for those guidelines.
- Ms. McGeein: In my mind, the testing and care payment issues are different questions.
- Dr. Yogev: The Advisory Committee on Immunization Practices recommended that the Government find funding to vaccinate all children. Can we learn how this mechanism works?
- Ms. McGeein: There is a Federal program that provides vaccines for children who are unable to get them anywhere else; that almost always implies children whose families live at or below the poverty level and are uninsured. It's a unique category of people.
- Dr. Yogev: With flat funding and the recommendation that we test 100 million people, this can't be covered through Ryan White.

- Ms. McGeein: Eighty percent of the American people have access to some kind of insurance. Ryan White provides care to 150,000 people. As a speaker rather than an executive, it was [my intention] to force some efficiencies into the Ryan White program and to ensure that money was used more productively. Even if Ryan White funding stays flat, the money will go further through efficiencies. It's an economically sound principle. We will never be responsible for providing care to 100 million people.
- Dr. Yogev: Seventy-five percent of Ryan White funding is for treatment, for groups of people already infected; it is not meant to be used to identify new cases. Maybe we should consider recommending this.
- Dr. Judson: Even without a law in 1996, we began testing all pregnant women at the Denver Center. As the inner city health care provider, we convinced ourselves we had to pay for it. Now with the new CDC protocols, DHHS is following this recommendation. I'm a member of Kaiser [Permanente] with 460,000 patients in Colorado. They've begun to implement HIV testing at the point of care according to the CDC recommendations. They're competing and comparing themselves with other health care providers; that's already happening. It's expensive, but it will work.
- Dr. Redfield: When you have a blank slate it's easy to learn something, but it's complicated to unlearn something. I'm trying to understand how we're proactively engaging the medical community. Let's get individual citizens to understand the importance of testing. I'd also say maybe there's still a need for a proactive medical program. [Mr. Gomez: Our partners are the American Medical Association, the American Nurses Association, and others. Their governing bodies need to discuss this. You are a powerful entity and can be declarative with those you serve.]
- Ms. Wise: If I was [a young person] at a testing event and considering that I might be at risk, and I'm with my friends, and we'll know our results in 20 minutes, I might [re-evaluate] whether I want to go through such a devastating event in the middle of a big party. Suppose all my friends test negative and I test positive? How are people counseled? [Mr. Gomez: We try to make sure that a person receives counseling along with his or her test; that occurs 90 percent of the time. We offer people options, so that if they don't want to take the test that day, they receive clear information on where they can find a test at another time. At least we can begin the dialogue. It sounds obvious, but the challenge is to keep it simple. The public health message is that we want people to get tested in routine settings. Not all Americans need to be tested, but those who think they might be at risk [must be encouraged to do so]. Testers must be skilled and have solid counseling skills. That's the rare opportunity to begin an HIV dialogue. We want to create behavior change.]
- Ms. Wise: What do you do to train someone to counsel? [Mr. Gomez: That's not my domain; I work with grantee communities to make sure appropriate training occurs.]
- Ms. Flucas: How do you get people to return for their test results? [Mr. Gomez: At DHHS, 25 percent of the people who took the test didn't show up for their results. We let people know where they can take the test or find additional information, and it's the fastest moving paper in the entire clinic. When someone leaves, they have a Web address so they can find additional information.]
- Dr. Judson: With name-based testing, it's now our responsibility to follow up with those who tested. That's why people do or don't get tested. In the 1980s, I made it a habit to ask my students what was the Number One reason they hadn't been tested.

Overwhelmingly, they said they didn't want to know the results; they didn't want to deal with it; they didn't want to change their behavior. [Mr. Gomez: People must be given alternatives.]

- Dr. Redfield: The early 1980s was a complicated time, and the American medical community didn't promote testing as a smart thing to do. Now we try to link it with medicine. I'd like to think that in 2009, we won't need national testing days. The environment in which you should be diagnosed would be in a medical center. The end goal is not to have more testing days, but to have HIV testing be integrated into overall medical care.
- Dr. Bush: The latest American Medical Association newsletter has an article about universal testing. It says that 100 percent of patients in emergency departments are offered HIV tests, but only 60 percent agree to be tested, and 40 percent opt out. Of the 60 percent who agree to the test, around 1 percent test positive. The snag is weaving the test [and counseling] into the overall flow of care in an emergency department, because the objective in emergency care is to get a patient in and out as quickly as possible.
- Dr. Malebranche: Why is there a focus on the emergency department as the place to test? If it's supposed to be a screening process similar to that for hypertension or breast cancer, it should be the focus in outpatient clinics.
- Dr. Judson: In inner cities, the emergency department population has disproportionately high risk factors for HIV. An emergency department by its very nature is the ideal setting for implementing an HIV program. [Mr. Gomez: Some people use the emergency department as their only source of medical care, and for some, emergency care may be the first contact they've had with a medical provider in 5 years.]
- Dr. Redfield: We don't have a comprehensive, effective health program for many Americans. The Global Fund and PEPFAR are asking how general health care can be integrated with HIV clinics. We need to strengthen access to the health system for all Americans.

Comments Not Directly Associated with HIV Testing

- Dr. Martin: I would like to have a hard copy of domestic resolutions in the premeeting agenda.
- Dr. Redfield: I would like to know the true cost of providing care to HIV-infected individuals. It would be useful to learn the status of previous resolutions we adopted. [Ms. McGeein: We had asked CDC what the yield would be if 100,000 people were tested and to delineate that population on the basis of their being uninsured, underinsured, etc.]
- Dr. Redfield: There is a significant gap in resources required to provide services to underinsured individuals and the reality that will unfold in the next several years. We need to review whether funding is adequate or whether a gap in funding exists. People want to be helpful, but without accurate information, we go on our biases, which is wrong. [Ms. McGeein: This is a market-based health system. I'm not sure what you're seeking. Describe "program."]
- Dr. Redfield: The contribution the Federal Government makes to HIV health care through Ryan White, Medicare, and Medicaid. My concern is that in my district, we will show disproportionately fewer people are infected versus those who are uninfected. I

agree that ultimately we need to bring an HIV diagnosis into clinical medicine and not influence providers.

- Mr. Schmid: CDC put out a program announcement last week for increased testing and they estimate they will find 20,000 new positives. Since 70 percent of the population living with HIV/AIDS rely on the public health system, that's a lot of people for whom we must provide care.
- Dr. Bush: I don't know the difference between a generalized and a concentrated epidemic, but I know we have a heightened crisis in the African American community. Has it been declared an epidemic, and what difference would it make in the community? We should be ringing alarm bells and putting the news on CNN. What would be the public health response?
- Dr. Green: In most of the world, HIV is concentrated in three populations, particularly commercial sex workers and injecting drug users. Most HIV in Africa and the Caribbean occurs in the general population, not in high-risk groups. Thailand declared a 100 percent condom use policy, and it seemed to work well there and in Cambodia as a first-line defense, but condoms don't work well in a generalized epidemic. Africans have been depicted in the West as being polygamous and promiscuous, but that's not true. By standard measures, Americans and Europeans are more promiscuous. Africans have more regular outside relationships and fewer outside partners. What has worked in Thailand, Cambodia, and the United States has not worked in Africa. People are afraid to admit this. HIV is spreading rapidly among heterosexuals in the African American and Hispanic communities. A lack of circumcision could be exacerbating higher prevalence. When I came on PACHA, we didn't have the circumcision data. HIV is spreading rapidly among heterosexuals in the United States.
- Dr. Bush: What is the threshold for declaring an epidemic?
- Dr. Green: Any national prevalence greater than 1 percent. But that ignores transmission dynamics, and Joint United Nations Programme on HIV/AIDS (UNAIDS) estimates have been acknowledged to be too high. Before, Rwanda had 30 percent prevalence, but it's been revised to 3 percent. David Wilson of the World Bank has suggested better definitions. There's not a magical cutoff point; it has to do with whether or not infections are occurring in the general population.
- Dr. Redfield: CDC announced years ago that 1 in every 52 African American women was infected with HIV, and Representative Maxine Waters (D-CA) called it a public health emergency. I was saddened to learn a couple of weeks ago that 5 percent of the population living in ZIP code 20210 (Washington, D.C.) has HIV. That's 1 in 20 people. I don't think all new infections can be traced to behavioral issues. I think one of the most important research questions is to explore nutritional, socioeconomic, and biological bases for new infections. The issue is critical and it needs leadership. What should be our course of action to curtail the epidemic?
- Dr. Primm: I was just in a consulting group to examine sexually transmitted diseases (STDs) and bacterially transmitted STDs. Social determinants are important in the transmission of bacterial infections. A sense of intimacy seems to be lacking. In 2002, at age 15, more than 30 percent of boys have already had oral sex and 29 percent have had vaginal sex; the figures for women are similar. We should be talking to youngsters at ages 10 and 12 years about sex. [Dr. Primm showed three slides to demonstrate the effects of HIV on the African American community in the United States.] We should be

focusing on this in the United States. It is shocking that HIV is affecting poor whites, blacks, Latinos, and Indians. We don't say much about the prison system and its role in HIV transmission. We need to talk about this.

- Dr. Bowers-Stephens: That's provocative. I've heard many statements today that are culturally and racially insensitive. Based on your three slides, what is your response regarding transmission determinants in the African American community?
- Dr. Redfield: If you look at transmission of HIV from one human to another, it is the CCR5 receptor that uses HIV as a coreceptor to gain entry to macrophages. As a person gets sicker, the virus evolves to use CCR6 or CCRX4. In couples who carry two different viruses, the virus still uses the same CCR5 for macrophage entry. How much virus does a person have? The average viral load among armed forces personnel is about 10,000 copies, but in Africa it is 100,000. The ability to transmit HIV from one human to another has an infectious dose threshold. In Africa, people have a higher threshold level. The average cell might have 3,000 to 6,000 molecules per cell, and if I can reduce that to 23 molecules, the cell doesn't get infected. We're now trying to do clinical research on vitamin A deficiency. Another good way to downregulate CCR5 is to give people methadone. We may not be as aggressive in treating vaginosis or other complicating infections that have immune activation; we may be doing things proactively. One of the most promising antiretroviral medicines is one that blocks CCR5.
- Dr. Bowers-Stephens: I'm a social scientist. I think HIV/AIDS has a biopsychosocial aspect to it.
- Dr. Redfield: How do we show how a person responds? People with a Type C personality are generally passive in dealing with their illness; we could examine chemokine expression biology and relate it to how a person responds to an illness.
- Dr. Bowers-Stephens: Environment can affect biology.
- Dr. Primm: There are 10 African American women for every 7 men; 3 or 4 of these 7 are in jail, and 1 of those is bisexual or gay. This disproportion creates many problems in the community. There's nothing worse than the way we approach prevention, such as through circumcision, where a white-gloved hand is ready to circumcise a black penis [Dr. Primm showed a slide]. That turns my community against circumcision; we don't have cultural sensitivity. We need to make some recommendations in this country to get people to think in completely different ways about HIV transmission. Bob, I agree with you about CCR5, but when we test we perform an antibody test. We need to do RNA and antigen tests.
- Mr. Gilmartin: In Botswana, the approach to HIV/AIDS was led from a national perspective, and it was comprehensive. They distribute condoms and antiretrovirals. They had to learn what was and what was not effective. Community-based organizations became engaged in counseling and orphan care. It strikes me that an opportunity exists to attack this problem in the United States through a community-led, comprehensive approach. I think that's the only way it can be done. Merck used statistics to promote the human papillomavirus (HPV) vaccine.
- Dr. Green [to Dr. Primm]: The broad trend in the past 15 or 20 years among teenagers is less teen pregnancy and less sexual activity; to understand the special dynamics, we have to look beyond teenage behavior. Conservatives are passionate about abstinence. You've touched on many of the major factors: disproportionate African American men in prison,

down-low behavior, drugs and alcohol, high rates of drug use, lack of circumcision. I think the behavioral factors need to be explored further.

- Dr. Malebranche: There was a great review by Millett et al. in the *American Journal of Public Health* (Millett GA, Peterson JL, Wolitski RJ, Stall R.Greater Risk for HIV Infection of Black Men Who Have Sex With Men: A Critical Literature Review. *Am J Public Health.* 2006;96(6):1007–19). Why is there disparity among black men who have sex with men (MSM) versus MSM of other ethnicities? It can be applied to the general African American community. Coinfection and late testing are factors. Down-low behavior is not predictive of anal STD rates or HIV infection. MSM of other ethnicities were more or as likely to have infections. Sexual networking, circumcision, bacterial vaginosis, behavioral practices of African American women who were more likely to engage in douching—these are factors. This is a social disease. It's about poverty and poor access to medical care. We can be just as promiscuous as other populations, but because of other things, that's where it becomes a bomb ready to explode. This epidemic didn't become a racial disparity overnight. We keep talking about testing and treatment, and personal responsibility. At the end of the day, I don't know whether this group is qualified or competent to discuss this; nor perhaps are the higher-ups. I hate to say it, but many people don't care about overcrowding in prisons. We have more people in prison than any other nation.
- Dr. Primm: 700,000 men were discharged from prison last year. It's a constant seeding mechanism. It's a rite of passage now [for a young black man to go to prison]. If we don't do anything about it now, it'll become a genocidal plot. Just a high school education is enough to promote prevention.
- Dr. Yogev: We avoid the issue and become depressed. For years I tried to get nurses to work with this population. You represent the few. We recommend an infrastructure to work with all populations. We talk about circumcision. We need to have the community leaders pick up the baton of prevention, and we as a community need to ask for the resources. The Hispanic community has the same problem. It's a different culture, a different approach.
- Ms. Wise: I agree about working with teens. Latina and black women are getting HIV at ages 15 to 24. They need hope. They engage in risky behaviors because they're trying to get their needs met; they're looking for either a sense of security or a sense of being worthy and loved. I think we need to get information to young people beforehand.
- Dr. Green: The data in Africa are quite clear that poverty and lack of education are not risk factors. Rather, it's just the opposite: Greater education and greater wealth tend to lead to greater mobility and more sex partners.
- Dr. Judson: No one disputes that if you don't deal with multiple partners you won't get very far. We should be examining how to change exposure behavior. Diseases that are coprevalent will be cotransmitted. As gonorrhea rates go higher, so do HIV rates. You have to reduce the number of sexual partners. Poverty is not associated with prevalence. Better educated/wealthier men and women command more than one partner. There is no direct correlation in Africa with economic levels and HIV. When 90 percent of HIV cases occurred among white, educated gay men, they had the highest disposable income levels, and they had rates 20 to 40 to 60 times higher than heterosexual men. They had more sexual partners. I don't think there's evidence that if people had more discretionary

income [HIV rates would come down]. I don't have an answer for controlling HIV rates in penal institutions; it's appalling. There are disproportionate sentencing practices.

- Dr. Bowers-Stephens: Besides the oversimplification of issues, more important, I think, when we talk about HIV/AIDS policies, we have to take them in the context of larger policy issues in this country: eradication of poverty and resolving our national health care crisis. Perhaps we need a more rounded committee that can examine these issues.
- Mr. Gilmartin: Botswana followed comprehensive, community-led principles. We can't spend $100 million over 5 years. The partnership began in primary schools; it was training. It was a national policy to have opt-out testing.

Summary of Public Comments

James Sykes, Global Advocacy Coordinator, The AIDS Institute: Malaria is the most important parasitic disease in the world. It kills 3,000 children every day and more than 1 million each year. That is one death every 30 seconds. The President's Malaria Initiative (PMI) targets 15 of the countries hardest hit by malaria. Seven of these countries are also PEPFAR countries. Studies have shown that malaria also increases HIV viral replication and viral load, which may hasten HIV disease progression. The AIDS Institute recognizes the President's commitment to reduce deaths due to malaria, but we are concerned that more funding is needed to keep the promise of universal access to HIV/AIDS care and treatment. We are committed to ensuring access to care and treatment for those most vulnerable in the world. It is our hope that the United States will maintain its commitments to fighting both HIV/AIDS and malaria in resource-constrained countries and will work with Congress and the Administration to fulfill these efforts.

Ronald Johnson, Deputy Executive Director, AIDS Action Council: A few days ago, President Bush announced the nomination of Dr. James Holsinger as his choice to be our Nation's next Surgeon General. After reviewing Dr. Holsinger's record, AIDS Action Council expresses its opposition to the confirmation of Dr. Holsinger as Surgeon General. We call on PACHA to also express its opposition to the nomination. Sadly, Dr. Holsinger has a long record of prejudice toward and bias against lesbians and gay men. The record shows his support for reparative therapy to "cure" homosexuals. Such therapy has been discredited widely by mainstream medical, psychiatric, and psychological organizations, including the American Medical Association. The notion that gay people need to be cured adds to the stigma and discrimination facing gay and bisexual people. AIDS Action believes that Dr. Holsinger will not inspire the confidence of people living with HIV/AIDS or of people at risk for HIV infection and therefore will not be a credible leader in the efforts to end the HIV/AIDS epidemic here in the United States. The commitment to combating the domestic HIV epidemic needs to be strengthened with public health leadership that commands respect. We feel that Dr. Holsinger will be unable to fulfill this important duty of the Surgeon General.

Suzanne Miller, Public Policy Director, The AIDS Institute: We understand that CDC will soon announce that the number of new HIV infections is substantially higher than the current 40,000 annual number—it may be as much as 50 percent higher. The AIDS Institute is pleased that CDC is about to finalize an addendum to the HIV Prevention Strategy. We are deeply disappointed that we did not make progress in decreasing HIV rates. Now with a strategy in place of decreasing new infections each year by 5 percent or at least 10 percent by the end of 2010, we hope leadership and resources will be directed toward comprehensive HIV prevention,

including a concerted effort to promote evidence-based prevention. Over the past 5 years, CDC's HIV prevention budget has been cut. CDC was able to stem the tide of cuts by transferring $45 million to the HIV prevention center for testing programs. This year, the President has proposed increases for testing and the House has recommended a $64 million increase for testing. A plan to reach national prevention goals must include comprehensive educational programs and programs that target specific populations. We congratulate CDC for adding a focus on men who have sex with men, African Americans, and other disproportionately affected groups for addressing the issue of comorbidities such as mental health and substance abuse. Syringe access programs must be part of a comprehensive plan to prevent HIV infections. We also strongly support comprehensive sex education. We are disappointed in the proposed increases in funding for abstinence-only-until-marriage programs. We support current efforts to create a Federal funding stream for comprehensive sex education.

James Albino, Government Relations and Public Policy Manager, National Minority AIDS Council: The HIV/AIDS crisis in Puerto Rico is deepening, and the service delivery system that provides life-extending care and treatment to more than 30,000 persons living with HIV/AIDS on the island is in danger of collapsing. The 2007–2008 Ryan White grant awards for Puerto Rico were reduced, and Caguas and Ponce, which were classified as Eligible Metropolitan Areas, have been redesignated as Transitional Grant Areas. The two agencies charged with the administration of nearly 75 percent of the funds designated to help Puerto Rico's HIV/AIDS community continue to be hampered by internal bickering, mismanagement/misappropriations, and ongoing FBI and IRS investigations on charges of possible corruption. The San Juan municipal government is under a criminal investigation on charges of misappropriations; this affects 32 municipalities in eastern Puerto Rico and 22 community-based organizations (CBOs), many of which have been forced to close. Since the last PACHA meeting, the ADAP waiting list has grown and more than a dozen CBOs have been unpaid since December 2006. Much of northeastern Puerto Rico, Vieques, and Culebra have little or no services. I implore PACHA to reach out to DHHS Secretary Michael Leavitt to take immediate and effective action to offer technical and financial assistance to the HIV/AIDS community in Puerto Rico.

DAY 2

PEPFAR Reauthorization: The Honorable Mark R. Dybul, Ambassador, U.S. Global AIDS Coordinator

Ambassador Dybul spoke to Council members by telephone from Kigali, Rwanda, where he was attending the 2007 HIV/AIDS Implementers Meeting.

The Ambassador reminded Council members that President Bush requested that Congress reauthorize PEPFAR at $30 billion, and that the Group of Eight Nations had committed to spending an additional $30 billion on HIV/AIDS. The goal is to have the law passed and signed by December 8 (World AIDS Day) so that countries would not have to be concerned about the availability of resources in 2009, but also to continue and expand the novel concept of partnership compacts with recipient countries. Services will continue in the 15 focus countries, which will cost approximately $26–$27 billion. Services will be expanded to other countries that demonstrate a commitment to fighting the epidemic through appropriate policies and workforce efforts, orphan protection, gender protection, rapid testing, and mandatory (i.e., opt-out) testing.

Partnership compacts between the United States and donor countries will determine which countries will receive PEPFAR funds. A new, major component of PEPFAR will be to connect HIV with the larger goals of development such as agricultural projects, clean water, food security, gender equality, and efforts to combat tuberculosis and malaria.

Ambassador Dybul reminded Council members that PEPFAR has seen great success: 2.5 million people are receiving treatment, 12 million new infections have been prevented, and 12 million orphans have been protected. Through PEPFAR reauthorization, the goal will be to provide treatment to 5 million individuals, prevent 24 million new infections, and protect and care for 24 million orphans.

Questions and Comments Addressed to Ambassador Dybul:

- Dr. Yogev: With the exception of two or three countries, pediatric drugs are not available in appropriate formulations. Is the Government working on a process to have drug companies commit to making such pediatric formulations? [Ambassador Dybul: Yes. We are working with the World Health Organization and pediatric AIDS groups to identify appropriate formulations. There's a limit to what the U.S. Government can do to press companies to make these formulations, but we take every opportunity to do so at public and private partnership meetings.]
- Dr. Judson: How much flexibility will the new law have to allow you to move money from countries that either cannot or will not achieve their performance goals to other countries that are more likely to have success in achieving their goals? [Ambassador Dybul: We have that flexibility now. Every year, we set country allocations on the basis of performance. Countries that perform well get greater increases than those that do not. A similar structure will be built into the partnership compact, although for humanitarian reasons we cannot remove people from treatment and children out of care. Some countries stipulate that a physician rather a nurse must see every patient with HIV and some require long tests rather than rapid tests and they don't offer opt-out testing. That is an inefficient use of resources. Even $60 billion is not enough to do everything. Countries that perform well will receive better resources; for example, South Africa will receive $500 million.]
- Dr. Green: There's a move underway in Congress to remove earmarks for antiretrovirals. Has the issue of promoting abstinence only come up at the implementers meeting? [Ambassador Dybul: The *National Review* published an article on this recently. Even people who are not normally kind to the Administration are praising the G-8 and the President. I believe we need to hold on to the directive that promotes abstinence only. There may come a time when we don't need a directive, but it's not now. Perhaps we can come up with language that includes abstinence, fidelity, and correct and consistent condom use. It'll be a tough fight. There's legislation afoot to remove it. We will strongly advocate retaining the directive related to abstinence.]
- Mr. Schmid: Since the dollar amount for PEPFAR will be doubled, will the goals for treatment be doubled? [Ambassador Dybul: We cannot withdraw what we will have achieved. By the end of 2008, we will be ahead of the original 2010 goals. It will cost the 2008 budget times five to maintain the number of people on treatment (about $27 million). While it doubles the commitment, it's not a doubling of the goal. These are lifetime commitments. We want to double the number of infections averted. This is why

the G-8 commitment is so important. Currently, 7 million people need care and treatment. The current estimate is that 10 million people will need treatment, or 5 million will need universal access to care.]

- Ms. McGeein: What do you want PACHA to do to help you? [Ambassador Dybul: I think education is important. Council members have influence around this issue. Understand the goals and how the vision was developed. Congress will have many questions. This isn't a political issue; it's a programmatic issue. If the law isn't passed, we will not achieve the 2008 goals. We must work through optimizing the resources. It will take many voices to push this. We want your insight and advice. I need your individual and collective thoughts, and please get the message out about why it's important to do this and to do it now. We will try to keep the law relatively clean and to turn it around quickly.]

Addressing the Linkages Between Drug Abuse and HIV/AIDS: Timothy Condon, Ph.D., Deputy Director, National Institute on Drug Abuse, National Institutes of Health

Drug abuse and HIV are cooccurring and intertwined epidemics. In 2001, nearly 40 percent of all AIDS deaths were linked to injecting drug use, whereas in 2005, 36 percent of all AIDS deaths were linked to injecting drug use. Drugs of abuse have had a major effect on the HIV/AIDS epidemic. The proportion of AIDS cases in adults and adolescents has dropped steadily among men who have sex with men (MSM), among injecting drug users, and among MSM who also use injection drugs, although the proportion of AIDS cases has increased among heterosexuals.

Drug use promotes the acquisition and transmission of HIV through high-risk sexual behaviors that result from drug use inhibition and other physiological factors. Drug use also affects HIV disease progression.

In 2005, an estimated 19.7 million people in the United States, or 8.1 percent of the population aged 12 or older, were current illicit drug users.

Advances in science in the past 10 years have revolutionized our fundamental views of drug abuse and addiction. We now understand that drug abuse is a biobehavioral disorder. In 1987, the Partnership for a Drug-Free America used a commercial that showed an egg sizzling in a frying pan and the slogan "This Is Your Brain on Drugs." Ten years later, we are able to depict the changes in brain chemistry using magnetic resonance imaging (MRI). The bottom line is that addiction is a brain disease. We have come to know a lot about the pleasure/reward/ reinforcement pathways in the brain, and drugs of abuse work on these pathways. In people who abuse drugs, memory and learning are also affected, as are cues and behaviors that affect craving, motivation, drive, and decisionmaking. Drugs of abuse (especially amphetamines) release tremendous amounts of dopamine, which leads to euphoria.

The science of drug abuse has generated a lot of new information. We know that any physiological system that is driven to extremes becomes habituated, leading to long-term sequelae, including fundamental, long-lasting changes in the brain. Dr. Condon showed several positron emission tomography (PET) scans to demonstrate metabolic activity in a normal brain and in the brain of a cocaine user after 10 days and after 100 days of drug use.

Dr. Condon explained that addicts cannot stop, because addiction changes the brain circuitry. He noted that drug abuse treatment must encompass pharmacological, behavioral, medical, and social services so that all the needs of an individual are met (i.e., a whole-person approach to treatment).

The National Institute on Drug Abuse (NIDA) uses the following principles of treatment:

1. No single treatment is appropriate for all individuals.
2. Treatment needs to be readily available.
3. Treatment must attend to multiple needs of the individual, not just drug use.
4. Multiple courses of treatment may be needed for treatment success (i.e., drug abuse is a chronic, relapsing disease).
5. Remaining in treatment for an adequate period of time is critical for treatment effectiveness.

Apart from obvious public health impacts, drug abuse and addiction treatment is also important for preventing and treating HIV/AIDS. In fact, drug abuse treatment *is* HIV prevention because treatment decreases levels of seroconversion, it decreases HIV risk behaviors, it increases HIV treatment adherence, and it decreases disease progression.

The NIDA strategy in treating drug abuse involves blending research and practice, and bringing science-based technologies into ongoing community practice. The NIDA Clinical Trials Network (CTN) has dual missions: to conduct multisite clinical trials to determine the effectiveness of drug abuse treatment interventions in diverse community-based treatment settings and diverse patient populations, and to transfer research results to treatment programs, clinicians, and their patients to improve the quality of drug abuse treatment throughout the Nation. The network consists of academic institutions and 240 community treatment programs in 34 States and Puerto Rico that perform real-life, real-time clinical trials.

NIDA is working with CDC to expand access to rapid HIV tests and counseling through the CTN 0032 study. The test has been approved for use by the Food and Drug Administration. It requires a finger stick for a drop of blood or a mouth swab, results are available in 20 minutes, it does not require laboratory facilities, and the test can be performed by drug counselors.

Dr. Condon explained that treatment strategies and clinical practice must have practical applications in communities and does so using a blending initiative in which CTN and other NIDA research are combined to assess how treatment research can be applied in practical settings. Dr. Condon explained how NIDA worked with the Substance Abuse and Mental Health Services Administration (SAMHSA) to devise a blending initiative that used buprenorphine in the short-term treatment of opioid withdrawal. The point of such an initiative, he noted, is to decrease the usual 17 years it takes to translate scientific findings into practical drug addiction treatment strategies and protocols.

Dr. Condon explained NIDA's work in reducing drug abuse in the criminal justice system, where 60–80 percent of people either have a problem with drugs or are incarcerated as the result of a drug issue. Again noting that drug abuse is a chronic, relapsing disease, Dr. Condon noted that with treatment, more people remain drug-free and arrest-free. He presented data from a recent

study that examined relapsing trends among inmates who were started on methadone before they were released into the community.

Questions and Comments Addressed to Dr. Condon:

- Dr. Green: Has anyone come up with something akin to a 12-step program similar to Alcoholics Anonymous? [Dr. Condon: I don't think a 12-step program provides treatment, but it serves a critically important role after care. That's why Weight Watchers works. People need behavior reinforcement.]
- Dr. Primm: I want you to mention your partnering with the American Psychiatric Association (APA) and mental health—the bench to the trench program. The minority fellowship program is being dropped because of a lack of funding at NIDA and SAMHSA. [Dr. Condon: Our partnership with APA was wildly successful, but the NIDA budget is not growing. All programs are getting cut. Eventually, the tide will turn and we will establish a new commitment for minority fellowships.]
- Ms. McGeein: When will you have results on your cooperative study with CDC? [Dr. Condon: I hope by the end of this year or early next year.]
- Mr. Schmid: Collaboration with CDC is important, and so is the ability to translate science into practical application. What work is NIDA doing on the crystal methamphetamine epidemic? [Dr. Condon: That would be another entire presentation. We started doing research on crystal meth 10 or 15 years ago, but only in the past 5 years has it been getting press attention. Midwestern cities—places like Omaha and Des Moines—are awash with crystal meth, but they didn't go through the crack cocaine epidemic and they don't have the addiction infrastructure to deal with such an epidemic. We're just beginning to talk more with CDC about methamphetamine prevention, and the Office of the Drug Czar is rising to the occasion because it is such an important issue.]

HIV and Multidrug-Resistant/Extremely Drug-Resistant Tuberculosis: The Perfect Storm: Timothy H. Holtz, M.D., M.P.H., FACP, Commander, U.S. Public Health Service, International Research and Programs Branch, Division of TB Elimination, Centers for Disease Control and Prevention

Dr. Holtz reviewed what is known about the interaction between HIV and tuberculosis (TB), particularly extremely drug-resistant TB (XDR-TB).

TB is one of the world's most prevalent diseases. An estimated 8.8 million new cases of TB cases are confirmed annually. TB claims approximately 4,400 lives per day, or 1.6 million lives per year. Twenty-two countries with a high burden of TB account for approximately 80 percent of all TB cases. India and China account for one-third of all cases of TB. Approximately 700,000 people newly diagnosed with TB are also believed to have HIV infection. The World Health Organization (WHO) estimates that approximately 420,000 new cases of multidrug-resistant TB (MDR-TB) occur each year; these are considered to be TB caused by an isolate that is resistant to at least isoniazid and rifampin. MDR-TB is a problem predominantly in Eastern Europe and Asia, but all areas of the world report some cases of MDR-TB.

Dr. Holtz showed a slide that compared the incidence of TB in 1990 and in 2005. In that period the incidence of TB had tripled in countries of the former Soviet Union, and it had increased by

2.5-fold in sub-Saharan Africa. Uganda, for example, has made great strides in reducing HIV prevalence, but the incidence of TB has risen dramatically.

MDR-TB results from poor TB control programs, low drug regimen completion rates and poor clinical practices, and erratic drug supply and poor quality of drugs. MDR-TB results in longer treatment (6–24 months); toxic, complicated regimens (4–6 months using injectable drugs); and increases in the number of cases and costs by 10-fold to 100-fold. It leads to lower cure rates (i.e., <75 percent) and higher death rates, particularly in individuals with HIV coinfection.

Where HIV appears to be linked with high mortality, studies of treatment show similar findings. For example, one study from New York City in the mid-1990s found that 62 percent of patients with HIV and MDR-TB died, whereas 26 percent of those with HIV but without MDR-TB died. Another study from New York City in 1996 found that 72 percent of patients with concurrent MDR-TB and HIV infections died versus 20 percent of those without HIV. A study from South Africa in 2002 showed that 20 percent of patients with MDR-TB died, but 41 percent of those with MDR-TB and HIV coinfection died.

TB and HIV have been called the "cursed duet" because each infection worsens the other. HIV is the most potent risk factor for developing TB, both through an increase in the reactivation of latent TB infection and through an accelerated progression from infection to disease. The risk of progressing to active TB in individuals who are not HIV-infected is 5–10 percent in a person's lifetime. In individuals with HIV infection, 50–60 percent will develop TB in their lifetime.

Multiple associations between HIV and drug-resistant TB are converging for what could be "the perfect storm": poorly performing TB control programs in settings with high HIV burden may lead to the emergence of anti-TB drug resistance; excessive global TB burden is largely due to HIV; overwhelmed health services will result in a deterioration in the performance of TB control programs; patient adherence to TB treatment suffers, which results in increased treatment default rates; acquired rifamycin resistance will occur among HIV-infected TB patients under treatment; and malabsorption of anti-TB drugs among HIV-infected TB patients will be associated with poor treatment outcomes.

A definite link has been identified between HIV and acquired rifamycin resistance among patients with TB under treatment. Multiple studies have demonstrated that poor treatment adherence, advanced immune suppression, concomitant treatment of other opportunistic infections, cotreatment with antiretroviral (ARV) medication, and treatment with intermittent TB treatment regimens play a role in the development of rifamycin resistance among those with HIV.

China, India, and Russia have the highest estimated annual burden of MDR-TB with 135,000, 90,000, and 35,000 cases, respectively. In contrast, fewer than 150 cases of MDR-TB are reported in the United States each year. HIV prevalence among patients with TB is well in excess of 20 percent throughout sub-Saharan Africa, and well over 50 percent in southern Africa.

The emerging worldwide epidemic of drug-resistant tuberculosis is a byproduct of ineffective or poorly organized systems for TB control. It is entirely a human-made problem. The natural

selection of rare drug-resistant strains inside the human body occurs when inconsistent or interrupted treatment occurs, when the wrong drugs are prescribed for the wrong amount of time, when drugs of inferior quality are given, or when the supply of drugs is interrupted. CDC first defined extremely drug-resistant TB (XDR-TB) in the March 2006 issue of *Morbidity and Mortality Weekly Report.* XDR-TB is widely distributed geographically and appears to be more present in countries that already have high rates of MDR-TB. Its development is likely due to the poorly controlled use of second-line drugs for MDR-TB treatment, something that CDC and other agencies are attempting to control through a mechanism known as the Green Light Committee.

XDR-TB is defined as MDR-TB that is also resistant to any fluoroquinolone and one of the three second-line injectable drugs. Inadequate treatment of MDR-TB will predictably result in the emergence of *Mycobacterium tuberculosis* strains with resistance to second-line drugs. If a patient with MDR-TB develops resistance to second-line drugs, that person may be virtually untreatable, because both flouroquinolones and injectable agents are critical to the successful treatment of MDR-TB. An analysis of XDR-TB treatment in Latvia has shown that treatment success is at best 35 percent; patients with HIV and XDR-TB may be virtually untreatable.

In KwaZulu-Natal Province, South Africa, in 2005–2006, 119 patients were enrolled in a TB/ARV integration study. Fourteen patients (12 percent) died (all from TB), and 10 (71 percent) were found to have had MDR-TB. Six of the 10 were subsequently found to have had resistance to all first- and second-line anti-TB drugs. This suggested that XDR-TB was present in the local hospital and possibly in the community. In a survey that followed, 1,539 consecutive patients presenting at the local hospital and clinic with symptoms suggestive of TB were fully evaluated with MDR-TB culture and drug susceptibility testing. Among those, 542 patients (35 percent) had culture-confirmed TB. Of those, 221 (41 percent) had MDR-TB confirmed. Of the 221, 53 were identified as XDR-TB, representing 10 percent of the culture-confirmed cases and one-fourth of the MDR-TB cases.

XDR-TB has now been reported in at least 390 provincial hospitals and elsewhere in South Africa. More than 30 new cases are reported monthly in KwaZulu-Natal Province. Other cases of XDR-TB have been reported in Iran, Spain, Italy, and Germany. To date, WHO has documented XDR-TB cases in 35 countries.

How is the world going to combat XDR-TB? A seven-point action plan emphasizes the essentials of proper TB control:

1. Conduct rapid surveys of XDR-TB (determine the burden).
2. Enhance laboratory capacity (with an emphasis on drug susceptibility testing).
3. Improve the technical capacity of practitioners to respond to XDR-TB outbreaks and to manage patients.
4. Implement infection control precautions with a focus on people living with HIV/AIDS.
5. Increase research support for new anti-TB drugs.
6. Increase research support for rapid diagnostics.
7. Promote universal access to ARVs under joint TB/HIV activities.

Questions and Comments Addressed to Dr. Holtz:

- Dr. Bush: Is the wearing of masks part of the goal to reduce the spread of TB? Are people restricted from traveling? What are simple measures we can take to reduce the spread of TB that is not drug-related? [Dr. Holtz: The surgical mask you often see in pictures is not protective against inhaling droplets that contain *M. tuberculosis*. They are not to be worn by anyone entering an infection control unit, but those who have TB can wear them because it prevents their sputum from being aerosolized. The masks you hear about in the media for health care workers are N95 respirators, but they are expensive; they prevent inhalation of sputum droplets and they filter air. They must fit, and they don't last forever. Providers such as nurses are most susceptible because they spend time on wards where patients are coughing. CDC now recommends that patients with TB should be isolated in separate rooms and not housed together in a ward, but that might lead to stigma. The best thing is to put people outside in the open air where there is ventilation. People should not be sitting together in hospital corridors waiting to be seen by a health care provider.]
- Dr. Judson: Is there evidence that MDR-TB or XDR-TB is associated with a decrease in infectiousness or pathogenicity? [Dr. Holtz: For many years the conventional thinking was that MDR-TB isolates are less competent or less hardy. I have heard that patients with MDR-TB are just as infectious as other patients with TB.]
- Dr. Redfield: The linkage between HIV and TB is real, and it is one of the reasons we focus on the first principle of *do no harm*. In a public hospital in Rwanda, I saw the first eight bays filled with women dying of AIDS, five or six of whom had active TB. One was holding her 1-year-old granddaughter, who was being exposed to TB. Infection control is not rocket science. Individuals who have HIV coinfection with XDR-TB need to have their immune systems reconstituted, which means that ARVs need to be effective. It is fundamental to use your experience with TB and to help educate smart organizations like WHO to preserve the integrity of ARVs. It's our only weapon against XDR-TB in HIV-infected patients for the next several years.
- Dr. Yogev: In places I visit, people are unaware that using ARV drugs is helping develop TB resistance. Is CDC considering encouraging a specialty in TB? [Dr. Holtz: Many countries are switching to favarones. The Global AIDS Program is working with this, and there's a specific HIV/TB team, especially in clinical management. It's recognized in sub-Saharan Africa. The standard regimens are changing to add favarones or other drugs that have less interaction.
- Dr. Malebranche: At my clinic, when we admit a severely immunocompromised patient, unless the patient has Kaposi's sarcoma or cryptosporidium, our first approach is to treat the TB. Do you have experience with that? [Dr. Holtz: In the past couple of years, when we first started working with PEPFAR, the recommendations were to wait and start ARVs when patients were well enough. But the trend now is to become more aggressive. Start TB therapy first, because it's life-threatening. If a patient has a very low CD4 count, you start within a month or two. There are not good studies or published data on this.
- Dr. Redfield: In some parts of the world, there is a trend to delay HIV therapy and to treat TB first; that keeps patients with TB from transmitting it to other people. HIV therapy is not an emergency. It is important to first obtain an accurate diagnosis of underlying infections.

- Dr. Judson: In Denver, our HIV experts are also the TB experts. If a patient doesn't have a desperately low CD4 count, we start treating that person for TB. As rates of MDR-TB and XDR-TB rise and people present with very low CD4 counts, that will create a different set of recommendations.

Motions and Voting

The following motion was proposed by the International Subcommittee. The motion was passed by the Council with one abstention.

International Subcommittee Resolution

WHEREAS, The President's Emergency Plan for AIDS Relief (PEPFAR) is the largest commitment of an international health initiative dedicated to a single disease by any nation;

WHEREAS, PEPFAR is in the 4th year of an initial 5-year program that has rapidly expanded access to essential, life-saving HIV prevention, treatment, and care services in 15 focus countries that constitute more than 50 percent of the global HIV epidemic;

WHEREAS, the PEPFAR program was begun as a humanitarian program designed to dramatically improve the health of, and provide hope to, millions of citizens in these focus countries;

WHEREAS, the PEPFAR program also has importance for long-term global economic development, stabilization of societies, and the strategic interest of the United States;

WHEREAS, the PEPFAR program is also a reflection of the U.S. Government's commitment to global health as an important component of U.S. foreign policy;

BE IT RESOLVED that the Presidential Advisory Council on HIV/AIDS (PACHA) recommends that the PEPFAR program be reauthorized before the end of Calendar Year 2007 and expanded for the purpose of maintaining the momentum of this unprecedented demonstration of the commitment of the American people to addressing one of the most pressing global health challenges of our time.

Public Comments

Larry Bryant, National Field Organizer, Housing Works; Member, Board of Directors, National Association of People with AIDS, Washington, D.C.: I am disappointed that PACHA doesn't seem to follow a model of leadership of being a collective voice of people living with HIV/AIDS with the goal to develop, encourage, and empower individuals to articulate their concerns, their issues, their fears, and their passions on local, State, and Federal levels. Even local planning councils and other advisory or planning bodies that provide input and insight do not accurately represent those affected by the epidemic. It is my belief that this body be more fully representative of the epidemic we are facing. Black and Latino men and women, youth, transgender, and other marginalized people are sorely underrepresented at the table. With

all due respect to the experience and expertise of the members around this table today, not one person comes close to speaking to me and my 21 years of living HIV-positive. It seems that repeatedly, the seats available for leadership in discussing, planning, and implementing strategies to end this disease are filled with the same minds that have steered us to a plateau of 40,000 new infections each year and the hardest hit areas just keep getting hit. Rather than just talk the talk, perhaps PACHA should pass the baton to the current and next generation of brilliant minds to further close the gap toward no new infections and ending AIDS in this country and around the world. It is true that the collective face of AIDS has changed. It should also be true of its leadership.

Robert Carroll, Ph.D., Director, Northwest AIDS Education and Training Center, Seattle, Washington: I speak on behalf of the National Association of AIDS Education and Training Centers (AETCs), the clinical training and education arm of the Ryan White HIV Treatment Modernization Act. We have asked Senators to provide an additional $15 million for AETCs for a total of $50 million in FY 2008. AETCs have received decreased levels of funding for the past 4 years; however, the important work of training medical professionals continues and is urgently needed in this rapidly changing field. Providing comprehensive primary care to patients with HIV, incorporating new medication combinations, meeting the challenge of drug resistance among those receiving combination ARV therapy, and intervening to prevent new infections are just a few examples of the training that AETCs provide in the complex field of HIV care and treatment for the entire range of health care professionals. Moreover, all our trainings are unbiased and evidence-based, with measurable outcomes. In the newly reauthorized Ryan White CARE Act, the AETCs have been given the additional tasks of providing education and training on hepatitis B and ensuring culturally competent care for Native Americans and Alaskan Natives. In addition, CDC has recently released recommendations for all patients to be offered HIV testing in all primary care settings. Additional training will be needed for clinicians in emergency rooms, clinics, and other primary care settings on how to test persons for HIV and link them to HIV services if needed. Ensuring quality HIV health care and meeting these increased responsibilities will require the ongoing excellence of the AETC program. I ask that PACHA recognize the importance of maintaining the successful achievements of the AETCs. We hope that as the national experts in HIV and AIDS, you will support efforts in both the executive and legislative branches to build on our training successes as we work together to meet the changing clinical dimensions of HIV care and treatment.

Donna Crews, Director of Government Affairs, AIDS Action, Washington, D.C.: I found the conversation held during yesterday's PACHA open discussion period to be disturbing. The views expressed by members that education, poverty, access to care, and racism do not play a role in the unprecedented spread of HIV throughout the African American community is startling. The African American community cannot be compared with African communities where the HIV epidemic is so generalized that everyone is at risk for HIV. Many African Americans who are living with HIV have never been to Africa, and more important, over five generations ago, their ancestors were brought to the United States in shackles to build this country. For a statement to be said for the record that "there are more blacks in jail, since they commit more crimes" disregards the sentencing disparities that have been the norm in this country for more years than anyone would care to remember. The clearest example is the Anti-Drug Abuse Act of 1986. The law's mandatory penalties for crack offenses were the harshest ever adopted for low-level drug

offenses and established drastically different penalty structures for crack and powder, under the belief that crack cocaine was more dangerous than powder cocaine and posed a greater threat. The result is that defendants convicted with just 5 grams of crack cocaine—the weight of less than two sugar packets and a quantity that yields about 10 to 50 doses—are subject to a 5-year mandatory minimum sentence. The same 5-year penalty is triggered for the sale of powder cocaine only when an offense involves 500 grams, 100 times the minimum quantity for crack, which yields between 2,500 and 5,000 doses. The mandatory sentencing structure that continues today results in average sentences for crack cocaine offenses that are 3-1/2 years longer than for offenses involving powder cocaine. Crack is the only drug that carries a mandatory prison sentence for a first-time possession offense. It is my hope that PACHA members will come up with culturally competent suggestions to take to the President, without the racially insensitive and demeaning conversations that were heard yesterday, to begin to address the state of emergency in African American communities. Action must be taken, and as the Presidential Advisory Council on HIV/AIDS, you have been sworn to take action.

Adjourn

Dr. Maxwell thanked members for their participation and adjourned the meeting.

Future meeting dates

Domestic Subcommittee: September 10, 2007
International Subcommittee: September 17, 2007
Full Council: October 15–16, 2007