

Presidential Advisory Council on HIV/AIDS (PACHA)

Thirty-sixth Meeting

Hubert H. Humphrey Building

200 Independence Avenue, S.W., Room 800

Washington, DC 20201

October 21-22, 2008

Council Members Present

Raymond V. Gilmartin, M.B.A., PACHA Co-Chair
Marilyn A. Maxwell, M.D., PACHA Co-Chair
Carl Schmid II, M.B.A., Domestic Subcommittee Chair
Troy Benavidez
Robert (Bob) C. Bollinger, Jr., M.D., M.P.H.
Freda M. Bush, M.D., FACOG
Joseph (Joe) Grogan, J.D.
Robert Kabel, LL.M., J.D.
Robert M. Kaufman, M.A., J.D.
David J. Malebranche, M.D., M.P.H.
John C. Martin, Ph.D.
Glenn R. Mattes, B.S.
Jose A. Montero, M.D., FACP
Zelalem Temesgen, M.D.
Antonio Enrique Urbina, M.D.
Sharon Valenti, M.S.N., NP-BC
Jean Ann Van Krevelen, M.S.W.
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.
Shenequa Flucas
Donald A. Holzworth, M.S.
Rev. Herbert Lusk II, B.A., M. Div.
Eric G. Walsh, Jr., M.D., M.P.H.

PACHA Staff Present

Marty McGeein, M.B.A., R.N., Executive Director

Nancy Barnes, Committee Manager

Melvin Joppy, Assistant Committee Manager

Presenters

Bernard M. Branson, M.D., Associate Director for Laboratory Diagnostics, Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (HHS)

Jane Cheeks, J.D., M.P.H., State AIDS Director, Division of HIV/AIDS Prevention and Care, Alabama Department of Public Health

Carl W. Dieffenbach, Ph.D., Director, Division of AIDS, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), HHS

Joxel Garcia, M.D., M.B.A., Assistant Secretary for Health, HHS

Charles F. Gilks, M.B.B.S., D.Phil., FFCP, DTMA, Director/Coordinator, Antiretroviral Treatment and Care, Department of HIV/AIDS, World Health Organization (WHO), Geneva

Frank Graziano, M.D., Ph.D., Professor of Medicine, University of Wisconsin Hospital and Clinics

Monica Sweeney, M.D., M.P.H., FACP, Assistant Commissioner, Bureau of HIV/AIDS Prevention and Control, New York City Department of Health and Mental Hygiene

DAY ONE

MORNING SESSION

Call to Order and Welcome

PACHA Co-Chair Marilyn Maxwell called PACHA's 36th meeting to order at 9 a.m., introduced herself, and reminded all present that this is the Council's last meeting before the Presidential elections and a change in Administrations.

2009 PACHA Meeting Dates

As a first order of business, Dr. Maxwell asked all members to note the 2009 PACHA meeting dates as provided in the meeting folder. They are as follows: Full Council Meetings—March 24 and 25 and October 27 and 28; Domestic Subcommittee Meetings—February 10 and September 9; and International Subcommittee Meetings—February 18 and September 15.

New and Retiring Members

Dr. Maxwell noted that the agenda includes swearing in new members and saying good-bye to those who are retiring.

She noted new members: Joseph (Joe) Grogan, who was PACHA's Executive Director from 2004 to 2006 and is now Vice President of The Marwood Group's Healthcare Research Group; Glenn R. Mattes, who is President of Tibotec Therapeutics; Antonio Enrique Urbina, who is an Associate Professor of Medicine at New York Medical College and an attending physician at St. Vincent's Hospital in Manhattan; and Jean Ann Van Krevelen, former Executive Director of the Cascade AIDS Project in Portland, Oregon. Donald A. Holzworth, Chairman and Chief Executive Officer of the Constella Group, LLC, is also a new member but could not attend today's meeting.

Dr. Maxwell welcomed all new members, noting that they "will quickly learn this is a very exciting place to be where things are happening." She noted that the Council would hear from new members later today, after they are sworn in by Assistant Secretary for Health Joxel Garcia.

Dr. Maxwell noted that Troy Benavidez, Cheryll Bowers-Stephens, David J. Malebranche, Jose A. Montero, and Ram Yogev will be rotating off of the Council after this meeting and would be giving farewell remarks during Day Two of this meeting. She noted that they will all be missed, as they all "brought something very special to all of us."

Dr. Maxwell noted a number of background materials provided to members in their packets, including *Working with Families in the Era of HIV/AIDS* and two newspaper articles, one from *The Washington Post* and one from *The Los Angeles Times*, as well as a series of U.S. Government (USG) reports involving testing recommendations, U.S. AIDS statistics, and U.S. security matters, including visas and entry. In addition, Dr. Maxwell noted the "Living with HIV/AIDS" booklet provided by the National School Boards Association, in which students tell their stories of living with HIV/AIDS.

Approval of the March 25-26, 2008, Meeting Minutes

Dr. Maxwell asked for and received approval of the "very thorough" minutes from the last full Council meeting in March 2008.

Member Introductions

Dr. Maxwell asked members present to introduce themselves and provide a brief statement of their backgrounds, beginning with PACHA Co-Chair Raymond V. Gilmartin. At the end of member introductions, Dr. Maxwell noted that everyone clearly “has a passion to control and to stamp out this epidemic” and that their expertise is welcome. She expressed the hope that the Council will “get great things accomplished” and noted that its resolutions, which go through the Secretary to the President, have a tendency “to get things done.”

Executive Director Statement of Background and Retirement

PACHA Executive Director Marty McGeein noted that her background is in nursing and that she spent a great deal of time helping very fragile newborns survive to adulthood. She came to HIV/AIDS via vulnerable population mothers and children. She has been active in “this part of health care for a very long time.” She can remember when it was said the HIV/AIDS epidemic “wouldn’t break into the heterosexual population.” Now, obviously, it has. “It was there all along. It wasn’t hidden. We just didn’t know that it was going to go there.”

Ms. McGeein went on to state one of her most fundamental beliefs: “Babies are the future. If they are not cared for, the Nation as a whole will not be well cared for.”

Ms. McGeein noted that this is her last meeting as Executive Director, adding that “it has been an absolute joy to serve with you and for this Secretary and this President.” Politics aside, “there has been no President with the stature of President Bush in relation to HIV/AIDS.”

Noting Dr. Maxwell’s point about what PACHA does, Ms. McGeein said that it does advise the Secretary and this advice “goes to the White House.” In addition, changes have been made because of PACHA. For example, recently, changes were made in the President’s Emergency Plan for HIV/AIDS Relief (PEPFAR) due to PACHA, not only in what the Administration transmitted publicly to the Congress but also “behind closed doors.” PACHA also made a difference earlier, in the Ryan White CARE Act (RWCA) reauthorization, during which PACHA held town meetings and made recommendations, “many of which were accepted.”

Ms. McGeein noted that RWCA is back up for reauthorization, and “one of the obligations of this Council, certainly of the Domestic Subcommittee, is to think about what worked, what worked in the last reauthorization, and where the Council can make big and little changes.” This brings Ms. McGeein’s tenure with the Council full circle. “I came in with Ryan White and I’m leaving with Ryan White,” as reauthorization of RWCA will be on the agenda for the Council for the next few months.

Ms. McGeein concluded by saying that she has “loved every single minute” of her tenure with the Council. “I love my job and the people I work with. Thank you for making my life so much fun.”

Dr. Maxwell thanked Ms. McGeein, noting that she “obviously loves” what she does and has brought “a lot of enthusiasm and guidance” to the Council.

Photo Opportunity

Dr. Maxwell asked all members to join her at the front of the room for a “class photo.”

Dr. Maxwell noted that the next photograph taken would be of Dr. Garcia and new members, in conjunction with the swearing in of new members. She noted that current PACHA members Barbara Wise and Robert Bollinger, Jr., would be joining brand-new members in the swearing in.

New Members Swearing-In Ceremony

Conducted by Joxel Garcia, M.D., M.B.A., Assistant Secretary for Health, HHS

Dr. Maxwell introduced Dr. Garcia, outlining his biography as provided to members in their meeting packets.

Dr. Garcia said it was a real pleasure and honor to be with the Council on this occasion. He added that he is excited that the Council will have strong new members to follow and continue the work that has been done in the past. He noted the many issues that now exist in terms of HIV/AIDS, including that “it is becoming a chronic disease.” We must “deal with prevention and testing and also translate from an acute disease to a disease that is becoming chronic, as well.” He is also quite aware, he said, of the impact that HIV/AIDS is having in our community, particularly the Latino and African American communities, as well as among new immigrants from Eastern Europe.

Many challenges lie ahead, Dr. Garcia continued, reminding Council members that they “are charged with a major task: to help the Nation, the President, and the agency in the short and long term.” He added that in addition to the challenges he already outlined, he professionally knows about and has had to deal with the stigma surrounding the disease. He asked the Council in particular to “help us see ways to tackle that issue” as it affects testing and has a “significant effect on the family, on the entire social network of the individual.” He concluded by asking God “to bless all of you.”

Members to be sworn in then proceeded to have their photograph taken with Dr. Garcia. Assisted by Dr. Maxwell, Dr. Garcia then swore into office, into the service of the President and of PACHA, PACHA members Ms. Wise and Dr. Bollinger and new members Dr. Urbina, Ms. Van Krevelen, Mr. Mattes, and Mr. Grogan. Members were provided with new members’ biographies.

Presentations Protocol

Prior to introducing Bernard M. Branson to give a presentation on HIV testing initiatives, Dr. Maxwell reminded the audience that presentations are for PACHA members and questions will be taken only from Council members and not from members of the public.

Update on CDC HIV Testing Initiatives

Presentation by Bernard M. Branson, Associate Director for Laboratory Diagnostics, Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, CDC, HHS

Dr. Branson noted that since PACHA's last meeting, CDC has released new estimates of HIV/AIDS prevalence and incidence.

As a result of new technology in incidence surveillance, CDC now estimates 56,300 new infections annually in the United States and 1,106,400 infected, based on 2006 data. The "good news" is the estimate that 232,700 or only 21 percent are unaware of their HIV infection, "so we have made some impact on those who know."

Dr. Branson noted the percentage of HIV/AIDS diagnosis among adults and adolescents by transmission category from 2003-2006 based on data from 33 States with named reporting (Slide 3). (He noted that as of April 2008, all States now have named reporting.) Slide 3 shows that predominant transmission in diagnosed adults and adolescents is men who have sex with men (MSM) (66 percent) for males and heterosexual transmission (79 percent) for females.

Dr. Branson explained the new incidence surveillance technology (Slide 4) as involving:

- Test specimens from people newly diagnosed with HIV with the BED HIV-1 Capture EIA assay, which differentiates recent from longstanding infections, in general;
- Comparison with HIV case reports and testing and treatment history; and
- An enabled estimate of new infections using mathematical models.

Showing Slide 5, Dr. Branson noted the newly estimated percentage of new HIV infections by sex and age in the 50 States and the District of Columbia, based on 2006 data, as follows:

- 73 percent males and
- "A pretty even distribution in terms of age" (34 percent among 13-29-year-olds; 31 percent among 30-39-year-olds; and 25 percent among 40-49-year-olds).

Similarly, the newly estimated percentage of new HIV infections by transmission category for the 50 States and the District of Columbia, based on 2006 data, is as follows (Slide 6):

- 53 percent MSM

- 31 percent heterosexual contact
- 12 percent injection drug users (IDU)
- 4 percent MSM who also inject drugs.

Dr. Branson noted particular concern about “increasing incidence among MSM.”

Dr. Branson went on to note newly estimated HIV/AIDS prevalence and U.S. population by race/ethnicity (Slide 7) which, with 46 percent prevalence among black (not Hispanic) populations against their representation in the U.S. population (12 percent), and 18 percent prevalence among Hispanic populations against their representation in the U.S. population (15 percent), shows “considerable disproportionality.”

Slide 9 also shows disproportionality in newly estimated rates of new HIV infections by race/ethnicity, as they indicate that 83.7 percent of blacks and 29.3 percent of Hispanics have become newly infected per 100,000 population as against 11.5 percent of whites.

An “important” but insufficiently highlighted probability sample—the National Health and Nutrition Examination Survey (NHANES)—which looks at the entire non-institutionalized (nonincarcerated) population, indicates on the basis of 1999-2002 data that black male and female prevalence was higher in the 40-49-year-old age group than in the 18-39-year-old age group, “which sends signals about what we have ahead of us in prevalence,” Dr. Branson commented (Slide 10).

Examination of the National Health Interview Survey (NHIS), which provides estimates for a broad range of health measures for the U.S. population, including HIV testing, has provided estimates that 40 percent of adults in 2006 were tested for HIV at least once and 10.4 percent were tested in the preceding 12 months (Slide 12). Of those tested in the latter category, 22 percent were black; i.e., “testing is higher among blacks.” In addition, 23 percent of those testing acknowledged risk factors, and 61 percent were pregnant, which “is significant and encouraging, but when you look at routine prenatal disease testing, the rate is 95 percent,” Dr. Branson observed (Slide 13).

Dr. Branson went on to break down where people were tested for HIV in 2003 and 2006 (Slide 14). The largest percentage of those who get tested do so in a private health care setting, which is “part of the reason for the CDC focus on health care settings.”

Dr. Branson showed the percentages of those ever tested and those tested in the preceding 12 months (according to NHIS calculations from 2002-2006) (Slide 15). He described his findings as indicating that the percentage of those ever tested—at about 40 percent—has remained constant, meaning “we keep testing the same people.” Therefore, part of CDC’s new recommendations is to increase the pool of those tested.

Early indications of progress on that score (Slide 16) are increased percentages as of 2007 of those ever tested—41.3 percent—and those tested in the past 12 months—10.7 percent. Dr. Branson emphasized that while these figures “are not yet statistically significant, we are making progress as the result of CDC’s changes.”

Dr. Branson then addressed legal or regulatory constraints to CDC's 2006 testing recommendations for opt-out testing with the option to decline after notifying the patient that testing will be done, and for no separate written informed consent in health care settings.

At the time the recommendations were released, 20 States had laws or regulations requiring written informed consent for HIV testing. Since then, 11 States have eliminated this requirement, including California and Illinois, "so we are making substantial progress there." In addition, 7 States are still considering legislative action to remove their requirements. Two States have taken no action to eliminate this requirement—Connecticut and Michigan. (Slides 19 and 20)

Dr. Branson also noted the www.nccc.ucsf.edu Web site funded by CDC, which provides a number of updates, including in terms of HIV/AIDS laws for consent and counseling (Slide 21).

Examples of expanded testing programs include the "Expanded HIV Testing Initiative" undertaken by the New York Health and Hospitals Corporation (HHC), which involves:

- The largest municipal health care delivery system in the United States for New York City residents,
- Nearly 5 million annual visits,
- 19,000 patients with HIV infection in care, and
- Signed informed consent for HIV testing.

Dr. Branson noted that CDC is closely tracking this initiative, which has substantially increased the number of individuals tested for HIV since 2006. The target was 150,000 per year. In FY 2008, the HHC documented 160,900 tested. In addition, the number of positive HIV tests has more than doubled since FY 2004, to 1,863 in FY 2008. (Slides 24 and 25)

Not all positive tests represent new HIV diagnoses, Dr. Branson noted (Slide 26); however, 80 percent of those tested in health care settings "do get into care, so location seems to be the key." Another sign of progress is that in the HHC system, 44 percent of unique eligible patients have now been tested for HIV.

However, in the Nation as a whole, Dr. Branson commented, "we are still seeing a lot of diagnoses late in the disease," adding that CDC's intention is to have "the greatest beneficial impact." Hence, under the President's Testing Initiative to increase HIV testing opportunities for populations disproportionately affected by HIV—primarily African Americans who are unaware of their HIV status—CDC awarded \$35 million in September 2007 to 23 jurisdictions with the highest number of AIDS cases among African Americans. In 2008, CDC increased the number of awards to include 2 additional jurisdictions. (Slide 29)

Examples of programs under this initiative include expanded HIV testing in Chicago, initiated in October 2007 and involving rapid testing in four emergency departments (EDs), six sexually transmitted disease (STD) clinics, one correctional health facility, and three community-based organization (CBO) clinics.

As of September 2008, this testing program, overseen by the Chicago Department of Public Health, had increased tests given to 16,000 (Slide 31), most administered through the STD clinics and EDs, 1 percent of which resulted in new positives—a “substantial” percentage against CDC’s goals to find 1 new positive per 100,000 population (Slide 32). In addition, the race/ethnicity of persons with positive HIV diagnoses in the Chicago program has, to date, been largely African American (71 percent) (Slide 33).

Another example of a program under the President’s Testing Initiative is a program in Florida, which involves:

- Rapid testing in 30 medical settings
 - 8 emergency departments
 - 17 primary care clinics
 - 4 community health centers
 - 1 urgent care clinic
- As well as rapid testing in
 - 10 STD clinics
 - 10 jails
 - 10 CBO clinics
 - 10 mobile units
 - 1 substance abuse treatment center.

Results from the Florida program through July 2008 show 44,000 HIV tests administered, largely through CBOs, a positive rate of 2 percent, and a new positive rate of 1.5 percent, “a substantial portion of whom are now in care,” Dr. Branson said. Of the tests given in clinical settings (57 percent), 1.3 percent turned up new HIV infections, and of the total tests given in nonclinical settings (43 percent), 1.8 percent turned up new HIV infections. (Slides 35 and 36)

Breaking the Florida data down further, Dr. Branson showed the race/ethnicity of those with new positive HIV diagnoses in the Florida program through July 2008 (Slide 37). This display indicates, similar to the situation in Chicago, a high percentage of positive diagnoses among African Americans—“closely mirroring where we are going with new infections in the United States,” Dr. Branson commented.

Dr. Branson then addressed CDC’s program for capacity building, which includes holding eight regional workshops for hospitals and EDs to develop strategic plans for HIV testing in EDs. Of the 26 facilities that sent representatives to the workshops, 18 are “now doing the test in EDs,” Dr. Branson reported (Slide 38).

In addition, CDC, in cooperation with the Health Resources and Services Administration (HRSA), is capacity building through HRSA's AIDS Education and Training Centers by providing:

- Training and technical assistance for more than 20,000 health care providers at 1,000 training sessions in 10 regions,
- A National Resource Center clearinghouse for informational materials and toolkits, and
- A National Clinician Consultation Center "warm line" for health care providers.

Remaining challenges include:

- Those who say testing is "not my job," in part due to the perception that HIV/AIDS "is special" (as well as due to EDs concerned about overburden),
- The perception that it is "too daunting to screen such large numbers of patients" (although the HHC is showing how it can handle 3 million annual visits through an incremental approach),
- The perception that HIV/AIDS testing interferes with primary missions and patient flow (again, EDs have this particular concern, but "we can add tests and allow the primary job to get done"), and
- The issue of reimbursement (which California has addressed by mandating reimbursement for screening).

In terms of reimbursement, Dr. Branson noted that in other areas of the country reimbursement for HIV/AIDS screening is confined to medical necessity, "which does not assist early screening."

Summarizing, Dr. Branson noted "signs of progress" based on data indications including:

- Reduction in the percentage of persons unaware of their infection to 21 percent from 25 percent,
- Initial evidence that the number of persons who have had an HIV test increased by 1.4 million in 2007,
- Reductions in late diagnosis in New York City hospitals after expanded HIV testing ("we are finding people earlier, as we had hoped"), and
- Legislative changes in 11 States to facilitate HIV testing in health care settings (which may facilitate test expansion in health care settings).

Question-and-Answer Period

Dr. Yogev asked about the necessity for back-up testing to the rapid test, to which Dr. Branson responded that CDC is working with public health labs to come up with an algorithm "to use tests in combination." CDC's "desire is to give those who are tested a correct answer, and our data show that if you have two tests, that works." He added that CDC is hoping by the end of next year to issue recommendations for using the rapid test

in combination in a new way. CDC is also looking further into false positives in pregnant women and is currently awaiting the results of this examination.

Dr. Yogev noted that Illinois mandates testing for newborns “when the mother’s condition is unknown” in relation to a number of STDs. Dr. Branson responded that CDC has proposed to the American Medical Association’s Current Procedural Terminology committee (AMA/CPT) that it add HIV testing to the common procedural terminology code, as that would “make a huge difference.” The agency’s proposal was turned down this past year, “in part due to different State requirements for consent.” Now CDC is working with the American College of Obstetricians and Gynecologists to move the proposal forward.

John C. Martin asked whether, in the expanded HIV testing initiative in Florida, those with positive test results transition to care at different rates. Dr. Branson noted that in New York City, transition to care was “twice as high for those testing in clinical settings.” While that might be “counterintuitive...because we thought CBOs were good at transition...that’s something to look at in other jurisdictions.”

Dr. Martin commented that it would be a good idea to get more data from the Florida program. Dr. Branson added that “the way they are doing it at minimum in most places is by looking at viral loads, so we’re trying to do that in each jurisdiction.”

Dr. Martin then asked about capacity building and data on how many tests it results in. Dr. Branson responded that CDC is in the process of collecting those data. One challenge is that those involved on the ground are saying “either we test or we collect data.” The bottom line is that “there is a lot of opposition to getting data.” However, within 3 months, CDC expects to get relevant data from the jurisdictions involved.

Dr. Urbina asked, in relation to the HHC study, about doctors offering testing on a routine basis and what the costs are. Dr. Branson said that there are many facilities within HHC using “a variety of ways to do testing.” Provider-initiated and separate counseling were compared, and HHC found “provider initiation more successful.” In short, in HHC, the overall process is different in each institution. Some use separate counselors, and some do not. No cost information is available from HHC at present.

Dr. Bollinger asked about data presented by Dr. Branson that suggest CDC is reaching “the most vulnerable communities.” Yet he is interested in data on new HIV diagnoses. In terms of the HHC data, “it looks like about 40 percent of positives were new,” but in Chicago and Florida, “it was 1-2 percent.” Dr. Branson responded that the Florida and Chicago data are “prevalence of new diagnoses” and that what he showed from HHC “were numbers.” In the HHC system, 80 percent of those who tested positive did so in health care settings, “so we are reaching the undiagnosed.”

Dr. Bollinger stated that among the three settings, there is still a range, so in terms of “reaching new diagnoses, how will you assess and compare” the three settings?

Dr. Branson noted that “the New York data were a surprise for us.” The Florida October 2007 to July 2008 slides from his presentation indicate that “many people not newly diagnosed are also not in care.” The “ultimate goal is to get people in care by trying to find those not diagnosed as well as those not in care.”

Mr. Schmid noted that CDC is in the process of releasing implementation guidelines for hospitals and EDs as well as other settings, but, he asked, first, “Where are the recommendations for general care settings?” Second, while PACHA agrees there are challenges with testing reimbursement, is CDC engaged in discussion with the Centers for Medicare & Medicaid Services (CMS) about that? Mr. Schmid went on to note that New York State’s Medicaid covers routine testing even though it still requires informed consent. He also noted California’s mandate for testing to be covered. Therefore, third, he asked, why should laws have to be enacted for reimbursement as opposed to testing being covered simply through insurance practices? And fourth, “how do we know when settings are testing that they are doing it properly?”

Dr. Branson clarified that “CDC is facilitating implementation guidance in each of the settings,” working with “the people from those settings to develop approaches that work best.” Guidance for corrections should come out shortly, and within the next few months, he expects the American College of Physicians to issue their recommendations for primary care physicians.

In terms of testing reimbursement, Dr. Branson said that “CDC recommendations are not congruent with the U.S. Preventive Services Task Force.” For most insurance companies, “whether it is policy or they are hiding behind it,” the Task Force’s recommendations have an effect. In addition, “there is a code for high risk, associated with lifestyle, that some don’t want reported to their insurance companies.” In terms of Medicaid, there is a “big range of reimbursement” State by State. These decisions are made by States. However, State Medicare and Medicaid directors will be meeting soon with respect to the differences.

Dr. Branson went on to note that in 2005, CDC recommended that all pregnant women be tested. The Task Force disagreed, deciding that only those at “high risk” should be tested, although some reimbursement was occurring “long before that.” Therefore, “what it will take in the end is guidance from other organizations so that testing becomes a standard of care.” In his personal opinion, Dr. Branson added, there will “continue to be a need for public funding for those who are uninsured.” In many testing settings, such as EDs, many of the patients don’t have insurance, not even Medicaid.

In terms of monitoring test giving, Dr. Branson said that CDC has developed evaluation tools for each program to use. There are two public health policy reports on that involving patient acceptance, which is “the first evidence of” whether test givers are providing the right information, for example.

Dr. Malebranche noted Dr. Branson’s data on provider testing and that most patients are getting tested in doctors’ offices or primary care settings. He then asked: if this is the

case, why emphasize other health care settings? He also commented that he has seen racial breakdown data on who is being tested, and “it always seems to be more black people getting tested,” yet many people question whether this is an “increased screening effect” and whether there are a “significant number of people not getting tested...missing risk behaviors in other communities.”

Dr. Branson responded that NHANES is a household sample “not affected by the screening effect.” Rather, it is a probability sample that tells us the proportion “is higher in those populations.” As to the first question, to focus on EDs, “that yield is not as high as in primary care settings,” despite a demonstration project that indicated that EDs and STD clinics were “where a larger proportion of people likely to be infected were going.”

Zelalem Temesgen observed that many of his patients “assume they are destined for HIV so even when there is no reason for them to be tested, they think they’ve been tested,” which indicates that information gleaned from the NHIS may not be reliable. Dr. Branson agreed that this is of concern. He went on to note that “many people believe they have been tested when they’ve had a health encounter, even when they haven’t been tested.” In the NHANES, “antiviral therapy questions will be used to help corroborate whether” respondents have “actually been tested.” In addition, “we do ask if they received results,” and “an increased proportion say ‘yes’.”

Mr. Mattes asked about a subset of NHANES that might be more granular than that. Dr. Branson responded that NHANES “doesn’t have further subsettings.” We do “attempt to do an analysis of treatment—the question is whether one is on therapy—but we are not monitoring that,” so we don’t have the proportion “actually in care.”

Dr. Bollinger commented that “one of the cultural goals of this program is to get people into care earlier but also provide prevention for those not yet positive.” Therefore, he asked, how will CDC be treating the transition to secondary prevention as well as prevention counseling for those who are not positive?

Dr. Branson responded that CDC worked with the Infectious Diseases Society of America to come out with recommendations on care a while back to “make sure that prevention services are available while in care.” Primary prevention poses “more of a dilemma.” This month, the Task Force alluded to earlier looked at behavioral health intervention for STDs and HIV/AIDS and concluded there is “insufficient evidence for low-intensity intervention and that, in fact, high-intensity intervention is what it takes to do primary prevention.” Therefore, CDC’s approach is “not to link this with screening programs but to support this specific [conclusion].” In addition, CDC has issued a compendium of information “about these types of interventions.”

Impact of the Reauthorized Ryan White Program

Dr. Maxwell noted that PACHA has spent a great deal of time discussing and supporting the Ryan White CARE Act (RWCA), then introduced three panelists to provide

presentations on the impact of its last reauthorization. She provided brief biographical information on the first presenter, Monica Sweeney, a former PACHA member.

Impact of the 2006 Ryan White HIV/AIDS Treatment Modernization Act on the New York Eligible Metropolitan Area (EMA)

Presentation by Monica Sweeney, M.D., M.P.H., Assistant Commissioner, Bureau of HIV/AIDS Prevention and Control, New York City Department of Health and Mental Hygiene (DOHMH)

Dr. Sweeney provided epidemiologic background; information on Ryan White Part A in the New York Eligible Metropolitan Area (EMA); information on the impact of the RWCA's most recent reauthorization (2006 Ryan White HIV/AIDS Treatment Modernization Act); thoughts on 2009 reauthorization and beyond; and information on New York City's DOHMH HIV/AIDS initiatives.

Epidemiologic Background

HIV/AIDS in New York City (NYC), 2006: Basic Statistics—

- 3,745 new HIV diagnoses (46.8 per 100,000 population)
 - 2,783 HIV without AIDS
 - 962 HIV concurrent with AIDS (26 percent)
- 3,672 new AIDS diagnoses, including the 962 concurrent HIV/AIDS cases
- 98,861 persons living with HIV/AIDS (PLWHA)
 - 1.2 percent of New York City's population and possibly higher, as "many more do not know they are infected because they have never been tested"
- 2,076 deaths among PLWHA (20.6 per 1,000 population)

Dr. Sweeney stressed that NYC has one of the highest AIDS case rates in the United States—45.4 per 100,000 population (2005) against the Healthy People 2010 goal of 1 per 100,000 population.

Showing Slide 6, Dr. Sweeney noted the breakout of reported persons living with HIV non-AIDS and those living with HIV with AIDS in NYC from 1981 through 2006, stressing that the totals have steadily increased, constituting "a very mature epidemic" that represents a special challenge, as those infected are living longer.

Showing Slides 7 and 8 on reported cases and deaths and new HIV diagnoses and rates, Dr. Sweeney summarized that AIDS incidence and mortality peaked in the mid-1990s in NYC and has been declining since, and that, while the number of new diagnoses declined by about 500 cases annually between 2001 and 2004, there was a smaller decrease between 2004 and 2006.

Quoting from national statistics and congressional testimony on the efficacy of HIV/AIDS treatment (Slide 9), Dr. Sweeney stressed:

- That the projected lifetime cost per person at the time of entering optimal HIV care is \$385,000,
- That treatment expense that could be avoided by preventing each HIV infection is \$303,000, and
- That by increasing HIV prevention funding to \$1.3 billion each year over the next 4 years (starting in 2008), the number of new HIV infections could be reduced by 50 percent.

Addressing a question raised earlier about the cost of testing, Dr. Sweeney noted that the costs per new positive diagnosis through the NYC Communities of Color contracts in 2006 were:

- \$11,660 for CBOs,
- \$10,014 for private hospitals, and
- \$6,641 for public hospitals.

Dr. Sweeney commented that these figures indicate that public hospitals do a “more efficient job” of testing for almost 50 percent less, not including the cost of test kits.

Ryan White Part A Program in the NYC EMA

Overview—NYC EMA Administration (Slide 12):

- The NYC DOHMH oversees the Ryan White Part A and Minority AIDS Initiative (MAI) grants, administering:
 - The HIV Care, Treatment, and Housing program, which includes public health practice and research and evaluation; policy, planning, and implementation; housing and Ryan White services; and Ryan White Planning Council support.
 - A number of contracts, including with Public Health Solutions for contract administration and with the Westchester County Department of Health for the Tri-County region (Westchester, Rockland, and Putnam Counties).

Overview—NYC EMA Funding (Slide 13):

- The 2008 MAI and the base grant award was \$118.8 million, which covered:
 - 251 contracts with 128 unique agencies
 - For a wide variety of service categories (76 percent core and 24 percent support).

Dr. Sweeney noted that while the Tri-County region covers oral health care, NYC does not upon the advice of the Planning Council, which advised use of other funding streams.

Impact of 2006 Ryan White HIV/AIDS Treatment Modernization Act

Part A Tier 1 Formula (Slide 16):

- Under the new Act, in name-based areas such as NYC and the State, living HIV/AIDS cases reported and confirmed by CDC are used for the formula grant.
- Although more HIV and AIDS cases have been counted, the total level of funding has remained the same.

Dr. Sweeney commented that funding against counted cases is a “challenge for everyone,” as there has been “a lag between diagnosis and treatment and reporting times.”

Varying Award Amounts (Slide 17):

- As shown in Slide 14, the NYC EMA award has fluctuated over the past several years.
- Variances in award amounts make it difficult to plan and implement services.
- With City and State budget crises, hiring freezes have been put into place, resulting in a lack of staff to execute work (which, Dr. Sweeney stated, is a particularly acute situation for the City that “has already affected us and will affect us more”).

Distribution of Funds (Slide 18):

- Part A distribution of funds changed during the last reauthorization from 50 percent formula/50 percent supplemental to 67 percent formula/33 percent supplemental due to the competitive nature of the supplemental grants, which makes funding amounts “uncertain from year to year,” Dr. Sweeney commented.
- Large urban EMAs, like NYC, have high unmet needs due to a mature HIV/AIDS population, so the change “limits local control.”
- In addition, Dr. Sweeney said, there are “no guidelines for combined treatment of AIDS and comorbidities in an older population.”

Dr. Sweeney emphasized particular concerns with the underspending limit under the new Act (Slide 19):

- Excessive formula underspending results in an inability to apply for future supplemental grants.
- It is a challenging task for the NYC EMA to meet this requirement, given that it has 251 contracts in 128 unique agencies.
- In 2005, DOHMH decided to pursue performance-based contracting under a new model, including “transitioning the portfolio by 2010,” which represents an additional challenge.

- DOHMH must routinely and closely monitor spending and spend Part A funds expeditiously.

Core and Noncore Services

Dr. Sweeney then reviewed the requirements for distribution of core and noncore services, including that 75 percent of funds under each title must be spent on core medical services and that the remaining 25 percent may be used for support services needed to achieve medical outcomes (defined as outcomes affecting the HIV-related clinical status of an individual with HIV/AIDS). She noted that the EMA portfolio has evolved over time with a commitment to funding core services. If the EMA does not meet the distribution requirements, it must ask for a waiver. (Slide 20)

Dr. Sweeney went on to note difficulties in effective and efficient coordination of services across the EMA when NYC's fiscal year begins July 1, formula awards are made in March, supplemental awards were made in May (in 2007), and MAI awards are made in August. Dr. Sweeney then spelled out medical case management by NYC and the Tri-County region and changes planned for 2009 that have been under development since 2007. (Slides 21 and 22)

HIV Testing and Prevention (Slide 23):

- Testing and prevention are important to all parties—DOHMH, the State, HRSA, and CDC, among others.
- While Part A Early Intervention Services makes HIV testing and linkages to care possible, the costs of confirmatory testing are not covered, and alternative funds must be found.
- HRSA guidance on providing Ryan White services to HIV-negative clients makes “it difficult to support” such services.

2009 Reauthorization and Beyond

Dr. Sweeney began this portion of her presentation by showing a chart (Slide 25) comparing the President's FY 2009 request for Ryan White programs and the result of markups by the House Labor/HHS and Senate Labor Subcommittees, concluding that, in terms of the future of Ryan White, “more money is needed.”

What is important for New York in terms of Ryan White reauthorization includes (Slide 26):

- The fact of emerging priority populations and the newly released HIV incidence figures, which necessitate increased Ryan White funding;
- The number of years covered by reauthorization (Dr. Sweeney advocated that the next reauthorization cover 5 years);
- The current 24-month housing limit (which is difficult to operationalize because of PLWHA mobility);

- The need for continued efforts in coordination with other Federal programs, such as those administered by CDC and the Substance Abuse and Mental Health Services Administration (SAMHSA); and
- The continued issue of continuity of care, as there is a gap in care for Ryan White clients who need inpatient and ancillary services (at present, Dr. Sweeney said, NYC “has to scrounge” to cover this gap in care; in addition, gap-covering programs do not run very smoothly without Ryan White funds).

DOHMH Bureau of HIV/AIDS Prevention and Control Initiatives

Dr. Sweeney briefly reviewed two slides in this section (Slides 28 and 29), emphasizing NYC’s Care Coordination initiative, which:

- Represents 25 percent of the Part A award budgeted for 2009,
- Incorporates the medical home principle and use of information technology to strengthen collaboration across disciplines, and
- Employs a hybrid model, which includes navigation-type case management, benefits coordination, health promotion, and outreach for return to care.

Dr. Sweeney concluded by suggesting that PACHA members interested in more information about DOHMH initiatives visit the Department’s Web site at:

<http://www.ci.nyc.ny.us/html/doh/html/ah/ahb1.shtml>.

Ryan White Part C Reauthorization: Impact on University of Wisconsin Health HIV Care Program

Presentation by Frank Graziano, M.D., Ph.D., Professor of Medicine, University of Wisconsin Hospital and Clinics

Dr. Graziano began by stating that “it is important that we all understand how important Ryan White is.” He noted that he is a physician and professor at the University of Wisconsin (UW) Hospital and Clinics. The HIV/AIDS clinic associated with the university is “relatively small,” but he intends to provide some sense of the impact of Ryan White Part C on that program.

Dr. Graziano noted that Wisconsin is “a low incidence State for HIV/AIDS,” with 10,000 cases reported since 1983 statewide and “about 400 new cases every year.”

Dr. Graziano then began his slide presentation with a graph showing the number of persons reported with HIV infection in Wisconsin and presumed alive at year’s end from 1990 through 2007 (Slide 2), commenting that his clinic had always had about 200 patients, and then, in 1995/1996, “we experienced a leap because people are living longer.”

Dr. Graziano showed maps of the State to display where the greatest number of cases in the State originate (Milwaukee) and the UW Health HIV Care Program catchments area,

which is principally Dane County (a rural county) but also includes Milwaukee and a number of other counties scattered across the south and central portion of the State. To his knowledge, there are “at least three Ryan White Part C programs in Wisconsin,” of which the UW Health Program is one, with two others located in Milwaukee. (Slides 3 and 4)

Dr. Graziano noted UW HIV Clinic demographics compared to the State’s population and HIV demographics (Slide 5), emphasizing that the clinic’s HIV patient demographics more or less mirror the State’s. He noted in particular that the clinic’s patients are 37 percent African American and 14 percent Hispanic, due in part to the clinic’s rural location near many farms. He said an important aspect of the clinic’s population is that 18 percent are women, more than half of whom are minorities.

Dr. Graziano noted risk groups involved in the UW program (Slide 6), noting that MSM are a large percentage of patients (46 percent) but not MSM/IDU or IDU. He also noted the “large population of heterosexual patients” at the clinic (31 percent).

Next (Slide 7), Dr. Graziano showed the bidirectional relationships between the clinic, the Wisconsin HIV/AIDS Bureau (Ryan White Part B), the Wisconsin prison system (10 State prisons send their HIV patients to the clinic and help provide money for labs), and an AIDS Network, which does testing and counseling prevention. There is also a relationship with the Beloit (Wisconsin) Community Health Center—which is situated in the corridor to Chicago.

Dr. Graziano noted the clinic’s staffing is designed to meet multiple needs of patients and that the clinic has contracts with the UW to ensure that fees are kept low—\$75-\$100 “to see a patient, no matter what staff is doing.” The clinic pays for this with Part C funds.

Turning to the Ryan White HIV/AIDS Treatment Modernization Act of 2006 (Slide 8), Dr. Graziano noted the medical case management goals of continuity of care, increased access to services and retention, integration of services, increased knowledge about HIV, and enhanced independence.

Dr. Graziano then noted the UW HIV Care Coordination Model (Slide 9; see also www.medicine.wisc.edu/hivuw) and, in particular, the fact that the State bureau pays out of Part B funds for a social worker who is “critical” to reaching and getting into the clinic prisoners from the State’s prison system. He also noted the importance of patients’ having access to an immunologist internist and a physician assistant provider as well as a psychiatrist and a psychologist in the clinic.

Dr. Graziano stressed that Ryan White funds help the clinic retain patients “so they don’t fall through the cracks.” However, with a growing number of patients (Slide 10)—a 36 percent increase in total patients since 2004 and 100 new patients each year—the clinic is experiencing “hardship.” In particular, “space is becoming a problem.”

Addressing whether the clinic is getting more HIV-infected individuals into care earlier as well as retaining them, Dr. Graziano answered “yes” with Slide 12, a graph of CD 4 counts of new patients over time and high percentages of viral loads reduced to less than 50. Pointing to the clinic’s 85 percent success rate for reducing viral loads treated, in particular, Dr. Graziano commented that “any clinician with the ability to treat people should be able to say this.”

Turning to prison case management (Slide 13), Dr. Graziano noted that it is important for the clinic to make sure prisoners get treated and that Part C has helped retain them in care, in large part because a Part C-funded social worker has had “some success in doing case management.”

Concluding, Dr. Graziano addressed challenges with Part C at the clinic:

- First, “while the caseload continues to grow, our space does not.”
- Second, as the patient load grows, our staff does not (“many people now have many jobs, making the nurse position especially challenging”).
- Third, staff attrition is a problem (the nurse’s job is “particularly fatiguing”).
- Fourth, transportation and weather are at times a problem in the community (but Ryan White helps, “as we have bus passes, thanks to the care manager”).
- Fifth, the hospital dentist is retiring.
- Sixth, the Wisconsin AIDS Drug Assistance Program (ADAP) may go to a waiting list in 2011. (Dr. Graziano commented that he “always thought Wisconsin could get drugs for all of our patients, but data suggest that we may be running out of funds by 2011.”)
- Seventh, the economy is in bad shape.

In terms of the last point, Dr. Graziano said “all of us want to say we need more money to give patients services. We’re different in that we have university affiliation, but even with that, the situation is becoming very difficult and it is “very important that we be able to continue our Part C.” Dr. Graziano added that he goes to Africa and has seen how people in need can’t get care, so PEPFAR “has made a huge difference.” Similarly, when he’s in his clinic, he sees “the same type of poverty. These people need Ryan White.”

Impact of Ryan White Reauthorization

Presentation by Jane B. Cheeks, J.D., M.P.H., State AIDS Director, Division of HIV/AIDS Prevention and Control, Alabama Department of Public Health

Ms. Cheeks noted that she has been working with HIV/AIDS for 30 years. She began her public health career in 1978 working in an STD clinic, where the “worst thing we saw was herpes, which we thought was going to be the end of the sexual revolution.” Then, in 1981, “we saw the first HIV/AIDS patient in Alabama. One of our residents called it ‘nodular syphilis’ and we began to see young gay men die. Through 1985, we could only tell people to get their affairs in order.” In 1985, when the first test came out, Ms. Cheeks was the State’s first and only test counselor “for some time.”

In 1989, she became State AIDS Director, and in 1991, her boss put her in charge of handling the State's Ryan White-related funding and programs. Back then the RWCA basically said, "Here's money, do good, then tell us about it in the end." Today, the RWCA "is the most complicated piece of legislation I've seen in 30 years of government."

Ms. Cheeks went on to note that the reason she went to law school was to try to understand the RWCA and put it into effect. Her task was to interpret the legislation and make it work with the "\$480,000" that the State received at that point. The State had a drug treatment program and kept the AZT (zidovudine) in a safe in the State Public Health Director's office. There was so little of it that a committee decided who got it, based on who had the most chance of survival if they received it. And, "if you think that was easy, it was not."

In 1991, as State AIDS Director, Ms. Cheeks began a drug program with the State pharmacy, whereby the pharmacy received a fee to fill AZT prescriptions for patients in the program. When the State received RWCA funding, it changed the program and was sued by the Pharmacy Association of Alabama.

Beginning her slide presentation, Ms. Cheeks noted that in terms of HIV/AIDS in Alabama from 1982 to 2006, deaths have gone down while the number of PLWHA has gone up (about 10,000 now in need of services and rising) (Slide 2). In short, "our epidemic is increasing."

Ms. Cheeks noted that, as someone "who was there from the beginning," she wants to convey the importance of Ryan White for Alabama and for the South as well as for Part B States in general. However, "there are also difficulties and challenges...when trying to put the Act into effect when every year there are more restrictions."

Ms. Cheeks noted there are differences among the States in terms of health department restrictions and in the policy arena. While "we appreciate the funding," she said, "you must understand that we have challenges in the States, too." In Alabama, "we work with Part B as well as Part C and don't have Part A because we don't have a Part A city." Further, Alabama has coordinated all its programs into one statewide program that works "for all our HIV/AIDS patients."

Structure of Alabama's Program in General (History) (Slide 3)

In 1987, Alabama decided to report STDs by name. The State also implemented "an active surveillance system, and we use those data in all our plans for direct care. We feel we have a very mature reporting program."

In 1988, the Alabama State Health Officer "decided that we would be HIV/AIDS testing and counseling in all the local health departments," and tests were analyzed by the State lab "at no cost." In fact, "we've never had funding to do testing within the State Health Department itself." Eventually, 11 HIV coordinators throughout the State facilitated and

coordinated HIV/AIDS activities working through the Enhanced Referral and Treatment System to make sure that those who tested positive were referred and got into care.

Ms. Cheeks said it is important to note that fairly early on, the State created an AIDS Network with no funding to coordinate health care professionals and volunteers working to prevent and manage HIV/AIDS in Alabama. In 1994, a Community Planning Grant from CDC was used along with the AIDS Network to develop the statewide plan.

African American Crisis

Turning to Slide 4, Ms. Cheek noted that among the HIV/AIDS cases reported since 1982, African Americans account for 75 percent of cases in women, 65 percent of cases in young people, and 69 percent of cases in infants and children. In 1988, Alabama declared “a crisis in the African American community.” Since 1998, more than 70 percent of newly infected individuals are African American.

Early Ryan White Funding

Ryan White funding in 1991 allowed development of a Direct Care Services Branch responsible for all direct patient services, including a drug reimbursement program and development and implementation of HIV Care Consortia. Each of the eight consortium members decided what their geographic area would be, and the State gave each \$10,000 to develop services. The consortia were discontinued in 2005 when “we went to a statewide program.”

At present, under the statewide program, about “75 percent” of those tested are being referred and getting into care in clinics.

Structure of Alabama’s AIDS Drug Assistance Program (ADAP) (Slide 5)

Ms. Cheeks outlined the structure of the State’s ADAP (Slide 5):

- Alabama’s ADAP operates a central pharmacy licensed to the Alabama Department of Public Health, using contracted pharmacy services.
- Distribution of drugs is to HIV clinics (eight Title C clinics and several private clinics and private physicians) for pickup by clients.
- Alabama has one lead agent—United Way in Birmingham—which subcontracts with 20-22 providers.
- Funds are allocated to providers based on formula calculated on the number of documented clients and available funding.

Immediate Impact of the Last Reauthorization

Turning to Slide 6, Ms. Cheeks noted:

- Alabama had a waiting list for drugs for 5 years but has not had one for the past 2 years, thanks in part to Medicare Part D.
- Additional Ryan White funding has allowed an almost doubling of funding for service providers. Direct salaries are being funded, which has helped service providers with their overhead.

- Alabama’s formulary was limited and remains so, but additional funding has permitted availability not only of U.S. Food and Drug Administration (FDA)-approved antiretrovirals but, as of 2 weeks ago, 45 “other medications” as well.
- Case managers used to spend a major part of their time working to get medications for clients on waiting lists as well as medications not on the formulary. However, now, with increased funding, they are able to case manage clients.
- With additional funding, the State has centralized ADAP eligibility, and all ADAP applications can be handled online from a central office. The State has also developed a quality management program, which was required.
- Ms. Cheeks noted that Alabama “has never had unobligated funds.” When the State received its supplemental \$2.5 million, however, it was a challenge to spend it in 6 months.
- The State also received \$112,000 in MAI funds, but “our epidemic is about 70 percent African American, and we already spend about 70 percent of what we have to spend on minorities, so that amount is really nothing in terms of the costs in Alabama.”

Southern States Manifesto, Update 2008

Turning to Slide 7, Ms. Cheeks noted that the Southern AIDS Coalition (SAC) was born 6 years ago when several State AIDS Directors met about perceptions of funding inequities for Southern States. In the context of disproportionate rates of HIV/AIDS, poverty, inadequate funding and resources, and infrastructure challenges, SAC’s goals are to:

- Reduce new infections,
- Identify infections as early as possible, and
- Provide adequate care, treatment, and housing.

Turning to Slides 8–12, Ms. Cheeks addressed the epidemic’s disproportionate impact on the Southern States. She stated that “all Federal funding should follow the epidemic,” yet, at present, “it does not meet the overarching needs of the Nation, particularly in the South” (Slide 12), which comprises 36.4 percent of the population but, in 2006, had 55 percent of the Nation’s AIDS cases (Slide 8). Ms. Cheeks noted that in 2005, the South led in AIDS case rates for adults and adolescents in Metropolitan Statistical Areas (MSAs) of all sizes (Slide 9); in the greatest number of those medically disenfranchised (Slide 10); and in the highest death rates (Slide 11).

Ms. Cheeks urged PACHA members to read SAC’s latest report, included in member packets. She went on to note that CDC conducted a site visit in Alabama “a few months ago with different priorities but no more funding.” Now the State’s difficult decision “is what we are going to cover now.” After providing her final thought (Slide 14) prior to her conclusions about issues that must be addressed in the RWCA reauthorization, Ms. Cheeks noted the benefits of Medicare Part D but also the fact that Alabama has no plan to cover the gap in Part D—the doughnut hole.

RWCA-Related Reauthorization Issues

Client-level Data Requirement—Concluding with RWCA-related reauthorization issues (Slide 13), Ms. Cheeks noted in particular as an issue “where a high level of consensus may exist” the requirement for client-level data, which has to be implemented by January 2009. “That’s a short turnaround time,” she commented, particularly for States that must coordinate Parts B and C and are uncertain “what the client-level data will be used for.”

Core/Support Services—Ms. Cheeks noted core medical services/support services definitions and the percentage split, which she characterized as warranting discussion by PACHA. She commented that while the percentage split is not a big issue for Alabama, for some States with consortia, it is a big issue.

Unobligated Funds—Ms. Cheeks also noted unobligated funds requirements as an issue warranting PACHA discussion, stating that there are “real problems with spending funds given the constraints of contracts.” It “takes 6 months to pull contracts together and 6 months to spend the funds.” In addition, as Dr. Sweeney pointed out, RWCA grant cycles do not coincide with State fiscal years, so it would be useful “to get grants on the same schedule.” Ms. Cheeks noted that, in general, the States as grantees “have many requirements, but we’re not given the authority to make sure everyone works together.”

Ms. Cheeks commented that, in general, the reauthorization legislation “looks like it was written by a number of different people who don’t talk, didn’t talk, to one another.”

Length of Reauthorization/TGAs—Ms. Cheeks’ last thoughts about issues to look at included length of reauthorization, which, for “a variety of reasons” HIV organizations have decided should be a 3-year extension. Consideration should also be given to extension of protection for States with maturing HIV data, the need for definition of Transitional Grant Areas (TGAs), and the need for decisions about “where the money is going to go.”

Question-and-Answer Period

Dr. Yogeve commented that he supports expressions of the need for simplicity and “less Big Brother looking over our shoulders.”

Mr. Schmid thanked all three presenters. He noted that, as grantees, they are required to comply with core medical services requirements, so his question is whether it has been difficult under the new requirements to fund transportation and nutrition—food—because these needs are not defined as core medical services.

Ms. Cheeks responded that in rural States, “transportation is an issue.” The definition of transportation is now so narrow—only for medical services—that Alabama cannot use transportation to help patients stay in care, such as by getting to Social Security services offices. “That’s a real problem, as are nutritional supplements, even when prescribed by a physician.”

Dr. Graziano said Wisconsin is experiencing similar difficulties. “Getting transportation is an issue.” In addition, “nutrition is so important. People won’t get better if their nutritional status is not good.” Dr. Graziano noted that the UW clinic has a nutritionist who has found it “very difficult” to get supplements for patients.

Dr. Sweeney said that in NYC, as food costs have gone up, people have less money to spend on regular nutrition. Therefore, patients and advocates “are asking that food and nutrition be moved to core services in the next authorization.” Dr. Sweeney added that transportation in NYC “is not a major issue” given the ready availability and relative reliability of the subway system. She added that “those with medical needs had transportation that was funded by Ryan White before the regulations changed.”

Mr. Mattes commented that Ms. Cheeks’ list of issues attendant to reauthorization “was very provocative,” then asked Ms. Cheeks to select her three highest priorities for change for PACHA to consider as it discusses the legislation going forward.

Ms. Cheeks responded that, based on her meeting with the AIDS community, one priority is a 3-year extension with full reauthorization to follow in order to address remaining issues. In addition, how ADAP rebate dollars will be treated is important, as they are currently “a major portion of ADAP funding.” Also, the penalties for unobligated funds should be revisited as a major issue, particularly as “2 percent is not very much.” In addition, there should be continued protection for States with maturing HIV data, as the needed data system won’t be in place until 2012. Also, definition is needed for TGAs and decisions about where “the funding is going to go and whether it will come into Part B or stay with Part A.” Ms. Cheeks added that is her “very short list.”

Dr. Bollinger commented that “too much regulation removes too much respect for the law, and it also costs money, but there has to be accountability.” He then asked the presenters for their highest priority recommendations in terms of regulatory requirements “that would save money and not compromise accountability.”

Dr. Sweeney nominated flexibility in use of unobligated funds as fitting into Dr. Bollinger’s category. “As mentioned, NYC is going to performance-based, not cost-based, contracting. As NYC moves from one system to the other, there will be a learning curve on performance, reporting of performance, and reimbursement. Yet, “when you have 2 percent hanging over your head, it makes it difficult to engage in innovative programs.” Dr. Sweeney advocated removing the requirement or changing “not only the percentage but what you could do, such as move the funds to the next year.”

Dr. Maxwell then asked Dr. Sweeney to provide PACHA with “support for what you are advocating,” to which Dr. Sweeney responded that “having a longer period of time where funds are available” would allow grantees “to concentrate on building programs rather than writing supplemental grants.” Every time “you have to write a competitive grant, you don’t know which programs you’ll be able to support. Doing new requests for proposals (RFPs) is very labor-intensive. The time and resources used to do them could be spent improving and evaluating programs.”

Ms. McGeein noted that the last 3-year reauthorization for the RWCA “was highly unusual” and that she thinks the next reauthorization will be for 5 years.

Responding to earlier questions, Dr. Graziano noted that the UW Clinic was one of the pilot institutions for client-level data reporting. The clinic has a data analyst and a very sophisticated computer program as a result, but he’s “not exactly sure what that has added to the program,” so that may be one area where “money can be spent a little differently.” Second, HIV/AIDS physicians need to look at “how we’re spending money on our patients. We spend a lot of money on drugs and see patients every 3-4 months,” so “we need to look critically at ways to cut back on that so that we have more money to spend” elsewhere. Dr. Graziano noted that PEPFAR “has generic drugs,” so “we have to look at ideas like that.”

Ms. Cheeks noted that in terms of client-level data, Alabama received HRSA’s requirements “at the same time we got CDC’s requirements.” The data collecting and reporting required “is unbelievable.” There are four different database reporting systems for HRSA and three for CDC, “and they don’t talk to each other.” As a consequence, “we’ve been asking for one data system across the agencies or at least one that converts from one to the other.” This is critical, as providing client-level data is a requirement “for each grant, and if you don’t do it, you don’t get funding.”

Coordination across programs is another issue that needs to be addressed, Ms. Cheeks added. “We have to work with CMS and Social Security for coordination of our programs as well as our own State agencies and assess what they’re doing before we spend our RWCA dollars.” In short, “coordination is needed at the Federal level to make our job simpler.”

Dr. Sweeney said that since a 5-year reauthorization “is likely,” she would like to choose a new priority—a reexamination of the role and composition of planning councils. “Those effected and affected should always be at the table,” yet, at present, the Planning Council in NYC has many agency director representatives and/or others “who have an interest in how priorities are set based on what their agencies do.” Despite recusal rules, sometimes Council decisions “are not always based on evidence.”

Dr. Bush asked Ms. Cheeks how Alabama conducts its post-test education sessions for those who test negative. Ms. Cheeks responded that “higher risk negatives are now included in the post-test program” as of this year. Post-test counseling is done by CBOs, and the health department does the followup. Referral for post-test counseling can be “as many as four visits in the year after the test, for positives as well as negatives.” Alabama is currently trying to implement the rapid test without funding, as it represents “the best educational situation,” as the client can be talked to as soon as the test results are known.

Dr. Bush asked about what happens with negatives who are not high-risk, because she is worried that “those who walk out the door and are negative...don’t see the significance of their vulnerability to becoming positive.” Ms. Cheeks responded that in Alabama, “we do

pre- and post-test counseling in all of our departments. The prevention projects we fund have a counseling and testing piece. If a person comes back in who is negative, they get post-test counseling. Other than that, we don't have staff or funding for followup on all negatives."

Dr. Sweeney responded that "post-test counseling of negatives is not effective" in terms of behavior change, suggesting that Dr. Branson would know the source of those data. Dr. Bush responded that she would like to get that information, as all agree that education is important. "My grandmother used to say that when people know better, they do better," so, in terms of behavioral research, which PACHA has been discussing, "perhaps there is something there we can follow up on."

Dr. Maxwell agreed that a followup is needed and that the Council would look into it.

Dr. Yogev commented that he had just finished a study on mothers in Illinois, trying to test "if abstinence would make any difference" as a message in pre- and post-test education. "To our surprise," there was an initial effect, but 6 months later, "the effect wasn't there." In short, "if there is no repetition, you are wasting your time," he said, adding that "repetition as part of the curriculum is what needs to be discussed."

Dr. Sweeney responded that Dr. Branson had said "low-intensity counseling doesn't work."

Dr. Maxwell stated that this last subject needs to be looked into in greater depth, thanked the panel for its passion and information, and announced that it was time for lunch.

Lunch

AFTERNOON SESSION

Dr. Maxwell reconvened the full Council by noting that the first order of business is remarks by new members.

Remarks by New Members

Joe Grogan said it was a great honor for him to be placed on the Council and rejoin so many people that he had the honor to work with before, when he was PACHA's Executive Director. His tenure with PACHA "altered the course of my life and my career" and has kept him involved in many interesting issues, including drug development at FDA, which led to his current job.

Mr. Mattes noted that he is a representative of Johnson & Johnson Company and is honored to be part of this group as a member of industry because PACHA is a "diverse group focused on a worthwhile cause." Mr. Mattes thanked Ms. McGeein in particular for considering his participation, then outlined how he has been involved in HIV/AIDS for

the past 6 years. For him, his current job is “more than a job.” He has been absorbed in running a business but wants to capitalize on his ability to make a difference not only for the company but for patients. “We have many opportunities to address the needs of most affected populations. That’s why I’m here...to do what we can do to improve the outlook for inner cities, people of color, adolescents, and women.”

“It’s not acceptable for any patient to die from AIDS,” Mr. Mattes continued. “It’s a lofty objective, but it’s one of the best things we can look at.” In his 6-year journey of working with people like Mr. Schmid, it has become clear that “there is a need for industry to step up and work with you to keep attention focused on the disease and its transition to a chronic disease, at a time when that transition has lost much of its cachet.”

Dr. Maxwell asked about specific areas Mr. Mattes would like to see addressed and changed. Mr. Mattes stated that PACHA needs to address the true needs of the inner city populations and “to figure out a way to put a model in place that best serves their diverse needs to improve the number on diagnosis and treatment.” He added that, “in the future,” he wants the Council to be able to “look back and see progress and improvement.”

Also responding to Dr. Maxwell’s question, Mr. Grogan said he would like to see PACHA make a recommendation regarding a cost-effective and evidence-based prevention strategy. He would like to see CDC have more resources and more effective fund deployment “to move the needle on new infections,” and “better data will help.” Mr. Grogan added that he is discouraged, as he is sure all PACHA members are, by the new incidence numbers and also discouraged about “the amount of time it took” CDC to come up with these numbers. Data need to reach the public earlier, and analysts need to look at them “so we can marry the new reality with new policy.”

Continuing, Mr. Grogan said he would also like to see the pharmaceutical industry’s “tremendous advances” continue and even accelerate. In light of the severe cost limitations “we will face for some time, we must also make sure there is cost-containment in Ryan White and Part D.”

In short, Mr. Grogan concluded, “many serious challenges exist for policymakers and opportunities for PACHA.”

Dr. Urbina (who noted that he goes by “Tony”) said he has been interested in HIV/AIDS ever since finishing his residency in Florida, after which he moved to St. Vincent’s Comprehensive HIV Center as Medical Director of HIV/AIDS Education and Training. Dr. Urbina said he is very pleased to be inducted into PACHA, in part due to his intense interest in “good quality-of-care models.” At St. Vincent’s, because of the hospital’s interdisciplinary approach, there has been no HIV-positive birth since 2004. St. Vincent’s patients have social-economic issues, and addressing these “makes for more successful outcomes.” At the hospital, there has been a 200 percent increase in adolescents diagnosed with HIV/AIDS, so he wants “effective campaigns” for them as well.

In addition, Dr. Urbina is interested in testing. He said that new testing technologies such as pool viral load testing should be employed. Also, to echo Dr. Branson, he thinks New York's separate form for consent "is a huge testing barrier for patients and providers." "We have to stop risk-profiling patients" this way, he said, evoking the concept of the Hilda Spitzer "effect," as in "who would have ever offered her HIV testing?"

Ms. Van Krevelen (who said she goes by "Jean Ann") has spent the last 18 years in social services and is "a social worker at heart" who thinks a great deal about people's access to care. She noted that the first part of her career was spent in clinical work and the last few years in administrative policy, which she very much appreciates as a way to "connect my work with the community and with higher level advocacy efforts." Most recently, she served as Executive Director for the Cascade AIDS Project in Portland, Oregon, but is now caring in her home for her young niece and nephew. Her passion hasn't left her, however. In the past 8 years, she has become "very passionate about Ryan White and equitable distribution and full funding of the Act so that we can stop squabbling over who gets what money."

Dr. Maxwell expressed best wishes to Ms. Van Krevelen in her parenting journey.

Dr. Maxwell then asked relatively new member Dr. Temesgen to address the Council, as he has not had that opportunity yet.

Dr. Temesgen noted that he is originally from Ethiopia, from a continent and a country affected by HIV/AIDS. His medical career has "paralleled the epidemic" in the sense that when he entered medical school, the epidemic was receiving its first real attention, and when he entered his residency, people were just coming into care and receiving AZT. Then he entered his specialty training a year or two before the advent of highly active antiretroviral therapy (HAART). Therefore, "I have been medically born in the HIV era. For me HIV provides everything I want in what I do in terms of world view, as in my need to help people really in need but who don't have access to those who can help them." Also, HIV/AIDS "is a complex discipline, and the ability to impact millions of people makes it a good field to work in."

Dr. Temesgen noted that he is primarily a clinician, and if he had to choose one thing that is of interest to him, it would be educating providers, which is what he does by teaching medical students at the Mayo Clinic. He noted the lack to date of structured education for medical students, residents, and fellows, as a consequence of which "what I teach might be completely different from what Dr. Bollinger teaches at Hopkins." Coming up with structured education that provides core information about providing HIV/AIDS care "is my primary focus," he concluded.

PACHA Members Open Discussion

Dr. Maxwell invited PACHA members to engage in open discussion.

Domestic Front

Mr. Schmid said he would like to review some things that have occurred on the domestic front since the full Council last met, some of which have already been discussed by previous speakers.

New Incidence and Prevalence Numbers

Mr. Schmid noted that the “biggest thing” that has happened is the report of new incidence numbers, which “as we all know went up 40 percent” and also confirm “that the epidemic is concentrated in certain communities and populations and is growing in some and has gone down in some.” That “should help guide the future direction of Government response and how PACHA interacts with and advises Government leaders.”

Mr. Schmid also noted the new prevalence numbers and a recent congressional hearing—“the first I recall on the domestic epidemic for a very long time” with the exception of hearings held around the last Ryan White reauthorization. Witnesses included Julie Gerberding and Kevin Fenton from CDC as well as Anthony Fauci from NIH. “Their statements and testimony are worth reading,” Mr. Schmid said, urging PACHA members to access the transcript.

PEPFAR Reauthorization and Legislative Lift of HIV Entry Ban

Mr. Schmid noted that the second biggest event was President Bush’s signing the PEPFAR reauthorization into law, in which the HIV entry ban was lifted, legislatively, “so that was a major significant change.” Mr. Schmid said that the Administration also finalized regulations to streamline the process for PLWHA to come into the country up to twice a year. It is his understanding that, while the ban was lifted, HIV/AIDS is still on the list of inadmissible communicable diseases, so a rulemaking process might be needed there as well.

Puerto Rico

Mr. Schmid noted that the Domestic Subcommittee has been watching what is happening in Puerto Rico vis a vis Ryan White. A report issued by the Office of the Inspector General states that Puerto Rico has overcharged ADAP by \$24 million, which will have to be returned to the U.S. Government. It is “not clear whether that will happen or not,” Mr. Schmid commented, noting that “Puerto Rico continues to be a problem” that should be monitored in terms of such issues.

California: Private Insurers to Pay for Routine Testing and Domestic AIDS Policy

Mr. Schmid noted California’s new mandate that private insurers pay for routine testing, which has been “a big burden and challenge for routine testing.” He predicted that as goes California, “so goes the Nation.”

Mr. Schmid also noted that both Presidential candidates have called for a Domestic AIDS Policy. He predicted, therefore, that “we will have a national AIDS strategy, whoever the President is.” However, PACHA may have to “hold their feet to the fire to make sure they actually do it.” PACHA’s job will also be to help draft that strategy and comment on it.

Financial Crisis

Mr. Schmid said that the current financial crisis will have an impact on care, as “over 70 percent of those living with HIV/AIDS rely on publicly financed health care...and it will be harder and harder for States and cities to come up with the money.” In short, “we want to provide care and treatment to the living, but it will be harder to do that, with competing demands.”

RWCA Reauthorization and Prevention

Mr. Schmid concluded by noting that the Council could also talk now if it wishes to about Ryan White reauthorization or extension. He noted that the Domestic Subcommittee had also been focused on prevention and at its last meeting had a good panel discussion on prevention and youth.

Publication Sent by Beny Primm and the HIV Entry Ban

Robert Kaufman said that he hopes all Council members will read the publication sent by former PACHA member Beny Primm, as it focuses on the disproportionate impact of HIV/AIDS on African Americans. He added that this disproportionate impact deserves priority attention by PACHA.

In terms of the HIV entry ban or visa waiver issue, Mr. Kaufman asked that a report be given to the Council. “This is an issue that keeps sliding away from us,” Mr. Kaufman said, “so we need a report and to take action.”

Defending HIV/AIDS Programs

Mr. Kaufman added that at times like now, with “the economy like it is, you have to defend programs against decreases,” which means that when it comes time for appropriations and reauthorization, HIV/AIDS programs “will be particularly at risk.” Therefore, PACHA “must look carefully at what to do to protect and grow and change” those programs. “It is a time for any social program to be a victim at the hands not only of opponents but of proponents as well,” he concluded.

International Subcommittee Update to Come

Dr. Bollinger said he had an update from the International Subcommittee but that it could wait.

Evidence-based Data and Attention to Prevention Research Needed

Dr. Yogev said he has been disturbed by CDC's incidence numbers for many years and has fought with the agency about "the way it was gathering data." Even now he wonders "if the number we have is the right one." This is in part due to what Dr. Urbina said about adolescents and the fact that, in Chicago, "we don't report the way we're supposed to on adolescents because it violates their privacy." Today, he added, "we still can't get from CDC numbers on HIV alone," so when PACHA discusses this issue in the future, "make sure that the numbers coming from presenters are evidence-based."

Also on the domestic side, Dr. Yogev said he would like PACHA to address prevention research. "When you look at what happened [with the vaccine], it is a disaster. A young researcher with the right ideas would not get those ideas accepted."

In addition, while "we have to support those who already have the disease," PEPFAR "costs a great deal," and "it is extremely difficult to get funding for innovative research." Therefore, Dr. Yogev asked that the Council "push for research to be consistent and creative."

Ms. McGeein expressed how much PACHA will miss Dr. Yogev.

HIV Entry Ban

Ms. McGeein noted that there were/are three elements to the entry ban. First, language in the PEPFAR statute "lifted the ban" but did not direct HHS to take HIV/AIDS off of the inadmissibility list. Instead, second, there will be a notice of proposed rulemaking to deal with this. Ms. McGeein said she is certain the rulemaking will go through, but she can't give a time line. Third, on the heels of the President's call for changes in the entry ban in 2006, "we found a way to publish a final regulation 2 weeks ago that allows [HIV-positive] guests to come to the United States on a visa for up to 30 days twice a year." Therefore, while the wheels at HHS are moving, "people can still come into the country for up to 30 days twice a year," and "that's huge in terms of change."

AIDS Off the Radar

Mr. Kaufman raised the issue that outside the AIDS community, AIDS "has largely disappeared from the radar screen of the American people, because AIDS victims have changed." Also, in the past, people found they couldn't get a hospital bed, but now we're back to having excess beds. "So, to a large degree, the focus is on other issues, and this has to be reversed." While he is not sure how that can be done, Mr. Kaufman said there is a serious need to reconnect much of the population to the issue of AIDS.

International Subcommittee Report

PEPFAR Reauthorization

Dr. Bollinger said the biggest most recent internationally oriented event was the PEPFAR (or PEFARTHER, as he said) reauthorization. He noted he has read that a number of the issues raised in PACHA's PEPFAR report were reflected in the legislation. These include increased funding and expansion of the "number of countries that would benefit," and improved coordination of resources being spent with other U.S. Government experts involved in health, particularly tuberculosis (TB) and malaria. In addition, there is new focus on monitoring, evaluations, and evidence-based decisionmaking and greater flexibility in how funds are used to target programs that reflect people in communities, as "solutions may vary from place to place." Finally, PACHA asked for more funding for capacity building to ensure that resources will be used most cost-effectively.

Concern in the field is about how "all this will be operationalized." Therefore, Dr. Bollinger said, the Council needs to hear over time about how these ideas will be implemented.

Financial Crisis: Need to Emphasize Importance of Global Health

Dr. Bollinger noted that if one is concerned about how the domestic budget will affect domestic programs, "imagine how foreign countries may be concerned, and they are." PACHA "may need to emphasize further how important this type of global health program is to our own domestic health and security so that we can protect and value" PEPFAR-like programs. Perhaps, Dr. Bollinger suggested, "we need to think of creative ways to communicate that."

The International Subcommittee recently decided to focus on specific issues that affect not only PEPFAR. For example, at the last Subcommittee meeting, "we talked about which therapy to start with because a lot of PEPFAR funding, until recently, went to medication purchased and distributed that we might consider now to be suboptimal." In addition, there are other medications "that are more expensive but easier and possibly safer to administer." Dr. Bollinger noted that the Subcommittee heard about changes in the national recommendations of countries like Zambia that "have taken some risk by recommending these new medications and therefore may not be able to treat as many."

Another area Dr. Bollinger will continue "to push for Dr. Yogev" is how we ensure that new medications and particularly new formulations for children will continue to be available for PEPFAR and The Global Fund, because, for example, the perinatal transmission success in the United States "is not mirrored in the rest of the world." One question is "how we incentivize the pharmaceutical industry to put R&D (research and development) dollars into that area and how we as a Subcommittee and as a Council can facilitate that."

Flat Funding for Research

Last, to reflect other concerns expressed by Dr. Yogev over time, "the flat funding for research has affected PEPFAR's ability to fund more evidence-based programs because we don't have enough evidence." If "we want to spend wisely, we should base decisions

on research.” If we cut funding for domestic and international research, “we have to be prepared for consequences—that we might not be spending dollars as effectively as we like.” In short, “investing in more research may save us money in the long run, both domestically and internationally.”

Double Dipping

Dr. Yogev thanked Dr. Bollinger, noting that about 2 or 3 years ago, he asked for a clearinghouse for funding requests to prevent double dipping. His desire was to make PEPFAR “more transparent to other agencies, for example.”

Ms. McGeein noted that in her daily work as Principal Deputy for Planning and Evaluation, she is about to put into the field an “analysis of philanthropic efforts” such as those of the Bill & Melinda Gates Foundation. She added that she now “has a germ of an idea to perhaps look at how many double, triple, or quadruple dippers are out there.” She noted that when she reviewed grants for HRSA and maternal and child health, “it was clear that grant requesters were applying to more than one agency, so this is not exclusive to AIDS.”

PEPFAR and Basic Needs

Dr. Maxwell noted a *New York Times* report about how in some African countries receiving PEPFAR funding, the ultimate in care for HIV/AIDS was being provided “but practical needs such as clean water weren’t being covered,” which represents “a paradox.”

Dr. Bollinger responded that language in the reauthorization addresses that, but whether that means that money can actually be used for such projects is not clear right now. In a parallel fashion, “if we don’t have trained providers, we won’t optimally spend, which has been recognized.” He added that if clean water is not available for taking medications and for nutrition, “this is the same thing, but how that will be operationalized is not clear yet.”

Ms. McGeein observed that often the things we draw a line at in terms of funding stem from limitations imposed by Congress. To prevent PEPFAR and domestic programs from providing food, for example, “displays lack of knowledge about the disease and how it is treated. In some disease entities, water and food are integral to regimen.” However, if Congress says we can’t use funds for that, “we can’t.”

Dr. Bollinger responded that PACHA needs more information about that.

Dr. Bush asked whether what was being discussed included philosophical or ideological statements, as her understanding from Government 101 is that Government “does for us what we couldn’t do for ourselves.” Therefore, she sees Government providing medicine and “talking with churches to fill in gaps that we can’t do.”

Ms. McGeein responded that she's not for expanding Government; rather "this group has the potential to generate the spark that says to the private foundation, this is what we'll do, and what are you going to do?" At present, the First Lady has a clean water initiative because "there is level of understanding in the Government that there hasn't been the spark." In addition, speaking to Dr. Yogev's point, "they get into a funding rut."

Dr. Yogev commented that, to put things in perspective, he has had some experience in Kenya, and therefore, he "doesn't understand how we don't support clean water, as it is relatively doable and cheap." Also, in terms of food, "it's amazing how much is over there—more than we are willing to admit." In fact, "the amount of money invested in food [over there] is more than three times what is invested in medication." Another example is that malaria can be prevented by mosquito nets. In short, "there are things that need to be identified that one can do to make meaningful change." The World Health Organization (WHO) also has to cooperate, he said, adding that "WHO doesn't collaborate with us. They are anti-American. When you go to a meeting, that is the first thing you hear."

Soliciting/Advising Volunteers to Meet Needs

Ms. Wise commented that volunteers exist who are trying to meet needs, so is there a way PACHA can look at what is needed and make those people aware of what is needed? Can we give them a plan, a model? She also noted that youth and HIV is her passion, and that it breaks her heart that infections are appearing among our youth, yet they don't realize it until it is too late. So they must get tested. She mentioned a group of parents who recently sponsored a village to help orphans overseas, then turned their attention to the domestic situation and brought her in to speak to young people. As a consequence, "all the kids want to get tested." And they are making a commitment not to put themselves at risk. Now this group of parents is asking what they can do next. Therefore, it seems to her that "we can create models of response for people in communities to meet needs not being met now."

In addition, Ms. Wise said she has a related draft resolution that she may try to bring forward tomorrow and asked Domestic Subcommittee members to let her know if they needed a copy.

Domestic AIDS Strategy

Dr. Malebranche asked the Council to return to discussion of a Domestic AIDS Strategy. He said he can't stress enough how profoundly sad he is that he won't be on the Council to follow through with this, but "we have an opportunity right now to push this agenda ahead." He added that he is glad to see Ms. Van Krevelen on the Council to provide a social worker's perspective, for without social workers, much of what needs to happen, like treatment, doesn't happen.

Dr. Malebranche cautioned that when the Council does push ahead on a Domestic AIDS Strategy it should watch the language it uses. “A lot of the time we get caught in dichotomies, but treatment is prevention. If you can get someone tested and into care with their viral load monitored, the risk of passing along the infection is reduced.”

Dr. Malebranche went on to say that many of the studies we have, particularly on medications and treatment, come from the international front, “so don’t make the generalization that one study in Africa applies to African Americans in the United States, because that has the potential for disastrous consequences in the United States.” Rather, “we have to focus on doing studies here, like randomized clinical trials.”

Pre-Exposure Prophylaxis

Dr. Malebranche noted that he was at a CDC meeting on pre-exposure prophylaxis, which he suggested PACHA may want to hear more about, and “some of the data that are about to come out have been characterized as promising. The idea of giving tenofovir to discordant couples trying to have a baby might be part of it, for example.” Also, researchers are looking at genetic issues, and he suspects that “we have enough studies now to show that HIV/AIDS disparity among African Americans has to do with social context but also things like antigens where specific genotypes may be exposed to more or less risk.” Therefore, when one looks at the data, disparity “can’t be explained away by behavior alone.”

Responding to Dr. Malebranche, Mr. Grogan said that if CDC knows something about pre-exposure prophylaxis and hasn’t released it, then that is part of a recurring problem. There is “too much of an emphasis on CDC researchers publishing in peer review journals, and the delay is too long.” Mr. Grogan also mentioned that it took 10 months for CDC to release its new incidence and prevalence numbers, even though he was told what the numbers would be nearly 6 months earlier. He added that while he understands the need to publish in peer review journals, this “should not be to the detriment of having data out there earlier, for analysis purposes as well as transparency.” In short, “the motivation of CDC to hold on so employees can get their names on peer review articles needs to be addressed in the new Administration. It’s the wrong trend when emphasis is on transparency and particularly when U.S. taxpayer dollars are involved.”

National Strategy

Mr. Mattes said that one thing critical to any strategy, such as a national strategy for AIDS, is to define “what you want to do as well as define what you don’t want to do.” With a new Administration coming on board, he urged PACHA to be very clear and not fragmented about key planks in a strategy “with full recognition of limited funding availability.” He urged the Council to work in that fashion and to be very clear about what it wants to support and what can be put on the back burner. He noted a number of individual causes among members of the Council, adding that it is nonetheless critical for the activist community to “rally around the central cause.”

Students Living with HIV/AIDS

On that note, Dr. Maxwell once again recommended that members read the amazing stories in the booklet that has been provided to them about students living with HIV/AIDS.

Adjournment

Dr. Maxwell adjourned Day One of PACHA's 36th meeting at 2:55 p.m.

DAY TWO

MORNING SESSION

Call to Order

Farewell Appreciation to Ms. McGeein

Dr. Maxwell and Ms. McGeein called the meeting to order, with the intent of closing it for unspecified administrative activities. First, however, Dr. Maxwell took a few minutes to express to Ms. McGeein the Council's appreciation for all her service to the Council as its Executive Director. Presenting a small gift and a photograph of Council members to Ms. McGeein, Dr. Maxwell said the Council will miss her but would be delighted should she become a Council member "at some point." Various individual members then expressed their gratitude to Ms. McGeein as well.

Ms. McGeein responded by saying that her association with the Council "has been a highlight of her career" and she "will miss you all," adding that PACHA "is one of the best Federal advisory councils the Government runs."

Administrative Activities

Closed. [Not recorded]

Welcome

Standing in for PACHA Co-Chair Raymond V. Gilmartin, Ms. McGeein reopened the meeting, welcomed everyone, and introduced Charles Gilks to give a presentation on drug treatment regimens in the context of International Subcommittee concern about drug regimens, the "best ones," and what we are funding overseas. In addition to his

responsibilities at WHO, Dr. Gilks is a visiting Professor of International Health at the Imperial College in London.

Drug Treatment Regimens: How and Why WHO Makes Its Global Recommendations

Presentation by Charles Gilks, M.B.B.S, D. Phil., FFCP, DTMA, Director/Coordinator, Antiretroviral Treatment and Care, Department of HIV/AIDS, WHO, Geneva

Dr. Gilks said he will discuss the following in the context of WHO drug treatment regimens:

- Why WHO is needed to make recommendations and to set global norms and standards,
- How WHO sets about doing this,
- How successful or not WHO's work has been in antiretroviral therapy (ART) scale-up so far, and
- The future in part in the context of revised (2008) WHO processes for making recommendations and issuing guidance.

Dr. Gilks noted when The Global Fund and PEPFAR were established and resourced and the target that was set of 3 million people on treatment by the end of 2005 (3x5), as well as the goal of universal access to ART as a human right to health to all in need. He said it was very important for the U.N. General Assembly to declare the treatment gap as a global health emergency in 2003; it was a declaration that “the world was taking this seriously.”

When the U.N. declaration was made, WHO moved into “emergency mode” by:

- Defining the extent of the problem, including that 91 percent of the treatment gap existed in 34 countries, two-thirds of which are in Africa, and
- Recognizing the extent of the challenge, including:
 - The need for new intervention with extremely limited experience,
 - That countries most in need had the weakest health systems, and
 - The prevailing view that, as practiced in the North, ART was complex and specialized, requiring special physicians, even though this was not feasible in countries like Malawi.

To deliver on the 3x5 target, WHO took a two-pronged approach: 1. Simplifying and standardizing ART as far as possible without compromising effectiveness so it could be universally scaled up and delivered in resource-constrained settings on a population level; and 2. Supporting countries in recognizing and responding to their HIV/AIDS treatment gaps and leveraging the necessary resources to enable ART to be scaled up rapidly in line with the 3x5 target.

Dr. Gilks said that WHO specifically looked early on at drug resistance at a population level and also drug toxicity monitoring. As recognized by Dr. Garcia yesterday, WHO was also already looking at the need for chronic disease management and to assist those living with AIDS in achieving “decades of life.” While thinking along those lines, WHO recognized that care and treatment needed to be integrated and decentralized through a process that was evidence-based, simple, and standardized. Lack of understanding of all this has “led to some confusion” about WHO’s one global standard of *CARE for ART* (see also Slide 6) as published in its final form in *Lancet* (2006) and its approach around managed care.

WHO’s “Harmonised ART Policy Guidance” document released in 2006 includes revision of WHO’s original guidelines (Slide 7). WHO wanted to make sure its public health ART strategy document (Slide 6) and its policy guidance document were internally consistent “but also harmonized across the three interventions, so that when we talked about women who were not pregnant this would be comparable with discussion of pregnant women, for example.” WHO also recognized the need for consistency in product supply delivery that would enable other interventions, such as post-exposure prophylaxis.

The audience for WHO guidelines was broader than care implementers and included national planners, policymakers, trainers, and methods and evaluation experts designing appropriate tools and materials to support national policy recommendations. The guidelines were and remain more than a desktop manual, in short, Dr. Gilks commented. (Slide 8)

Turning to Slide 9 and 2008 HHS guidelines for the use of ART agents in HIV-infected adults and adolescents, Dr. Gilks said, “WHO’s approach is very different.” The International AIDS Society (IAS) recommendations on the right side of the slide were intended to give advice to individual physicians on the current state of ART and what decisions should be based on in terms of individual patients, not designed to help standardize what first- or second-line therapy would be.

Elaborating (Slide 10), Dr. Gilks said WHO’s guidelines “do not have a separation between first-line, failure, and second-line.” Rather, “our guidelines take a more managed care approach for public sector provision of treatment.” After the 2006 guidelines on Slide 10 were released, “we were criticized for being ambiguous about these drugs and where they should be, but some countries were grateful for flexibility, and some have switched to tenofovir for first-line treatment.”

In WHO’s recommendations on when to start in adults (Slide 11), Dr. Gilks said it is important to note that CD 4 technology “is lacking in many countries, so that’s difficult in terms of when to start.” Therefore, WHO “has always emphasized” clinical staging when CD 4 testing is not available as well as when it is available.

Moving on to Slides 12 and 13, Dr. Gilks emphasized that one “critical issue we are facing is the optimal time to switch therapies,” given the ways in which failure of

treatment can be viewed. In the United States, the goal of maximum suppression of the virus means that failure is almost entirely defined as virologic, but in a second- or third-line approach, “if we recommended viral load, we would be switching early.” In short, “we could wait and have more years of efficacy on the first-line therapy, assuming the second-line was not too compromised during that period of time.” At present, Dr. Gilks added, “we don’t know with our public health approach which is the better approach, as we haven’t trials for it and are only beginning to see patients fail, virologically and clinically.”

At present, WHO’s switching recommendations is based on expert opinion and modeling (Slide 14), the latter of which projected that switching when viral loads increase “didn’t add up to much in terms of population level survival and would not have much of an effect on drug resistance.” These are controversial recommendations, Dr. Gilks added, that deal in part with program setup and “how we may not want to invest in viral load versus CD 4 technology.”

Dr. Gilks then noted work supported by the Gates Foundation in helping countries set up surveillance and monitoring of drug resistance in order to give advice to policymakers on what levels of drug resistance “would need to occur” to spark the need to make new recommendations. (Slide 15)

Moving to Slide 16, Dr. Gilks noted that the G-8 had committed to the goal of universal access in 2005, although it was recognized that to do so by 2010 “wouldn’t be quickly achieved in all countries.”

In terms of the numbers of people receiving ART in low- and middle-income countries from 2002 to 2007, Dr. Gilks noted that the target of 3 million was missed in 2005 but was achieved in 2007 according to annual data published by WHO in cooperation with UNAIDS and UNICEF. “Globally, countries have done pretty well in scaling up,” particularly in 2006 and 2007, Dr. Gilks commented, which indicates that “our approach...has been successful” beyond low-hanging fruit.

However, “we have done much less well with children,” Dr. Gilks said (Slide 18). One issue is that products aren’t available, and another is that when they are “they are difficult to use.” Dosing is a particular problem, so WHO “has worked very hard to simplify dosing” and has “managed to get agreement on fixed doses of drugs” (Slides 19 and 20).

Dr. Gilks then detailed the Revised (2008) WHO Process for ensuring the quality of global recommendations pertaining to malaria and other diseases as well (Slide 21) and evidence-based approaches to guidelines (Slide 22), which, at present, “tend to favor clinical data from randomized trials.” However, in low- and middle-income countries, few randomized trials have been conducted around which to base treatment recommendations, so “we have to extrapolate from the way drugs are used in the North and in those countries.” Dr. Gilks added that “we will be able to deal with this and have done so already with some of the pediatric recommendations.”

Turning to Slide 23, Dr. Gilks emphasized that WHO now has delineated five different factors that must be taken into account and documented in its recommendations. These include not only quality of evidence but also costs/financial implication and feasibility, which “are most important in resource-limited settings because there is no point in making recommendations that are not cost-effective” in a given resource-limited country as defined by its gross domestic product (GDP). The “huge constraints” in resource-limited countries must be kept in mind “when we look at products and monitoring.”

Concluding, Dr. Gilks said:

- Developing WHO drug treatment regimens is challenging, but they have had great impact in ART.
- There is a balance between being permissive and driving the ART agenda forward, as with tenofovir, and maintaining relevance to all countries (and making recommendations countries will be able to use).
- Processes are being updated in WHO so that they are even more rigorous and transparent and costs and feasibility are taken into account.

Question-and-Answer Period

Dr. Urbina asked about first-line agents and the use of d4T (stavudine) in terms of whether there is enough evidence to support lower dose d4T. Dr. Gilks responded that “we had d4T at higher and medium strength, and it was a supply management problem.” That is, countries would get it wrong. When WHO saw that the lower dose was less toxic with equally positive effects, “we produced a Web alert to countries that they could move to just that” and backed it up with evidence. What is interesting, Dr. Gilks added, is that five or six countries are still using the higher dose “because of a lag in process,” even though the toxicity of the higher dose has been a particular issue “for many nations.” Therefore, although some nations “don’t have the extent of data available in North America and Europe,” they have experienced the limits of the higher dose, which is “why some countries have gone to therapies that are four times more expensive, like tenofovir.” In short, “nations are having to make a difficult tradeoff between costs and other factors.”

Dr. Yogev noted that, as a pediatrician, his major concern is dosing in children and what it is based on. Dr. Gilks stated that WHO had several problems and challenges to face in terms of dosing in babies and young children. We “often had to extrapolate from data on adults. We have had long discussions about what we needed to simplify and how simple we could make it, and we have agreement that dosing by weight is usable and won’t run into too many problems because dosing changes very rapidly in babies.” Dosing by weight is “how antimalaria combination therapy is delivered, for example,” he added, and while not perfect, “it will allow expansion of treatment where kids are dying.”

In terms of different ratios of fixed doses, Dr. Gilks added, a Web-based tool was used to analyze this, and “we agree that we would go for slightly higher PK (pharmacokinetic) drugs rather than lower, initially.” WHO is in the process of finalizing “all this,” as many European pediatricians “are also concerned,” which can be discussed at length later.

Mr. Mattes asked about WHO's position on pre-exposure prophylaxis. Dr. Gilks commented that "on paper, this is a potentially exciting intervention for some at risk," adding that WHO will be working with evaluation groups in the future to make recommendations that countries can use quickly based on the trials and risk groups that show benefit. WHO did something similar with circumcision. In the case of circumcision, "there was some controversy, but we hope to try to translate good randomized trial data into policy recommendations."

Responding to Mr. Mattes' query about what percentage of the affected population is currently on recommended therapy, Dr. Gilks said "that depends on your definition of population in need of treatment." Conservatively, "there is about 27 percent coverage globally of treatment needed." WHO's guidelines for adults, prevention of mother-to-child transmission (PMTCT), and children will be reviewed next year, and "one issue will be when to start." While he can't predict what the outcome will be, "the United States and Europe have been emphatic about 350 [CD 4 count] to start, and that will increase the numbers by possibly 40 percent."

Dr. Temesgen commented that in terms of the process of guideline revision and quality of evidence over the past few years, there are "good randomized trial data comparing the nucleoside backbone and other drugs." He asked if that is applicable to treatment issues in developing countries as well. Dr. Temesgen also noted that "there are differences in some nucleoside backbones as second-line therapy," and asked Dr. Gilks to comment.

Dr. Gilks responded that WHO has had extensive discussions around nucleoside backbones and the importance of clinical failure other than viral load. WHO "has tried to incorporate the limited data from Africa and Asia into preliminary discussions about being more specific in second-line recommendations." In the next 4 weeks, "we will have a summary of our meeting on the Web." While "we still don't have enough data from the field on how current use will impact second-line recommendations," some people believe "we'll have functional monotherapy because we have allowed people to accumulate drug resistance specificities, and that will be a big problem."

So far, Dr. Gilks added, "we've said we will reserve ddI (didanosine) for the second-line." In addition, "those using tenofovir are often using it with AZT." Dr. Gilks further noted that "we are looking forward to a fourth class of drugs so that we can have two first-line and two second-line, in which case resistance won't be so much of an issue for choice of second-line." The major market for new drugs will be Africa, he noted, "so it is a shame that drugs are only being trialed in America and Europe."

Dr. Gilks added that "modeling data is controversial, in terms of appropriate viral load. Or are we safe to wait for clinical manifestations?" In short, "studies need to be done in developing countries because, at the moment, the way we're using ART is quite different."

Ms. Valenti asked about patient safety in light of the fact that some combinations are “very deleterious to patients.” Dr. Gilks responded that “patient safety is paramount, as all antiretrovirals are toxic.” WHO “has tried to promote fixed-dose combinations because it is easier to get them out, and they are prone to fewer prescription errors.” In terms of drug resistance, “you are less prone to resistance if you just stop all your medicines.” Meanwhile, he added, progress has been made on both branded and generic infant products.

Dr. Bollinger thanked Dr. Gilks for his excellent review of many difficult and challenging issues. He noted that the Council is in the position to make specific recommendations on PEPFAR and its operations, and some of its discussions from a programmatic perspective have involved challenges around PEPFAR’s possible early propensity to “Ready, Fire, Aim.” Therefore, “should we try to aim programs more carefully?” He noted Dr. Gilks’ outline of major challenges around optimal therapy and getting it to the field. Therefore, first, he would like Dr. Gilks’ specific recommendations about shortening the time gap between the availability of new information and operationalizing it. Second, for countries like Zambia that have decided to use tenofovir as a first-line therapy, he would like Dr. Gilks to comment on why these countries have made this decision, particularly when budgets are limited and the outcome might be to reduce access.

Dr. Gilks responded that in terms of translating evidence into guidance, “we need to reflect the best and most up-to-date information, but we also have to remember that these are fragile countries, so we can’t change global recommendations too often.” Elaborating, Dr. Gilks noted that some countries “find it challenging to get national expert panels together,” for example. At present, WHO is looking to change its guidelines no less than every 2 to 3 years. Any shorter time frame “will not benefit the countries involved.” In addition, “we are trying to make the guidelines permissive enough to allow for changes, such as to tenofovir, so that when they make a decision that can be supported by evidence, it can be within the framework of our recommendations.” In short, “we have to give them room to make their own national decisions.”

In terms of how countries make or interpret guidelines, Dr. Gilks continued, at the beginning, “people were interested in cost and availability, and the latter was very important in terms of d4T because the relatively cheap fixed dose was available and made an impact.” Hopefully, “as we move to the long haul, countries can make more studied recommendations.”

Zambia “was interesting,” Dr. Gilks said, because “lab infrastructure is an issue.” To use tenofovir, “you have to do a renal screen... and in Zambia, that’s a big problem. They have far less ability to do urine tests than CD 4 counts.” However, Zambia decided that the costs are “something they will invest in because they believe that the overall benefits will outweigh the costs.” Dr. Gilks added that WHO is studying Zambia and Namibia very carefully “because other countries will be coming to us” about this. As for PEPFAR, “two-thirds of the global success has come from PEPFAR and the U.S. Government. We

all recognize the major impact the United States has had. Your deliberations and thoughts are very important for global treatment and scale-up.”

Ms. McGeein noted that transition to second-line therapy in the United States doesn't generally occur until an individual patient's viral load is at a certain level. Dr. Gilks responded that WHO does not have a guideline for switching, because “there are no data to say what the optimal time is for going to second-line in terms of viral load or CD 4 count” but that viral load at 10,000 shown in his slides “was expert opinion.”

Responding to Ms. McGeein's second question regarding limited lab infrastructure in many PEPFAR countries, Dr. Gilks said that three important things needed to make a diagnosis are “not easy for infants” in particular. With regard to those three things, first, WHO has just made a new global recommendation that any infected or expected-to-be-infected infant should be diagnosed at 6 weeks and treatment started. Second, patient management is needed, and here critically lacking is diagnosis of opportunistic infections, particularly TB, in part due to lack of labs but also of radiology availability. Third, lab capacity is needed to monitor treatment—toxicities, CD 4 counts, and viral load. However, “viral load is probably the least important at the moment.”

Dr. Bollinger asked what WHO is doing to incentivize the availability of new formulations for children. Dr. Gilks stated that “we have an essential medicines list for low-income countries, and our position is that it should be made available, including in the right doses, and that links to our regulatory approval for pediatric medicines.” Dr. Gilks added that WHO's position has received much European and U.S. Government support.

Dr. Temesgen asked about differing results between the WHO modeling exercise and a certain study from Africa. Dr. Gilks cited two relevant randomized trials, one of which has been completed showing data “entirely consistent” with WHO's modeling exercise, and another underway to look at lab monitoring, for which he is the principal investigator. He characterized the latter trial as a big one “that will confirm the modeling,” or so it is hoped.

New HIV Vaccine Initiatives

Presentation by Carl W. Dieffenbach, Ph.D., Director, Division of AIDS, NIAID, NIH, HHS

Dr. Dieffenbach said he will be providing an update on NIH vaccine initiatives and good as well as bad news.

He noted that the last time he appeared before the Council was the day after a major NIH summit on vaccines. Just the fall before, NIH had announced the discontinuation of two major HIV vaccine trials, of a Merck product (the STEP trial) and of HVTN 503 (the Phambili trial). Now he will talk about changes made in current and new vaccine

initiatives and the direction of research, for “we have turned a battleship around on a dime, and you will see why.”

STEP Study Results

Dr. Dieffenbach outlined the following results:

- The vaccine did not protect against infection nor lower the viral “set point,” and
- More infections occurred in vaccinees than in placebo recipients (a trend more pronounced in participants with high baseline Ad5 titers).

Additional analysis indicated:

- Increased risk of HIV infection among vaccinees was most evident in uncircumcised men with pre-existing Ad5 immunity.
- No evidence of increased risk was seen among vaccinees who were circumcised men without pre-existing Ad5 immunity.

Now further studies are underway to provide clues to the possible biological mechanisms involved.

Immunogenicity Summary

- Immune responses as measured by ELISPOT were similar in infected and uninfected subjects.
- There is no clear explanation for the increased number of infections observed in vaccinees among the Ad5 seropositive volunteers.
- Therefore, a process is in place to prioritize further studies.

Dr. Dieffenbach explained that the first bullet tells us we’re still in search of correlates for protection and the second that activated PBMC (peripheral blood molecular cell) seen in volunteers with high Ad5 antibody titers at baseline may play a role, as HIV requires activated cells for growth, but “no blood” difference was seen between vaccinees and placebo recipients, so “we will have to go back and look at mucosal sites.”

Dr. Dieffenbach further noted that NIAID now has a rapid peer review process in place to prioritize and fund further studies to look at these questions with samples generated from the STEP process. In short, “we have moved rapidly to engage the best minds to participate.”

In terms of the STEP trial’s unique scientific contributions, Dr. Dieffenbach emphasized that one lesson learned is “we can probably drop the size of future trials down to fewer than 1,500 participants.” Another is that STEP “recalibrated the NHP (nonhuman primate) Challenge Model” (see Slide 4) and demonstrated that vector-induced immunity needs to be evaluated in vaccine development, including tissue-specific responses. The

STEP trial “taught us to listen to more stringent models,” in short, and to renew emphasis on nonhuman primates and primate research at an NIH-wide level, with partners who are investing heavily in those resources now and in the future.” We also, Dr. Dieffenbach added, “have to take into account immunity to the vector.”

***Summit on HIV Vaccine Research and Development (March 25, 2008):
Classical Vaccinology versus HIV Vaccinology***

Dr. Dieffenbach said that NIH came out of this summit with ideas for a different direction, i.e., to “go back to basics.” He then described classical vaccinology, including that it falls more in the development than the discovery category, with the former generally being a more orderly process. (Slides 7–11)

HIV Is Different

Common elements in classical vaccinology include proof of protective efficacy and long-term immunity. But HIV is tough, as in:

- The natural immune response to HIV is inadequate.
- HIV hides from the immune system.
- HIV targets and destroys the immune system.
- HIV mutates rapidly.

In short, “HIV mutates from the moment it enters the body to promote immune escape and to promote growth.”

Dr. Dieffenbach then turned to the May 2007 publication (*New England Journal of Medicine*) of a paper (by Johnston and Fauci) on evolving concepts for an HIV vaccine, “which discussed all this,” the bottom line of which was that “as we move forward we have to be clear on the expectations we have of HIV vaccines.” (See also Slide 11.) In the meantime, “we’re turning the knowledge knob back toward discovery with the emphasis on underlying processes associated with the infection.”

Back to Basics

Dr. Dieffenbach then described NIH’s new approach: back to basics (Slides 15–18). In the back-to-basics approach, “new strategies...rest squarely on our unraveling the basic biologic conundrum of HIV and its interaction with its human host,” Dr. Dieffenbach said, emphasizing that “we’re now looking at prevention as a holistic proposition, whether we are talking PrEP or vaccines, where the goal is to gain information on multiple fronts from the studies we are planning.”

The new Vaccine Discovery Branch (Slide 16) will scan the literature and talk to researchers to look for advances that could potentially lead to an HIV vaccine, Dr. Dieffenbach said, with the major emphasis on “getting an antibody-based approach going.”

After the March 2008 meeting, he added, NIH released “several millions of dollars per year to look at grants involving B cells.” As a result, “we’ve seen some fabulous new ideas come in the door, some only recently presented at the vaccine conference in South Africa.”

In addition, NIH recently released another RFA (request for application) on basic vaccine discoveries “to build a strong foundation in disease vaccines but also focus on new investigators, new investigations, and new ideas.”

Dr. Dieffenbach clarified that the money set aside that he referred to earlier was \$15-\$20 million per year to be spent “if we have meritorious applications.” But they have to be “for the best science out there.” Dr. Dieffenbach went on to characterize the insights he is looking for and some of the institutions, individual scientists, and techniques of particular interest at present, emphasizing NIH’s “major commitment to discovery research and moving forward with NIH partners on primate research.” He noted in particular a workshop planned for November at NIH on specific areas “we should focus on in terms of nonhuman primates.”

Dr. Dieffenbach added that NIH will continue “to maintain population-based research on efficacy of treatment, which is important for PrEP, and also maintain its level of funding for development.” In short, by turning the knob to discovery, “we are not abandoning development.”

Beginning his conclusion, Dr. Dieffenbach asked, “Will there ever be an HIV vaccine?” (Slide 19) He noted that in the STEP trial there were strong immune responses and protection, and some individuals with interesting biological signatures “that will help us map out how to get to the best scenario, hopefully.” He expressed hope that we can go from the middle scenario, which would be a vaccine providing protection against HIV acquisition but only in some individuals, related or not to their genetic profile, to the best scenario, where there is “high-percentage protection against HIV acquisition.” Nonetheless, there is the last scenario, which is a slowing of disease progression in some patients.

Dr. Dieffenbach then quoted NIAID Director Dr. Fauci as saying to him that “failure is not an option.” And “he’s holding me to that.”

Turning to his last slide, Dr. Dieffenbach noted that “we are not looking for vaccines to work by themselves.” A fair number of the activities shown on Slide 20 “are proven and can be delivered in standard packages that the U.S. Government and others should be delivering,” while others, “like microbicides,” are still subject to research.

Question-and-Answer Period

Dr. Urbina noted the emphasis on looking at HIV pathogenesis and interest in primate models. He said, if nonhuman primates are infected with SIV, they have high viral loads

and yet don't progress and don't transmit perinatally, so is there interest in looking at coexisting with this virus as opposed to development of a vaccine?

Dr. Dieffenbach responded that NIH has a fair amount of investment in primate models, and when one looks over the millennia of coexistence of retroviruses with species they infect, one finds ample examples of multiple viruses we carry in our genome that we've adapted. But from the public health perspective, "we don't have a millennium. We must work on vaccines and drugs to get us protection now." When smallpox and plague erupted during the Dark Ages, "this caused contraction." If "we can't get a handle on this, that is where we're headed." But "it doesn't mean we can't learn from those models."

Dr. Malebranche asked about the implications of the STEP analysis and the increased risk in uncircumcised men for MSM and other behaviors. Dr. Dieffenbach responded that the trial was done primarily on MSM, so this is a very important question. Most MSM think the insertive male partner is less at risk. However, the risk factor for insertive partners "was significant" in the STEP trial, so "most likely the vaccine is being trapped under the foreskin, but, more probably, there may be a herpes factor or something else we don't know about yet." An analysis of the herpes factor is nearly finished, he added.

Dr. Malebranche also asked, in relationship to the HIV genotype, whether there is other genetic information on subpopulations, on late responders, that Dr. Dieffenbach can provide at this time. Dr. Dieffenbach noted that "we're approving a molecular genetics and population study."

Mr. Grogan commended Dr. Dieffenbach on funding "a shift on approach" to HIV vaccine research and asked if international efforts are also engaged in different approaches. Dr. Dieffenbach cited NIH participation in a consortium "now chaired by Alan Bernstein." NIH has a leadership role in this organization, as studies to date have been primarily funded by the U.S. Government and the Gates Foundation.

Dr. Martin noted post-exposure prophylaxis studies in monkeys and how, even when therapy was delayed, the monkeys never got sick. Even when rechallenged, the monkeys "were immune." Dr. Dieffenbach responded that "in a series of studies done in 1994-1997, all the monkeys ultimately did get infected." Subsequently, others have redone some of these experiments, and when the monkeys were rechallenged with high doses on multiple levels, the results were that "the animals do not seem to be protected the way we thought they were."

Dr. Temesgen asked about therapeutic versus preventative vaccines. Dr. Dieffenbach noted that therapeutic vaccines were not part of his presentation "but are on our agenda." The question is "Can we create immunity that would allow people to reduce, delay, or stop retroviral therapy?" The Merck product "was tested on that score, and it has significance in reducing viral load." Dr. Dieffenbach added that "products are being looked at" for their therapeutic value, but "there is just not as high a level of interest" in that at present.

Mr. Schmid asked about the relative expenditure of funds on vaccine research versus basic research. Dr. Dieffenbach responded that “we may be spending a little less money, but we have not significantly reshuffled funds from vaccine research to basic research.” He added that “we have also redirected other funds internally so that we have a full-court press on PrEP and prevention,” which represents one-twenty-seventh of NIH funding and one-half of the AIDS budget.”

Dr. Yogev asked if part of the plan is to look into pilot studies “to give more exposure to a smaller amount of the antigen.” Dr. Dieffenbach responded that “the vast majority of experiments done in structured treatment interruption have not yielded success.” He noted that there is an ongoing relevant trial “and we’ll see where it goes, although we seem not to be seeing one universal theme we can point to.” He added that “a structured interruption will have to be built into vaccine tests in the future, but we have to be careful, as we don’t want to cause harm.”

Noting Dr. Dieffenbach’s final slide, on comprehensive HIV prevention, Dr. Bush noted that while PrEP is not a vaccine, she would like to know about any results from it. Dr. Dieffenbach responded that PrEP “is a work in progress.” He explained that it arose out of a series of model experiments dating back to 1995-1996, which showed that pretreatment with antiretrovirals, even a single agent or post-exposure as prophylaxis, “worked very well.” To a certain extent, this work is built on PMTCT—“the first major success we’ve had.” If it works there and in other animals, “it should work in other forms of HIV/AIDS transmission.” But PrEP “has to be specific populations and specific modes.”

Eight PrEP studies are underway, he added. The first scheduled for completion is a Thai study due to be reported out within a year. Immediately behind that is a study supported by NIH and the Gates Foundation regarding the effect of antiretrovirals in transmission in MSM populations in South Africa, South America, and the United States, as well as similar CDC studies. The sponsors’ attitude is to demonstrate that this is feasible. If so, then “we’ll work on dosing and additional agents for the formulary.”

Conclusion

Ms. McGeein noted that it was time for PACHA’s Subcommittees to break into their separate groups for a Working Lunch and further deliberations, including of resolutions. When the Council reconvenes, it will hear remarks by retiring members, then take motions and vote on resolutions.

Working Lunch

AFTERNOON SESSION

Council Reconvenes

Ms. McGeein reconvened the full Council and noted that the next major agenda item would be remarks by retiring Council members Troy Benavidez, David Malebranche, Jose Montero, and Ram Yogev. It was noted that retiring member Cheryll Bowers-Stephens could not attend today's meeting.

Subcommittee Conference Calls

Ms. McGeein noted that the next set of Subcommittee conference calls is scheduled for November 6, 2008. The International Subcommittee conference call will take place at 1 p.m. on that day, and the Domestic Subcommittee conference call will take place at 3 p.m. on that day. Nancy Barnes will send out conference call information and agendas.

Remarks by Retiring Members

Ms. McGeein said that it breaks her heart for these five members to be rotating off the Council. She then asked the four retiring members present to provide a few retrospective remarks, including major accomplishments. (All retiring members also received a small present and certificate of appreciation for their service.)

Troy Benavidez

Mr. Benavidez said that, in retrospect, what he will miss most "is working with all of you." He said it has been a tremendous honor and privilege to be part of the Council and to work with members present and others who have come and gone over the past few years. He noted that the Council's work "is of great importance here and around the world" and that he has come to realize PACHA's impact. He noted that the Council has had some tremendous speakers over the years who provided very impactful data. He then noted that he goes home every night to his partner, who has been battling HIV/AIDS for a little over 10 years. "So far, things are going well," he reported, adding that he wanted the Council to know that his service has also been a personal matter for him. He then implored the Council to do all it can do, because "there are real people involved."

David Malebranche

Dr. Malebranche said it had been "a real honor to serve on the Council for the past 2 years." He noted that he came onto the Council at the tail end of the Ryan White reauthorization when former member and Domestic Subcommittee Chair David Resnik was still here. The Ryan White reauthorization and the PEPFAR reauthorization were the two most important "things I've seen." One of the best things about the Council is the people on it, he added, and he is particularly sad that Shenequa Flucas is not here so that he could say good-bye. He noted that he has enjoyed his association on the Council with many other members, including but not limited to Drs. Martin and Bush and Ms. Wise, for the Council is wonderful in the diverse backgrounds and ideologies it represents and how, "even given that, we tend to come to a common solution." He noted that he has

many friends who have been affected by this disease and that it is personal to him as well. He asked the Council to keep up its good work, particularly the Domestic Subcommittee, adding that he will smile when he reads in the newspaper that “the domestic plan has been implemented” because “I know you will have had a big part in it.”

Jose Montero

Dr. Montero said that he wanted to echo what Dr. Malebranche said, in terms of how much of an honor it has been to be part of a very diverse group. While ideologies have been sometimes “quite different,” the Council has tended to come up with consensus, “for the most part.” Dr. Montero remembers when Brent Minor was a Council member about 4 years ago. His message was “keep attention on HIV.” Mr. Minor thought a great deal about the need for a domestic summit on HIV/AIDS, “and we need to continue to push that into the limelight.” Dr. Montero said he also wants to remember former Council member Rev. Edwin Saunders—“a very great person.” Rev. Saunders’ thrust was two-fold: first, that greater attention must be paid to the African American epidemic, and second, that a great deal can be accomplished locally, through education. Dr. Montero also remembers Dr. Resnik, whose passion was just like Ms. Krevelen’s. During the Ryan White reauthorization, he said, “Don’t forget the impact.” Now that we are coming full circle back to reauthorization, Dr. Montero asked the Council not to “forget his message.”

Dr. Montero also invoked the memory of Dr. Primm’s Council membership: “Everyone remembers him” and his last message, which was, “Don’t forget about a domestic PEPFAR.” In short, Dr. Montero said, “We need leadership, direction, a plan.” The momentum is here now, “but we have to continue that momentum.” Concluding, Dr. Montero said he is proud to say he was a member of the Council these past 4 years.

Ram Yogev

Dr. Yogev thanked the Council for the privilege of addressing its members. He said he hopes to be brief and say things that merit the Council’s attention, adding, however, that he “will probably fail at both.” Dr. Yogev noted that he has often said publicly and privately how much he appreciated being nominated to the Council, as he has high regard for its members. Over the years, he has enjoyed interaction with the many fine minds on the Council, sometimes in opposition yet really more like two prisoners whose cells are joined and who communicate by knocking on the wall. “The wall sometimes separated us, but it was also a means of communication and of reaching consensus.” The best example Dr. Yogev can think of is the ABC issue. Some insisted on abstinence, and some insisted on condom use, yet importantly, the Council adopted a resolution that represented “the middle way.”

Noting that he is a pediatrician, Dr. Yogev said that he adopted the pediatrician perspective on the Council because sometimes it seemed to be forgotten. Now he has been reassured by Dr. Bollinger that he will continue to represent the pediatrician’s

perspective to the Council. Dr. Yogev said he is proud that he “kept children on the screen of the Council,” and he hopes this will continue.

To new members, Dr. Yogev expressed his envy at their opportunity and also imparted some advice: “Never measure the height of the mountain until you have reached the top, because then you will see how low it was.”

Dr. Yogev concluded by wishing all good luck “on the hard road ahead.” He thanked staff and contractors, too. He said he hoped to have the pleasure of seeing Council members again in the near future.

Motions and Voting

Ms. McGeein asked PACHA Subcommittee Chairs to present their draft resolutions for consideration.

International Subcommittee

On behalf of the International Subcommittee in the absence of Subcommittee Chair Robert Redfield, Dr. Bollinger introduced the following draft resolution:

Presidential Advisory Council on HIV/AIDS

International Subcommittee

Draft Motion

WHEREAS, PACHA commends President Bush and his Administration on the success of PEPFAR and its global leadership in fighting the HIV/AIDS pandemic;

WHEREAS, PEPFAR serves as a unique humanitarian program that has improved the health of millions of HIV-affected individuals around the world;

WHEREAS, PACHA commends the bipartisan support for the *Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act* which will continue and expand the success of the PEPFAR program;

THEREFORE, BE IT RESOLVED that PACHA encourages the next Administration to act expeditiously to fill key policy and leadership positions with clearly defined responsibilities for this program.

Background

Dr. Bollinger noted that the Subcommittee did not define the key positions referred to, as they may be redefined. The primary thrust of the resolution is that “we don’t want an interruption of the program due to leadership issues.” Dr. Yogev added that the Subcommittee is also concerned about the economy and the budget as well, because it does not want “people to suffer for delay.”

Motion and Vote

Ms. McGeein asked for a motion to approve the resolution, and receiving a first and a second, asked for a vote by hand. The Council then unanimously approved the motion to approve the resolution.

Domestic Subcommittee: Two Draft Resolutions

Mr. Schmid announced that the Domestic Subcommittee has two draft resolutions for Council consideration, the first of which addresses appropriations for the domestic HIV/AIDS program.

Mr. Schmid briefly noted that the Subcommittee also worked today on a draft resolution on HIV and youth, which it will bring to the Council’s next meeting. In addition, the Subcommittee will be discussing two other main issues over the next few months: a national AIDS strategy and how PACHA should help develop that with the next President; and reauthorization or extension of Ryan White.

Appropriations Resolution

Background

Prior to introducing this draft resolution, Mr. Schmid noted that some domestic HIV/AIDS programs have received only minimal funding increases, some have been flat-funded, and some have been cut at the same time that health care costs and case loads are going up. Therefore, the Subcommittee wants to urge the President as he works with Congress on the FY 2009 budget and the next President as he comes up with the FY 2010 budget to recommend increases for domestic programs for the purposes outlined in the draft resolution.

The Subcommittee has discussed the resolution, entitled “Resolution in Support of Increased Appropriations,” and finalized it for Council consideration as follows:

Presidential Advisory Council on HIV/AIDS

Domestic Subcommittee

Draft Motion

WHEREAS, the Centers for Disease Control and Prevention (CDC) recently announced that the annual number of new HIV infections in the United States in 2006 was 56,300, which is 40% [sic] higher than previous estimates;

WHEREAS, while there is no cure for HIV, to keep people with HIV/AIDS alive and healthy, new drug therapies must be developed;

WHEREAS, to prevent HIV infections, which is [sic] rising in certain communities and populations, behavioral and structural interventions, [sic] biomedical prevention programs, such as microbicides and a vaccine, must be developed and implemented along with HIV testing programs;

WHEREAS, people with HIV/AIDS require specialized health care and lifelong drug treatment to control the virus; and support services, including housing, to remain healthy; and an estimated 530,000 people with HIV/AIDS rely today on Ryan White HIV Programs for their health care and drug treatment; and that number is likely to increase as more people are identified as positive through HIV testing programs;

WHEREAS, the Biomedical Research and Development Price Index increased by 3.7 percent in fiscal year 2007, and health care costs are estimated to increase by 6.7 percent in 2009;

WHEREAS, funding for HIV/AIDS research at the National Institutes of Health (NIH) was flat-funded in fiscal year 2008;

WHEREAS, funding for HIV/AIDS prevention and surveillance at the Centers for Disease Control and Prevention (CDC) was cut by \$3.5 million in fiscal year 2008;

WHEREAS, funding for the Ryan White HIV Programs increased by only 1.4 percent in fiscal year 2008, while the AIDS Drug Assistance Program (ADAP) received only a .6 percent increase;

WHEREAS, funding for the Housing Opportunities for People with AIDS (HOPWA) increased by only 4.9 percent in fiscal year 2008;

THEREFORE, BE IT RESOLVED The President's (sic) Advisory Council on HIV/AIDS urges the President, as he finalizes the Fiscal Year 2009 Appropriation measures with the Congress and develops a Fiscal Year 2010 budget, to provide increases for (1) HIV/AIDS research at NIH; (2) HIV/AIDS prevention, testing, and surveillance programs at CDC; (3) HIV/AIDS care, treatment, and support services through the Ryan White Program, including ADAP; and (4) housing through the HOPWA program.

Discussion

Ms. McGeein said she would entertain a motion to consider the draft resolution, and upon receiving a first and a second, asked for discussion.

International Subcommittee Changes for Consideration

Dr. Yogev said the International Subcommittee has some changes to suggest, which he has provided to Mr. Schmid. The proposed changes were characterized primarily as streamlining the draft resolution language by cutting back or deleting two paragraphs of background (paragraphs 4 and 5) and adding an adjective to “increases” in the Be It Resolved paragraph, either “meaningful” or “percentage.”

Mr. Schmid said he appreciated the International Subcommittee’s interest in streamlining the resolution and that the Domestic Subcommittee had discussed that. In the end, Subcommittee members had felt it was important to discuss in the body of the resolution why research, prevention, and care and treatment are needed. He added, however, that he is willing to entertain streamlining changes and that he favors adding the word “meaningful” before the word “increases” in the last paragraph.

Mr. Schmid also noted that the resolution in its current form has been ready for the past month. Therefore, “all members should have had it in advance to prevent last-minute requests for changes.”

Dr. Bollinger said the International Subcommittee was raising questions and that he is not sure significant changes should be made. However, “some of us felt a little concerned that each of the issues raised is critically important and lumping them together could potentially dilute” the resolution’s impact. Because a domestic strategy will be a high priority in the future, “many of these are important issues to be wrestled with and fully dealt with in the national strategy.” Therefore, it may be that this resolution “preempts that a bit.” Last, there is a question about the timing of the FY 2009 budget and whether it has already been defined.

International Subcommittee member Robert Kabel added that, on that last point, President Bush “has had his last impact on the FY 2009 budget,” because Congress has passed a continuing resolution through March. He said he wanted to reiterate what Dr. Bollinger said about some of the International Subcommittee’s concerns; that is, as we look at a domestic strategy, the resolution “says we just need more of the same.” If the consensus is to move forward with that, that is fine, “but a whole rethinking of the whole strategy is needed.”

Mr. Schmid asked if there was opposition to the resolution.

Domestic Subcommittee member Mr. Kaufman stated that no points had been made so far in discussion that hadn’t already been discussed by the Subcommittee. “The Subcommittee pretty unanimously thought this is the language we should have, and I strongly support it,” he added.

Domestic Subcommittee member Dr. Bush commented that perhaps the point about its being too late to affect the 2009 budget should be taken into consideration. Mr. Schmid

responded that the next President will have to deal with both fiscal years—2009 and 2010, in terms of specific appropriations, as noted by Mr. Benavidez.

Mr. Schmid commented that it is not a good idea for discussion of national strategy to put funding issues in limbo, as it will take years to come up with the strategy while more funding “is needed now.” He added that a strategy “is a way to better coordinate efforts, a way of defining goals, identifying resources for how to achieve goals, and measuring efficacy over time.” A strategy “doesn’t mean that we will stop asking for funding for prevention, research, and care and treatment.”

International Subcommittee member Mr. Grogan commented that “a strategy is a priority at a time when there are limited resources.” As the resolution reads at present, he added, he doesn’t see prioritization. Dr. Dieffenbach said earlier that “he would rather keep funding in his back pocket than fund research that isn’t good,” so “what more are we going to fund at NIH?” What should the priorities be? Mr. Grogan asked.

Mr. Mattes said the FY 2009 appropriations “are not necessarily set.” He then suggested that some thought be given to separating research initiatives from therapy initiatives as a way to streamline or prioritize the resolution.

Mr. Schmid reiterated major points in support of the resolution as written, adding that CDC “is in good hands with Kevin Fenton, and we all want to see more research.” He then asked for guidance on moving forward.

Ms. McGeein stated that since the resolution is the Domestic Subcommittee’s recommendation, Mr. Schmid could ask for amendments and/or edits, or call for a vote.

Dr. Yogev asked Mr. Schmid to “think about what you are asking for,” adding that he is “not against what you have here.”

Mr. Schmid responded that he hears opposition to the resolution and that he dislikes the seeming situation of one Subcommittee versus another. “This Council has not been operating this way,” he added.

Mr. Kabel responded that while he has some concerns about the resolution, “if the full Council wants to go along with it” that is fine. The International Subcommittee was raising discussion points, to which Mr. Schmid responded again that the resolution should have been made available to all members earlier.

After further brief discussion, Domestic Subcommittee member Dr. Malebranche noted that “we could do four different resolutions, but that’s fragmenting, and I’ve been in the situation where we did that, and people objected to that.” At present, the resolution’s language is lined up so that by the time one gets to the last paragraph, “you understand” what is being requested and why. Domestically, he added, “we don’t have just one program.”

Mr. Schmid then described the structure of the resolution once again and how the paragraphs line up to make the point of “why we want increases.”

Dr. Bollinger said he doesn’t “have a problem with the ‘whereas’ statements.” Rather, he wants to understand in light of the specificity of those statements why the recommendation “is not very specific about percentage increases or the amount of increases,” and therefore would like to hear about why the decision was made not to be specific about that.

Mr. Schmid noted that the original draft contained the word “meaningful,” but it was dropped after Domestic Subcommittee discussion. In addition, the Subcommittee made a decision not to prioritize. Responding, Dr. Bollinger asked if HHS would make that decision, to which Mr. Schmid responded that the resolution’s general thrust is that “these programs need increased funds for a number of the reasons stated.”

Ms. Van Krevelen then asked as a point of process whether resolutions are usually changed by the full Council or whether resolutions are usually sent back to Subcommittee for changes. Ms. McGeein responded that resolutions “are often edited here... although sometimes a Subcommittee decides to take them back.”

Mr. Schmid then asked that the full Council vote on the resolution as is, stating that if it doesn’t pass, the Subcommittee will take it back for next year.

Motions and Vote

Ms. McGeein called for a vote. By hand count, the full Council then voted by majority to approve the appropriations resolution, with one member voting in opposition.

Behavioral Research Resolution

Mr. Schmid characterized this draft resolution entitled “Draft Resolution in Support of Increased Behavioral Research for Populations Most at Risk for HIV Infection” and its contents, as follows, noting that behavioral interventions for MSM, especially for MSM of color, are particularly lacking at present in CDC’s approved list of interventions despite the prominence of MSM in the epidemic and among new infections.

Presidential Advisory Council on HIV/AIDS

Domestic Subcommittee

Draft Motion

WHEREAS, the Centers for Disease Control and Prevention (CDC) recently announced that the annual number of new HIV infections in the United States in 2006 was 56,300, which is 40% [sic] higher than previous estimates;

WHEREAS, HIV infection is increasing in certain communities and populations;

WHEREAS, a person's behavior can be the prime reason that puts an individual at risk of being infected with HIV;

WHEREAS, it is important to understand the social determinants of behavior among those at greatest risk of being infected with HIV, and develop interventions to reduce the incidence of HIV infections among these populations to prevent HIV infection;

WHEREAS, there is a basic lack of behavioral research and effective interventions for certain communities and populations at high risk of being infected with HIV, including men who have sex with men (MSM), particularly black and Latino MSM;

THEREFORE, BE IT RESOLVED The President's (sic) Advisory Council on HIV/AIDS (PACHA) urges the Secretary of Health and Human Services, through the National Institute [sic] of Health and the CDC, to invest the necessary resources to conduct research that will identify and develop effective behavioral interventions for those populations who are most at risk of HIV infection.

Motion and Vote

Ms. McGeein entertained a motion to consider the resolution and, receiving a first and second, asked for any changes, edits, and/or discussion.

Mr. Schmid noted that the Subcommittee had added "for HIV Infection" to the end of the title during its last discussion, at lunch.

Ms. McGeein then called the question, asking for a vote. The full Council then voted unanimously by hand to approve the resolution, ending full Council consideration of motions for this meeting.

Public Comment Period

Joe Moser, Vice President, Government Relations, AIDS Alliance for Children, Youth, and Families, gave the following statement:

"AIDS Alliance is a national nonprofit organization whose mission is to enhance and expand access to quality, comprehensive, family-centered care for America's children, youth, and families affected by HIV/AIDS. We represent the Nation's network of over 650 Ryan White Part D-funded community-based organizations. Part D programs serve more than 53,000 HIV-affected women, children, youth, and families through sites located in 35 States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands.

"AIDS Alliance would like to stress the importance of Part D of the Ryan White HIV/AIDS Treatment Modernization Act in providing care and support services to low-

income women, children, and families affected by HIV and would like to urge PACHA to support its reauthorization or extension in 2009, recognizing the unique role of the services provided by Part D grantees in their communities. Without these services, HIV-positive women and youth would be unable to tap into the health care continuum.

“One of the programs administered by AIDS Alliance is the Consumer Leadership Corps Training Program, which trains HIV-positive women that are consumers of HRSA-funded Ryan White CARE Act Part D services to conduct community workshops aimed at empowering and mobilizing HIV-positive women in accessing medical and other supportive services in their communities. Most of the women who participate in our programs are women of color and represent minority populations. AIDS Alliance views HRSA as a vital partner in these efforts and commends HRSA for its outreach to community-based organizations to reach specialized populations through Part D to ensure access to care for HIV-positive women and youth.

“AIDS Alliance participates in coalition efforts to strengthen the Ryan White Program and supports increased funding for all Parts of the Ryan White HIV Program. We would recommend PACHA make increased authorization levels for Ryan White a priority for a reauthorization or extension in 2009.

“Let me also take a moment to mention that AIDS Alliance is a proud national partner in the National HIV Vaccine Research Education Initiative. Through a variety of programs, we work to empower women and young people around community mobilization for HIV vaccine research. We encourage researchers to continue their commitment to inclusiveness — the vaccine research endeavor cannot be a success without ensuring the representation of women and young people in this effort.

“Finally, since this will be the last PACHA meeting in this Administration, I would like to take a moment to recognize President Bush's commitment to Global HIV/AIDS through the PEPFAR program. Through his leadership, the \$63 billion total PEPFAR commitment from this Administration and Congress will support treatment for 4.7 million people, care for 19 million, including 7.7 million orphans and vulnerable children, and the prevention of 20 million new infections. This is the largest commitment to any single disease by a Nation in history, and President Bush and the thousands of men and women who have worked to give hope to a continent through PEPFAR should be commended.”

Jessica Ladd, Public Policy Associate, The AIDS Institute, gave the following statement:

“Today I would like to share with you our comments on the impacts of the Ryan White HIV/AIDS Treatment Modernization Act and what actions Congress and the new Administration should take before it expires September 30, 2009.

“First, The AIDS Institute would like to applaud HRSA for implementing the law so quickly and professionally in a very short period of time. The new law contained many

new components that had to be interpreted and implemented quickly [and] that required a great deal of staff time and leadership.

“After nearly 2 years, we can now see some of the new law’s impacts. One of these effects was funding shifts; some jurisdictions saw increases, while other experienced painful decreases.

“These shifts were the result of the new law and a changing epidemic, and were buffered for some by hold-harmless provisions. The cuts could have been prevented if Congress and the President had decided to increase funding for all Parts of the Ryan White HIV Program. This is perhaps the most disappointing aspect of the 2006 reauthorization. The authorization levels in the new law were too low to keep up with increased costs and caseloads, and the appropriators did not properly fund the program.

“Another impact has been that the ADAP situation greatly improved in some States. States with weak ADAPs were allowed additional funds, because the law increased the ADAP supplemental from 3 to 5 percent and decoupled it from funding the hold-harmless provision. In fact, the supplemental in FY 2007 was nearly \$40 million, or three times larger than the previous year. These policy changes, combined with the effects of the formula changes and the advent of Medicare Part D, helped a great deal, but we are now seeing further strains on State ADAPs. Additional appropriations must be directed at ADAP, along with all Parts of the Ryan White Program.

“It is still too early to learn all the impacts of the new law. We were very pleased that the law addressed the issue of unobligated balances, since in the past this money was returned to the U.S. Treasury, while other jurisdictions desperately needed funds. Hopefully, soon we will learn from HRSA how much money has been returned and how much will be redistributed next year. We also look forward to hearing how the core medical services and hepatitis coinfection requirements have played out on the ground, along with greater accountability and coordination provisions.

“The repeal of the law is less than 1 year away, yet implementation is still underway, and we don’t know all of its impacts yet. Furthermore, there will be a new Administration and a new Congress who may not have time to properly address this important issue. The AIDS Institute supports a general extension of the current law with some very minor changes for a period of at least 3 years. We recently have embarked with others in the AIDS community to work on a consensus proposal.

“As we approach the extension of the current law, The AIDS Institute strongly believes there must be increased funding for all Parts of the Ryan White HIV Program. We would also like services to continue to be delivered to clients in the face of grantee mismanagement or negligence. We are alarmed to hear that some jurisdictions are not making their grant awards or paying vendors in a timely manner.

“We approach this extension knowing that the current law is not perfect. There are too many low-income people with HIV/AIDS in this country who are not receiving adequate

and affordable health care and access to medications. We will continue to push for a health care system that guarantees that everyone who is in need of HIV/AIDS health care and treatment can receive it, no matter where they live.”

Adjournment

Following the close of the Public Comment Period, PACHA’s 36th meeting was adjourned at 3:05 p.m.