Presidential Advisory Council on HIV/AIDS (PACHA)
Thirty-seventh Meeting
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 800
Washington, DC 20201

March 24–25, 2009

Council Members—Present

Raymond V. Gilmartin, B.S.E.E., M.B.A., PACHA Co-Chair
Marilyn A. Maxwell, M.D., PACHA Co-Chair
Robert R. Redfield, M.D., International Subcommittee Chair
Carl Schmid II, B.A., M.B.A., Domestic Subcommittee Chair
Robert (Bob) C. Bollinger, Jr., M.D., M.P.H.
Freda M. Bush, M.D., FACOG
Joseph Grogan, J.D.
Donald A. Holzworth, M.S.
Robert M. Kaufman, B.A., M.A., J.D.
Rev. Herbert H. Lusk II, B.A., M.Div., D.Min.
John C. Martin, Ph.D.
Glenn R. Mattes, B.S.
Zelalem Temesgen, M.D., AAHIVS
Antonio E. Urbina, M.D.
Sharon Valenti, M.S.N., NP-BC, RNCS
Eric G. Walsh, Jr., M.D., M.P.H.
Barbara Wise, B.S.

Council Members—Absent

Shenequa Flucas
Robert Kabel, J.D., LL.M.
Jean Ann Van Krevelen, M.S.W.

PACHA Staff Present

Christopher Bates, M.P.A., Interim Executive Director, PACHA, and Director, Office of HIV/AIDS Policy, Office of Public Health and Science, U.S. Department of Health and Human Services (HHS)
Melvin Joppy, Committee Manager

Presenters

Carla S. Alexander, M.D., FAAHPM, Assistant Professor of Medicine and Director of Palliative Care and Support, University of Maryland School of Medicine, Institute of Human Virology

Larry Bryant, Director, National Advocacy and Organizing Housing Works, Inc.

Christine Campbell, M.S.O.D., Vice President, National Advocacy and Organizing Housing Works, Inc.

Jeffrey S. Crowley, M.P.H., Director, Office of National AIDS Policy, The White House

Laura Hanen, M.P.P., Director, Government Relations, National Alliance of State and Territorial AIDS Directors (NASTAD)

Sharon L. Hillier, Ph.D., Professor, Department of Obstetrics, Gynecology, and Reproductive Services; Director, Reproductive Infectious Diseases and Immunology, University of Pittsburgh School of Medicine; and Director, Center of Excellence in Women's Health, Magee-Womens Hospital, University of Pittsburgh Medical Center

Amy Lansky, M.P.H., Ph.D., Acting Deputy Director, Surveillance, Epidemiology, and Laboratory Science, Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), HHS

William D. McColl, Esq., Co-Chair, Ryan White Working Group and Political Director, AIDS Action

Andrea Weddle, M.S.W., Executive Director, HIV Medicine Association (HIVMA)

DAY 1

MORNING SESSION

Call to Order and Welcome

PACHA Co-Chair Marilyn A. Maxwell called the meeting to order at 9:02 a.m., introduced herself, and welcomed everyone to PACHA's 37th meeting, its first under President Obama's Administration.

Dr. Maxwell also welcomed Christopher Bates as PACHA's designated Interim Executive Director.

Dr. Maxwell noted that since PACHA's last meeting in October, the Nation has observed three HIV/AIDS Awareness Days: for African Americans (February 7); for Women and Girls (March 10); and for National Natives (American Indians, Alaskan Natives, and Native Hawaiians) (March 20). Dr. Maxwell noted that these observances "provide a unique opportunity for local communities to highlight the importance of the epidemic and to educate the public about healthy sexual behaviors and to encourage testing by those who are sexually active."

Agenda Highlights

Dr. Maxwell noted that after lunch today, Admiral Steven K. Galson, M.D., M.P.H., RADM, USPHS, Acting Assistant Secretary of Health and Acting Surgeon General, HHS, is scheduled to address PACHA, and that tomorrow, Jeffrey S. Crowley, M.P.H., Director, Office of National AIDS Policy, The White House, will provide greetings and remarks.

Dr. Maxwell also noted that the meeting's Public Comment period has been moved to the first day of the meeting and that public comment is encouraged as "a valued part of this meeting."

Members Absent

Dr. Maxwell noted that PACHA members Shenequa Flucas and Jean Ann Van Krevelen would be unable to attend the meeting due to demanding personal and professional commitments.

New Members

Dr. Maxwell extended a particular welcome to new PACHA members Donald A. Holzworth and Eric G. Walsh, and asked them to introduce themselves. She also noted that these members would be officially sworn in on the second day of the meeting.

Mr. Holzworth's Remarks

Mr. Holzworth apologized for missing the first PACHA meeting after his appointment, in October. He was engaged in work that he is passionate about, in Africa, on issues related to capacity building. At present, he is Chairman of Futures Group International, working on infectious diseases, child and maternal health, and "other problems in the developing world." Mr. Holzworth noted that he serves on other boards as well. He has also worked in support of major Government programs related to his passion, initially for the CDC as well as for the National Institutes of Health. He has also worked or is working with initiatives out of the United Kingdom (UK) and the Bill & Melinda Gates Foundation.

Mr. Holzworth concluded that he has traveled many places "where the burden of infectious disease is most profound and sees and feels the pain of others subjected to not ideal living conditions and resource constraints." His work and passion make him happy to be on the Council. He looks forward to "learning a lot from the rest of you to take back to those" he works with.

Dr. Walsh's Remarks

Dr. Walsh said his passion began the summer before he began medical school at the University of Miami, when he was placed in a clinic in South Beach, Florida. It was an HIV/AIDS treatment clinic, in the early days of the epidemic. He stayed on there during his first 2 years of medical school, and then continued his work with HIV/AIDS in residency in California. Today, he serves as the Medical Director for the Family Health Services Division of Orange County's (California) Public Health Department. He also engages in work abroad and will be going to Kenya and Zambia this summer "trying to support work there." He is also in discussion with counterparts in the People's Republic of China through the National Physicians Center.

Dr. Walsh concluded his remarks by noting what a Nigerian doctor told him last week: "This is a disease that places a burden on those who are burdened." As a member of PACHA, Dr. Walsh said he "hopes to help and to learn," adding that Orange County expects him to return from PACHA meetings "with really good information."

Introductions by Other Members

Dr. Maxwell then asked all other members present to introduce themselves, and members responded by giving their current titles as reflected on the PACHA Members List.

Interim Executive Director Remarks

Mr. Bates said he will serve as PACHA's Interim Executive Director, but he is "not sure how long that will last." He noted that he has had some conversations with Mr. Crowley from The White House, and the upshot so far is that "many decisions have not been made about this body or its future." Mr. Bates has told PACHA's Co-Chairs to "continue the good work of this Council, including engaging in some issues that have not been on the table."

Mr. Bates noted the International Subcommittee's discussion on the provision of pharmaceuticals and "the challenge" pharmaceutical companies feel they face "in making them available and also the challenges they see in terms of research." This discussion opened up for Mr. Bates "an opportunity to think about how this body comes together with colleagues in the Federal Government and in the private sector and how to create some synergy around that topic, internationally and domestically."

Mr. Bates noted that the Council has a robust agenda both today and tomorrow, including hearing from community representatives "who have not spoken to this group before." In addition, research and internationally oriented individuals "will share with us the challenges around their work." Most important, Mr. Bates said, is that the presentations and discussions will provide backdrop for some of the decisionmaking and work PACHA will be engaged in "in the very near future."

Mr. Bates concluded that he looks forward to the opportunity to work with PACHA and urged members to contact him at any time.

Approval of the October 21-22 Meeting Minutes

Dr. Maxwell noted that a correction is needed on page 46 of the minutes from PACHA's 36th meeting (October 21-22, 2008). In the third paragraph from the bottom of the page, where reference is made to "vaccine" trapped under the foreskin, the word "vaccine" should be changed to the word "virus."

Dr. Maxwell then asked for a motion to approve the minutes with that correction and, upon receiving the motion and a second, the Council approved the minutes by voice vote.

Infectious Research and Service Delivery

Dr. Maxwell introduced Sharon L. Hillier to give a presentation on this topic, noting Dr. Hillier's credentials from the biography provided in members' packets. Since 2006, Dr. Hillier has been the principal investigator (PI) for the Microbicide Trials Network, one of six NIH-funded clinical trials networks devoted to the treatment and prevention of HIV/AIDS.

Biomedical Prevention of HIV in Women: Microbicides and PrEP

Presentation by Sharon L. Hillier, Ph.D., Professor, Department of Obstetrics, Gynecology, and Reproductive Services; Director, Reproductive Infectious Diseases and Immunology, University of Pittsburgh School of Medicine; and Director, Center of Excellence in Women's Health, Magee-Womens Hospital, University of Pittsburgh Medical Center

Dr. Hillier said she will be talking about research in prevention of HIV, adding that she is excited about opportunities "to harness drugs we've used for treatment to work toward prevention." The promise is of better coalescence of treatment and preventative services and the "hope that we can do much better."

Dr. Hillier noted that her entire professional life has been devoted to women's health and prevention research—"how we can keep women healthy by providing opportunities to them to protect themselves from infection."

Newly Infected Globally

Dr. Hillier then began her PowerPoint presentation with a slide noting the global total estimated number of adults and children newly infected with HIV in 2007 (2.5 million). While she will discuss the epidemic in women in North America to a certain extent, much of the research she will review today is being conducted in sub-Saharan Africa, "since that is truly the epicenter of the epidemic."

Prevalence in Africa

Moving on to prevalence rates (Slide 3), Dr. Hillier noted that the last time she addressed PACHA was in 1995, during President Clinton's Administration. At that time, she noted countries with prevalence rates greater than 20 percent. As of 2004, the number of countries in Africa with a prevalence rate that high has grown. Dr. Hillier commented that "it is really shocking now to see women coming in to bear children and to pick up a 25-30-35 percent infection rate." In many countries, including in Africa, "women want desperately to remain uninfected so they can raise their children." Sometimes, they are not only raising their own children, but their sisters' children as well and also caring for their parents and siblings.

Women and HIV: United States (Slide 4)

Dr. Hillier noted the recent "disappointing news" about high HIV infection rates in the District of Columbia, then emphasized the following:

- In 2004, teen girls represented 43 percent of AIDS cases reported among people aged 13-19.
- AIDS is the leading cause of death of African American women aged 25-34.
- African American women are 24 times more likely to have AIDS than white women (which, Dr. Hillier said, "is simply not acceptable").
- African Americans and Hispanics represent 25 percent of all women in the United States, but they account for 82 percent of AIDS cases among women.
- Seventy-one percent of women diagnosed with AIDS in 2005 contracted the disease through heterosexual sex.

In short, Dr. Hillier said, "clearly something we've been doing isn't enough. We have to find better ways, better tools, and more opportunities to make changes because this is simply not right."

PrEP

Turning to Slide 5 and the case for pre-exposure prophylaxis (PrEP) to prevent HIV in women, Dr. Hillier noted that when she goes to Kampala, she takes antimalarial drugs. This is the way that "some people think" about PrEP; i.e., that you take a "preventative to protect you when you are in a high infection area." Specifically:

- Use of antiretroviral (ARV) drugs has been proven to be effective in reducing mother-to-child transmission (MTC) of HIV in the United States and internationally.
- Women are at increased risk of HIV due to biological and cultural factors.
- Women cannot control condom use by their partners and have limited options for protecting themselves from HIV.

Summarizing, Dr. Hillier noted that the United States today has a "great" program, which "effectively screens 95 percent" for HIV all women coming in to give birth. At that point, "we are able to apply antiretroviral drugs so that, today, in the United States, MTC transmission is a "small burden of infection."

Globally, women are at increased risk "for biological reasons because their cervix area is an important target for infection." Dr. Hillier added that "the women in our studies are married, monogamous, and lifetime partners, but they still get infected.” She said “it doesn’t do any good to say be married or be faithful because they are. And sometimes they don’t use condoms because they want children.” In short, “we’re looking for messages beyond ABC” because, additionally, “women can’t always control condom use.”

The HIV Prevention Spectrum (Slide 6)

Dr. Hillier commented that, prior to exposure, “we know that behavior change works. It is one of the most important things to do.” Also prior to exposure is the promise of vaccines. Vaccines, Dr. Hillier commented, “are the holy grail, but, unfortunately, we’re not there yet.” Then there is PrEP.

At this point, Dr. Hillier said she would touch on the first three items on the middle column of the spectrum dealing with point of transmission: cervical barriers, male and female condoms, and microbicides.

How Does HIV Invade (Slide 7)

Dr. Hillier explained that the virus enters through tiny cracks in the outer surface of the vagina, and then attaches to dendritic cells, which present the virus to T cells. She noted that “it is important to consider that early work was to put a barrier on the outer surface.” Other research has looked at how, topically or orally, “we can get medicine to the virus and keep it from replication.”

Female-Initiated Barriers (Slide 8)

Dr. Hillier detailed one of the “oldest” notions, e.g., using diaphragms and female condoms to “cover the cervix.” Researchers were interested in this as an option that did not require active male participation, that could be inserted in advance of sex, and that did not require partner use of male condoms.

Research results included that:

- Providing female-initiated barriers increased protected sex acts from 31 percent to 65 percent in Brazil (Babosa et al. 2000).
- In the United States, use of female condoms had the effect of increasing protected sex from 44 percent to 59 percent (Choi et al. 2003).

Slides 9-11

In Slides 9-11, Dr. Hillier detailed the results of the MIRA or "Gates Diaphragm Study," which involved nearly 5,000 women at sites in South Africa and Zimbabwe, testing the effectiveness of diaphragm with Replens gel use in preventing heterosexual HIV acquisition in women. All participants received condoms, intensive safe sex counseling, and sexually transmitted infection (STI) treatment. The study was randomized to condom use alone or condom use plus use of the diaphragm with the gel (a lubricant).

The results of the study were released in 2007. Dr. Hillier noted *The Wall Street Journal* story's headline on July 13, 2007, which stated: "Gates AIDS-Trial Failure Stirs Questions." She added that "this was an important study to do because we kept finding that women were being instructed to use diaphragms for protection, and it was valuable to get the answer."

Specific findings from the study included that the results of using condoms only versus using condoms and a diaphragm "were pretty much the same," Dr. Hillier explained, given an annual incidence percentage overall of 3.9 percent for the former and 4.1 percent for the latter. Dr. Hillier commented that although this trial was conducted in South Africa and Zimbabwe, "it is important that we give accurate information to American women too," particularly as "there had been some thought here that diaphragms would work."

The Ideal HIV Prevention Drug (Slide 12)

Dr. Hillier commented that the ideal HIV prevention would be "if we could get everyone to live safely, but that's not always possible," then detailed the concept of PrEP, including:

- PrEP used orally, vaginally, and/or rectally to present potent activity against HIV
- PrEP involving one dose daily or less
- PrEP involving good tissue penetration at the site of infection
- PrEP that is well tolerated and safe to use, including during pregnancy
- PrEP that involves minimal drug interactions and resistance, to preserve options
- PrEP that is affordable and also that requires a minimal amount of monitoring.

Dr. Hillier emphasized that PrEP should be safe to use during pregnancy, as in sub-Saharan Africa, at any given time, 33 to 40 percent of women at risk are pregnant or breastfeeding. She added that these women are "usually or often excluded from studies."

How Could Microbicides or Oral Drugs Prevent Infection? (Slide 13)

Dr. Hillier then explained that researchers have thought about or explored a variety of transmission interruption concepts, including: viral disruption (inhibition of HIV uptake by dendritic cells, for example); prevention of sexually transmitted diseases (STDs) to preserve barriers; maintenance of normal microflora; and topical gels and/or creams as physical barriers as well as lubrication.

Nonoxynol-9 (Slide 14)

What was "really unfortunate" is that "a lot of advocates said we have products over the counter, so why not use them," principally nonoxynol-9 (N-9), Dr. Hillier said, then noted that:

- N-9 was tested in three large studies including 2,000 women.
- Findings included that use of an N-9 sponge increased HIV risk; use of an N-9 film was "not harmful or protective"; and use of an N-9 gel showed a trend toward increased HIV among high-frequency users.
- In short, N-9 was recognized to be both irritating and ineffective at preventing HIV.

Dr. Hillier said that while she wouldn't spend a great deal of time on N-9, she would like to point out that "you have to have evidence for recommending that something will work," so it "was imperative to get these data, to show that it was not effective." She noted that N-9 is still sold in the United States as an over-the-counter contraceptive, "but we've done a lot to get people to understand its limitations." In addition, "evidence helped change our counseling."

History of Microbicide Development (Slides 15 and 16)

Using a time line, Dr. Hillier noted as the first generation of development an emphasis on surfactants and trials that involved N-9 and SAVVY (1 percent C31G vaginal gel) through 2003. The second generation of development then emphasized polymers and trials that involved PRO 2000, Carraguard, and cellulose sulfate (CS) through 2005.

Dr. Hillier explained that the notion of polymers was that perhaps cheap, safe, easy-to-use vaginal products could be developed to block HIV. The prevailing concept was that a microbicide is a product that can be applied to the vaginal or rectal mucosa with the intent of preventing or significantly reducing the transmission of STIs, including HIV infection.

Microbicide Trial Design (Slide 17)

Dr. Hillier noted development of a microbicide trial design involving healthy women that would include safer sex counseling, diagnosis and treatment of STIs, and condom provision, if desired by participants, as well as randomized testing of two active drugs and a placebo, with the primary endpoint being measurement of HIV seroconversions. She emphasized that “some people said you’ll never be able to do” this type of study.

Summary of Completed Nonspecific Microbicide Studies (Slide 18)

Dr. Hillier noted that of four studies of Carraguard, SAVVY (C31G), and cellulose sulfate stopped or reported out last year, “none were shown to be beneficial,” which “caused a huge outcry in the field.” Some researchers said that “products were being developed or picked by investigators without a good basis,” which, Dr. Hillier commented, “was fair.”

BufferGel (Slide 19)

Dr. Hillier then turned to BufferGel:

- BufferGel acts by enhancing the body’s natural defenses and maintaining a low vaginal pH.
- Preclinical data indicate that:
    - Sperm and many STD pathogens are inactivated at pH less than 5.
    - BufferGel has a well-documented safety record in mice, rats, dogs, rabbits, and macaques.
    - BufferGel blocked HIV-PBL (peripheral blood lymphocyte) transmission in humanized-SCID (severe combined immunodeficient disorder) mouse.
- Clinical data:
    - Phase I safety and acceptability has been established in the United States and several international sites.
    - Phase III contraceptive trial showed good safety and contraceptive efficacy when BufferGel is used with a diaphragm.

PRO 2000 Gel (Slide 20)

Dr. Hillier emphasized that *in vitro*, a formulation of 0.5 percent PRO 2000 Gel “looked terrific, and it also seems quite effective against herpes.” Preclinical data also indicated no evidence of toxicity in rats, rabbits, or macaques and showed “protection in a macaque SIV challenge model.” Clinical data include Phase I studies among 136 women from four countries, which show “no safety concerns and good acceptability.”

HPTN 035 Study (Slides 21 and 22)

Dr. Hillier then detailed the HPTN 035 study, which:

- Was designed to estimate the safety and effectiveness of BufferGel and 0.5 percent PRO 2000/5 when applied intravaginally by women at risk for sexually transmitted HIV infection.
- Involved seven sites (six in Africa and one in the United States) between February 2005 and August 2007.
- Followed all participants for a minimum of 1 year, with some women enrolled early for following for a maximum of 30 months.
- Was completed in September 2008, with results presented at the Conference on Retroviruses and Opportunistic Infections (CROI) in February 2009.

Dr. Hillier noted that the U.S. site was in Philadelphia, involving 200 women. She noted that, while rates of infection "are not very high" in the United States by comparison to some other parts of the world, the study included American women in order to get safety data from American women. She added that "we don't find African women and American women are any different."

Question

Queried on whether there were any seroconversions among American participants in the study, Dr. Hillier said yes, 2 or 1 percent, "even in Philadelphia, even when the women were coming in every month for study visits."

HPTN 035 Study Retention and Adherence (Slide 23)

Dr. Hillier noted HPTN 035 study retention and adherence rates with an average followup of 20.4 months, emphasizing that retention "at the end of 2 years was nearly 94 percent, which is really good."

A First in the Prevention World

Dr. Hillier went on to note further results from the HPTN 035 study in Slides 24 and 25, emphasizing that data on HIV incidence and effectiveness "created quite a stir" when presented, as they indicated a "30 percent reduction in HIV/AIDS among those who used PRO 2000 Gel." This was "the first time in the prevention world that we'd had biomedical prevention that was able to reduce HIV among young, sexually active women. It was a first-base hit, not a home run."

Dr. Hillier went on to explain that, while some reacted to the results by saying the gel should be made available all over the world, "others said that the results are not statistically significant." Dr. Hillier commented that "prevention is such a difficult area. It's hard to talk about a partially effective product. However, this is what we most likely will have for a little while."

Dr. Hillier then went on to note the highlighted findings on Slide 25, which "hint" at the possibility that even if women had only low condom access, "you might see some effectiveness."

MDP-301 Study of PRO 2000/5 (P) (Slide 26)

Turning to Slide 26, Dr. Hillier noted a new trial underway, MDP-301, of PRO 2000/5 (P):

- The trial will use PRO 2000 at 0.5 percent and 2 percent.
- It is sponsored by the Microbicide Development Programme (MDP) of the United Kingdom.
- The intended sample size is 9,590.
- Participants are 16 years of age or older, except in South Africa and Zambia, where participants are 18 years.
- The decision was made last year to test PRO 2000 at 2 percent.
- First enrollment occurred in October 2005, with complete enrollment expected this fall and results in early 2010.

Questions

Mr. Holzworth asked if the HPTN 035 study measured whether sexual activity increased during the study, to which Dr. Hillier responded that the study looked "carefully at that," and found that sexual activity "remained completely unchanged over the course of the study." She explained that extensive sexual histories were taken every 3 months as well as brief interviews every month. The results, she added, match data from Lee Peterson and her colleagues.

Responding to Zelalem Temesgen, Dr. Hillier said that the molecule used in the HPTN study was "slightly better" than those used in other studies, although "it was not great." She added that the study "was probably well conducted."

Responding to Antonio E. Urbina, Dr. Hillier said 5 percent of study participants reported ever having had anal sex. In addition, the participant women were counseled in safe sex, including that anal sex "is a risky sex behavior and something to be avoided." An important point, she added, is that an intensive analysis was conducted in Malawi, which found that perhaps 4-5 percent of women were having anal sex in 3 to 4 months. That was "counseled against, but it did happen."

History of Microbicide Development (Slides 27 and 28)

Dr. Hillier then moved to the third generation of microbicide development involving ARVs such as tenofovir gel. She explicated the tenofovir gel study in macaques presented last month at CROI by the CDC, which had "worked out a terrific way to do these studies" with macaque monkeys (which are "very similar, of all the monkey species, to humans"). She stressed that instead of giving the macaques a big dose of the virus, the study gave smaller doses, 20 all told, over the course of 10 weeks, which simulated "many exposures, like humans." After the gel was applied, blood was collected to see how much of the drug was being systemically absorbed. Dr. Hillier observed that this was a "nice way to study small exposures over time, which gets to the heart of using these drugs."

Efficacy Evaluation of 1 Percent Tenofovir Gel (Slide 29)

Dr. Hillier noted the study arms involved in efficacy evaluation of 1 percent tenofovir gel applied vaginally in macaques: no gel; placebo gel; combination gel (5 percent FTC [Emtriva] and 1 percent TFV [tenofovir]); and TFV gel alone (at 1 percent). The results (Slide 30) showed that over the course of 20 challenges, those receiving TFV (or Truvada-type gel) "were completely protected," Dr. Hillier said, adding "that's exciting."

These results "have us thinking a lot about what we're trying to do with HIV prevention in women. We want to get drug where the virus infects from the sex act, most in the tissue and least systemically, where the drug can cause toxicity," Dr. Hillier explained.

Comparative Drug Levels for Oral Versus Topical Tenofovir (Slide 31)

Dr. Hillier then moved to Slide 31, which shows the comparative drug levels for oral versus topical tenofovir from a number of studies, concluding that the graph shows how, over time, "you can get 100 times more drug in the tissue if you apply it there, instead of orally."

CAPRISA-004 Study (Slide 32)

Dr. Hillier then explained the CAPRISA-004 study, which is using 1 percent tenofovir gel versus placebo in a way designed to help determine whether women who apply the gel "have a reduced risk." Dr. Hillier noted that:

- This is a proof-of-concept trial involving 980 women in Durban who are 18 years of age and older.
- Participants are required to use contraception.
- The trial is coitally dependent, i.e., gel use within 12 hours before and 12 hours after sex, with a maximum of two applications within 24 hours.

- The study was fully accrued as of January 2009 and is expected to be completed in January 2010.

Questions

Responding to a question about compliance with gels versus compliance with oral medication, Dr. Hillier said, “men uniformly say women would rather use a pill, whereas women uniformly say sometimes they would rather have a pill and sometimes gel,” adding that “we don’t have evidence to support either approach.”

Dr. Hillier went on to note that one study is now looking at compliance along these lines, monitoring drug adherence by measuring drug levels. She added that, in her view, “either that works will be great.”

Responding to a further question about compliance elements, social impact, and acceptance of tablets versus gel, Dr. Hillier said that she would address this a bit later in her presentation. However, “we hear different things,” she noted. “Some are saying, if I have a tablet and I’m not infected, my sick cousin will get the tablet.” In short, “we will have to do a lot of work on how this can be implemented, because using antiretrovirals for prevention could be quite complicated.” She added that “we’ll have our first proof-of-concept on topical tenofovir in about a year.”

Oral Pre-Exposure Prophylaxis (Slide 33)

Dr. Hillier read the premise of oral PrEP, as follows: “If women are willing to use contraceptive pills every day to prevent pregnancy, maybe they would be willing to use drugs active against HIV prophylactically to prevent HIV infection.”

Topical and Oral PrEP Agents (Slide 34)

Dr. Hillier then ran down a list of advantages for topical versus oral PrEP agents, as follows:

- Topical agent advantages include:
    - Higher concentrations in genital tissues
    - Potential for long-acting formulations (something that Tibotec is working on, Dr. Hillier noted)
    - Potential for combination products
    - Little systemic toxicity (and therefore less need for safety monitoring)
    - Use in pregnancy and during breastfeeding.

- Oral agent considerations include:
    - Systemic exposure

  - Potential for greater toxicity (and more need for safety monitoring)
  - The question of more resistance and concomitant population impact
  - The question of whether oral would be “limited to ART”
  - Overlap with treatment.

Dr. Hillier noted that discussions are under way with the U.S. Food and Drug Administration (FDA) on use of topical agents with pregnant women in Pittsburgh so that “we can get the safety data we need.”

Questions

Asked about how many people believe that oral drugs will work better, given their potential for greater toxicity and concerns about resistance, Dr. Hillier said, “it is tricky to explain that you are taking ART and are uninfected.” In addition, “we’re really worried about drug sharing on the ground, and we’re not sure how this will play out.”

The VOICE Study (Slide 35)

Dr. Hillier then turned to “her favorite study,” the VOICE study, which involves:

- Assessing the safety and effectiveness of tenofovir gel, tenofovir tablet, and Truvada tablet for prevention of HIV infection in 4,200 women
- Randomization with five study groups
- Use of product for an average of 21 months.

Dr. Hillier went on to characterize the purpose of the study as not only testing safety and effectiveness but also “which of these products women will use.”

Partners PrEP Study (Slides 36 and 37)

Dr. Hillier then turned to the Partners PrEP study, sponsored by the Gates Foundation, which involves:

- Multisite (eight sites in Kenya and Uganda) trial of PrEP against HIV in 3,900 HIV-discordant couples
- Randomized comparison of TDF (tenofovir disoproxil fumanate) once daily, TDF/FTC once daily, and placebo once daily in HIV-negative partners with normal liver, renal, and hematologic function
- All partners to receive “best prevention services”
- Couples to be followed for 24-36 months
- Goal is parallel comparison of TDF and TDF/FTC PrEP to prevent HIV-1 acquisition within HIV-1-discordant couples.

Dr. Hillier described this as a “very important” opportunity to “think about how PrEP could roll out,” with the first primary targets being HIV-discordant couples.

FEM-PrEP: Trial Overview (Slide 39)

Dr. Hillier also noted the FEM-PrEP Phase III trial in six sites in four countries (South Africa, Malawi, Kenya, and Tanzania) involving 3,900 women at high risk of HIV infection on a regimen of daily oral Truvada or a placebo. Followup on drug will be 52 weeks, and seroconverters will be followed for 52 weeks.

Question

Responding to Mr. Bates’ question about consideration being given to use of PrEP for discordant couples who may want to have a child, Dr. Hillier said, “one of the tragedies” in her view is that women want to have children and therefore “have reasons not to use contraceptives” when in a study like the Partners study. However, Dr. Hillier hopes that, through the VOICE study, “we could allow the gel arm” during breastfeeding or pregnancy.

State of the HIV Prevention Field for Women (Slide 40)

Concluding, Dr. Hillier provided a snapshot view of the state of the HIV prevention field for women, as follows:

- Female barriers (diaphragms) and over-the-counter contraceptive products are not effective at reducing acquisition of HIV in women.
- First-generation microbicide gels have been evaluated in efficacy studies; only PRO 2000 showed some level of effectiveness.
- Potent antiretroviral microbicides and oral drugs (topical and oral PrEP) are now in efficacy studies, and linkages between HIV prevention and treatment programs will be critical.
- Women urgently need (and deserve) prevention methods to reduce risk of HIV.

Dr. Hillier emphasized that the field “is rapidly moving toward convergence on treatment and prevention through antiretrovirals, and this will force us, when people come in for testing, to get them into treatment earlier if they are positive, and if they are negative, to do an assessment of risk factors and whether they could benefit from a biomedical approach.” This “will have to be done very carefully,” she added. Synergism between treatment and prevention will be required, “but it will be very powerful if we’re able to figure it out.”

Dr. Hillier finished with a quote from Melinda French Gates, Co-Founder and Co-Chair of the Gates Foundation (*Newsweek*, May 15, 2006), as follows: “Ten years ago, 1 percent of women in South Africa had contracted HIV; today the number is 25 percent. These women are living a nightmare, but we in rich countries are the ones who have to wake up. We need to develop prevention tools that can give women a chance to defend themselves. We need to deliver them as soon as they're available, and we need to deploy now the prevention tools we already have."

Dr. Hillier added that "we can do better. I think we have the capacity to do better."

Question-and-Answer Period

Sufficient USG Microbicides Research Investment?

Carl Schmid thanked Dr. Hillier for a very enlightening presentation, then asked if the U.S. Government (USG) is investing enough in microbicides research and whether there are any studies PACHA can recommend along the lines of those already mentioned.

Dr. Hillier noted her and her Institute's affiliation with NIH and receipt of NIH funding. She also noted Gilead's donation of drugs for many of the latest studies she mentioned. If the question is whether NIH has invested enough in the prevention agenda, Dr. Hillier said "quite frankly, a vaccine is a really important holy grail that needs to be pursued," but "an adjustment and investment is also needed in biomedical prevention," because "it is entirely possible that through that, we can identify ways to slow down the epidemic."

Pregnant Participants

John C. Martin asked if pregnant women are being taken out of the Partners study; Dr. Hillier responded in the affirmative. Dr. Martin then observed that he wouldn't think "that would be an issue." Dr. Hillier said the issue was about Truvada. Dr. Martin asked if the Institutional Review Board is in the United States or Africa. Dr. Hillier responded that the responsible party is FDA, because "there is uncertain benefit," and confirmed that she had indeed spoken "to the right people about this."

Philadelphia Involvement

Herbert H. Lusk II asked why Philadelphia women had been involved in the HPTN study. Dr. Hillier responded that, at the time, "we needed expanded safety and effectiveness data, more data, from American women." Dr. Hillier noted that large studies have been conducted in the United States, and that "we need answers for American and developing world women." She added that the study team chose Philadelphia because "we had a terrific team of investigators there and high retention rates."

Making the Economic Case for PrEP

Glenn R. Mattes said that if PrEP is “embraced on a large scale, there will be concerns about overall ability to pay.” He commented that “if you can show positive pharmacology, that will make a better case for getting reimbursement” for populations in both the United States and the developing world. He then asked if Dr. Hillier had thought about economic measures “to make the case.”

Dr. Hillier noted that the studies she mentioned are proof-of-concept studies and that financial impact studies are needed as well. At present, “we don’t have the right kind of structure and design to answer those kinds of questions, but such studies will have to be done.”

Gels and Serodiscordant Couples

Dr. Walsh commented that one of the best places to use gels would be with serodiscordant couples. Dr. Hillier responded that some of the VOICE trial women will be in such couples. Operationally, however, it is more difficult to identify such couples for the study, “so we decided to focus on women first and not necessarily identify the specific parameters of the partners’ diseases.” In short, “when you bring a couple in as a couple, you become manager of the man’s infection too, and sometimes men don’t like to get medical care here or abroad,” which can make it more difficult to recruit them. However, Dr. Hillier agreed with Dr. Walsh that serodiscordant couples “would be an ideal population to study.”

Care and Treatment

Dr. Maxwell introduced Carla S. Alexander to give the next presentation.
Palliative Care and Care and Support for HIV/AIDS

Presentation by Carla S. Alexander, M.D., FAAHPM, Assistant Professor of Medicine and Director of Palliative Care and Support, University of Maryland School of Medicine, Institute of Human Virology

Dr. Alexander said her presentation would not be scientific. Rather, it is designed to “ask you to think about things that are often overlooked.”

Presentation Objectives

- Emphasis, both here and abroad, on the importance of continuum of care and support in management of HIV/AIDS.
- Identification of challenges, both here and abroad, in caring for persons with HIV/AIDS.

Dr. Alexander showed a slide of a market in Zanzibar, off the coast of Tanzania, where she has been living, in order "to begin to make a point about quality of life."

Quality of Life

When making a point about quality of life in the context of AIDS relief, Dr. Alexander noted a few key questions one should ask:

- Are we measuring outcomes that actually mean something in the life of a person living with HIV/AIDS (PLWHA)?
- Can care manipulated by competitive agencies be offered in a manner that provides a lifetime of quality time with family and friends?
- Who is to say what quality is from one day to the next for you? For me? For someone living with HIV?

Chronic Illness

Dr. Alexander emphasized that, in terms of outcomes, HIV/AIDS is "totally a chronic illness now." She noted that she was in a medical diploma course in Africa recently, and "it was interesting to hear the way people were approaching the disease, as if they had to learn the history of what happened" with various HIV/AIDS treatment medications over the years. Yet "we're now 30 years down the line, and we don't need to keep processing those tiny details and issues when trying to figure out how to offer people the best quality of life."

Dr. Alexander added that those of us who are getting older "are bringing with us the burden of the epidemic we have all suffered from. We keep trying to make people live through that when all they are trying to do is live their lives."

PACHA Cares

Elaborating on care, Dr. Alexander said she respects PACHA "a great deal," because throughout the epidemic, it is "the only Council that has maintained a vision of where we're going and how it is affecting our own lives and the people we love and care about." Dr. Alexander added that PACHA "is still in that role of giving the best advice to the leaders of our country." This, she said, "is a heavy burden for you to carry" and she respects PACHA for the fact that it takes on this burden and that new members come to it and listen, then figure out how to use the information they have received. It is in this context that she wants PACHA to continue "to think about the people we're trying to take care of."

Hard To Measure Quality of Life

In terms of quality and who is to say what it is, Dr. Alexander said that “it is extremely difficult to manage your quality of life today” because it would be very difficult to put together a simple questionnaire that even begins to address what is important to you and your daily life. Some outstanding qualitative studies have been done on this, “but they are burdensome.” The bottom line is that it is hard to measure quality of life. Nonetheless, we must ask whether “we are measuring the right things.”

Appropriate Indicators

Dr. Alexander said she is asking that question because, when setting up goals for the President’s Emergency Plan for AIDS Relief (PEPFAR), for example, issues arise. When identifying indicators to measure to be able to tell whether funds are being used successfully, should those indicators be primarily the number of people who come into a given clinic or “is it important to know the number of families who are able to continue to raise children so that they can grow up to govern their own communities and countries?” This kind of issue is “not simple,” but PACHA is the kind of Council that asks “how we can look at what is actually important.”

AIDS Death Rate

Turning to Slide 5, Dr. Alexander noted estimated incidence of AIDS and deaths among adults and adolescents with AIDS, 1985-2000, in the United States. She apologized for the age of the data but said the point is that since the advent of protease inhibitors and a dramatic fall in the U.S. AIDS death rate, the death rate seemed to have stabilized at around 14,000 to 15,000 people each year, until recently. Now “the annual death rate is beginning to go back up again,” to 22,000 according to the most recent data, Dr. Alexander said. Yet, we don’t hear about these people anymore “because they’re not concentrated in one little community. They are invisible. They are us. The epidemic in the United States is now the epidemic we have in Africa. It is heterosexual. Everyone has access. Everyone can get it.”

Reasons Death Rate Won’t Decrease

Dr. Alexander then showed “why the death rate is not going to go down,” as follows (Slide 6):

- Of 10 people living with HIV disease:
    - 2 have progressive hepatitis C.
    - 1 has substance-associated renal failure.
    - 1 is on maraviroc and has a failing backbone.
    - One has miliary tuberculosis (TB) (in Africa).

  - One has disseminated Kaposi's sarcoma.
  - One has cryptococcal meningitis with a headache of 7 over 10 severity.
  - One has recurrent panic attacks.
  - One has lost 30 lbs. and his ability to talk.

Which Will Die?

Dr. Alexander then asked PACHA members which of these 10 people will die. Robert Redfield responded that all 10 will. Dr. Alexander noted that all 10 of the people she just described are people she has seen as patients over the past 3 weeks and, yes, they are all going to die, including pretty soon, depending on their environment and medical care. "As much as we would like to believe that some will get through this," she added, "that's not going to happen because we're all going to die."

Dr. Alexander commented that the hospice movement developed in this country because people saw individuals being placed on ventilators and kept alive for extended periods of time "because ventilators existed." Today, "we're in the same place in the epidemic. We have antiretrovirals. We can keep people alive. And that is fantastic. But the point is we want to keep them alive so they can live, work, build their countries, grow the economy, and be happy before they die."

Focus Shift

Dr. Alexander then shifted focus with Slide 9:

- From life of the virus to life of the host
- Goal = viral suppression plus HRQoL (health-related quality of life)
- Impact on family, community, and self.

Training Slides

Noting that she used the next few slides in training some doctors in Zambia a few weeks ago, Dr. Alexander outlined her thinking regarding the first bullet of Slide 9. She said HIV has done a lot for medicine and the world but we should look at the fact that HIV lives in a person. When we look at the goal of durable viral suppression (bullet two), that's "what we want" when "we go into these countries in Africa." Dr. Alexander and others conduct hands-on training to get "people to understand that's what we're looking for but also for quality of life, and the impact on family and community."

Referring to bullet three in Slide 9, Dr. Alexander explained that what she spends the most time doing in training others is "talking about family and community but also the self." That's because, if we don't take care of ourselves, "we're not here to take care of our families and communities." She said that if "we don't build in a way to say that the money being sent to these countries has to be used to support individuals and caretakers there, we end up having to take care of the caregivers because they are getting exhausted."

Dr. Alexander explained that caregivers are typically walking for 90 minutes to get to work with nothing to eat until, possibly, after they are finished working. The concept of taking breaks is "just unheard of," as is the concept that you could enjoy your job and "laugh when at work." She said "people can't keep going like that. We have to give them something."

OGAC Task-Shifting Report

Dr. Alexander then noted an Office of the Global AIDS Coordinator (OGAC) report on task-shifting, which she called "fantastic." Basically, she said, it says "we can teach anyone how to do different aspects of HIV care and treatment if we give them the right training." However, the report does not address "how we take care of the people who are taking care of the people." It does address the need for "good, supportive supervision and mentoring, and that's very important." But the report did not say "how to do that or give references on what that might be. It didn't talk at all about the need to extend the life space of the people who are helping in these countries who live there." This, she added, "applies in the United States, too."

Slides 10 and 11

So a shift in focus is needed, Dr. Alexander said, to where (Slide 10) "we understand care of patient within the context of life (trajectory of illness) in terms of care targeted to stage of illness and the role of family and community." One way to view this is shown on Slide 11, with circles representing community, clinic, and patient overlapping with staff in the middle, including the doctor, "whose shoulders upon which all this rests," Dr. Alexander observed.

Continuity of Care Model: Stages of Care and Support

Dr. Alexander then showed Slide 12, which represents a continuity of care model she is working on with a colleague. She asked for feedback on it and the stages of care and support it depicts. She emphasized that the time between diagnosis and when a patient starts ART "is a very difficult and prolonged period," adding that she has no idea how much time is involved. She said that in the United States, the Health Resources and Services Administration (HRSA) has always found it difficult to "understand how to engage people in care" or get them to come back to the clinic even before treatment. In Africa, she said, "this is where we're getting the big loss-to-followup rate. Nothing is being done for these people if their CD 4 count doesn't fall in the range for treatment." For PEPFAR, Dr. Alexander added, "we've focused on sending people out to the home to count pills to support people when they are first starting therapy. We haven't clearly defined when we decrease that amount of support."

Further explaining the model, Dr. Alexander moved to Stage 3, which is when a patient is taking ART and is doing well, but then there is the appearance of resistant viruses, "and we can't get rid of them." Dr. Alexander said that "when we start people on single-dose tenofovir, we're not getting rid of these resistant viruses. And at some point in time in the PEPFAR countries, people get to the point where they need to switch to second-line therapy."

In Nigeria, Dr. Alexander continued, there are people who have failed second-line therapy, and the question then becomes "what can we do?" That's when "we have to go to the Government and find medications no one has thought about." In short, "we are not far from the time when we have to think about where to go next." Some will get started on a new regimen. But there will be others who will get Kaposi's sarcoma or other co-morbidities from which they will die.

Therefore, Dr. Alexander continued, "we have to have a system of care and support for those people on new regimens to help them best address quality of life." In addition, "there are some who will die, and we need a care system for them, too."

Context of Care

Dr. Alexander noted that the original PEPFAR funding "was to include set-aside palliative care, but now it is being called care and support." Then she reviewed Slide 13 on context of care, as follows:

- Care of the individual
    - Goals of care and health-related quality of life, with impeccable attention to detail clinically
- Continuity model of care over time
    - Importance of interdisciplinary team
    - Hospital, clinic, home
- Impact of care
    - On patients and families
    - On the bereaved and community
    - On ourselves.

Dr. Alexander explicated that most people who find out they are infected with HIV think they are going to die, which is what people think when they get cancer or hepatitis C. The point, she said, is that we "can't just give people 15 minutes to decide that they will disclose their infection to their mothers as treatment buddies and get on ART right away. Feelings have to be dealt with. Time needs to be allotted for this. And it is not happening." Dr. Alexander asked if it is reasonable for people to be told their diagnosis and CD 4 count and then told to go on therapy "right away."

Care Skill Set

Dr. Alexander then reviewed Slide 15 on care skills, as follows, emphasizing that “most U.S. doctors don’t even know pain management”:

- Needed are
    - Communication skills
    - Management of total pain and other symptoms, including mental health issues
    - Addressing end-of-life issues—dying, grief, and bereavement
    - Care of care providers
    - Measuring and improving impact of care and support on patient, family, and community.

Underlying Motivation for Palliative Approach

Showing Slide 16 on the palliative approach, Dr. Alexander noted that her underlying motivation for using this approach is that attention to physical concerns often displaces time needed for essential elements that are then neglected, e.g., physical pain versus psycho-social-spiritual issues, and concrete daily needs versus end-of-life closure and effective grieving.

Continuum of Care

Showing Slide 17 and a model of palliative medicine and care, Dr. Alexander emphasized that “what we’d like to see while giving disease-modifying medications is also the giving of symptom-modifying care and support that extends into the home and community.”

Goals of Palliative Care

Showing Slide 18, Dr. Alexander noted goals of palliative care, as follows:

- Modify management based on prognosis.
- Approach patient and “family” as unit of care.
- Provide comfort measures.
- Assist end-of-life closure.
- Address ethical, cultural, spiritual issues.
- Address grief and bereavement.

Care Is a Team Effort

Dr. Alexander then emphasized that care is a team effort (Slides 19 and 20) and noted a chart of symptoms experienced at all stages from different hospitals, both here and in Africa (Slide 21). She said that the symptoms people have are all the same for HIV, adding that pain, as addressed in Slides 22 and 23, is a "representative symptom."

Palliative Care for HIV/AIDs and/or Cancer

Dr. Alexander then turned to Slide 24 on palliative care for HIV/AIDS and/or cancer from several studies published between 2001 and 2003, noting that in the African countries studied:

- Less than 1 percent [of those infected] can access ARVs.
- Less than 5 percent of cancers reach chemotherapy or radiotherapy.
- 40 percent of Africans never see a health worker.
- World Health Organization (WHO) research in sub-Saharan Africa shows preference for dying at home.

Dr. Alexander said the point is that most people in Africa never see a health care worker, and many come in at the end stage of their diseases.

Barriers to Discussing and Improving End-of-Life Care and Multiple Family Loss

Dr. Alexander briefly noted these relative barriers in Slide 25, then emphasized with the next slide the loss of life in whole families and communities as a result of the Rwandan genocide. HIV similarly results in such loss. In addition, "orphans are the bereaved in many African countries." These "are just children," Dr. Alexander noted, yet "they're all that's left." Not only do they have all the normal physical needs, but they also have their own concerns about being infected without "a capsule to protect them while they grow."

Methods for Supporting Staff

Beginning her conclusion, Dr. Alexander detailed her methods for supporting staff (Slide 31) and how she teaches that we all need a source of inspiration (Slide 33).

Dr. Alexander also provided a "Maker of Dreams Reflection" on Slide 36, which reads: "As we bring healing…Not to forget…To remind us that the answers to life are within each of us. Our role is to accompany on the journey."

Conclusion

Concluding, Dr. Alexander noted that “life is a journey” (Slide 37) and that she uses her last slide (38) “to help people look at what is positive.” When she presents the words on Slide 38 to those she teaches, she asks them to pick out “the one that is most important.” Personally, she thinks the word “presence” is the most important word on the slide because “being present means that you will accompany and you will sit by and be there, even when you’ve run out of things to do.” In addition, “faith” (Slide 39) is her mantra.

Question-and-Answer Period

Task-Shifting

Mr. Holzworth commented that while he doesn’t question that health care workers have an extreme burden, task-shifting is one way to reduce that burden by increasing those who are adequately trained. He then noted that his foundation has been given a Gates grant to look at the effectiveness of task-shifting in Uganda.

Dr. Alexander responded that she is not minimalizing task-shifting, as “it is excellent,” and the OGAC report was “a wonderful document.” She invited members who haven’t looked at it to do so, in part because “that document is going to come back to people in the United States.” That is, “it shows that we don’t have to keep everything as regimented as we have in the past in health care.” She added that the report is “a positive document. It just left out that one thing.”

Hospice Concept

Robert Kaufman noted his affiliation with a hospice in New York City with a high percentage of AIDS patients, then asked whether these patients need to be treated in any way that differs from the general hospice concept. Dr. Alexander responded no, they don’t, and that is her point, i.e., palliative care is care throughout the continuum of illness, meaning that “you respect the individual where they are in their life and in their disease.”

Need for Continuum of Care and Treatment

Dr. Redfield said that part of the challenge involves the exciting transition that has occurred in HIV/AIDS but also the need to confront comorbidities. Part of the “sensitization” that must occur still is “the enormous need for continuum of care and treatment.” Despite PEPFAR’s great work, “more die every day than we are effectively treating every day.” He added that OGAC defined care and support because “it wanted to look at the continuum; ultimately, the epidemic is measured in family and community terms."

Dr. Walsh asked whether continuum of care is being delivered on the ground now, in most of the world, particularly in sub-Saharan Africa. If not, what is the approach we should take?

Dr. Alexander said providing continuum of care "is difficult." When we hit the ground running in countries in need, we wanted to try to get as many people on treatment as possible. But in doing that, we've come to recognize that in our country, we have a chronic care medical system that functions, while in the PEPFAR countries, "there is little infrastructure and everything has been handled as an acute illness." So, there is "more that needs to be put in place than anyone had anticipated."

Now, in PEPFAR's second phase, "one thing we need to do is step back and more qualitatively evaluate what we see when it comes to communities," Dr. Alexander said. We need to figure out "what really are problems, then begin a progression from there so that we can target what we are doing a bit better." She added that "the infrastructure is not in place" in PEPFAR countries to support a full continuum of care.

Dr. Alexander went on to note that some countries are "in the same place we were 20 years ago in terms of their desire to even confront some of these issues." One thing she often sees is that because the United States has worked through many of the issues, "we assume everyone else has that knowledge base, but they don't, and we have to honor that." The difference in Africa and in the United States is that "we have Federal roads, which is an incredibly important thing." Africa is a huge continent that contains the United States plus a few others, and it doesn't have a Federal system to pull together all the countries. So many things are lacking, she added, commenting that "each country in Africa functions as an island, dependent on imports."

Important To Employ Pathos and Emotion

Rev. Lusk thanked Dr. Alexander for the compassion with which she goes about her business. He can sense the pathos and emotion, and it is "very important that we employ those."

Be Aware of Unintended Consequences

Dr. Redfield noted his first visit to Africa as a physician 22 years ago and his frustration at coming home to see patients in American hospitals without food trays by their bedsides. He would return to their rooms 2 hours later to find out that these patients still hadn't been fed. Yet when he visited hospitals in Africa in 1984 or so, no patient ever missed a meal because they were fed by their families. Now, when he goes to Africa, he is struck by how many patients on antiretrovirals are not being fed. The point is that "we need to be aware of the unintended consequences of applications of science and that we don't lose our humanity in the process."

Addressing the Whole Person

Barbara Wise then thanked Dr. Alexander for addressing "the whole person." She said she understood exactly what Dr. Alexander was talking about. "Every time I take my medicines," she added, "I remember how many others are taking and those who are not." Resistance is important, and "it is important for us to focus on that, too, in facing this disease."

Conclusion

About to take her leave, Dr. Alexander noted that Dr. Robert Gallo, Director of the Institute of Human Virology, recently pulled her into an Advisory Board meeting. What she told the Board was "what I teach in every clinic I go into where there is little money and no time." She told them that the one thing they can do when they get to work in the morning "is take a deep breath and let it out, and take another deep breath and let it out." Then, "remember, it is not about you. It is about all of those people living with HIV, and what you're here to do for them."

Break

Admiral Galson Not Coming

After the break, Dr. Maxwell announced that Admiral Steven K. Galson, M.D., M.P.H., RADM, USPHS, Acting Assistant Secretary of Health and Acting Surgeon General, HHS, would not be able to address the Council today as planned.

Health Care Reform: Implications for HIV/AIDS Treatment

Dr. Maxwell introduced Laura Hanen and Andrea Weddle to give a presentation on health care reform and implications for HIV/AIDS treatment. She noted that Ms. Hanen is Director of Government Relations for NASTAD, which represents the chief HIV/AIDS program administrators responsible for managing federally and State-funded HIV/AIDS prevention, care, and treatment services in every State and Territory, and that Ms. Weddle is the Executive Director of HIVMA. Biographies were provided in members' packets.

HIV and Health Care Reform

Presentation by Laura Hanen, M.P.P., Director, Government Relations, NASTAD, and Andrea Weddle, M.S.W., Executive Director, HIVMA

Ms. Hanen noted that both she and Ms. Weddle are affiliated with the HIV Health Care Access Working Group and that their presentation today will focus on information and concepts the Working Group is advancing on Capitol Hill.

Low Incomes and Unemployment

Beginning a PowerPoint presentation, Ms. Hanen showed Slide 2, on the U.S. population, people with HIV/AIDS, income, and unemployment, noting that as can be seen from the bar graph, low-income and unemployed people are “overly represented” in the U.S. population of people with HIV/AIDS. Whereas 8 percent of the general population have incomes below $10,000 per year, 45 percent of people with HIV/AIDS have such income levels. Whereas 5 percent of the general population are unemployed, 62 percent of people with HIV/AIDS are unemployed.

Insurance Coverage

Similarly, between 2000 and 2002, people with HIV/AIDS were “overly represented” among those who were uninsured for health care (29 percent), on Medicaid (36 percent), and dually covered (14 percent) (Slide 3).

Disparities in Access to Care

Ms. Hanen noted disparities in access to care according to HIV Cost and Services Utilization Study (HCSUS) findings published in 2006 (Slide 4). Specifically, HCSUS, a nationally representative sample of HIV-infected patients who were interviewed over a 3-year period beginning in 1996, found that:

- African Americans and Hispanics, as well as those uninsured or on public insurance, were less likely to receive ARV therapy.
- Other factors affecting access to ARV therapy included
    - Geography (access more difficult in rural areas)
    - Race/ethnicity of physician
    - Ability to meet basic needs, such as food, housing
    - Cooccurring conditions
    - Case management services.

Eligible for But Not Receiving HIV Antiretroviral Therapy

Ms. Hanen noted that of individuals aged 15-49 estimated to be eligible for highly active antiretroviral therapy (HAART) in 2003, 30 percent were not in care; 15 percent were in care but not receiving HAART; and 55 percent were both in care and receiving HAART (Slide 5).

Federal Funding for HIV/AIDS Care

Ms. Hanen noted the breakdown of Federal funding for HIV/AIDS care by program for FY 2008, as follows (Slide 6):

- Medicare received $4.5 billion or 39 percent of the funding.
- Medicaid (Federal share only) received $4.1 billion or 35 percent of the funding.
- Ryan White (programs authorized under the Ryan White HIV/AIDS Treatment Modernization Act of 2006) received $2.2 billion or 19 percent of the funding.
- Other programs received $800 million or 7 percent of the funding.

Ms. Hanen observed that Medicare "inched" out the Federal funding share of Medicaid in FY 2008, adding that 50 States' shares of Medicaid funding could not be accessed.

Federal Spending on HIV Care, FY 2006-2008 Comparisons

Showing a comparative bar graph of Federal spending on HIV care for FY 2006, 2007, and 2008 (Slide 7), Ms. Hanen noted that Medicaid's and Medicare's shares "are getting bigger."

Medicaid and HIV

Ms. Hanen said Slide 8 was "very important" because it shows that Medicaid:

- Is the largest provider of care to the HIV population
  - Covering 1 in 4 persons with HIV receiving care (or about 200,000 people)
  - With estimated Federal spending of $4.1 billion in FY 2009.
- Covers about 55 percent of adults living with HIV/AIDS and 90 percent of children and youth.
- Importantly provides prescription drugs, as an optional benefit.

Medicaid Eligibility

Ms. Hanen noted the following facts on Slide 9 about Medicaid eligibility for people with HIV and that they contain a “Catch 22”:

- There are two main groups of coverage—mandatory and optional.
- The majority of HIV-positive individuals are covered under the mandatory group.
- One must be disabled and low-income to be eligible for mandatory coverage.
- HIV diagnosis does not make an individual eligible for Medicaid.
- Rather, an individual must have an AIDS diagnosis to be considered disabled and eligible, including for Supplemental Security Income.

Medicare Overview

Showing Slide 10, Ms. Hanen noted that:

- Medicare is the second largest source of HIV/AIDS coverage, serving about 100,000 people at an estimated cost of $4.5 billion in FY 2008.
- There was an 80 percent jump from 1997 to 2003 in the number of Medicare beneficiaries with HIV.
- The majority of Medicare beneficiaries with HIV/AIDS qualify through Social Security Disability Insurance (SSDI).
- Medicare beneficiaries are more likely to be male, under age 65, disabled, African American, and living in urban areas.
- There is a 5-month waiting period for SSDI benefits.
- There is a 24-month waiting period for an SSDI beneficiary to get on Medicare.

Medicare Part D

Ms. Hanen noted that a number of dual-eligibles were moved from Medicaid to Medicare Part D to receive the Part D prescription drug benefit. Slide 11 shows the standard Part D benefit in 2009 and when the coverage gap or “doughnut hole” occurs, in which some nonsubsidized individuals pay 100 percent of their prescription drug needs out-of-pocket. Slide 12 explains that:

- The majority of HIV-positive Medicare Part D beneficiaries are dual-eligibles.
- All Part D plans must cover all ARVs in all formulations, and prior authorization is not allowed.
- Plans have complete control over tier placement of drugs.
- Many State AIDS Drug Assistance Programs (ADAPs) provide wrap-around services to Medicare-eligible clients, paying premiums and copays and covering expenses once in the doughnut hole.
- In addition, ADAP expenses don’t count toward true out-of-pocket (TrOOP).

- ADAPs cover only drugs on their formulary.

Ms. Hanen emphasized that if a person with HIV/AIDS goes into the doughnut hole through Part D, his or her AIDS medications "may be covered" but "not necessarily" other medications, such as for heart disease or diabetes. Ms. Hanen also noted that "we no longer have" enhanced plans to cover the doughnut hole. Some regular plans do cover it, but "only for generics."

Disability Standard

On Slide 13, Ms. Hanen noted some of the differences between Medicaid and Medicare overall and for persons living with HIV, emphasizing that "both programs have the same cruel disability standard" for HIV-positive individuals. That is, "you have to get sick and disabled to get access to the health care services that could have prevented you from getting sick in the first place."

Disability Health Care System

In short, as noted on Slide 14, "we have a disability care system, not a health care system." Specifically:

- The two primary publicly funded health care programs in the United States don't provide care that meets the USG's own HIV treatment guidelines.
- To get access to almost three-fourths of the pie chart (of publicly funded health care programs), you have to get sick and disabled in order to get the care and medications that could have kept you healthy.
- This is the primary barrier.

Ryan White Program

Ms. Hanen emphasized that the Ryan White program (Slide 15):

- Serves more than 500,000 people.
- Is the only health program for nondisabled people with HIV.
- Is not funded to keep up with need.
- Cannot, as an annual, discretionary-funded program, meet all the health care needs of persons living with HIV/AIDS (PLWHA).

Moving Forward

Ms. Weddle proceeded to outline specific recommendations for improving access to health care for PLWHA as adapted for the most part from the HIV Health Care Access Working Group's 2009 "Principles and Platform."

Ms. Weddle explained that the recommendations she will outline do not represent "an exhaustive list" but, rather, those recommendations considered "most viable and that could make a big difference."

Start with Federal Programs

Showing Slide 17, Ms. Weddle said an important improvement would be to eliminate Medicare's 2-year waiting period for health care, which, she added, is being discussed on Capitol Hill. Another option, put forward by Sen. Max Baucus (D-MT), is to offer younger populations (aged 55-64, for example) an option to "buy in" to Medicare. Ms. Hanen commented that this option makes sense from a continuum-of-care perspective and also because it is harder for this age range to get coverage.

Make Medicare Part D Work for People with HIV/AIDS

Important improvements could be made to Part D, Ms. Weddle said, including (Slide 18):

- Elimination of cost-sharing barriers—
    - Allow ADAP to count as TrOOP
    - Modify specialty tier status
    - Impose a cap on cost-sharing
- Continuation of formulary protections for drug classes critical to vulnerable populations
- Elimination or reduction of burdensome prior authorization requirements
- Subsidization of a mandatory enhanced Medicare Part D option to offer comprehensive coverage for generic and brand-name drugs with no coverage gap.

Ms. Weddle emphasized that cost-sharing is a "real barrier" for PLWHA who don't quality for the low-income allowance; therefore, it is important to allow ADAP to count as TrOOP. She also noted that plans have a great deal of "latitude" on where they place drugs in the tiers. Many ARVs appear on a high or specialty tier, which means that "co-pays can be as high as 33 percent." In addition, if an ARV appears in a specialty tier, "beneficiaries don't have the right to challenge that." Also important is "generally imposing a cap on cost-sharing."

Ms. Weddle continued to explicate improvements to Part D for PLWHA, stating that the Centers for Medicare & Medicaid Services (CMS) "was wise to protect ARVs" in formularies, and "we hope the protections continue." She added that "we need to look at the latitude given to plans to apply prior authorization to medications," given that "we've heard that some" doctors "have to be completely devoted to getting medications for their patients" before such medications can actually be accessed. Last, "we want a federally subsidized mandatory enhanced Part D option."

Medicaid

Turning to Medicaid (Slide 19), Ms. Weddle noted the following recommendations:

- Eliminate categorical eligibility for Medicaid, e.g., expand eligibility to all low-income persons regardless of disability status.
- Increase income eligibility for Medicaid up to 200 percent of the Federal poverty level (around $22,000 per year).
- Enact an Early Treatment for HIV Act to offer enhanced Federal support and ensure adequate eligibility and coverage for PLWHA.

Explicating, Ms. Weddle said these recommendations are designed in part to recognize and address Medicaid's "great geographical disparities." Medicaid is "an important program for many with HIV in large part because of its beneficiary protections," yet, at present, there is a range in what States can choose to cover. Redefining low-income is important, too, because "right now in order to qualify, one has to be below the poverty level." Last, the Early Treatment for HIV Act is much needed and "something we've been advocating for years."

Meaningful Coverage

Turning to Slide 20, Ms. Weddle said meaningful coverage is "key." She said one of her "fears" is that health care reform will result in fewer services to more people. Meanwhile, "HIV is a good benchmark for everyone" because a system that meets the needs of those with HIV/AIDS will "meet the needs of anyone in the United States." Specifically:

- Comprehensive benefits are critical to retain "people with AIDS" in care, support adherence, and treat comorbid conditions.
- Treatment costs are 2.6 times higher per year at later stages of HIV disease (largely due to increased patient hospitalization and also to treatment of co-morbid conditions).

Ms. Weddle emphasized the importance of comprehensive benefits for everyone because, in addition to "being beneficial for the individual, such benefits are more cost-effective for the health care system overall."

Promote Earlier Diagnosis and Access to HIV Care

Recommendations in this area (Slide 21) include:

- Require coverage for voluntary, routine HIV testing in standard preventive services packages for private insurers.
- Incorporate prevention benefit into Medicaid, and mandate coverage for routine HIV testing.
- Cover voluntary, routine HIV testing under Medicare.

Ms. Weddle noted that the first recommendation is grounded in CDC recommendations on routine HIV testing and that “we are working hard to get it added” to standard preventive services packages, not only as offered by private insurers but also by Medicare and Medicaid. Ms. Weddle noted that a week and a half ago, Medicare began to take “an important first step” toward covering testing—for high-risk populations. The U.S. Preventive Services Task Force has been “a little slower” to upgrade HIV testing, “but we’re hoping it will catch up soon.”

Opportunity To Prevent Comorbidities

Turning to Slide 22, Ms. Weddle noted the following:

- At least 25 percent of PLWHA have hepatitis C, and 10 percent have hepatitis B.
- The recommendation that prevention benefit for PLWHA should cover
    - Hepatitis A and B vaccination
    - Hepatitis C screening (and, Ms. Weddle added, treatment).

Build on What Works: Ryan White HIV Clinics and Programs

Turning to Slide 23, Ms. Weddle commented that our current health care system does not address disparities very well; however, “the good news is Ryan White,” which has “helped us develop coordinated, comprehensive HIV care programs” in the form of medical homes. The medical home concept is being “looked at closely in Congress as a model” for a reformed health care system, Ms. Weddle said, adding that “it will be important to develop reimbursement systems to adequately support and improve access to such programs” and for the HIV medical homes concept to be used as a model that “raises the bar for other chronic conditions.”

In short, Ms. Weddle emphasized the desirability for health care reform of a “patient-centered model that takes into account the whole person and is also cost-effective.”

Challenges

Ms. Weddle then noted a slide of graphics (Slide 24) meant to illustrate the many challenges people with HIV/AIDS face as well as others in the health care system. These challenges are what have driven her association and other organizations to advocate comprehensive care programs. She pointed out in particular the issue “we’re all dealing with—aging” as well as “stigma.”

What Makes Ryan White Programs Work

Showing Slide 25, Ms. Weddle went on to note key factors that make comprehensive care programs under Ryan White work:

- Flexible funding
- Multidisciplinary care teams, including experienced HIV medical providers
- Provision of (or coordination of access to) comprehensive medical and social services (to make sure the whole person is treated)
- Culturally competent and dedicated staff.

Recruitment of Primary Care Providers

Medical Workforce Crisis

Ms. Weddle turned to the subject of how difficult it is for Ryan White Part C programs to recruit primary care providers by showing bar graph results from a recent (summer 2008) survey (Slide 26). She emphasized that nearly all of the 252 Ryan White Part C grantees responding to the survey “are having a difficult time recruiting all primary care staff, particularly physicians.” Chief barriers include reimbursement “and a general lack of qualified HIV providers.”

Expanding on the HIV medical workforce crisis (Slide 27), Ms. Weddle emphasized that it is “critical as we move forward that HIV medical workforce issues are incorporated into larger primary care workforce initiatives.” In addition, loan forgiveness should be offered to health care workers in Ryan White-funded clinics. Also needed is a federally supported study to assess regional variations in need and to identify barriers. Last but not least, reimbursement systems are needed that support primary and specialized primary care, such as for HIV. Ms Weddle emphasized that “this is really about supporting the programs, many of which have been operating at a loss,” adding that she knows of two programs recently evicted from their locations.

Improve Private Insurance Access

Ms. Weddle noted that she has focused a great deal on Federal programs, in part because so many HIV patients rely on them, “but much of what has been said so far applies to improved access to private insurance.” Recommendations here include (Slide 28):

- Access that ensures coverage regardless of health status; that eliminates pre-existing conditions exclusions; and that ensures coverage portability.
- Affordability that limits the cost of premiums and caps total out-of-pocket spending.
- Coverage that includes comprehensive benefits packages.

Expanding on the subject of private insurance access, Ms. Weddle noted a Kaiser Family Foundation study conducted many years ago that found that individuals with HIV were denied coverage by all the private insurers they contacted. Therefore, a public insurance plan option, similar to Medicare, should also be available, in part due to experiences with Part D, which “hasn’t worked so well for those who need access to medicine, are less well off, and are sick.”

Conclusion

Ms. Hanen and Ms. Weddle ended their presentation with a contact slide noting that Ms. Hanen is Co-Chair of the HIV Health Care Access Working Group.

Question-and-Answer Period

Testing Reimbursement

Sharon Valenti asked whether Ms. Weddle’s reference to Medicare, testing reimbursement, and high-risk populations was to high-risk prevalence or high-risk groups. Ms. Weddle responded that she was addressing high-risk groups. Under the Medicare law passed last summer, she added, testing reimbursement is possible for more populations than just those who are at high risk but only if the U.S. Preventive Services Task Force gives additional populations testing a grade B or higher, which has not yet happened due to “stringent data requirements.” Ms. Weddle noted that many organizations support broadening reimbursement for testing.

Ms. Valenti commented that, given that HIV infection is a chronic condition and HIV an infectious disease, “it amazes me that funding for HIV programs is not more of a priority.”

Using HIV as a Benchmark

Freda M. Bush asked about using HIV as a benchmark of the unmet health care needs in the United States. Obstetrician/gynecologists have always used infant mortality as a benchmark, "and those numbers are going up." In short, how can the two indicators "work in tandem"?

Ms. Weddle responded that the point is a good one. When speaking to scientists and physicians, she should remember to point out that use of an actual data measure is desirable. However, "when we say use HIV as a benchmark, we mean that any sort of benefits package that is developed is likely to meet the needs of anyone in the United States if it meets the needs of those with HIV."

Workforce Issues

Dr. Bush noted that she sits on the Federation of State Medical Boards, which is interested in workforce issues, and "one thing we've tossed around has to do with incentivizing physicians to go into underserved areas by forgiving loans." Ms. Weddle agreed that this is "a good suggestion."

Corrections Settings

Dr. Temesgen commented that so many of the topics under discussion, such as prevalence, are "amplified in corrections settings." He then asked how such settings are being addressed in health care reform. Ms. Hanen responded that there is a "huge need" to address HIV/AIDS in corrections, but she hasn't seen it addressed yet in the broader health care reform discussion. From an HIV public health perspective, she added, how "we take corrections on" depends on "who owns the setting." Reform discussions so far in Congress do not really deal with corrections except for transition out from corrections settings, she said. That "is not to say there hasn't been legislation addressing testing and treatment in settings as well as condoms and education, but we haven't seen corrections in the main health care debate" so far. Meanwhile, however, Ms. Hanen advocated keeping corrections "on the front burner."

Recruitment

Dr. Walsh commented that he hasn't seen many advertisements for HIV physicians. In short, "need isn't reflected in recruitment" from what he has seen. He suggested that family medicine would be a good place to provide funding or loans. He added that "it will be critical" for HIV-infected individuals to be able to buy in to Government-provided insurance and to make sure those who work "can get health insurance, period," especially for this population and “for the reasons stated.” He also commented that using HIV as a model makes sense because “you can track outcomes…including delay of AIDS and comorbid conditions.”

Corrections

Dr. Walsh then advocated addressing the corrections system. He noted that California is pursuing testing before and after incarceration, but feedback so far indicates that “the corrections system doesn’t want the burden of caring for those who are positive while they are still in corrections settings, which has implications for when they come out.”

Fellowships for Primary Care Physicians

Dr. Maxwell noted a presentation to PACHA “about a year ago” that involved offering fellowships to primary care physicians geared at intensive HIV care and also placing these physicians in clinics.

Case Management Funding

Mr. Mattes asked for specific thoughts on funding case management in the interests of better care. Ms. Weddle responded that case managers “play a critical role behind the medical home model,” which is “one reason we want to see more individuals with HIV/AIDS have access to Ryan White-funded clinics.” Case management can be covered under Medicaid, she added, particularly for targeted populations, and “many States have said they think this is important to do for HIV.” Ms. Hanen commented that case management is “really critical” for those who are coinfected, and there is evidence that “case management makes a difference where it is available.”

Unemployment Impact

Mr. Kaufman commented that with rising unemployment, “we’re seeing choices made between food and medicine.” When individuals give up medicine that is necessary for their lives, “there is an immediate impact that needs to be looked at.” Ms. Hanen responded that examination of State ADAPs indicates a “doubling of the number of people knocking on the ADAP door from this time last year,” and she suspects unemployment is the reason.

Health Care Reform and Ryan White

Mr. Schmid asked what both sides of the aisle are saying will happen to Ryan White “once we make sure we all have health care,” adding “how can we ensure that new programs providing health care to those who don’t have it ensure that people living with HV/AIDS have the specialty care and support services that Ryan White provides right now?”

Ms. Hanen responded that Ryan White “is a critical program,” and “it is important that it continue” because “it is the program that undergirds all the other important safety net programs, and the need for it has not gone away.” Ms. Weddle responded that having access to medical homes, which is “what is needed to treat HIV…makes a world of difference to an individual.” But it is “also a way to provide comprehensive, high-quality care at a reasonable cost. That is why our gold standard is to have everyone in that kind of program, and, if not, Ryan White would be around to fill the gaps.”

Mr. Schmid commented that “maybe if programs like this are set up, Ryan White can fill the gaps.”

Workforce Issues and HIV Provider Education

Dr. Urbina commented that consistency is lacking across the country in education of HIV providers. Importantly, he said, the American Board of Internal Medicine “was looking to establish a subspecialty for HIV.” However, Dr. Urbina said that the model of HIV “will have to shift a bit, as the disease has become a chronic disease.” As an indication of how management of HIV infection will have to shift as patients age, Dr. Urbina noted that he has a 90-year-old patient “who is doing well with medication, but he has heart failure, cancer, and diabetes.”

Need for Focus

Mr. Bates suggested that the Council “not just get lost in the weeds here” but, rather, engage in a conversation about “integration of all these services and collapsing all these programs to provide a comprehensive system.” We “need to have a conversation of what needs to be addressed in the currently segmented system,” such as “more efficiency and more accountability.” We also need “to challenge the availability of services in States that don’t have fluid and aggressive resources for a normal standard of care that brings everyone into a comprehensive setting that looks at them as a whole person.”

If health care is reformed, Mr. Bates continued, “we need to reform it in such a way that we have normative availability and we don’t have to worry whether or not they have as good health care in Mississippi and New York.” The goal should be “the same outcome everywhere, so people can be integrated back into our society and maybe contribute to our tax base, too.”

Conclusion

Dr. Maxwell thanked everyone for bringing forth ideas that PACHA "can consider," then asked members to break for lunch.

Lunch

AFTERNOON SESSION

Admiral Galson Unable To Join Meeting

Welcoming everyone back from lunch, Dr. Maxwell congratulated PACHA Committee Manager Melvin Joppy on the quality of the food and reminded members that Admiral Galson would not be meeting with the Council at this point as previously scheduled.

Public Comment Period

Dr. Maxwell called for the public comment period to begin and noted that each speaker has 3 minutes.

James Sykes, M.P.H., Director, Global Programs, Policy, and Advocacy, The AIDS Institute:

Mr. Sykes said he was glad to see new faces on the Council as well as old friends, as he appreciates PACHA's input and insights. Reading from a prepared statement, Mr. Sykes then asked PACHA to remember the U.S. commitment to the millions of people alive today because of the American people's benevolence. He provided background on PEPFAR, noting that when it began in 2003, approximately 55,000 people in developing countries were receiving ART. Today, more than 2.1 million are receiving ART. Therefore, he asked PACHA to urge President Obama to fulfill the promise to "fully fund" our foreign assistance programs, specifically PEPFAR, and "to urge the United States to pay its fair share of The Global Fund."

Mr. Sykes noted that the 110th Congress reauthorized PEPFAR at the level of $48 billion. Yet "many of the countries who have benefited from this very successful program have already started to turn away many people in dire need of lifesaving treatment and care because of uncertainty about the future of the program." HIV/AIDS, TB, and malaria "are global scourges that claim more than 6 million lives every year," he said, adding that PEPFAR and The Global Fund "are vital resources needed to slow the carnage these scourges wreak in the developing world."

In conclusion, Mr. Sykes said the Institute is requesting “full funding for PEPFAR and $2.7 billion for The Global Fund to fight HIV/AIDS, TB, and malaria.” He noted that today is “World TB Day” and that while TB is curable, it is “now the leading cause of death for people living with HIV/AIDS in the developing world.”

Jessica Ladd, Public Policy Associate, The AIDS Institute:

Reading from a statement regarding ADAPs and “the ways in which they can be improved,” Ms. Ladd noted that the Institute and AIDS Action recently released a policy review of how ADAP ensures access to HIV/AIDS drugs for PLWHA in the United States and where the system “is headed in the future.” The review reflects input from many sources, including PLWHA across the country, and recommends 25 policy options to improve ADAPs’ effectiveness, including full funding.

Ms. Ladd said that 45 percent of people in need of medications are not receiving them. In addition, ADAP patients “have trouble accessing medical and support care.” Given the current fiscal crisis, “this situation will only worsen if we don’t take steps to address these problems.” Noting increasing health care costs, diagnosis of new infections, and loss of health insurance due to job loss, Ms. Ladd said a “$270 million increase in Federal funds will be needed next year” if ADAP “is to keep pace with the growing demand.”

The Institute and AIDS Action report lays out both Federal and State policy options, which Ms. Ladd outlined. She concluded by expressing the hope that these options will be taken into account by policymakers as they consider budgets and appropriation measures, draft the National AIDS Strategy, and craft health care reform legislation. She noted that the entire report is available at http://www.theaidsinstitute.org/downloads/ADAPReportMarch2009TheAIDSInstitute.pdf.

Jennifer Heitel Yakush, Assistant Director for Public Policy, Sexuality Information and Education Council of the United States (SIECUS):

Reading from a prepared statement regarding abstinence-only-until-marriage programs and sex education, Ms. Yakush noted that President Obama entered the White House “with a strong record of support for restoring the basic principle that Government decisions should be based on ‘the best available, scientifically valid evidence’ and not on…ideological predispositions.” Therefore, SIECUS feels that “this is the year we need to see an end to the Federal Government’s failed abstinence-only-until-marriage program.” Ms. Yakush maintained that since 1998, “Federal policymakers have allocated more than $1.3 billion…for… [such] programs, despite overwhelming evidence that this…has failed completely to achieve its stated goals.”

Ms. Yakush said that such programs have long been criticized, and Federal support of them should end, “but that is only one side of the coin.” President Obama has expressed, she said, “strong support for what he calls ‘common sense approaches’ to preventing

HIV, namely comprehensive sex education that teaches both abstinence and safer sex methods," including as recently as this past World AIDS Day.

Ms. Yakush noted that as a U.S. Senator, President Obama cosponsored a Federal comprehensive sex education bill entitled the Responsible Education about Life (REAL) Act, which "would fund comprehensive, evidence-based, and age-appropriate sex education programs." Now, she added, is the time "to invest in programs that will work for us and, in fact, evidence shows that a more comprehensive approach even does a better job of helping young people be abstinent and delay sex than do abstinence-only-until-marriage programs."

Concluding, Ms. Yakush said that given CDC's recently released report on HIV incidence in the United States, including among youth, "it is time to reinvigorate the fight against HIV/AIDS in the United States." She said SIECUS "stands ready to work with PACHA and any of its members…to ensure that young people are getting the information they need to make healthy and responsible decisions over the course of their lives."

Ariana Childs Graham, International Director, SIECUS:

Reading from a prepared statement, Ms. Graham addressed the need for "prevention to return to PEPFAR." Ms. Graham said SIECUS is committed "to restoring integrity" to PEPFAR's prevention portfolio, adding that "now is the time to put into place the lessons we have learned during PEPFAR's first phase about which prevention interventions are effective and which are not."

Noting that SIECUS has been monitoring PEPFAR program implementation for some time, Ms. Graham made the following recommendations:

- Increase transparency of PEPFAR prevention funds.
- Enact appropriate oversight mechanisms of PEPFAR prevention grantees.
- Rescind the anti-prostitution loyalty oath requirements and eliminate the refusal clause.
- Improve integration of reproductive health and HIV/AIDS-related services.

Ms. Graham noted that SIECUS had conducted on-the-ground research in Vietnam and Zambia. Some of SIECUS' "troubling" findings, to be published in a report next month, include:

- A continuing "disproportionate emphasis" on the abstinence-until-marriage approach to HIV prevention, "which does not include any information about condoms, puberty, or broader issues regarding sexuality and emotional development."
- Despite "the astounding prevalence of HIV among women engaged in commercial sex work," there remains "not enough emphasis on meeting the needs of this population." While the anti-prostitution loyalty oath requirement "does not prohibit outreach to this population, we heard many accounts on the

> ground about its chilling effect. Unfortunately, there is not sufficient evidence being gathered to fully understand the impact of" this pledge.

Concluding, Ms. Graham said that "prevention efforts must be elevated to a priority status within the PEPFAR framework and must be in sync with the particular needs of the epidemic in each country."

Sable K. Nelson, AIDS Alliance for Children, Youth, and Families:

Speaking from prepared remarks, Ms. Nelson addressed the need for PACHA to support "reauthorization or extension of the Ryan White HIV/AIDS Treatment Modernization Act in 2009" and to stress "the importance of Part D in providing care and support services to low-income women, children, youth, and families affected by HIV."

Ms. Nelson noted that the Alliance represents more than 650 community-based programs, the majority of which receive funds through Part D. Part D grantees serve more than 53,000 HIV-affected women, children, youth, and families through sites located across the country and in Puerto Rico and the U.S. Virgin Islands. Ms. Nelson emphasized that Part D focuses on family and that "it is well documented that when the entire family unit is the client, the health of each infected and affected family member improves," which, she added, Dr. Alexander "stressed this morning."

This family-centered approach is unique to Part D of the Ryan White Act, Ms. Nelson noted. In addition, through efforts to reduce mother-to-child transmissions, "Part D provides a critical and essential link between care and prevention." Moreover, without the provision of necessary support services, "many HIV-positive women and youth would be unable to tap into the care continuum."

Concluding, Ms. Nelson said that expanded testing "has led to more people needing to be linked to the care and support services that Part D provides and that are not covered by private or public insurance." Therefore, continued support of Part D services is "critical" to prevent a "downward spiral." Meanwhile, the Alliance urges PACHA "to support the Early Treatment for HIV Act as part of a National HIV/AIDS Strategy" because "access to medical care and effective treatment will limit the number of people whose health status progresses to full-blown AIDS and minimize health care costs."

Last, Ms. Nelson offered the Alliance's assistance in PACHA's discussions of a National HIV/AIDS Strategy.

Public Comment Period Conclusion

Dr. Maxwell announced the conclusion of the public comment period.

PACHA Members Open Discussion

Dr. Maxwell asked for open discussion to begin with comments by Subcommittee Chairs and synopses of recent Subcommittee meetings.

Domestic Subcommittee

Domestic Subcommittee Chair Mr. Schmid noted that the Domestic Subcommittee meets by phone every month and in person 1 month prior to each full Council meeting.

The Subcommittee's last meeting focused on three areas: prevention, a National AIDS Strategy, and reauthorization of Ryan White.

Prevention

Richard Wolitski, Ph.D., Acting Director, Divisions of HIV and AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, CDC, addressed prevention during the last Domestic Subcommittee meeting by reviewing data on the current U.S. epidemic and also what the CDC would like to do in prevention, if it had the resources. Dr. Wolitski also provided some "startling projected numbers" on what the epidemic "will look like" if resources aren't provided for prevention.

National AIDS Strategy

At its last meeting, the Domestic Subcommittee also heard from Chris Collins, who is a consultant with the Coalition for a National AIDS Strategy and who also "wrote the first book on the need for such a strategy." Mr. Collins briefed the Subcommittee on the Coalition, which is advocating such a strategy. As a result of the Subcommittee's interest and Mr. Collins' presentation, the Subcommittee will advance a National AIDS Strategy resolution to the full Council tomorrow for its consideration. Mr. Schmid noted that PACHA has already gone on record in support of a National AIDS Strategy, but in this new proposed resolution, the Subcommittee congratulates President Obama for coming out on this since his election and offers PACHA's expertise to help craft such a strategy.

Ryan White

Douglas H. Morgan, who is Director of the Division of Service Systems of the HIV/AIDS Bureau (HAB) at HRSA, also addressed the Domestic Subcommittee at its last meeting. Mr. Morgan outlined some of HRSA's studies and analysis of implementation and impacts of the last Ryan White reauthorization. Mr. Morgan also discussed "some of the challenges HRSA and States and cities are facing," focusing on unobligated balances as "hard to implement," as "about one-half of the States and one-half of the cities will be returning money because of new requirements.” As a result of the Subcommittee’s interest in extension of Ryan White and Mr. Morgan’s comments, the Subcommittee will be advancing a Ryan White resolution to the full Council for its consideration tomorrow. The resolution supports a 3-year extension of Ryan White and recommends some proposed modifications to the Act’s current provisions.

Mr. Schmid added that he will have further comments later.

Discussion

Joseph Grogan asked Mr. Schmid to elaborate on the group working on a National AIDS Strategy and how Mr. Collins fits in. Mr. Schmid responded that the Coalition mentioned previously is composed of “community folks” from all over the country. They have a Web site and a steering committee. However, ultimately, a National AIDS Strategy is up to President Obama, and he has come out in support of a strategy. Mr. Schmid observed that perhaps PACHA will learn more from Mr. Crowley tomorrow. The bottom line is that Mr. Collins’ group advanced the need for such a strategy and mapped out an outline, but it is up to the Administration “to do the job,” as the strategy would be a Federal Government strategy. Mr. Schmid noted that under the proposed resolution for the full Council’s consideration, PACHA would be “advancing that we’d like to part of that effort.”

International Subcommittee

International Subcommittee Chair Dr. Redfield noted that, like the Domestic Subcommittee, the International Subcommittee has monthly calls and face-to-face meetings the month before full Council meetings. In the International Subcommittee’s most recent face-to-face meeting, the focus was on two different areas that feed into the issue of sustainability of global health efforts, which “we all believe the United States needs to take a leadership role in” from the perspective of becoming more involved in global health diplomacy, particularly as it relates to chronic disease.

One sustainability challenge, Dr. Redfield said, is to understand how to keep the pharmaceutical industry engaged and involved, particularly from the perspective that “the medicines optimal today are not those that will be optimal tomorrow.” In addition, there may be “broader indications of the need for medications,” such as, as malaria and TB evolve, the need for a “chemoprophylactic role.”

Therefore, in its last meeting, the International Subcommittee “had a fairly rigorous discussion which took advantage of the fact that” Mr. Gilmartin, Mr. Mattes, and John C. Martin are or have been part of the pharmaceutical industry.

Dr. Redfield then asked if Mr. Gilmartin, Mr. Mattes, or Dr. Martin would like to comment on the discussion or the issues at hand, adding that he is particularly concerned about different standards of care here and abroad, even though “that is not the current intent of the United States.” To keep that from happening, however, “we have to keep the pharmaceutical industry engaged.”

Emotional Commitment and Innovation Model

Responding, Mr. Gilmartin noted that he, Mr. Mattes, and Dr. Martin had shared with the International Subcommittee “the high level of emotional commitment our companies have” and provided examples over the years of that commitment, which, Mr. Gilmartin said, “will continue.”

Mr. Gilmartin also noted that during the meeting, he and his colleagues described the unique innovation model in the United States for developing pharmaceuticals. It is a model in which NIH funding goes out to universities to develop new knowledge and then there is interplay in further development between venture capital, universities, and “big pharma.”

Intellectual Property

Mr. Gilmartin commented that it is important to industry “to have an efficient and transparent regulatory system.” Intellectual property, too, is “very important as a powerful incentive for continued investment.” When it comes to trade issues, he described an approach that “has been worked out” to balance the principles of “intellectual property as an important incentive” and access; that is, “not to let intellectual property be a barrier to access, particularly in national emergency.” As a result, “many countries that have not had respect for intellectual property in the past are moving forward.”

Differential Pricing

Mr. Gilmartin continued that in terms of the U.S. pharmaceutical industry’s being able to participate globally, the economic principle of differential pricing is important to understand. That is, “when you have high fixed costs and low variable costs, you maximize social good and performance by the companies by pricing differentially across the world.” This policy “is followed by most companies,” as well as engagement in licensing and access programs in partnership with local governments.

In sum, Mr. Gilmartin concluded that he, Mr. Mattes, and Dr. Martin had “highlighted what is important to understand in terms of context for continued innovation.”

Discussion

Mr. Kaufman asked what the impact will be of mergers in the pharmaceutical industry and cutbacks in research functions. Specifically, can the domestic and international impact be minimized? Mr. Gilmartin responded that in the mid-1990s, some companies thought sale was important to innovation and research. But “that experiment has been run, and it was not very successful because it disrupts research cultures.” In addition, “not all acquisitions and mergers are the same.” Mr. Gilmartin added that, as someone who doesn’t view mergers “particularly favorably,” he has to look at them circumspectly. However, there are ways to “make them work, particularly if they preserve the research cultures of the organization.”

PACHA Message To Send?

Mr. Kaufman asked if there is a message PACHA can send on the importance of continued pharmaceutical research. Mr. Gilmartin responded, “perhaps, particularly in HIV/AIDS research.” At the same time that the industry faces some “pretty powerful disincentives, the only thing that makes a company successful is its research capability.” He added that, in the industry, “we’ve moved away from size to science as most important.”

Dr. Martin noted that at one time, there were relatively few biotechnological companies. But now, “there’s a lot of competition, and a lot of drugs that come out of companies that didn’t exist before.” For example, if there was no Gilead, “there would be no tenofovir.” However, at present, he knows of a number of companies “on the verge of failure because venture capital is not available,” which has led him to be “very concerned that innovation will go down and worried about jobs for those who are trained.” He added that he hopes “as we address all health care issues as a Nation, we don’t throw away the United States’ unique capacity for innovation.”

PACHA Presentation on Innovation?

Mr. Schmid commented that the role of innovation is both a global and a domestic issue. In terms then of what Dr. Redfield said, “What can we do as PACHA?” Noting that he is unsure when health care reform will happen, Mr. Schmid nonetheless suggested that PACHA have a presentation on this important issue, perhaps in October, because it is a “heated and controversial issue” that needs to be informed by others’ points of view so that the Council “can make an informed decision in terms of a recommendation to the Secretary and the President.”

Dr. Redfield responded that Mr. Schmid had made a good comment. He added that the analogy he will continue to use is that of ensuring a vibrant and healthy weapons capacity; that is, having medicine that can provide health and healing as part of something “as fundamental as global health diplomacy” is equally important. There is, however, a lot of work to be done on the issue of the transition.

Dr. Redfield continued that, in terms of sustainability and capability, “we need to maintain strong support” for global programs, adding that this subject was just addressed in public comments by The AIDS Institute.

International Subcommittee Presentation

Dr. Redfield noted that at its last meeting, the International Subcommittee heard a presentation given by Shellie Berlin Bressler, a professional staff person with the Senate Foreign Relations Committee, on the play-by-play and importance of the last PEPFAR reauthorization. One reason the Subcommittee wanted to hear from Ms. Bressler is that “if we are going to send messages… it is not too soon to be thinking about PEPFAR reauthorization.” Dr. Redfield characterized Ms. Bressler’s presentation as “an enlightening opportunity for all of us to get a better understanding of the process,” including in terms of Ryan White sunset, extension, or reauthorization coming up quite soon.

Comments

Transmission and Needles Program

Mr. Kaufman said that he would like to bring forth two topics, one of which was discussed recently, and the other “not discussed at all for 8 years.” The first is the issue of opt-in and opt-out testing. He noted that PACHA has heard recently about responsible behavior by those who have tested positive, adding, however, that CDC statistics on further transmission provided during the Domestic Subcommittee meeting “were incredible.” Therefore, “we need to pursue that issue again,” because “receptivity is out there.” The other topic is needles, whether exchange or just delivery. Mr. Kaufman said that “we ought to stop hiding from this discussion.” Needle exchange or delivery “should be on the table, because silence on that issue doesn’t serve the cause we’re all interested in.”

National AIDS Strategy and Prevention

Dr. Walsh commented that “when all these issues come together, they speak to the need for a really strong National AIDS Strategy so that there is a balance in terms of big pharma, whether you like it or not.” He added that “many wouldn’t be alive if big pharma didn’t exist.” Dr. Walsh went on to note public comments heard today and wondered if PACHA has reached the point when it should be discussing changes in prevention strategy so that “it is balanced and as evidence-based as possible,” possibly as part of a comprehensive National AIDS Strategy.

Dr. Redfield responded that he believes there’s an opportunity for PACHA to address the National AIDS Strategy, adding that he hopes it will be a strategy “without artificial boundaries between domestic and international concerns.” At present, he “hears that the current thrust is mostly domestic,” although harmonization and a truly national approach is “critical,” and he hopes for that in the debate going forward.

Cost Pressures

Mr. Grogan noted that Mr. Schmid mentioned earlier the real cost pressures being felt in Massachusetts in the aftermath of that State’s health care debate and how that points to the need “not to lose site of the fact that there are real costs associated with health care reform.” The Part D doughnut hole, for example, “represents about $50 billion per year alone.” In short, “we have to be creative and realistic about cost pressures and recognize, as Carl said, that as we try to cover more people, there will be serious pressures to limit the options.” Mr. Grogan concluded that “as we move forward and begin to think about recommendations, I hope that we don’t come up with recommendations that will not be seriously considered.”

NIH Use of Stimulus Money

Mr. Schmid noted that he brought up the economic stimulus package earlier and that NIH “is getting $10 billion.” Therefore, he thinks that PACHA should “say something about where that money goes,” possibly “speaking out about innovation and vaccine research” as well as a “wellness fund that’s going to prevention,” although he believes that “none of it is going to HIV right now.” Mr. Schmid noted that PACHA has “talked about behavioral research,” and “we ought to talk about that money.”

District of Columbia Epidemic

Mr. Schmid noted the fact of new surveillance data on the epidemic in the District of Columbia, which PACHA “needs to discuss.” Mr. Schmid said that he hopes this will be discussed at the Domestic Subcommittee’s meeting tomorrow. He noted that, in the past, PACHA had a meeting at Howard University to focus on this epidemic.

Health Care Reform and Its Impact on HIV

PACHA should also continue to discuss health care reform and its impact on HIV, Mr. Schmid concluded.

Health Care Financing

Dr. Redfield said he would find it useful for someone, perhaps from The AIDS Institute, to help PACHA look “at the current hydraulics of health care financing for people who are engaged in that” but who “aren’t currently working with us in terms of impacting this epidemic.” That is, at present, “in order to get access to publicly funded programs,” there is an “enormous disincentive for individuals to take care of their health.” Health care financing, he added “will drive the ability for us to have a health strategy, just as Joe said. But we can’t have health care financing that works against us.” Therefore, “it’s time for those who are most astute to somehow put together something that looks at current health care financing in different programs in HIV and whether or not it is aligned or not aligned with our ability to respond to this epidemic, because I’m struck by how out of line we are.” Dr. Redfield mentioned PACHA’s 5-year plan and the International Subcommittee’s PEPFAR white paper as models for what PACHA could put together on health care financing and alignment.

National AIDS Strategy and PACHA Recommendations

Dr. Bush asked what PACHA is doing to “weigh in with recommendations” on a National AIDS Strategy, adding that “we ought to weigh in some way.” She too noted PACHA’s 5-year plan with the goal of an HIV-free generation, which, she said, “may be idealistic but is doable.” At least, she believes it is doable, as she knows that “an ounce of prevention is worth a pound of cure.”

Dr. Bush recalled Dr. Urbina’s earlier statements about how individuals who know they are HIV-positive behave differently, and also a past Domestic Subcommittee presentation on HIV/AIDS education and youth, during which panelists “really hammered on the need for research on behavior modification.” Therefore, it is important as we move forward with a national strategy for PACHA to “push prevention and behavior modification, whether we’re talking about youth or adults.” She urged PACHA “not to get hung up on ideology” but, rather, to focus on “how we do research to help us get to the place we want to be.” In short, “the science is still lacking on comprehensive sex education,” but what is most important is “what we can do that saves lives.”

Mr. Schmid responded that “we’re waiting for the Administration to set up a process for a National AIDS Strategy, then we will speak.” He advocated not getting ahead of the Administration and noted that the Domestic Subcommittee’s resolution for full Council consideration tomorrow “reiterates certain points and asks for PACHA to be involved.” Mr. Schmid noted that “we haven’t gotten to the point of what we want,” adding that’s “for the future.”

Resilience

Dr. Walsh commented that something “we’re getting at” in this discussion is the issue of resilience, including the strength of the virus and social resilience. He noted that after he spoke at a recent HIV conference, an individual approached him to tell him about how he is positive and “approached by men who want to sleep with me all the time because they want to get the virus.” Dr. Walsh noted some documentation that “this is a phenomenon,” but it makes the point that “all of these strategies we talk about won’t make a difference if the individual doesn’t value himself in the first place and doesn’t have resilience.” It’s not as if “people don’t know this is high risk.” Rather, the question is “why you do it even when it is high risk.” Therefore, “some part of this strategy should tie into that.”

Dr. Walsh added that “we in Government and academia need to say to these people that we care about their lives.” There needs to be an investment “in concern and in care in verbalizing that and showing it on the ground level.” Dr. Walsh said that this kind of action “will turn the tide.”

Dr. Walsh also commented that “if you help big pharma save money, they’ll help you save money.” So, he asked, “How do we partner with institutions to drive costs down so that we can treat more people?”

No Time To Wait

Mr. Bates said PACHA “has no time to wait.” Even though The White House and HHS “have not given any specific instructions, the end goal is to come up with the plan.” PACHA “needs to acknowledge that the plan has to be comprehensive,” Mr. Bates said, and, therefore, “there are myriad issues we need to address.”

Mr. Bates said he appreciated Dr. Redfield’s comments about a report that will contribute to understanding “about where we are in our epidemic.” The United States “has never had all the parts in place on how we’ll represent ourselves in that report,” and, in fact, “many other countries” don’t do such reports. However, such reports are part of the mandate PEPFAR “puts on receiver countries.” Meanwhile, “we’re kind of limping along.”

Mr. Bates further commented that members’ conversation over the last few minutes “illustrates that the United States is not removed from but rather is part of the global picture.” Whatever “happens outside this country will be reflected inside this country.”

Mr. Bates noted that CDC has already begun to look at social determinants of health, adding that “we can’t move forward with a comprehensive plan until we consider all of these other factors, such as education and mental health” This will take time and research, he said. That means, he predicted, that “it will take a year, perhaps even a year and a half, to have a plan with all the elements and milestones.” However, “it won’t happen without our starting our dialogue today.”

Challenge for PACHA Co-Chairs and Subcommittee Chairs

Mr. Bates concluded that “the next challenge” for PACHA Co-Chairs and Subcommittee Chairs “is setting up some pattern of discussion so it can feed into the plan once devised by The White House and, I hope, HHS.” In short, Mr. Bates said that he is “looking for this body to be squarely involved in this conversation. This is not about being passive, waiting for instructions. It’s about exercising leadership to which you have been assigned.”

Valuable Comments

Mr. Kaufman noted that PACHA is his third Federal advisory committee, and experience has taught him that “events pass you by when you meet twice a year.” Therefore, Mr. Bates’ comments “are valuable.”

Don’t Eliminate Any Possible Approach

Rev. Lusk noted that he was once a sports professional and “when we played against our nemesis team, we threw everything at them.” Similarly, “when talking about this disease, you can’t eliminate any possible approach.” Rev. Lusk added that he represents the church community, and “it will be concerned about abstinence because we have local evidence that the abstinence message has hit some important milestones.” He believes that this is “not about the science of abstinence or sex education” but, rather, “it’s about kicking the ball and passing the ball.” The discussion is about “the African American population,” he emphasized, “so we don’t want to alienate the church by throwing away half its messages.”

Public Health Emergency

Dr. Urbina said that the latest District of Columbia statistics indicate a “public health emergency” that requires a public health campaign. “If Nike and Coca Cola do it, we should be able to commandeer those services,” he added.

Bottom Line

Ms. Wise observed that the “bottom line is that we want to do something to stop this.” She noted that she has been speaking with young people across the country for 6 years, stressing abstinence, and “after I’m done, they get tested. They want to find a cure. They want to take action.” She advocated looking at things “that don’t cost a lot of money.” For example, looking “at why some choose abstinence would be cost-effective.” In addition, “the churches want to get involved as well as other organizations that are not federally funded.”

Ms. Wise agreed that “we need a national plan,” adding that she hasn’t seen the science yet that supports consistent condom use, but “I want to see it.” Most of all, “when I talk to young people, I want to tell them the truth.”

Stigma

Following up on Dr. Urbina’s statement, Ms. Valenti said one problem continues to be stigma, which “is what prevents individuals from coming forward.” It has been noted that many American cities now “mirror the epidemic in Africa in terms of prevalence,” so, indeed, “this is a public health crisis” and there is “no reason it shouldn’t be on the front pages of the newspaper.” In short, Ms. Valenti said, “if you’re going to spend time and money, you have to spend time and money on that.” In the meantime, “people will have to get over their problems with the fact of sex, needles, and so on,” because “we have a national and social obligation to get this out into the news.”

Disease and Funding Competition

Reinvent the HIV/AIDS Conversation

New PACHA Charter

Mr. Bates observed that HIV/AIDS “is not the only disease facing the United States,” which means “we’re in competition with all the other advocacy organizations and their diseases and their place in the public health world.” In addition, “we are moving rapidly toward limited funding.” Therefore, “we have to reinvent the conversation about HIV/AIDS because, whether we like it or not, there’s an exhaustion point.” Mr. Bates added that “we have missed opportunities to take advantage” of events involving celebrities and pop culture, for example, when “people like Britney Spears get married, divorced, get yet another boy friend,” meaning that “we didn’t use that to have a national conversation about sex, behavior, and responsibility and also about the virtues of abstinence.”

Mr. Bates continued by noting that “we live in a country of 350 million people, and we’re not going to be on the same page.” Therefore, as a health agency, “we have a responsibility to be out there with the most diverse, responsible approaches possible. We’ve got to open up the spectrum, and it will be the responsibility of this body and a few others and Government to open up this conversation—a diverse, comprehensive, national conversation about where we are with sexuality and behavior and our response.”

Mr. Bates observed that 5 years ago, he would not have been able to talk about HIV/AIDS before a church congregation and use the word “penis.” Now “I can put pictures of penises and vaginas on the wall.” The point is that “we are moving, and I don’t want to miss the opportunity to continue this movement.” Mr. Bates added that “I think we have it in this President and this Administration, but we have to commit ourselves to talk and send a message back to the Administration that we’re willing to take on this responsibility.” We “just have to start doing it.”

Mr. Bates concluded by saying “there will be a new charter for this body. It will be opened up and not just reporting to the Secretary but to the President and the American people.” PACHA “has the power.” Now “have the determination and move the conversation.”

OGAC Director and Letter to Secretary Clinton

Dr. Redfield noted that he failed to mention earlier the International Subcommittee’s concerns about the fact that the OGAC Director position is still vacant. He also noted that the Subcommittee wrote a congratulatory letter to Secretary of State Clinton “in the context of that, strongly recommending and encouraging the filling of this position in light of the fact that its counterpart domestic position has been filled.”

Mr. Bates noted that he “moved the letter” without great encouragement from legal counsel and that “it should go out by the end of the week.”

Other International Subcommittee Items

Dr. Temesgen noted that the International Subcommittee also discussed the lag in development of pediatric formulations and evaluation of PEPFAR programs.

Significant Charge

Dr. Maxwell asked for other comments and, hearing none, said PACHA had been given “a significant charge by our new leader.” She added that members are pleased Mr. Bates is “in this position with us” and thanked him for “energizing and motivating us to do all the things and work this body does need to do.”

Adjournment

Dr. Maxwell adjourned the meeting at 2:53 p.m.

Day Two

MORNING SESSION

Call to Order and Welcome

PACHA Co-Chair Mr. Gilmartin called the meeting to order shortly before 9 a.m. He characterized yesterday's session as excellent and involving an impressive series of presentations. He noted that today's agenda is equally important, with a lot of ground to cover, so he promptly introduced Jeffrey S. Crowley from The White House to say a few words.

Remarks of Jeffrey S. Crowley, M.P.H., Director, Office of National AIDS Policy, The White House

Mr. Crowley said it was a pleasure to be meeting with PACHA in this, his fourth week on the job. He has been meeting with many people.

Mr. Crowley provided information about his background: He has been working for 15 years in AIDS, nearly half that time at Georgetown University's Health Policy Institute; before that, he was with the National Association of People with AIDS (NAPWA). In short, he has "been around for a while."

Now, Mr. Crowley is "thrilled" to be in his new job at The White House where, in addition to serving as the Office of National AIDS Policy (ONAP) Director, he works on disability policy as well. Mr. Crowley noted that his Office is within the Domestic Policy Council and that he reports to Council Director Melody Barnes, which is a "good thing because it helps integrate our work into the broader portfolio."

Domestic Epidemic Focus

Mr. Crowley noted that his Office's responsibilities are 85 percent domestic policy and about 15 percent international policy. He does care about and is committed to the international piece, in part because 20 years ago, he served in the Peace Corps in Swaziland. Mr. Crowley stressed that his primary role is "to focus on the domestic epidemic."

PACHA

Mr. Crowley noted that when he started this job, he was asked a lot of questions, which included what the President plans “to do with PACHA.” His answer is, “We don’t know.” The “way I see it,” he added, is that when you look at the resources in AIDS, “we have a lot—PACHA, Mr. Bates’ Office, and the HRSA Advisory Committee,” for example, and “other groups don’t have that.” We, he added, “want a clear plan on how all these pieces fit together and are taking a fresh look at everything.”

Charge from the President

Mr. Crowley said that his charge from the President “is clearly to develop a National AIDS Strategy.” President Obama “said that during and after the campaign” there is a need “to focus on getting people into care, on incidence, and on reducing disparities.”

President Obama “wants inclusive, transparent” efforts “involving all Federal agencies,” Mr. Crowley continued, adding that “he expects us to reach broadly to the country, not just typical stakeholders.”

Mr. Crowley’s Questions

Some of Mr. Crowley’s questions include “how do we engage Federal agencies and State and local governments?” He added that “it is easy to imagine meetings, but what is the best structure to fully engage” these entities? What he is “looking at is to ask tough questions and look for some answers” because “we’re not necessarily doing everything right.” We want, he said, “to reevaluate and focus efforts.”

Mr. Crowley said he also is “trying to figure out, if the goal is to develop a strategy,” what it should look like. He added that “we don’t want to come up with 200 points or action plans to monitor.” Rather, “we’re looking at a few top issues and key goals, but it is still not clear.” Internationally, his Office has “been talking with PEPFAR about global strategies and country plans.” Here, at HHS, Mr. Crowley noted that “we have Healthy People 2010.”

Mr. Crowley asked if PACHA “has any thoughts on how to structure this,” because “we need a clear sense of goals.”

Process for Going Forward Possibly Shortly?

Thinking about “how to develop the strategy” over 6 weeks ago, Mr. Crowley thought that “we need to do initial consultation broadly.” He noted that “we have legal questions that we are still figuring out." In coming weeks, he added, "we hope to announce initial thinking" at a "very appropriate time," while Congress is appropriating funding for development of a National AIDS Strategy. In short, "over the next few weeks, I hope we will announce a process for going forward."

Mr. Crowley stressed that "we want to do things right, even if it takes us longer." He noted that as a new White House employee, "how you move all these processes takes time." He noted that not only he but "all my colleagues are brand new." Nonetheless, "we are trying to move quickly."

Other Key Priorities

In addition to a National AIDS Strategy, Mr. Crowley said he wanted to "signal other key priorities" for his Office, and "one is prevention." We "have this window of opportunity to make some changes and focus our prevention efforts and do more," he added. He noted that PACHA members "might have seen that the President's top-line budget signaled focus on prevention and also health care reform." Mr. Crowley also noted that, given his background, "the fact that I was selected, if that signaled anything, is that the President is interested in integrating HIV into the broader reform debate." This "is a huge opportunity," Mr. Crowley said, noting that The White House is working for the Early Treatment for HIV Act and predicting that "we can do 100 times more through reform." If "everything we're talking about" goes through, "we could do a lot of good things to get people into care," which is "an appropriate focus." He added that PACHA members may have heard that the former CMS Administrator is now White House Director of Health Reform.

Ryan White Reauthorization

Concluding, Mr. Crowley said that he has been hearing a great deal about Ryan White reauthorization and that there "seems to be a clear consensus that we need to be careful about that request this year and about what we can do." The White House has heard from many "inside and outside groups." Now "we want to see how to make key decisions and move forward clearly." It would be "helpful to figure out a game plan and move expeditiously, as we want to avoid a late August fear that we haven't addressed the sunset."

Question-and-Answer Period

Domestic Subcommittee Resolutions

Mr. Schmid congratulated Mr. Crowley on his appointment, then noted that as Chair of PACHA's Domestic Subcommittee, he had two draft resolutions to bring to Mr. Crowley's attention, which the full Council will be considering later this afternoon. Mr.

Schmid briefly characterized the two resolutions, and Mr. Crowley expressed interest particularly in a previous PACHA resolution addressing the need for a domestic AIDS strategy. Mr. Schmid said he would send that resolution to Mr. Crowley and also expressed the hope that Mr. Crowley would receive the final version of the two new resolutions as or if they are adopted by the full Council.

PACHA Support

Dr. Martin thanked Mr. Crowley for taking his current position, noting that “it will be difficult work.” Dr. Martin said he was “gratified” by Mr. Crowley’s statement about looking at all the resources available to him and encouraged Mr. Crowley to look at all those resources for the opportunity for viewpoints and consensus, as “there is far more agreement among stakeholders than disagreement.” Meanwhile, Dr. Martin said, “you have our support,” adding that “we have a lot of different viewpoints on this body and anyone here is willing to work with you on that.”

Conclusion

Mr. Gilmartin then thanked Mr. Crowley, extended his congratulations and best wishes, and noted that PACHA “looks forward to working with you.”

Ryan White CARE Act

Mr. Gilmartin introduced William D. McColl to give the next presentation, noting that Mr. McColl has been an advocate on behalf of criminal justice reform, alcohol and other drug treatment and reform issues, and the HIV/AIDS community for nearly 15 years.

The HIV/AIDS Community and Next Steps for the Ryan White CARE Act

Presentation by William D. McColl, Esq. Co-Chair, Ryan White Working Group and Political Director, AIDS Action

Mr. McColl began by noting that he is here today primarily in his capacity as Co-Chair of the Ryan White Working Group, for which Ms. Hanen serves as Acting Co-Chair.

Community Activities

Using a PowerPoint slide presentation, Mr. McColl said he would outline community activities around the Ryan White CARE Act in terms of:

- Background and process
- Division of issues

- A consensus document
- Next steps.

Choice of Issues To Work on (Slide 3)

Mr. McColl noted that the Ryan White Working Group considered 100 issues and has chosen “a number to work on.” The Group has come to consensus on the need for a 3-year extension of the current Ryan White Act and is working toward consensus on a number of other issues through a document that Mr. McColl has provided to members. So far, the document has 151 signatories, a number Mr. McColl said he hopes “will increase.”

Mr. McColl noted that the Group is one of the original Working Groups of the Federal AIDS Policy Partnership.

Background and Process (Slide 4)

Mr. McColl noted that the last reauthorization contains a sunset or repeal provision effective as of September 30, 2009. This is “obviously troubling to us,” as the CARE Act “has been a real backbone of the AIDS community in addressing treatment and care.”

Mr. McColl detailed how the last reauthorization process was “difficult,” in that compromises were reached “very late” both politically and in terms of the community. Many organizations “were locked into position statements early on,” so what was lacking was an “overall community process.” Therefore, for the next reauthorization, “we worked to change that,” in part because we heard from HRSA and others that “it would be helpful to create a process where we came together.”

After the last reauthorization, Mr. McColl said that “we spent a lot of time working on implementation issues,” principally:

- The switch to HIV/AIDS name-based data
- “Very problematic” late grants for the Minority AIDS Initiative (MAI)
- The “continued” issue of housing
- Carry-over funding issues, such as the requirement to apply for waivers “before the grant period was over.”

As a community, Mr. McColl added, “we’ve worked out a lot of those issues,” and people are “feeling more stable now.”

Question

Dr. Redfield asked by way of background about the reason for the sunset clause. Mr. McColl responded that the sunset clause "was an effort to require not just the community but Congress itself to come back and deal with some of the questions they wanted answered, and to the best of its ability, the community has tried to do that."

Community Process Begins (Slide 5)

As a community, "we worked out a lot of the issues just described," Mr. McColl reiterated. He noted that the community process really took hold when about 40 major national and local AIDS service organizations came together on September 10, 2008, and began to sort out implementation issues, case by case and into baskets (see also "Ryan White Working Group Consensus Process" document).

Issues that are crossed off in the document, Mr. McColl noted, indicate issues that were "in one basket and usually moved" to another (such as Eligible Metropolitan Area [EMA] "hold harmless" under the "Legislative Fixes" basket).

Division of Issues (Slide 6)

Mr. McColl said it is important to understand the baskets in which various issues were placed. For example, there are "legislative or technical fixes" needed immediately, before extension, such as "ADAP rebate dollars." Here, "the basic issue is that HRSA has ruled these are program dollars that need to be spent prior to other dollars, which creates a problem with the new unobligated funding requirements," which "we believe" Congress is willing to change.

Then there are regulatory fixes, "the main one being the 2-year housing rule, which has largely been resolved," Mr. McColl said, as well as "working with means testing of programs, which will probably resolve itself."

However, "some things can't be taken care of through the CARE Act" as last reauthorized, Mr. McColl said, and these are issues to address in the extension itself or issues that will wait for full reauthorization in 2012. Issues or discussions about such matters as a National AIDS Strategy and health care reform "have been sent to other working groups and committees."

Consensus Document (Slides 7 and 8)

Mr. McColl explained that the final consensus document lists six specific extension requests and four technical fixes.

The request for extension for 3 years addresses:

- Incomplete changes from the current reauthorizations—
    - Funding distribution formulas changed from estimated living AIDS cases to actual living HIV and AIDS cases
    - Client Level Data system
    - Testing of the Severity of Need (SON) Index
- Ensuring continuity during health care reform
- Impact of health care reform and creation of a National AIDS Strategy on the CARE Act as a gap filler.

Mr. McColl stopped to explain that, while the consensus document was unanimous, a "few minority viewpoints have been added in," which he will highlight. However, "mostly people are signed on to the whole document."

Mr. McColl then explained the reasoning behind seeking an extension rather than full reauthorization. First, he said, "we don't have the data from the last reauthorization that would allow us a complete picture of what further changes we need." In fact, CDC says that it will not have mature name-based data systems until 2012. But other things need testing, such as the Client Level Data system and SON.

Mr. McColl also noted that the CARE Act is a gap filler, in that it is "where you go when you have no other program to turn to," as PACHA heard yesterday, particularly "if you have HIV but are not disabled." Yet, as the Government makes changes to major programs, such as Medicare and Medicaid, in part to expand coverage, "we don't necessarily know where the gaps will appear, so we wanted to preserve the stability of what some believe will be needed even after reform." In addition, "we felt the Strategy would have a negative effect in the way funding is distributed."

Overall, the underlying philosophy, Mr. McColl explained, was that once "we decided on an extension, we could decide what to really work on." He added that "we were hearing from congressional allies and some others that the easiest way to make extension work for us was not to make huge changes." This would have the effect of preserving the underlying system, which would give us "the stability we were seeking for 3 years."

Authorization Levels (Slide 9)

Mr. McColl moved on to authorization levels and "what can be addressed." The consensus document:

- Notes that current authorization for each of the 3 fiscal years is for a 3.7 percent annual increase for Parts A, B, and C, and 0 percent increases for Parts D and F.
- Calls for authorization at "such sums as necessary" for each fiscal year 2010 through 2012.

Mr. McColl commented that “we have to deal with authorization levels that have been very difficult for the community,” as “this may be a sticking point for Congress.”

Protection for States with Maturing HIV Data (Slide 10)

Mr. McColl noted that a number of States “don’t have mature data, which potentially puts them at severe disadvantage.” The Working Group thus recommends that such States be allowed to submit HIV data to HRSA but incur a 5 percent penalty until their State reporting systems are deemed accurate and reliable by the Secretary.

Extension of Transitional Grant Area Eligibility (Slide 11)

Mr. McColl noted two tiers of Part A jurisdictions—EMAs and Transitional Grant Areas (TGAs)—and that six current TGAs are “in jeopardy of losing eligibility in FY 2010.” Therefore, the consensus document recommends that TGAs “retain their status and continue to receive Ryan White funding” through a “resetting of the clock.”

Extension of Hold Harmless Provisions (Slides 12 and 13)

Mr. McColl noted that extension of hold harmless provisions “has been difficult for the HIV community to discuss because it is difficult to address.” The current Act states that “there should be” a 5 percent drop in funding for hold harmless Part A EMAs and Part B formula grants to States in the first year and a 0 percent drop in the next 2 years.

Here, the consensus document reflects community concerns that formulas will continue to fluctuate as new name-based HIV reporting systems mature, with potential for destabilization, so “again we suggest resetting the clock” by simply adjusting the dates on the current legislation, Mr. McColl explained. He noted that the minority view is reflected in Slide 13.

Allow Provision of Food (Slide 14)

Mr. McColl noted that 13 services were included as core medical services for Parts B and C and that “many issues popped up on this, four of which were important.” First, the Working Group felt it was important to move a number of services back into the core medical grouping but “felt most strongly about food prescribed by a physician,” which provoked a minority view from physicians organizations as reflected in Slide 14.

Alter the Definition of Medical Transportation (Slide 15)

Altering the definition of medical transportation to allow it as a core medical service "was also a major community issue," Mr. McColl said. Initially, the Working Group "thought to take this proposal out as a contentious issue for Congress, but there was so much pushback that we had to retain it."

Consensus, although a minority viewpoint is reflected on Slide 15, was to remove the word "medical" from "medical transportation" in support services and include "medical transportation" in core medical services.

Mr. McColl noted there was substantial discussion on this issue and that he'd be happy to come back to it.

ADAP Rebate Dollars (Slide 16)

Mr. McColl noted the following in terms of implementation of the current reauthorization and the consensus document's proposal:

- Rebate model ADAPs have been instructed to spend rebate dollars before using their Federal ADAP grant award, leading to potential loss of funding.
- Proposal: Rebate funds associated with ADAP should be made exempt from "program income rules."

Unobligated Funds (Slide 17)

Mr. McColl noted the following:

- Parts A and B grantees are ineligible for supplemental awards if more than 2 percent of their award is unobligated after the grant year.
- Community concern includes undue burden on grantees (such as hiring freezes, spending caps, and so on).
- Consensus document proposal: Strike or suspend the Act's "Corresponding Reduction in Future Grant" section, and change the exception from 2 to 5 percent.
- Minority view: Expand unobligated balances up to 5 percent and strike jurisdictions' ineligibility for future supplemental funding.

Mr. McColl said that the Working Group had "real concerns about the first bullet, as a number of States had serious trouble meeting" this provision. In striking or suspending the Act's "corresponding reduction" section, "we are proposing suspending all penalties."

Part D Medical Expenses (Slide 18)

Mr. McColl noted the following:

- Part D grantees were instructed by HRSA to include medical expenses in their program budgets despite exemption from core medical services set-aside.
- Consensus document proposal: Add language to ensure funds are not required to be used for primary care when other payers are available for such care.

Mr. McColl noted that HRSA's instructions were a "real mismatch" with congressional intent. The document's proposal is intended to fix that, especially since Part D clients are primarily women and children, "who are usually covered under Medicaid."

Client Level Data and SON (Slide 19)

Mr. McColl noted the following:

- Development of both Client Level Data (CLD) and SON was allowed under the current Act but without implementation. CLD began testing on January 1, 2009, running parallel with the current HRSA data systems, and SON has been developed but not tested.
- The consensus document proposes to maintain the current system and allow ongoing testing.

In short, Mr. McColl explained, "we want to see CLD and SON move forward and be tested, but we don't want implementation until we have data."

Next Steps (Slide 20)

The next steps in Ryan White CARE Act extension are meeting with Administration officials and Members of Congress and staff, and continuing the effort to maintain community support.

Mr. McColl stressed that "we would like to move an extension quickly and continue outreach into the community."

Conclusion

Concluding, Mr. McColl said that "it's important for us to be able to brief you" and that he "looks forward to coming back and reporting that we managed to extend the Act."

Question-and-Answer Period

SON Index

Mr. Gilmartin asked about the SON formula. Mr. McColl responded that 19 variables have been defined by HRSA and are available in every jurisdiction; these include poverty, the death index, and HIV rates. HRSA "has done of nice job of explaining SON on its Web site," he added. He will provide the URL to Mr. Bates for distribution.

Mr. McColl went on to say that the formula is very interesting and "has some strengths." Concerns in the community include use of death rates and, if more funding is realized, "more funding's flowing to those places, rewarding a jurisdiction for not doing a particularly good job. This needs to be teased out."

Mr. Schmid noted that HRSA's HIV/AIDS Bureau recently presented on SON to the Domestic Subcommittee, and that PACHA has also congratulated the Bureau in a resolution for working on the SON. Mr. Schmid will get a copy of relevant documents to Dr. Urbina, as requested.

Mr. McColl responded that it is "not clear how SON will be applied in the care category and not clear it will work better than the current grant-writing system." What "we want to see is testing and understanding of its impact."

Gap Filler

Dr. Redfield said he is an advocate of Ryan White but has two questions: (1) Is the Act what we really want it to be? and (2) If we want to preserve its integrity as a "greater model for health reform," do we want it as a gap filler?

Mr. McColl said one should probably say Ryan White is a payer of last resort rather than a gap filler. His concern about Ryan White is that "if our health care system is a very bumpy road, then the CARE Act is the gravel you fill potholes with when care is not available." At present, the Act "has gone beyond the health care system with the concept that a number of things are medical issues that aren't in some ways understood in the traditional system." He pointed out that the Act is an outgrowth of HIV activism in the 1980s and recognition of the need to have stable housing, for example. In short, "it is a model for the way health care should look at other diseases," because, for example, someone who has renal failure or cancer "will do better if they have stable housing."

Mr. McColl added that AIDS Action has created a document that addresses lessons of the epidemic and the CARE Act for health care reform. He is sending it to the Office of AIDS Policy and will send it to PACHA as well. He added that "we want to see a lot of the philosophy of the CARE Act extended into health care as much as possible."

Mr. McColl added that some of the CARE Act services are provided by traditional services. Medicaid has home health care, for example. But the CARE Act is nonetheless “a helpful model, particularly for chronic disease.”

Dr. Redfield noted that his institution provides care for about 5,000 patients in Baltimore City, and those he is able to provide the most effective care to are “in the CARE Act.” Therefore, he would “just as soon not see the Act get absorbed into a lower capacity of care comparable to what one has now through health maintenance organizations, which are more complicated than the CARE Act.”

Mr. McColl responded that “the community is fully in support of a strong, flexible Ryan White CARE Act and is trying to stabilize it.”

Dr. Redfield said an enormous opportunity exists to educate people “in a broader sense” about the Act as a “public sector model of care.” Mr. McColl responded that that is “part of the charge of the Ryan White Working Group,” adding that “we work closely with the Access Working Group in trying to develop a paper on how Ryan White works and provides a model” because “it does need to be brought out in this environment.”

Core Medical and Support Services Percentage Split

Noting the debate during the last reauthorization around the 75/25 percent split between core medical and support services, Mr. Bates asked if many waiver requests were sent to HRSA for exceptions so that “communities could fit their needs.” Mr. McColl noted that there were a few waivers, perhaps two. Ms. Hanen added that that “had a lot to do with the waiver process itself.” Mr. McColl elaborated that no waiver process existed for a period of 6 months, which was “after people had to submit grant requests.” In short, “there was a mismatch between what they were being required to do and their ability to ask for a waiver,” as a result of which “everyone adjusted their funding.” That is why “we continue to hear complaints about food and transportation,” among other issues, he said, adding that “we might have tried for a stronger position on core medical services if we were pursuing reauthorization and not extension.”

Moving Resources to the Current Epidemic

Dr. Redfield asked about the “thinking behind the challenges of moving resources to where the epidemic is today.” For example, “we’ve been getting better at having good intelligence.” CDC just reported data for 2007, and “we’re trying to transition but do it in a way so that people are not harmed.” All of “these programs are operating at the edge.” Yet Jacksonville, Orlando, Memphis, and Columbus are “being hit,” and historically “they don’t have resources to respond to that like the big cities.” Therefore, “it is really important that we constantly try not to push for a reallocation of limited resources but recognize that we have an epidemic that is changing from the big major cities and old formulas to smaller cities, especially in the South, and they require a more timely response.”

Mr. McColl agreed, commenting that "this is the third rail of Ryan White politics." In discussion of hold harmless, one of the concerns is "a balance between responding effectively and destabilization." We "might very well design a different system today." If we did this, "it would be absorbed into health care reform." Therefore, "you have to go back to what you've got." In short, his response is that we have "had a very difficult 8 years in appropriations." Many of the issues around hold harmless would "go away with more aggressive appropriations." He added that "there was a miscalculation about the level of funding we'd be able to sustain through this system" and "it is discretionary funding."

In the last reauthorization, Mr. McColl continued, "it was made clear by many organizations that there is an ongoing issue, particularly in the South, developing in the rural areas, which we need to be responding to." And the reauthorization "was responsive." For example, a number of smaller Southern cities "did change status."

Mr. McColl added that he would like to push for a "more aggressive response, but a lot of that would be funding." Meanwhile, the issue of hold harmless "is an ongoing debate, in many ways, in the community." Consensus is as he reported, which "we've decided is in the community's best interest" because "we are trying to tamp down some of those issues while we deal with health care reform." That "could set us up for having this issue re-emerge in a tougher way in 2012, but one of the good things about the process we've built is that we'll be able to continue dealing with that."

People Living with HIV/AIDS: Consumer Survey

Mr. Gilmartin moved to the next topic, introducing Christine Campbell and Larry Bryant by reading their biographies provided in members' packets.

Creating New Ryan White Comprehensive HIV/AIDS Care and Services Legislation: 2009 Report

Presentation by Christine Campbell, M.S.O.D., Vice President, National Advocacy and Organizing House Works, Inc., and Larry Bryant, Director, National Advocacy and Organizing House Works, Inc.

Ms. Campbell began by noting that the process leading up to the 2009 Report, a preliminary copy of which was provided to members (marked "confidential"), began 2 years ago. It was a process that brought the Campaign to End AIDS (C2EA) and the National Association of People with AIDS (NAPWA) together with support from the Gill Foundation to ensure that PLWHA will be part of the discussion on Ryan White reauthorization.

Ms. Campbell noted that she and Mr. Bryant would primarily be discussing “our successes” in this effort, as well as barriers.

Context (Slide 3)

- A request was made by the Senate Health, Education, Labor, and Pensions (HELP) Committee to hear directly from PLWHA about their recommendations for future reauthorization considerations.
- C2EA and NAPWA reached out to their constituents to invite their participation in town halls, both orally and via a written survey.
- C2EA and NAPWA partnered, combining resources, human and financial, to reach more regions throughout the country.
- The resulting report will be formally released during AIDS Watch 2009.

In short, Ms. Campbell explained that “we wanted to provide ground-level, real-time information to the Committee.”

Concurrently with development of the C2EA and NAPWA report, a CARE Coalition report was developed with NAPWA to provide “a broader view of services in general,” Ms. Campbell added. This second report “will also be released in April.”

Goals (Slide 4)

Goals of the C2EA and NAPWA effort were:

- To develop a set of guiding principles that will guide any Ryan White legislation.
- To establish networks of communication with Congress and other policymakers that inform HIV/AIDS treatment and service delivery systems.
- To ensure a sustained, structured role for PLWHA’s receiving services in design of a new or revised Ryan White service delivery system.

Ms. Campbell elaborated that “we wanted to make sure a broad spectrum of HIV-positive people” were involved “going forward.”

Strategy and Method (Slide 5)

- Stakeholder meetings
- Town hall meetings
- Town hall meeting toolkits
- Consumer surveys
- Data analysis
- Guiding principles development

- Strategic Report rollout.

Ms. Campbell elaborated that the first stakeholder meeting was held in 2007 at the "Staying Alive" conference sponsored by NAPWA, where people "talked opening and honestly" about their "horror stories and ways to develop better care at the local level and how that could blossom nationally." No facilitators were present at this meeting; rather, core groups of co-chairs from across the country oversaw the process, including venues. Ms. Campbell noted that Mr. Schmid helped with the process.

Ms. Campbell described stakeholder meetings as "sometimes a little messy and unrehearsed." But "what came out of each scenario," Mr. Bryant added, "were people willing to tell others—more than their own case managers—about" their experiences.

Ms. Campbell then noted that "we went to a number of national organizations and had conversations with them on what processes to engage in to provide feedback to policymakers and legislation writers." It was at this point that "we engaged in a series of town hall meetings at a variety of locations across the country." Ms. Campbell commented that one of the "weakest" areas was the Idaho and Montana area. One reason for this was "leadership." However, "as leadership emerged in each jurisdiction, we provided assistance and toolkits."

Organizational structure for the town hall meetings was to begin with needs, issues, successes, and challenges, Ms. Campbell explained. "The second piece was where we had policy wonks respond to those needs and talk to the audience about policy." The "third part of the meeting was problem solving." That is, if participants could write new legislation, "what would it look like?"

Organizers provided information from the Kaiser Foundation, for example, in English and Spanish. Consumer surveys were also used. Ms. Campbell noted that she reviewed data received prior to the writing of the Strategic Report, as did an independent analyst.

Mr. Bryant added that the town hall meetings helped "break the bonds of stigma." What also happened and continues is that "leadership was developed in smaller and larger groups that provided information to the national process and to local processes as well."

Results: Description of Services (Slide 6)

Turning first to results from the survey and description of services, Ms. Campbell noted that:

- A total of 1,726 individuals were surveyed using a SurveyMonkey© tool.
- 86 percent were receiving medical care, and 28.5 percent were "very happy" with the services they received.
- Over 15 percent received their medical services from a Ryan White-funded program.

- 46 percent were receiving medical case management services, 1l percent from a Ryan White-funded program.
- Slightly over 33 percent of respondents reported that they were receiving mental health services, 6.8 percent from a Ryan White-funded program.
- Slightly over 6 percent of respondents reported issues pertaining to substance, less than 1 percent from a Ryan White-funded program.

Ms. Campbell elaborated that the results reflect “a little over a year of data collection and a lot of outreach to make sure many knew about” the survey. In addition, the survey “was framed in terms of Ryan White services.” Findings included the “surprise” that “many were educated about their services.” In short, “people were more informed than we thought they would be.”

Question

Mr. Kaufman asked about the 28.5 percent who said they were “very happy” with the services they received and asked what would happen if “you combined” happy with very happy responses. Ms. Campbell responded that that level of detail is in the report, but she thinks the answer is that the percentage would come out to be around 40 percent.

Mr. Kaufman responded “that’s troubling because that means the majority was not happy or very happy.” Ms. Campbell responded that qualitative data indicate customer service as a reason and “organizations being overwhelmed and not having a lot of time to spend on customer service.”

Results: Description of Services, Continued (Slide 7)

- Over 22 percent of respondents reported that they were receiving housing services, 6 percent from a Ryan White-funded program.
- 47 percent reported that they were receiving dental services, slightly over 41 percent from a Ryan White-funded program.
- Slightly over 6 percent were receiving early intervention services, 6 percent from a Ryan White-funded program.
- 12 percent were receiving treatment adherence services, with almost 9 percent from a Ryan White-funded program.
- 15 percent were receiving medical nutrition services, with almost 10 percent from a Ryan White-funded service.
- Nearly 4 percent were receiving home health care services, 2.9 percent from a Ryan White-funded program.

Ms. Campbell said that “some of what this tells us is that there tends to be a larger need for some of these services, but few are receiving these services under Ryan White” even though Ryan White “is a key percentage of the larger pie.” However, “we expected the percentages to be small.”

In addition, “we did extensive outreach beyond those who normally came to us because we understand that a lot of folks we surveyed were those with a sense of access and an ability to navigate some kind of system to get to us at all.” Therefore, “that is a challenge in the data.” That is, “we have to take into account that these people had some degree of access.”

Ms. Campbell added that “one of the things we’re seeing for some of these services is that they are supportive, and Ryan White seems to be the primary way for people to get them, such as dental, early intervention, and adherence.” Therefore, when “we look at the 75 to 25 split” between core medical and support services in Ryan White, “we have to look at this.”

Results: Description of Services, Continued (Slide 8)

- Slightly over 56 percent reported that they had no assistance with gaining access to service.
- Nearly 31 percent utilized the services of a medical case manager.
- Over 26 percent used other case management.
- Over 6 percent had friends assist them in accessing services.
- Over 53 percent had to wait 2 weeks or more between when they requested an appointment and when they saw their provider.
- Slightly over 11 percent of those (noted above) “have to wait 3 months.”
- 89 percent were on medications for HIV/AIDS.
- Nearly 84 percent were on antiretroviral therapy.
- Nearly 45 percent of respondents received their medication from ADAP programs.
- Slightly over 32 percent had private insurance.
- Slightly over 24 percent get their medication paid for by Medicaid.
- Over 31 percent get their medication paid for by Medicare Part D.
- Over 32 percent reported having problems getting their medication.

Ms. Campbell noted that the survey “let people answer more than once to access questions.” She highlighted as a challenge waiting times to see a provider, sometimes 3 months.

In terms of ADAP, Ms. Campbell said that survey analysis did not look at whether access was to local or Federal ADAP, so “we need to go back and do that.” She highlighted that those who reported having problems getting medications indicated as reasons lack of availability at their pharmacy or a gap between the end of one prescription and obtaining a new one.

Results: What Consumers Would Change (Slides 9 and 10)

Ms. Campbell then outlined and elaborated on “emerging themes of what consumers would like to see changed in Ryan White,” as follows:

1. Improve the quality of care: Respondents wanted more time with their physicians, better communication with their physicians, and more information about how HIV/AIDS was impacting their overall health. (“We heard over and over again how doctors would talk about HIV but not their diabetes and how these were intertwined. Respondents wanted to be treated as a whole person.”)

2. Decrease waiting time between call to schedule a visit and appointment as well as time spent in the waiting area of the doctor’s office. (“We would hear stories of people waiting 1 to 2 hours even when they had an appointment at clinics. In short, it was a ‘pack a lunch’ day.”)

3. Address the costs of services, unaffordable copays and medications, limited Medicaid eligibility for people with HIV, and not being allowed to take full advantage of Medicare Part D benefits when ADAP cannot be applied toward TrOOP expenses. (“I remember when I learned that ADAP as TrOOP became an issue for me, and how many people there were who were having to deal with this and knew a lot about it. This seems to be a major issue we need to address. This is more the case for the working poor, that is, those with some degree of insurance.”)

4. Establish broader and more aggressive goals around HIV, such as the pursuit of a cure, universal access to health care, and freedom from stigma. (“We need to address specific issues, but as society, we need to address broader issues that could help end the epidemic. There was a feeling of being part of a science project rather than part of ending this thing. Stigma is a big thing, so make treatment of HIV part of standard procedures. When you’re going to any doctor, they should have basic knowledge about HIV/AIDS, so that you are not bounded around.”)

5. Improve customer service. (“Improving customer service was a big issue on multiple levels. There was understanding of staff being overwhelmed, but some felt they were getting the short end of the stick. Short face-to-face time with doctors is a problem as well as breaches of confidence. There was a sense that there was a need for training.”) (Mr. Bryant commented that in terms of 4. and 5., “we are talking about a much larger population than those who responded to the survey, like those who are getting the test for the first time. Stigma paralyzes action. There’s a disconnect between patient and client, positive and negative.”)

6. Increase resources and availability of psychological and mental health services. (“There is a strong push to get people into medical care without necessarily addressing psychological and mental health services. Many had to enter another system to get this and sometimes had to serve as a case manager for themselves.”)

7. Several respondents stated that their health care was great, and there was nothing they would change (18 out of 241 who replied with a qualitative answer or 7.4 percent).

8. Increase psychosocial and mental health support through the availability of support groups, addressing depression and quality psychotherapy.

9. Assistance with prescriptions and pharmaceutical issues, from increasing the number of drugs on the formulary to having to take less medication, looking at natural treatment.

10. Decrease travel time to medical appointments. ("Some reported 2 to 3 hours' travel to get to medical appointments and some planning of overnight stays. How can we provide services more locally?") (Mr. Bryant commented that "because of the travel time in areas such as the rural South and because of lack of opportunity and lack of transportation, the trip isn't made. If you cut out opposition for local AIDS organizations to address this, people will be able to access their medical appointments as well as other services appointments.")

Results: Recommendations for Policymakers (Slide 11)

Mr. Bryant noted the following recommendations:

- Improve access to care (across the board).
- Increase funding for services provided through Ryan White.
- Increase access to Medicare and Medicaid.
- Improve private insurance so that it covers more of the necessary treatment.
- Improve comprehensive access to health care for all.
- PLWHA deserve the right to play an integral role in the development or expansion of any HIV/AIDS service delivery system.

Mr. Bryant commented that when "we go back to the 10 points, if you took HIV out of that, you'd be talking about quality basic health care needs for anyone in the United States with any health issues." In short, "there are barriers to care and disconnects on priority and need for quality health care for everyone in this country." He added that when "you eliminate those flaws, you come closer to ending the epidemic we call HIV/AIDS."

Question-and-Answer Period

Dr. Urbina thanked the presenters. He noted that Ms. Campbell had noted "a bit of a sampling bias, in that these are patients more engaged in care." However, he is also interested in those "less engaged in care." He asked that if over 50 percent report not being assisted with getting into care after diagnosis, and “if we have to push to test, isn’t that a huge hole?”

Ms. Campbell responded that “we acknowledge this to be true, too,” and not just in the District of Columbia, because her organization gets calls “from all over the country.” When her organization answers these calls, “we ask ‘didn’t your doctor tell you anything?’” And “many times,” the answer is “no.”

Mr. Bryant said part of that disconnect is an overworked case manager or outreach workers who do intake, and “people get frustrated.” Noting that he has been HIV-positive for 23 years, Mr. Bryant added that “you’re lucky if you get tested and counseled pre- or post-, and lucky if that same person can connect you with a phone number and not just a pamphlet.”

Who, Mr. Bryant continued, “is going to say that we, as positive people, need to be more desperate to access a system and not take ‘no’ or ‘I don’t know’ as an answer?” We “have to be persistent that followup occurs and treatment for those individuals. And we need to do a better job of how we think about and structure conferences because the person living homeless on a little rock is invisible to the process.”

Helps To Hear from Consumers

Mr. Schmid also thanked the presenters for their report because “it helps guide us to hear from the consumers.” He thought “we’d just hear about Ryan White, but obviously this combines health care reform, Medicare and Medicaid, the uninsured, and Ryan White.” It’s “about how all health care systems can be improved for everyone in this country.”

Not Reflected in the Report?

Mr. Schmid then asked and/or commented about: (1) Whether geographic locations were considered when people filled out the survey, because “it was disturbing to hear wait times for appointments”; and (2) Why a certain subject was not reflected in the report, which is that people want to work, live healthy lives, and be part of society, yet they feel they don’t have that opportunity under some of the public health-financed systems right now.

Ms. Campbell responded that “we can slice the data regionally.” We “can get trends where different answers came from because of the way the data were collected and entered.” In terms of wanting to return to work, “we heard a lot about that, but we didn’t have a specific question on that on the survey.” She commented that that subject “could’ve been reflected better in the narrative, qualitative piece,” but it wasn’t because “we were addressing services directly related to Ryan White.”

Mr. Bryant responded that “it’s scary and crazy but not new that the people most affected by the epidemic are poor people.” He said, “It is horrifying to understand that people have to choose between being positive or living below standards.” Yet, “we have a system set up so that even that option is available.” He added that when he applied for a job several years ago, the response was “why don’t you just rest on Ryan White services?”

Demographic Breakdown of Respondents and Internet Access

Dr. Temesgen asked if a demographic breakdown of respondents by gender, ethnicity, and so on is available and also whether the way respondents replied implies Internet access. Ms. Campbell responded that “we have gender and regional” breakdowns. She added that “this is a trends analysis, not a scientific study,” but when PACHA members get a chance to see the CARE Coalition Report, they will see a more detailed demographic breakout with more of a scientific research base.

Ms. Campbell added that hard copies of the survey were provided, so respondents “didn’t necessarily need Internet access.” However, those desiring to fill out the survey had to ask for those hard copies “or we needed to intersect with them.” In the end, 600-700 paper-copy responses were hand-entered.

Fragmented System for Many

Dr. Walsh thanked the presenters for a very informative presentation, then commented that much of what the results say reflect “pretty much what every patient in America would say,” particularly if the cohort was of cancer or lupus patients. This signals the need “for overhaul of our currently fragmented system.”

Challenges for Physicians

Dr. Walsh added that when information, technology, and protocols for HIV “change as rapidly as they do,” it is “tough” on medical doctors. He noted that the South Beach clinic where he served for some years closed down 4 or 5 years after he left. Part of the problem was keeping doctors “in the loop.” Doctors “often don’t know where the resources are and often don’t have a social worker in their office,” and family doctors, for example, “aren’t getting fellowship training.” Plus, “they don’t feel comfortable” with some patients in part “due to concern about litigation.”

Dr. Walsh said he would love to see what a physician survey would show and also love to see “a control group of noninfected with no disease states” answer as well, “as compared to those with other immunocompromised diseases.”

Mr. Bryant commented that something else to look at is “the doctor’s ability to overcome his own stigma” in a case, for example, “when someone is positive and can’t get treatment for something else.”

Dr. Walsh responded that “a lot of the other things need to be fixed soon,” because “the system allows the doctor to say that.”

Ms. Campbell responded that, as we look at Ryan White and the epidemic, “the scope of this is larger than a public health epidemic.” Social structures “need to be addressed.” That is, “we could reduce rates but still have a raging epidemic.” If “we have a comprehensive HIV/AIDS system, we will have health care reform,” she predicted. “We have to address those larger opportunities. We have an opportunity with such an epidemic to look at the larger system.”

Break

After the break, Mr. Gilmartin introduced Amy Lansky to give a presentation on some more recent data from various surveillance systems. He outlined her credentials and accomplishments from her biography, which was provided in members’ packets.

HIV/AIDS Surveillance Update

Presentation by Amy Lansky, M.P.H., Ph.D., Acting Deputy Director, Surveillance, Epidemiology, and Laboratory Science, Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, CDC, HHS

Overview (Slide 2)

Dr. Lansky said her PowerPoint slide presentation would provide information about:

- CDC data on HIV incidence
- CDC data on HIV/AIDS diagnoses
- CDC’s prevalence estimates
- CDC’s behavioral surveillance
- Implications and looking ahead.

HIV Incidence in the United States (Slide 3)

Dr. Lansky said that new incidence estimates published in August 2009 tell us that the HIV epidemic is, and has been, worse than previously known at 56,300 new infections in 2006, which is 40 percent higher than the prior estimate.

Dr. Lansky said that the new estimates are the result of “a new way of looking at the data.” They are a more “precise and direct estimate.”

Estimated Percentage of New HIV Infections, by Sex, United States, 2008 (Slide 4)

This slide shows that men represent 73 percent of the estimated percentage and women 27 percent.

Estimated Percentage of New HIV Infections, by Race/Ethnicity, 2006 (Slide 5)*

*50 States and District of Columbia

This slide shows that the estimated percentage of new infections breaks down by race/ethnicity as follows: 45 percent African American; 35 percent white; 17 percent Hispanic; 2 percent Asian/Pacific Islander; and 1 percent American Indian/Alaska Native.

Dr. Lansky said she would be emphasizing in the next few slides estimated rates of new HIV infections, because “this is a good way to compare across groups.” She added that the rates “clearly show a disproportionate impact.”

Estimated Rates of New HIV Infections, 2006 (Slide 6)*

*50 States and District of Columbia

This slide shows that African Americans had the highest estimated rate of new HIV infections in 2006 per 100,000 population, followed by Hispanics, American Indian/Alaska Natives, whites, and Asian/Pacific Islanders.

Estimated Percentage of New Infections, by Sex and Race/Ethnicity, United States, 2006 (Slide 7)

Showing this slide, Dr. Lansky commented that “the breakdown is different” here. That is, white men had the highest percentage of new infections among men (41 percent), followed by African American men (40 percent) and Hispanic men (19 percent). Among women, African American women had the highest percentage of new infections (61 percent), followed by white women (23 percent) and Hispanic women (16 percent).

Estimated Percentage of New HIV Infections, by Transmission Category, 2006 (Slide 8)*

*50 States and District of Columbia

Dr. Lansky emphasized that this slide shows that more than half of all new infections in 2006 were among men having sex with men (MSM), followed by heterosexual contact (31 percent).

Estimated Percentage of New Infections by Sex and Transmission Category, United States, 2006 (Slide 9)

This slide shows that among men, MSM had the greatest percentage of new infections in 2006 (72 percent), followed by heterosexual contact (13 percent). Among women, heterosexual contact resulted in the greatest percentage of new infections (80 percent).

Estimated Percentage of New HIV Infections, by Age, 2006 (Slide 10)

Dr. Lansky said this slide shows that "a full third of new infections are among those aged 30-39," but the "biggest impact is among those in the 30-49 age category (56 percent) by proportion of cases."

Estimated Rates of New HIV Infections, by Age, 2006 (Slide 11)*

*50 States and District of Columbia

This slide shows that the estimated rates of new infections by age in 2006 per 100,000 population were as follows: 26.8 percent for ages 13-29; 42.9 percent for ages 30-39; 30.7 percent for ages 40-49; and 6.5 percent for ages 50 and older.

Estimated Number of New HIV Infections in MSM, by Race/Ethnicity and Age Group, United States, 2006 (Slide 12)

Dr. Lansky emphasized that it is "very interesting" to look at these estimates, because they indicate that "we clearly need to be thinking about younger age groups and minority age groups for MSM." We "always have to be thinking about prevention for the next generation," because "if the young are contributing to greater new infections, that's where we have to think about devoting resources."

HIV/AIDS Diagnoses

Overall, Dr. Lansky said, "as we see from these data so far, the most severe impact is on MSM among all races" and also among "African American and Hispanic men and women." However, she added, it is also important to look at diagnoses, which "remain important at the local level and across jurisdictions."

2007 HIV/AIDS Surveillance Report (Slide 14)

Dr. Lansky noted that this report has just been published and is now online at http://www.cdc.gov/hiv.

Estimated Percentages of HIV/AIDS Cases among Adults and Adolescents, by Sex, 2007, 34 States (Slide 15)

This slide shows that men represented 74 percent and women represented 26 percent of the estimated percentages of HIV/AIDS cases in 2007, as noted, based on data from 34 States with confidential name-based HIV infection reporting as of 2003.

Estimated Percentage of HIV/AIDS Cases by Race/Ethnicity, 2007, 34 States (Slide 16)

This slide shows that African Americans represented 51 percent of HIV/AIDS cases, followed by whites (29 percent) and Hispanics/Latinos (18 percent), based on data from 34 States with confidential name-based HIV infection reporting as of 2003.

Estimated Percentages of HIV/AIDS Cases Among Adults and Adolescents, by Transmission Category, 2007, 34 States (Slide 17)

Dr. Lansky noted that one can see that "these diagnosis data look much like the incidence data," with, for example, MSM as the highest percentage transmission category (53 percent), followed by high-risk heterosexual contact (32 percent). Dr. Lansky added that "we will be going forward to monitor both types of data."

Estimated Rates of HIV/AIDS Cases among Adults and Adolescents, by Sex and Race/Ethnicity, 2007, 34 States (Slide 18)

Dr. Lansky called attention to this bar graph in terms of incidence rates per 100,000 population for males and females among various racial and ethnic groups.

Reported AIDS Cases among Adults and Adolescents, by Area of Residence at Diagnosis, 2006 (Slide 19)

Dr. Lansky said she guesses that 2007 data will not be radically different from what is shown on this slide. What the slide shows is "that the vast majority of cases are coming from large, Metropolitan Statistical Areas (MSAs) with over 500,000 population (82 percent). Then 11 percent are coming from "smaller cities" and 7 percent from non-MSA areas. In short, the epidemic remains one of "large cities," although that is "not to say that care and access and care and treatment issues in rural areas are not profound." We "need to consider that," Dr. Lansky added, but also to keep in mind that "HIV/AIDS remains a largely urban epidemic."

Questions

Mr. Schmid asked how the pie chart in Slide 19 corresponds to the general population. Dr. Lansky responded that she "believes there would be a large proportion in the nonmetro areas."

Dr. Temesgen asked to return to the bar graph on Slide 18, adding that he seems to remember that the estimated rate of cases "used to be larger for African American females than for African American males." Dr. Lansky responded that the bar graph shows the rate among African American women and the rate among African American men, and that the rate for women "used to be higher." Mr. Bates added that these comparative rates are "starting to level." That is, "we're not seeing as large an increase from 2006 on, and we are hoping it will continue to move down."

Returning to Slide 19, Dr. Urbina asked if CDC has data on new HIV cases by geographic region. Dr. Lansky responded that she didn't think "that's been done."

Rate of Reported AIDS Cases for Selected MSAs of Residence, 2007 (Slide 20)

Dr. Lansky said that with this slide she was returning to the discussion about cities, principally New York, Fort Lauderdale, Miami, Washington, D.C., and Baton Rouge, which represent the top rates in the Nation for MSAs of residence. Some of these MSAs are really big, she noted, so they are then broken out into divisions, and "in some ways you get more information when you look at divisions, which correlate to cities, such as San Francisco, rather than entire MSAs."

Reported AIDS Case Rates by Region, 2006 (Slide 21)

Dr. Lansky said that one must be careful about this slide, as this type of analysis hasn't been conducted yet with current data. Nonetheless, this slide shows that the South and the Northeast have a high number of cases per 100,000 population, at 19.7 and 21 per 100,000 population, respectively.

Dr. Lansky said that "what we can take away from this" and previous slides, "is that the epidemic remains a problem, with an estimated 56,000 new infections per year, largely among MSM and African American men and women, disproportionately in urban areas."

Rates of Reported AIDS Cases for Selected States of Residence, 2007 (Slide 22)

This slide shows AIDS case rates per 100,000 population for New York (24.9), Maryland (24.8), Florida (21.7), Louisiana (20.5), and Delaware (19.8).

Estimated Numbers of Cases of HIV/AIDS, by Year of Diagnosis, 2004-2007, 34 States (Slide 23)*

(*Note: Data include persons with diagnosis of HIV infection regardless of AIDS status at diagnosis; data from 34 States with confidential, name-based HIV infection reporting since at least 2003; and data have been adjusted for reporting delays.)

Dr. Lansky noted that one of the "new developments looking at 2007 was an increase in the number of diagnoses over the past 4 years," which is 15 percent.

Dr. Lansky then asked, "Why do you think that's the case?"

Questions

Mr. Grogan asked for an explanation of the relationship between the estimates shown on Slide 23 and the estimate of some 56,000 new infections. Dr. Lansky responded that the incidence estimates are new HIV infections and "that estimate is made for the 50 States plus the District of Columbia," whereas Slide 23 is "based on data from 34 States" and therefore is "a little more limited, plus it estimates diagnosis" at 42,655 persons in 2007.

Dr. Martin asked if major metropolitan areas are not addressed in Slide 23, to which Dr. Lansky responded "yes." California, for example, is not represented in these estimates because "it is not one of the 34 States." However, the incidence data "are different."

Dr. Martin commented that the number of cases diagnosed in 2007 in the entire United States is therefore "obviously larger." Dr. Lansky responded that the data in Slide 23 "do not represent all States and the District of Columbia."

Responding to a comment by Mr. Kaufman, Dr. Lansky said that "the difference from the 56,000 new infections rate estimate to the previous estimate is based on a change in methodology in producing these estimates. If we make the estimate in the old way and in the new way, the new way suggests it is higher. That's not an increase. It is higher." Dr. Lansky added that new infections data and diagnosis data are not the same, as the new infections data involve data from all 50 States.

Possible Reasons for Increases in HIV Diagnoses (Slide 24)

Dr. Lansky noted the following as possible reasons for increases in HIV diagnoses:

- Changes in surveillance practices
- Increase in HIV testing
- Increase in new HIV infections
- Estimates for most recent year least stable.

The “bottom line,” Dr. Lansky continued, is that “time will tell which of these has contributed to this increase.” In terms of surveillance practices, “some States have adopted viral load and CD-4 reporting, which might help identify cases not previously reported.” Also, “there may have been an increase in HIV, given the 2006 recommendation for routine screening in health care settings.” It is “important,” she added, to thinking about that “in terms of what we’ve been testing,” as “it is not likely that surveillance systems or types of testing are sensitive enough to pick up this kind of increase in a short time period.” In addition, “it is possible there is an increase in new HIV infections,” which is suggested by trend data on incidence not presented today, particularly “an increasing trend among MSM.”

Dr. Lansky added, however, that the “diagnoses data show increases not only among MSM but also heterosexuals and other racial groups.”

Last, Dr. Lansky addressed how the most recent year of data is always the least stable. Therefore, “we need to keep an eye on this.” If CDC is following trends in incidence data, in about 3 years, “we will have an idea of whether new infections have increased.”

HIV Prevalence Estimates—United States, 2006 (Slide 26)

Dr. Lansky noted that prevalence estimates were updated this past fall “for the first time in several years.” The results indicate that in 2006, 1.1 million people were living with HIV in the United States, including 21 percent undiagnosed infections, down from a previous estimate of 25 percent.

Question

Dr. Redfield asked if the undiagnosed percentages represent a difference of 4 percent. Dr. Lansky responded that she didn’t know offhand.

Estimated HIV Prevalence, United States, 1977 to 2006 (Slide 27)

Dr. Lansky said that “we’ve had some updated methods for 2006 and applied them, so you can see that prevalence continues to increase.”

Question

Responding to a question from Dr. Temesgen, Dr. Lansky said that the estimate in Slide 26 is for the 50 States and the District of Columbia, and that in terms of the estimated 21 percent with undiagnosed infections, “we still need to work on testing and getting them into care and then, for those who know, prevention and treatment services.”

Behavior Surveillance and the National HIV Behavioral Surveillance System (Slide 29)

Moving on to behavioral surveillance, Dr. Lansky noted the National HIV Behavioral Surveillance System (NHBS). The slide notes how the system works, which Dr. Lansky expanded on in explicating the next slide.

Unprotected Anal Sex with Male Partners in the Preceding 12 Months, by Participant Race/Ethnicity, NHBS-MSM, November 2003-April 2005 (N=10,030) (Slide 30)

Dr. Lansky noted that results such as these are based on community-based surveys. The idea of a surveillance system, she added, is working with the same populations over time.

Thus, Slide 30 reports that over the noted time period, the percentage of white MSM who had unprotected sex with “main” male partners was higher (over 60 percent) than for other racial/ethnic groups included in the NHBS report. The same was true for the percentage of white MSM who had unprotected sex with “casual” partners (almost 40 percent). Overall, Dr. Lansky noted, the percentage was 47 percent among all groups included, and the proportion was “generally higher” with main rather than casual partners.

HIV Testing Ever and in the Preceding 12 Months, by Participants’ Race/Ethnicity, NHBS-MSM, November 2003-April 2005 (N=10,030) (Slide 31)

Dr. Lansky noted that “92 percent had ever been tested, which is good news,” and 77 percent in the preceding 12 months. She noted recommendations for testing at least annually, depending on partners and risk.

Prevention Counseling Session in the Preceding 12 Months, by Age in Years, NHBS-MSS, November 2003-April 2005 (N=10,030) (Slide 32)*

*Excludes counseling that is part of HIV testing

Overall, Dr. Lansky noted, 15 percent received individual-level counseling and 8 percent received group-level counseling, for a total of 23 percent. She noted that in terms of age breakdown, "the younger age levels are having more counseling."

HIV Prevalence in MSM in Five Cities—NHBS, 2004-2005; and Proportion with Undiagnosed HIV Infection in MSM in Five Cities—NHBS, 2004-2005 (Slides 33 and 34)

Dr. Lansky noted that overall prevalence in this high-risk category was 25 percent, and the prevalence for African Americans was 46 percent. She noted a total 48 percent of undiagnosed HIV infection in this high-risk category. In short, as shown on Slide 34, "about half overall didn't know they were positive" and, again, the greater percentage of undiagnosed was among African American MSM.

Implications of Higher Incidence Estimates and Increasing Prevalence (Slide 36)

With higher incidence estimates and increasing prevalence, there is a potential increase in diagnoses, so, Dr. Lansky noted, "more people will need HIV treatment and care, and more people living with HIV will need prevention services."

Question

Mr. Kaufman noted that the third bullet that should be on Slide 36 should note also that "more people will need testing." Dr. Lansky agreed.

Implications for MSM (Slide 37)

Implications for MSM:

- Incidence and diagnosis data show that MSM continue to account for a substantial proportion of the epidemic in the United States.
- Behavioral surveillance data show that risk behaviors are prevalent among MSM, and prevention services may not be reaching enough people.

CDC Professional Judgment and Priorities (Slides 38 and 39)

Dr. Lansky noted that CDC was asked by Congress to develop a professional judgment budget. The agency responded by forwarding to Congress its judgment that an additional $877 million is needed in FY 2009 and an additional $4.8 billion over 5 years. Recommended priorities for expenditures are to:

- Increase HIV testing and number of people reached by HIV prevention programs.
- Develop new tools to fight HIV (such as new types of interventions, including biomedical interventions, as well as new testing).
- Improve systems to monitor HIV and related risk behaviors and evaluate prevention programs.

Prevention Works (Slides 40 and 41)

Dr. Lansky stated that:

- HIV testing significantly reduces risk of transmission among people with previously undiagnosed infection.
- Individual and group interventions for people previously diagnosed with HIV significantly reduce risk.
- Individual, group, and community interventions for at-risk persons significantly reduce risk (both for those infected and for “those at high risk”).
- HIV incidence is declining among injection drug users and heterosexuals.
- Mother-to-child transmission has been dramatically reduced, and this dramatic reduction “continues.”
- Fewer people have undiagnosed HIV infection (given a reported decrease from 25 to 21 percent).

Opportunity and Responsibility (Slides 42 and 43)

Ending her presentation on the subject of opportunity and responsibility, Dr. Lansky emphasized the costs of treatment versus prevention and how “preventing 240,000 infections by 2020 could save $40.5 billion in treatment costs.” She said that “we know prevention works when we apply what we’ve learned.” Now “we need to focus on reaching people who need these services,” as underscored by the last presentation.

Dr. Lansky concluded that “we have a tremendous opportunity and responsibility to change the future course of the epidemic.”

Question-and-Answer Period

Reliable Projections?

Mr. Holzworth said he is struck when he sees statistics such as those just presented, given the relative age of the data. He then asked, given challenges and gaps in surveillance capabilities, whether CDC has enough power in the data today to make reliable projections into 2009 and beyond.

Responding, Dr. Lansky noted that the diagnosis data came out of "our longstanding system." She added that the 2007 data she presented were collected all the way through December 31, and that "it then takes time to get the data in from all jurisdictions, clean them up, look for problems, put it all together, and get a report out." She underscored that these data "are being used for really important purposes, so we want to make sure that what we put out is our best effort."

Dr. Lansky then commented that "we have issues because any large data project has issues," but "it's almost like there are different issues each year." For example, when one sees a 15 percent increase in diagnoses, "that stops everything." CDC "has to make sure" and "ask why" and "look at alternative explanations." With regard to incidence data, the system that was used for the 2006 estimates is new. Now "we are planning to publish incidence data every year." In fact, going forward, "we've had discussions about putting out a more detailed report with the incidence data."

Additional Power for Forward Projections?

Mr. Holzworth noted that he consulted with CDC in the 1990s "on these very issues," so he agrees that "you want to make sure the data are good." He then asked if Dr. Lansky feels she now has "additional power for forward projections." Dr. Lansky responded that "where we've been spending the effort is to try to get the new estimates." In short, "we've been focused on going backwards." She added that she "doesn't believe we have specific plans to project out, but that is potentially a possibility." At present, she is "not sure that would be recommended right away with the new incidence system."

CDC Data Timeliness and Transparency

Mr. Grogan commented that CDC has a "difficult job with State reporting systems." He then noted that Mr. Crowley was here earlier in the day and referenced a National AIDS Strategy, "which this Council has called for and President Obama has endorsed." Mr. Grogan noted that Mr. Crowley also referenced Healthy People 2010, which "has clear benchmarks." Last, Mr. Grogan noted that Dr. Lansky had mentioned that serious decisions are based on CDC data, so he "suggests that your Division lead on transparency on methodologies and getting data out there quickly."

Mr. Grogan added that his most recent professional experience has been with the FDA, and that CMS is “under pressure for transparency and benchmarks,” so “it will be a challenge for you personally and CDC to get out there.” He added that the Council will “definitely support you.”

Dr. Lansky responded that “we hope our data will be used in a central part of that process.”

Dr. Martin said that his next comment will parallel Mr. Grogan’s. “You can work forever and do your best,” but the “release of the new incidence numbers took a long time.” Dr. Martin said he understands the need “to scrutinize and for peer review,” but “with that new methodology, you should be able to turn the numbers around faster.”

Dr. Lansky responded that “we may go through the *Morbidity and Mortality Weekly Report (MMWR)* or through a surveillance report,” but added that she agrees “absolutely.” She acknowledged that “it took a long time to get the first report out, but our intention now is to put out new estimates each year.”

Prevention

Dr. Urbina commented that “in addition to burden and prevalence, we’re very interested in incidence and also as much as we can know about who and where to push prevention forward.” Dr. Lansky responded with thanks.

Dr. Redfield noted Dr. Lansky’s statement that “prevention works,” but “there really aren’t two camps, one for prevention and one for treatment,” because “we really are integrated,” as Dr. Hillier stated yesterday. He noted the policy for those of us over 50 years of age to have colonoscopies, but “does that prevent cancer or give me a better outcome?” Dr. Redfield said he is “troubled” when he sees data, after 20 years, that “in a highly educated population, over 50 percent are still having anal intercourse without protection and even in light of counseling.”

By our prevention methods “right now,” Dr. Redfield added, “my observation is that, particularly sadly, this epidemic is still alive in MSM,” so “perhaps we need to broaden our view of strategies for prevention, not just behavioral, but a comprehensive biological approach.” Dr. Redfield said he would argue for “getting them diagnosed and into therapy,” because “I’m concerned that maybe our prevention efforts aren’t working.”

Dr. Lansky responded that Dr. Redfield “makes a good point.” She noted that she did emphasize behavior prevention, “but there are exciting potential biomedical interventions and thinking more about treatment as prevention,” as well as “male circumcision, combined with behavior.” She added that “what a comprehensive prevention program” could look like in terms of “all the pieces and how big each piece should be” is “being considered now.”

Incarceration Rates and Deaths

Dr. Walsh asked about correlations to incarceration rates and also deaths due to HIV/AIDS. Dr. Lansky responded that the surveillance report she referred to in her presentation includes death data. There are “two ways to look” at that, she added, deaths among persons with HIV/AIDS and “what proportion died of HIV/AIDS in terms of incarceration.” The behavioral surveillance effort “collects that information.” Dr. Lansky explained that the case surveillance data are “based a lot on medical records,” but the behavior data are gathered “face-to-face, so those questions can be explored more that way.”

More on Transparency

Mr. Kaufman said he agrees about “transparency,” adding that “the softest number to me is the number of undiagnosed.” He said in “that area, it is particularly important that methodology for determining undiagnosed be public and open to discussion, because it is the crux in where you are going.”

Dr. Lansky said she appreciates that, adding that “those data were published in *MMWR* last October with a description of methods used.”

Counseling

Ms. Wise asked Dr. Lansky to explain her slide about prevention counseling at the individual and group level. Dr. Lansky responded that “when we ask the question ‘have you participated in one-on-one?’, we say that we don’t count test counseling.”

Ms. Wise asked if more African American MSM youth “are getting counseling in the time period noted.” Dr. Lansky responded that her Office “just finished the second round of these data and will have another comparison point to look at.”

Ms. Wise commented that “when we are trying to do more counseling, they’re getting it, but it is still not working.” Dr. Lansky noted that “to be the optimist, we can say counseling works, but it’s not reaching.” She added, “these are really intensive counseling” efforts that “are reaching a small proportion,” but “other studies show that those reached by these efforts do change their behaviors.” We “do need to raise these percentages,” however.

Those Tested Not Always Counseled

Mr. Schmid commented that those who get tested “don’t always get counseling when tested.” Dr. Redfield responded that the requirement “is for that,” to which Mr. Schmid responded, “you’d hope so.” Noting the 23 percent bottom line of those counseled on Dr.

Lansky’s slide (Slide 32), Mr. Schmid commented “that represents a percentage not receiving” this counseling. Mr. Schmid added that this counseling is “intensive,” but “it may be more community-based.”

Mr. Bates responded that “we need to consider that this is not just CDC’s responsibility,” adding that “State and local governments have an obligation to take lessons learned and CDC guidance and apply it locally.” At present, “we don’t see consistency in that application.” As a result, there “is a lot of imbalance across the country on availability and kinds of interventions and State responses to assessments,” all of which “contributes to what we’re seeing today.”

Mr. Bates continued that “we have a job to tell the States what their responsibilities are as assigned.” He added that it “might be one imperative that States do more based on their communities,” because “there is no consistency on need.” In short, he doesn’t want “us to think we have one sock that fits all,” because “that’s not the case.” It must be remembered that all this is “highly complex, partly driven by environment and social context on self-perception, and availability of things based in part on cultural perspective” or the lack thereof.

Need for More Funds and Studies

Mr. Bates said he wants to come back to the fact that “we need more money because we have to diversify approaches to prevention intervention all over this country.” We need “to dig deeply into realities in communities and provide a level of prevention intervention to meet specific needs.” But we lack “sufficient studies.” CDC’s challenge, he said, “has included decreased levels of funding.” We “don’t even know the real, earnest numbers in terms of new infections.”

PACHA and a National Strategy

As the Council starts thinking about presentations from yesterday and today, “particularly on CDC data,” Mr. Bates urged members “to think about the implications for a National Strategic Plan, the completion of that plan, and moving out of the comfort zone we’ve been in with a narrow set of prevention interventions and start moving to a broader context.” We’ll “have to combine treating with behavioral interventions on the ground.” While that “may put more demand on the medical community, we’re going to need that.”

Eva Margolies, CDC program planning and policy coordination official in the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, rose from the audience to echo what Mr. Bates and Dr. Lansky said. “When you look at intervention” in the obesity epidemic by contrast and comparison, for example, she said, “the idea of one intervention for African American MSM is” striking. “It takes lots of interventions,” and when one considers that less than 25 percent have been reached by behavioral interventions, “that’s a huge gap.” Ms. Margolies added that “a lot of the research wasn’t done early on in the population that has needed it." While "we have a waiting list of organizations waiting to be trained," most people don't have access to interventions and "even if they do, some will change, and some will need something different."

Evidence Needed

Dr. Redfield said he has never suggested that one intervention is sufficient, adding that "we haven't embraced treatment as part of our prevention strategy." He said, "we made a huge mistake in the 1980s by not enlisting those living with AIDS, as they are the cornerstone of our strategy," adding that "all I'm suggesting is look at prevention strategy with the same scientific rigor as vaccine efficacy." In short, "we need evidence-based data" such as longitudinal studies "to see if these intensive counseling sessions are efficacious." And if they are, "resources might be forthcoming."

Dr. Redfield concluded that "it is time for prevention and therapeutic people to see that they have common goals and that both prevention and treatment need to be enhanced." However, "there has to be scientific rigor and compelling evidence," and if that is forthcoming, Dr. Redfield said he is confident "we will come to similar conclusions."

Mr. Bates commented that "for a long time, we invested in communities to do prevention work without investing in evaluation." We "missed so many opportunities to have a clear understanding of all the money out there." At present, "CDC is making an attempt to turn that around, but it is a slow process," in part due to the fact that "we don't have talent in this area commensurate with what we need." In the interim, "CDC is making great strides in what it is doing," and States need to start doing behavioral studies with colleges and universities and not wait for the Federal Government to lead it all. That, he concluded, "is a major challenge." However, "we can't wait any more. We need to take action."

Breaking for Lunch

Mr. Gilmartin asked Council members to break into their Subcommittees for a Working Lunch.

Working Lunch

Council Reconvenes for Motions and Voting

Dr. Maxwell reconvened the full Council for motions and voting on two resolutions.

Dr. Maxwell asked Mr. Schmid to present the first proposed resolution for discussion and consideration.

Domestic Subcommittee Resolutions

Mr. Schmid noted that the Domestic Subcommittee is advancing two draft resolutions, one on a National AIDS Strategy and the other on Ryan White extension. The Subcommittee decided to advance these two resolutions at its last meeting, and drafts were sent to the full Council several weeks ago. No comments were received.

National AIDS Strategy Resolution

Mr. Schmid characterized the first draft resolution, on a National AIDS Strategy, as congratulating the President for coming out in support of such a strategy, which he has done twice now since his election, after he was sworn in and also on World AIDS Day. Mr. Schmid noted that Mr. Crowley had also mentioned such a strategy as a "high priority."

The resolution also addresses how PACHA came out in a past resolution in support of a national strategy, reiterates PACHA's support for such a strategy, and notes that the Council has "great expertise" among its members. The resolution then "offers our expertise to be directly involved."

The draft resolution as provided to the Council reads as follows:

Presidential Advisory Council on HIV/AIDS (PACHA)
Domestic Subcommittee

Draft Motion

WHEREAS, President Obama has stated in the first year of his presidency he will develop and begin to implement a comprehensive national HIV/AIDS strategy that includes all Federal agencies. The strategy will be designed to reduce HIV infections, increase access to care, and reduce HIV-related health disparities;

WHEREAS, President Obama has appointed a Director of the Office of National AIDS Policy and when doing so reiterated his commitment to developing a national AIDS strategy and that it will be a top priority for the Office of National AIDS Policy;

WHEREAS, the Presidential Advisory Council on HIV/AIDS has previously gone on record in support of the development of a comprehensive National HIV/AIDS Strategy, a "Domestic President's Emergency Plan for AIDS Relief (PEPFAR)," in order to create an HIV-free generation in the United States and to ensure the proper coordination of the necessary health care and treatment to those with HIV/AIDS who are in need;

WHEREAS, the Presidential Advisory Council on HIV/AIDS remains committed to the development of a National AIDS Strategy and exists to inform and advise the President and the Secretary of Health and Human Services regarding HIV/AIDS and its impact on our Nation;

WHEREAS, the members of the Presidential Advisory Council on HIV/AIDS possess great expertise and knowledge of the domestic HIV/AIDS epidemic;

BE IT RESOLVED the Presidential Advisory Council on HIV/AIDS congratulates President Obama for his commitment to a National AIDS Strategy and offers its expertise and [sic] that it be directly involved in the development and implementation of a comprehensive National HIV/AIDS Strategy.

Discussion of Draft Resolution

Mr. Schmid moved the draft motion from the Subcommittee with a second from Mr. Kaufman and opened the floor for discussion.

Mr. Grogan noted International Subcommittee discussion earlier about how, given some of the presentations over the past few days, including the one by Dr. Hillier, “we should recognize somewhat in the AIDS strategy” that “we learn things overseas that can be deployed domestically and vice-versa.”

Therefore, it was proposed that the following two items be added to the draft motion:

1. “WHEREAS, the United States continues to lead global HIV prevention, care and treatment, and research efforts, especially in its support of The Global Fund and the President’s Emergency Plan for AIDS Relief (PEPFAR); “

2. “BE IT RESOLVED that in developing this strategy, we draw upon the experience and knowledge of our ongoing PEPFAR programs.”

Mr. Schmid said both additions were “fine.”

Mr. Holzworth explained that the International Subcommittee “felt this was an opportunity” for making the resolution “stronger,” especially in light of Mr. Bates’ “call to arms” to “put out a timeframe” for development of the strategy. Also discussed was that aligning domestic and international efforts to make a national plan “truly national” would make it clear that there “should be input from a wide range of stakeholders and wide participation by all Cabinet-level agencies, including the Justice Department and the Department of Defense.” He added that the debate “should be led by experts as well as PLWHA.”

Mr. Schmid reiterated that “all that sounds fine.” He added that PACHA “did pass a resolution before” in which it addressed the need for input by stakeholders, Federal agencies, and so on.

Mr. Schmid then asked how the draft resolution should address timeframe. Mr. Holzworth said that the International Subcommittee doesn’t have a specific suggestion. “We ought to be saying,” he added, “that we’re anxious to move this along as well as participate.”

Mr. Schmid suggested that timeframe could be added to the resolution’s last sentence. He and Mr. Holzworth worked out that the last sentence could call for “immediate development.”

Quorum?

Mr. Bates noted that 11 members were present and that he assumes “that is a simple majority.” Mr. Schmid responded that “if no one questions a quorum, don’t worry about it.”

Submission of Resolutions

Mr. Schmid noted that both resolutions when adopted will be submitted to Mr. Crowley at the same time as they are submitted to the Acting Assistant Secretary.

Further Discussion

Dr. Maxwell asked if there was further discussion. Mr. Holzworth asked about the previous resolution’s reference to stakeholders and Federal agencies. Mr. Schmid noted that resolution is referenced in the draft motion.

Mr. Grogan suggested that a “that” be placed in the first “whereas,” as in “has stated that.”

Discussion Suspended for Photos and Swearing In

Swearing in by Donald Wright, M.D., M.P.H., Principal Deputy Assistant Secretary for Health, HHS

Further discussion of the first draft motion was suspended while official photographs were taken of the Council and Dr. Wright swore in the Council’s new members, Mr. Holzworth and Dr. Walsh.

Vote on First Draft Resolution

Given no further discussion, a vote on the draft motion was called for and seconded. All in favor voted by hand. The draft motion on a National AIDS Strategy was then adopted unanimously with amendments, as follows:

Presidential Advisory Council on HIV/AIDS (PACHA)
Domestic Subcommittee

Draft Motion

WHEREAS, President Obama has stated that in the first year of his presidency he will develop and begin to implement a comprehensive national HIV/AIDS strategy that includes all Federal agencies. The strategy will be designed to reduce HIV infections, increase access to care, and reduce HIV-related health disparities;

WHEREAS, President Obama has appointed a Director of the Office of National AIDS Policy and when doing so reiterated his commitment to developing a national AIDS strategy and that it will be a top priority for the Office of National AIDS Policy;

WHEREAS, the United States continues to lead global HIV prevention, care and treatment, and research efforts, especially in its support of The Global Fund and the President’s Emergency Plan for AIDS Relief (PEPFAR);

WHEREAS, the Presidential Advisory Council on HIV/AIDS has previously gone on record in support of the development of a comprehensive National HIV/AIDS Strategy, a “Domestic President’s Emergency Plan for AIDS Relief (PEPFAR),” in order to create an HIV-free generation in the United States and to ensure the proper coordination of the necessary health care and treatment to those with HIV/AIDS who are in need;

WHEREAS, the Presidential Advisory Council on HIV/AIDS remains committed to the development of a National AIDS Strategy and exists to inform and advise the President and the Secretary of Health and Human Services regarding HIV/AIDS and its impact on our Nation;

WHEREAS, the members of the Presidential Advisory Council on HIV/AIDS possess great expertise and knowledge of the domestic HIV/AIDS epidemic;

BE IT RESOLVED the Presidential Advisory Council on HIV/AIDS congratulates President Obama for his commitment to a National AIDS Strategy and offers its expertise and [sic] that it be directly involved in the immediate development and timely implementation of a comprehensive National HIV/AIDS Strategy.

BE IT RESOLVED that in developing this strategy, we draw upon the experience and knowledge gained from our ongoing PEPFAR programs.

Draft Resolution on Ryan White Extension

Mr. Schmid characterized the Domestic Subcommittee's draft motion on Ryan White extension as supporting a 3-year extension and recommending some minor changes to correct for unintended consequence as well as funding authorization adequate to address unmet and growing needs. The resolution recommends that any changes to formula funds take into account the change in the epidemic but not, in the process, destabilize existing systems of care while still respecting the need to distribute funding based on living case counts. The resolution also recommends review of the percentage funding jurisdictions are allowed not to obligate and of penalties associated with exceeding these requirements. Last, the resolution supports extension well before expiration of the current law.

Discussion of Draft Resolution on Ryan White Extension

Dr. Maxwell asked for discussion.

Mr. Holzworth asked if the draft resolution should say something about PACHA's availability to support development of legislative language. Mr. Schmid responded that "the extension is legislation, and these are our comments on that legislation."

Mr. Bates asked if Mr. Holzworth was "getting at whether there would be a new reauthorization." Mr. Holzworth responded with a query as to whether there would "not be an opportunity to make some changes in the legislation." Mr. Schmid responded that "those are outlined here."

Dr. Redfield noted that the draft resolution addresses "unmet needs," then asked if there is an opportunity here to support "full implementation of CDC recommendations on expanding early diagnosis."

Mr. Schmid responded that Ryan White is a HRSA-administered care and treatment program, i.e., "Ryan White is a program for those living with HIV/AIDS already."

Dr. Redfield said his intent was "to get people to recognize that a number of people are being newly diagnosed." In short, not only are there "unmet needs but probably 20-30 percent we hope to diagnose."

Mr. Schmid said he sees Dr. Redfield’s “nexus.” However, “there are many reasons why there are unmet needs.” Among them is “that people are losing their jobs.” He added that “if we start listing” reasons for unmet needs, “we should list them all.”

Further Discussion

Dr. Maxwell asked if there was further discussion. Hearing none, she called for a vote.

Vote on Draft Resolution

The draft motion was moved and seconded. By a show of hands, Council members voted in favor of the draft motion. The result was unanimous approval.

Mr. Schmid noted that the Domestic Subcommittee tries to get resolutions to the full Council in advance, “so we encourage people to review them before they come to the full Council.”

Executive Director’s Parting Notes

Mr. Bates thanked Council members for their participation in this 37th meeting of the Council, “but the real work is to be done.” He noted that “we’ve had conversation at the Subcommittee level” about the fact PACHA has a report that was produced under Mr. Grogan’s leadership as PACHA’s Executive Director that “we need to revisit because it embodies many of the themes you would like to see in a national plan.” Second, there are other documents, such as the Healthy People 2010 document, that could be reviewed. If members can’t find this document online, “we’ll send it to you electronically” in addition to anything else “you’d like to review before you engage in further conversations.”

Meeting Schedule

Mr. Schmid noted that the Domestic Subcommittee has discussed skipping its next conference call and wondered if the International Subcommittee wants to do that as well. It was noted that the two Subcommittees could combine their meetings and put that time into focusing as a group “on what you want to contribute toward the strategic plan discussion.”

Subcommittees Meeting Together

Dr. Redfield observed that most pressing “is getting engagement in this national strategy discussion.”

Mr. Bates' suggestion that members look back on PACHA's last large report was noted and the comment made that "you may be surprised at how scholarly it was." It was also noted that if PACHA is "going to influence the debate, it is probably happening as we speak, so the idea of our coming together might make a lot of sense."

Mr. Schmid said that his personal view, which he mentioned during the Domestic Subcommittee's meeting at lunch, is that he dislikes "the separateness of our two groups," which, at present, come together only twice each year, during full Council meetings. Therefore, he said, "it is a good idea" for the two Subcommittees to meet together.

Mr. Schmid said the Domestic Subcommittee's next meeting (conference call) is scheduled next week. He had suggested not having it, because he didn't think "we needed it so soon." However, "for the next month it might be well to open up the whole discussion by opening each others' meetings to each other."

Dr. Redfield said the International Subcommittee had had a similar discussion. He noted that in the last decade, the number of PACHA Subcommittees has changed along with their titles. He suggested that the Domestic Subcommittee could simply open its meeting up, "as all of us on the International Subcommittee are much grounded in the domestic arena right now." He noted that there are subjects the International Subcommittee will want tackled as well, including "OGAC replacement."

Charter Permission Not Needed

Responding to Mr. Schmid's query as to whether PACHA's charter allows the two Subcommittees to meet together, Mr. Bates said in terms of a group meeting, "whether you meet as a Subcommittee or not is not impacted by or relevant to the charter."

Task at Hand Warrants Full Participation

Mr. Bates said that "the task at hand warrants full participation of the group, so it doesn't make sense to have separate meetings." He went on to note that the PACHA-approved resolution on a National AIDS Strategy today indicates "a marriage, if you will, in participating in what is happening in both the Domestic and International Subcommittees."

Executive Director's Schedule

Mr. Bates noted that he will be away for a month for executive training. However, he will have a phone and a Blackberry. He will work through Mr. Joppy "to make sure your meeting happens." Mr. Joppy will be communicating with members on a time and date for a conference call, and "recorders will be on line to capture the discussion."

Mr. Bates noted that "by your second meeting, I will be back." He suggested that in their first meeting, members talk about a timeline "for completing the core of what you want to do," and that in their second meeting, members "tweak that."

Adjournment

The 37th PACHA meeting was adjourned at 2:21 p.m.