Presidential Advisory Council on HIV and AIDS (PACHA)
Twenty-Fifth Meeting
Hubert Humphrey Building
200 Independence Avenue, S.W., Room 800
Washington, DC 20201

November 9 and 10, 2004

Council Members Present—
Louis Sullivan, M.D., Chair, PACHA
Abner Mason, Chair, International Subcommittee
David Reznik, D.D.S., Proxy Chair, Treatment and Care Subcommittee
Anita Smith, Chair, Prevention Subcommittee
Cheryll Bowers-Stephens, M.D.
Jacqueline S. Clements
Mildred Freeman
John F. Galbraith
Cheryl-Anne Hall
Jane Hu, Ph.D.
Karen Ivantic-Doucette, M.S.N., FNP, ACRN
Rashida Jolley
Franklyn N. Judson, M.D.
Joe McIlhaney, M.D.
Jose Montero, M.D., FACP
Beny Primm, M.D.
Debbie Rock
Edwin Sanders
Lisa Mai Shoemaker
Don Sneed
M. Monica Sweeney, M.D., M.P.H.
Ram Yogev, M.D.

Council Members Absent—
Brent Tucker Minor, Chair, Treatment and Care Subcommittee
Rosa M. Biaggi, M.P.H., M.P.A.
Edward C. Green, Ph.D.
David Greer
Sandra McDonald
Henry McKinnell, Jr., Ph.D.
Dandrick Moton
Prem Sharma, D.D.S., M.S.

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

Wanda Chestnut, R.N., M.S.N., Staff Fellow; LT, U.S. Public Health Service

Day One

Welcome Remarks

PACHA Chair Dr. Louis Sullivan thanked members of the Council and of the public for attending. He noted that since PACHA's last meeting, a number of important events had taken place, including the Presidential election and Mr. Joseph Grogan's marriage. The Council joined Dr. Sullivan in congratulating Mr. Grogan.

Mr. Grogan outlined the agenda for the meeting. He noted changes. Mr. Christopher Bates would not be able to present to the Council on the Minority AIDS Initiative due to jury duty. He also noted that Dr. David Reznik would be sitting in for Mr. Brent Tucker Minor as the Chair of the Treatment and Care Subcommittee. Mr. Grogan noted the presence of the Council's newest member, sworn in that very morning, Dr. Cheryll Bowers-Stephens.

Dr. Bowers-Stephens said she is from New Orleans and presently serves as the State of Louisiana's Commissioner for Mental Health. In the past year, she has done outreach work in Zimbabwe on mother-to-child HIV/AIDS transmission (MTCT). She particularly wants to address the mental health needs of HIV/AIDS patients.

Sandra McDonald will not be able to attend the meeting due to the critical illness of her brother.

International Subcommittee Report

Mr. Abner Mason, Chair, International Subcommittee, proceeded to give his report. He said the Subcommittee would offer two resolutions, one on international AIDS conferences and one on development of mechanisms for monitoring mechanisms for HIV/AIDS treatment in PEPFAR countries and by the World Health Organization (WHO). He noted that the Subcommittee had discussed concerns about MTCT. Therefore, the Subcommittee had arranged for the following presentation.

Presentation topic: Perinatal HIV Prevention: Successes and Challenges in the United States and Internationally
Presenter: Mary Glenn Fowler, M.D., M.P.H., Divisions of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (DHHS)

Dr. Mary Fowler gave an overview of perinatal HIV prevention in the United States and internationally by outlining U.S. successes and remaining challenges and the epidemiology, current and planned research efforts, and program activities of the international situation. She then provided issues and conclusions.

In the United States there has been major progress since 1994 in decreasing perinatal HIV. Before then, the U.S. perinatal transmission rate was 20-25 percent. Today, rates of 2 percent or less can be achieved using combination therapies and obstetrics intervention.

Current estimates are that 6,000-7,000 HIV-infected women deliver each year in the United States. The status of most is known by the time of delivery. Ten-12 percent receive little or no prenatal care. The CDC estimates that 280-370 babies are infected each year in the United States, with most current rates at about 300 each year.

Dr. Fowler said rates of transmission cases were expected to continue to decline.

Current CDC perinatal HIV prevention strategies in the United States are:

- Increase awareness among pregnant women of the importance of HIV screening
- Reduce barriers to universal perinatal HIV screening—support opt-out approach
- Promote rapid HIV testing at labor and delivery (L and D) for women whose status is still unknown
- Integrate HIV perinatal screening with other maternal and child health (MCH) programs and services that screen for and prevent other congenital infections (syphilis, group B strep, hepatitis B).

Dr. Fowler called the latter very important.

CDC perinatal HIV prevention projects in the United States:

- Have had $10 million in congressional funding per year since 1999
- Support perinatal prevention programs in 16 high-prevalence States
- Provide perinatal HIV surveillance and assessment of States' prenatal testing rates for 10 States
- Provide five national organizations with monies for development of training and education materials
- Support the MIRIAD study of the feasibility of rapid testing at L and D.

General types of perinatal prevention programs in high-prevalence States are:

- Social marketing
- Outreach
- Case management of high-risk women
- Training of health care workers, including in HMOS and private settings
- Rapid testing at labor/delivery.

In the MIRIAD study, CDC supported research at five university sites with 15 related hospitals in 1999. The objectives were:

- To assess feasibility of offering rapid testing at L and D and intervention
- To assess use of rapid test kits for sensitivity and specificity
- To assess rates of seroprevalence and transmission among late-presenting women of unknown HIV status

- To provide linkages to comprehensive care and treatment for women identified by rapid testing as HIV-infected, as well as for their infants.

MIRIAD was found to demonstrate the feasibility of rapid testing and intervening at L and D in the following ways:

- Between November 2001 and June 2003, 69,094 women were evaluated
- Of these, 5,374 (7.8 percent) were eligible based on undocumented HIV status late in pregnancy or at labor
- Uptake of rapid testing was 85 percent
- Two-thirds of HIV-infected women in labor received antiretrovirals, as did all the newborns
- To date, 52 HIV-positive women have been detected by rapid testing and 4 infants are infected (about an 8 percent infection rate).

Followup translation efforts to support rapid testing at L and D include:

- Recent FDA licensing of rapid tests—OraQuick and Reveal
- CDC model protocol for implanting rapid testing at L and D
- Regional trainings on rapid testing in L and D settings.

Dr. Fowler noted that the CDC trained trainers at 50 hospitals to make sure the test was widely available.

In conclusion, there have been dramatic declines in perinatal transmission related to:

- Increased uptake of prenatal testing and access to rapid testing at L and D
- Availability at 38 weeks of potent combination ARVs and obstetrical interventions, including C-section
- Generally adequate public and private health care infrastructure
- Feasibility of not breastfeeding in the United States—safe water, availability of formula for low-income women, lack of stigma.

The DHHS/CDC goal is elimination of any new infant infections.

Remaining challenges are to:

- Achieve universal prenatal HIV testing
- Implement rapid HIV testing in labor/delivery settings for women whose status is still unknown
- Ensure adequate followup, comprehensive treatment for HIV-infected women
- Develop mechanisms to monitor possible late adverse events among ARV-exposed infants, as 70,000-plus infants have now been exposed to perinatal antiretrovirals, and questions exist as to how best to follow them into adulthood for potential though rare late effects.

On the international front, Dr. Fowler reported that the epidemiology of perinatal HIV in international settings is:

- 95 percent of HIV-infected children are born in resource-limited breastfeeding settings

- The World Health Organization (WHO) estimates that there are more than 700,000 new infant infections each year, most due to MTCT
- Transmission rates are generally in the 25-40 percent range without antiretroviral interventions
- With antiretroviral interventions, late transmission rates at 18-24 months are currently 15-25 percent
- Maternal HIV seroprevalence is up to 35-40 percent in some settings
- Adolescent females are at high risk of infection (17-year-old girls in Kenya are infected at the rate of 17 percent, for example)
- Breastfeeding accounts for one-third to one-half of all transmissions.

Dr. Fowler showed a slide of the baseline high antenatal clinic HIV prevalence in 14 African countries, with Botswana at the highest prevalence—more than 35 percent.

Dr. Fowler noted that President Bush announced an International Mother and Child Prevention Initiative in June of 2002 funded at $500 million, to be jointly implemented by DHHS (CDC and HRSA) and the U.S. Agency for International Development (USAID), the objectives of which were to reach up to 1 million women annually and to reduce MTCT by up to 40 percent among treated women. This program was then folded into the President's Emergency Plan for AIDS Relief (PEPFAR) in January of 2003. Dr. Fowler outlined the well-known parameters of PEPFAR, including its goal to build on earlier efforts such as the Mother and Child HIV Prevention Initiative.

Dr. Fowler outlined research addressing breastfeeding transmission. Postnatal transmission from breastfeeding accounts for at least one-third of all transmissions among breastfeeding women. Timing is an issue. Several studies have suggested that much transmission occurs very early, before 1-2 months of age. However, there are also findings of a low continuous risk through lactation—0.6-0.8 percent risk per month into the second year of breastfeeding. At the Bangkok conference, it was reported that early breastfeeding cessation could prevent a sizable fraction of postnatal HIV infections.

At present, WHO guidelines for resource-limited settings try to balance risks, based on individual counseling. When acceptable, feasible, affordable, sustainable, and safe, formula should be used; otherwise, exclusive breastfeeding with early weaning is recommended. Dr. Fowler added that individual decisions are up to mothers and their families.

Issues regarding breastfeeding and HIV in resource-limited settings are:

- Breastfeeding improves overall infant survival in resource-limited settings
- Safe, feasible, and sustainable alternatives to breastfeeding are not available to most HIV-infected women in international resource-limited settings
- To not breastfeed goes against cultural norms and may stigmatize a mother or lead to disclosure of her HIV status
- Decisions on infant feeding are often influenced by the father and other family members (such as the mother-in-law)

- Research is underway to determine effective strategies to reduce transmission risk for HIV-positive women in resource-limited settings who choose to breastfeed.

Recent international perinatal HIV trials include:

- Short-course (at 36 weeks) maternal ZDV regimens—Thailand and West Africa
- Combination and short-course ZDV/3TC—a PETRA multisite trial in East Africa and South Africa
- SD NVP to mother and newborn—in Uganda (the simplest regimen).

At present research trials are also looking at transmission and breastfeeding in terms of ARVs transmitted to mother or infant during breastfeeding, and immune strategies, such as vaccines.

Dr. Fowler showed a slide of results of trial regimens shown to prevent MTCT, both in the United States and elsewhere, noting that in Thailand, short courses have proven as effective as longer courses. The "most exciting" success rate to date has been in the 2004 Thai trial of early efficacy at 6 weeks to 4 months, where AZT is administered from 28 weeks plus a single dose of NVP at labor to the mother and the newborn.

Brand-new trials are looking at:

- Maternal HAART in the last trimester and during 4-6 months of breastfeeding to lower maternal viral load
- Infant ARV prophylaxis during the first 4-6 months of breastfeeding
- Exclusive breastfeeding followed by early weaning, at 4-6 months
- Active and passive immune strategies.

Dr. Fowler said remaining challenges are great. Goals are to:

- Increase uptake of HIV testing among pregnant women
- Conduct safety monitoring of ARVs among pregnant women and ARV-exposed infants
- Translate perinatal research into deliverable, sustainable programs, particularly in international settings
- Integrate with other mother-and-child programs
- Use the current program as an opportunity for ARV treatment and care for HIV-affected families
- Assess ARVS for the program and their potential impact on later treatment options.

In summary:

- There has been major progress in perinatal HIV prevention in the United States and in international research, but challenges remain.
- Current program activities provide a gateway for families to access HIV treatment and care.
- Remaining issues include breastfeeding transmission and the health care infrastructure.

- At present, current international research is focused on reducing breast milk transmission as well as resistance and the effects of transmission on later treatment options.
- Primary prevention of HIV infection among adolescents and women of childbearing age is a key to reducing the perinatal HIV pandemic worldwide.

Question and Answer Period

Two questions were posed: In terms of using antiretrovirals in triple combination administered during the perinatal and breastfeeding periods, if this strategy were expanded abroad would we be more effective? Also, are we monitoring the outcomes of training in this area?

Dr. Fowler responded that, in the United States, most women do receive HAART or a triple combination. Internationally, however, the first issue is deliverability. It is not known if triple or dual or single drugs provided during breastfeeding could prevent transmission. Once current trials on this are completed, the CDC might be able to make recommendations. It cannot do that on the basis of current data. However, the data from the Thai study that used two regimens together, AZT and single-dose NV, showed that transmission can be reduced to 2 percent.

Dr. Fowler added that when you are using two drugs, toxic reactions occur less often than with three drugs. The need for close monitoring might not be sustainable in resource-limited settings. This is currently being examined in West Kenya. If we push for HAART in limited-resource settings, Dr. Fowler said, we have to be very clear about results and benefits.

In terms of training, the current Global AIDS Program at CDC is looking into the effects of training. Outcomes are not yet available. The emphasis has been on physicians and nurse practitioners. Dr. Fowler commented that you can't just train once.

The question was raised about the advent of drug-resistant viruses as a result of use of short-course therapies.

Dr. Fowler said this was an important area. In the short-course Thai study, when very stringent criteria were used, "there was decrement in terms of 'maximal suppression'." The women were doing well clinically. Other studies involving larger numbers are underway. This concern exists not just with single-dose NV but also with triple combinations and HAART. The bottom line is that most women are asymptomatic and often don't need drugs for their own health care until several years later. If they had had the drugs earlier, would later regimens be less effective? This is not known.

How about newborn testing in cases where the mother refuses testing or tests late, including in the United States?

Dr. Fowler said the CDC recommends that women be tested at L and D and, if not, that the newborn be tested. Most transmission occurs around the time of L and D, as the baby goes through the birth canal. She noted that all babies in the MIRIAD study received AZT.

Dr. Ram Yogev said he was impressed by the results of NV administered alone in Uganda, noting that there was almost no increase in infant risk in the first months of life. NV is effective, yet issues of resistance put it on hold at the moment.

Dr. Fowler noted that NV does last for a long time. That may be part of the explanation of its effectiveness on early transmission in breastfeeding. The issue of resistance is important. It needs careful study. Other drugs must also be examined for resistance.

Dr. Sullivan commended Dr. Fowler on her overview and on reductions in transmission. He asked, when infants are given combination drugs, how long is that continued, what questions exist about safety, and what immune strategies are being pursued?

Dr. Fowler said: First, in the United States, infants are given AZT for prophylaxis for 6 weeks. Internationally, the regimens use either a mono drug, such as NV, given for 6 months during breastfeeding, or, in one study in Malawi supported by the CDC and the National Institutes of Health, two drugs—AZT and NV. Safety data on daily NV administered in babies are quite good. There's some nutropenia, but the source is uncertain. A large study is planned with NV to check on that. AZT effects are fairly well understood: health care workers usually monitor for anemia, but most babies do very well with AZT.

Dr. Fowler added that the CDC is following up on late toxicities. Since 1994, relevant populations have been followed through their young school-age years, and so far, it looks like they are experiencing normal development and growth. A worry comes from studies of middle-aged mice and late effects on them. One huge challenge with the human populations is, if we do find problems from previous exposures to AIDS drugs, how will the families be notified? At present, CDC is using cohort studies to look at shorter term effects as well. On the international front, the first several years of life are the followup period for children. For women, the focus is on short-term toxicities. The possible risks need very careful attention.

Dr. Fowler continued that, if successful, immune strategies, such as vaccines given to babies postnatally, might permit women to be able to breastfeed into the second year, as is normal in many settings abroad. Phase I of a study in Uganda this year will look at vaccines already assessed for safety here. Researchers are also looking at globulin immunoglobulin, given to mother and baby, as well as short-term antiretrovirals. A third approach, in South Africa, is a cocktail of polymonoclonals based on successful animal model data. Not only might women be able to breastfeed into the second year, but such strategies might also be useful in later life for the children.

What about programs to ensure that recommended infant formulas are safe?

Dr. Fowler: When we discuss breastfeeding from 4 to 6 months, then weaning, we're looking at babies using local foods, not formulas. Distribution programs for safe formula have been generally unsuccessful, not due to the formula but due to water supply problems, such as in Kenya, where they have regular cholera epidemics. So we have been focused on local foods. In some urban areas, such as Nairobi, the water might be relatively safe, but this is not relevant to many in rural settings in Africa.

In terms of the MIRIAD project and offering of testing to women: The uptake on rapid testing was about 85 percent, but what about the other 15 percent? What were the women's reasons for refusal and how can we combat those reasons? Second, if two-thirds of those infected received antiretrovirals during labor, what happened to the other one-third?

Dr. Fowler: The fact of women not getting tested in that study is based in part on structural issues at the hospital, where some women said, for example, that they had already been tested, but then those test results were never ascertained. Another structural issue at the hospital was staffing: on weekends—it went down. This was an important factor. Then there was a small group of women who wouldn't be tested. Some knew they were infected but hadn't disclosed this to their health care provider. All the babies got AZT and NV. It's partly a matter of timing; if the mother is about to deliver, it might be too late to administer to her, but not to the baby. Internationally, most women show up late, so we are more likely to offer interventions to the baby.

Rev. Edwin Sanders suggested a future presentation to PACHA on contextual stumbling blocks to success in this area, such as lack of adherence to drug therapies in some communities in the United States and issues of infrastructure in Africa.

Dr. Fowler agreed this is a critical area. Internationally, despite barriers, adherence is very good—more than 90 percent. But we need to look at this programmatically. There are a lot of stigma issues. Getting partners involved might help. Dr. Fowler said she is more optimistic internationally than in some U.S. settings, where adherence can be very low.

Different regions of the world experience different health problems, so, for example, in Asian countries, hepatitis B is a chronic epidemic. Those people are immune-compromised. In Korea, many are living with HIV/AIDS but experience serious side effects with AZT, such as severe anemia. Is 3 TC a substitute for AZT in these circumstances?

Dr. Fowler responded that this is an important topic, and that safety and efficacy will sometimes be a matter of the drug, and sometimes of dosing and weight. AZT has a good safety record in the United States, and anemia can be treated. She noted that all the drugs, including 3 TC, can confer resistance—another factor. She noted there have been psychological effects from 3 TC.

Presentation topic: Update on the Status of PEPFAR and the Global Fund
Presenter: Ambassador Randall Tobias, Coordinator, Office of Global AIDS

Ambassador Tobias recalled a recent trip to Africa, where he visited a woman dying of AIDS in a 12' x 12' mud brick hut with a metal roof. She was on a mattress on a dirt floor, and sitting at the end was her 5-year-old daughter. Ambassador Tobias asked what would happen to her, and no one knew. Her father, too, had died of AIDS. Every day, 8,000 die, and it's too easy for those to just seem like numbers instead of people. Worldwide, HIV/AIDS is a human tragedy. But it also poses social development and global security threats. Young adults embody the potential of their countries, but they are among the hardest hit. When HIV/AIDS kills people in their prime, it is a blow to a society's previous capital and to a country's ability to continue to move forward.

HIV/AIDS is a destroyer of hope. Without hope, people are driven to extremes. Recently President Bush spoke about this as a humanitarian crisis but also about its relationship to other international challenges in the wake of 9/11. The U.S. near-term security challenge is clear, including how our longer term strategies must rest on a foundation of promoting peace, freedom, and hope around the world.

Ambassador Tobias was disappointed in the press coverage last week of the President's press conference. You had to read the entire transcript to see his references to poverty and HIV/AIDS around the world, even though these are on his priority list.

Ambassador Tobias continued: "We now have a special focus on 15 countries that account for roughly one-half of global HIV/AIDS infections. It's our intent to support drug treatment to 2 million, to prevent 7 million new, and to support care for 10 million infected and affected, including orphans. We are holding ourselves and the organizations we're funding to account for achieving those goals.

"This past year was the first year for dramatic departure from business as usual. We made a tactical decision to get resources into the field as quickly as possible, even if we had to rely on ad hoc approaches. This is an emergency, so we're moving as quickly as we can. We do need to get sustainable processes in place, and to focus on emergency plan management. We have 50 people meeting in our offices this week, some from here, some from countries where we are working, to follow up on management issues that have emerged. We have lots of incomplete procedures and rules and regulations. For example, we have had horrible problems getting the organization staffed because of all the rules and regulations. I'm about to bring on board a chief operating officer to report directly to me. He has long experience in procurement. He will take on operating responsibilities, which have taken up too much time from programmatic people.

"Even with ideal management, our task is difficult. The single greatest obstacle is the desperate lack of health care workers and infrastructure where we are working. All the AIDS drugs in the world will not do any good if they are stuck in a warehouse, unable to be managed, moved, and provided by trained people. In the United States, we have 279

physicians for every 100,000 people. In Mozambique, it's 2.6. In Ethiopia, they have brain-drain problems; there are more Ethiopian doctors practicing in Chicago than in the entire country of Ethiopia. In Vietnam, I visited a hospital where AIDS patients spend their final days. Patients were sleeping two to a bed. That's why we're making investments in training and infrastructure. This year we are supporting 145 training programs for antiretroviral therapies and 140 additional programs training people to provide palliative care. Improving capacity is essential for these countries to take ownership, as I believe they surely must."

Ambassador Tobias then gave the timeline of the emergency plan to date: He was appointed in July of last year; then he was confirmed, then the Office received its first funding 9 months ago and, 3 weeks later, began to commit those funds. Within days, the money began going out the door. It wasn't perfect, but the Office got things moving. PEPFAR can now count 24,900 patients receiving treatment, and that number is growing rapidly. More data will be available at the end of the year, but "we are on the path to meeting or exceeding 200,000 additional people in treatment by the beginning of the year."

Ambassador Tobias noted that there was doubt whether antiretroviral drug therapy could be successfully delivered on such a large scale. But his Office is making it clear it can be done with very high compliance rates and with standards—all the drugs used have been proven safe and effective. This latter point is a moral imperative, the Ambassador stressed.

The Global Affairs Office is also making progress with companies who are making copies of drugs. They can now get expedited U.S. Food and Drug Administration (FDA) review of their drugs. Prevention efforts are in place as well. The United States has carefully studied prevention successes and will continue to put results-based programs in place. It will take time and attention to implement because, in some cases, what the United States is doing is different from historical programs. The key is adapting to reflect the realities of the societies the United States is working with. In countries with a generalized epidemic, like those of sub-Saharan Africa, these innovative programs have been proven to work, Ambassador Tobias said.

One of the Ambassador's focuses at present is finding the right partners on the ground. About 61 percent of PEPFAR's partners today are indigenous organizations critical to the program's success. PEPFAR is working with many nongovernmental organizations (NGOs) as well, but increasingly, "we want our partners to think about their long-term exit strategy through training and capacity building. Local ownership of this fight is critical. We need to be providing both fish and fishing poles."

Ambassador Tobias added that he has begun routinely and visibly to meet with leaders living with HIV/AIDS to get them more directly involved in management of the disease in their countries and that he is also seeking to ensure that multilateral partners, such as the Global Fund, are doing likewise.

The Global Fund remains a very important venture, the Ambassador said. It offers a vehicle for other donor nations and other donors to sharply increase their commitment. In 2002, the United States made a large donation and remains the largest donor. DHHS Secretary Tommy Thompson has done a great job as chair of the Global Fund. His term will end early next year, but the Fund will remain a critical piece of our overall strategy. In addition to the Fund and the United Nations AIDS organization, the United States will continue to support and partner with a number of other organizations and host governments.

Beginning his conclusion, Ambassador Tobias said one of his abiding focuses is the changing face of the epidemic. In the hardest hit countries, women and girls are disproportionately sharing the burden. World AIDS Day this year (December 1) will focus on women's issues. In sub-Saharan Africa, women account for 57 percent of all infected people. In some African communities as many as 20 percent of 15- to 20-year-old girls and young women are HIV-positive compared to perhaps 5 percent of boys and young men of those ages. Where the disease is spread by heterosexual contact, women and girls are especially vulnerable, and cultural patterns give rise to that: 71 percent of the girls and 33 percent of the boys in South Africa have reported they personally have been forced into some kind of sexual act, and 58 percent of them said this was not sexual violence. Even when not infected, women and girls bear the brunt of the impact, as they are primary caretakers, they are especially likely to lose their jobs and income, and they remain undereducated. Where will the next generation of leaders in sub-Saharan Africa come from? This loss is just one of the catastrophic dimensions of this killer. Also these women face the tragic possibility of passing this virus on at childbirth.

In 1996, Ambassador Tobias recalled, he was named CEO of the Year by *Working Mother* magazine. His children quipped that their Dad had been named Mother of the Year.

The Ambassador went on: "Our strategy focuses on prevention, treatment, and care for those affected or infected, and on making our services broadly available. This is the most significant interventions we can make for women and girls. For example, a woman in Zambia was in a coma in her home and was taken to a hospital. Her neighbors had given her up. Her aunt brought her to the U.S.-supported clinic anyway. Two weeks later, she opened her eyes, then walked with support, and after a month she was discharged and driven back home. The woman who was considered dead was ready to resume her role in her family and her community. When people see this happening, they will go get tested."

Earlier the Ambassador noted he had provided statistics about South African young people. The United States recently supported a program about men as partners, HIV counseling, and testing on a given day in that country. Attendees were encouraged to get tested and involved in preventing violence against individuals. Many went away that day saying they now understood the message.

Leadership is the biggest single word in this effort. All of you, the Ambassador said, are leaders in this crisis. It doesn't require a lot of money. He recalled being in a testing clinic in Addis Ababa and asking to be tested. The next day, he attended a ribbon-cutting at a hospital with a new testing facility, funded by Addis Ababa. He encouraged all the leadership present to get tested and to tell people that they had. The mayor got up and gave his speech, then said he was going to get tested right then and there. It was all over television and the newspapers. Getting tested has become the "in" thing to do. That's the kind of leadership needed throughout this program.

In sum, Ambassador Tobias said, "We're off to a good start. I'm very pleased with the speed with which we're moving. On November 1, the country plans arrived on my desk. We will get 5-year strategic plans from each of the PEPFAR countries also. From 2006 on, it will be easier to continue than it has been. I admire President Bush for understanding the magnitude of this issue. His support has been critical to me."

Question and Answer Period

If we want to treat 2 million people, that will require more money than you have. It would be very helpful if your agency would encourage companies to go through the expedited approval process at FDA. Are you doing that?

Ambassador Tobias responded that his Office has been as aggressive as it knows how to be. FDA, DHHS, and his Office have been traveling around the world to visit all the major players making copy antiretrovirals. He has also encouraged some companies by phone. At this point, the process is moving slowly because sometimes companies haven't been sure they have all the necessary data ready. Some were waiting for the election results. He added that he thinks we'll start seeing a stream of drugs coming through the process.

Training and capacity building are critical, but are we looking at outcomes?

Ambassador Tobias responded that his Office wants to measure outcomes to make sure we have the right objectives and that the money is being spent the way we intend. He said he worries about exporting broadly too much the way we conduct such training in the United States. He said it is important to find balance between the lessons we can learn and exporting those lessons to everyplace where we are working. That's why local ownership is critical.

Following up on that, how are you ensuring that in the Caribbean, for example, your funding is being used the way you intend?

Ambassador Tobias said his Office is building on long-established mechanisms already used in various U.S. agencies to disperse and track money. He noted that the United States has signed onto the concept of the "three ones": to encourage every country to have a single strategy; to ensure there is a single coordinating mechanism in every country, made up of a number of the parties; and to support one system of monitoring and

evaluation so we're all looking at the same data to know what we're doing. For example, if you look at treatment, what do you count? The Ambassador said his Office reviews all the grants from the Global Fund to ensure against duplication and that this needs to evolve in each country.

Is the Caribbean, where there is an annual 65,000 infection rate, being overlooked?

Ambassador Tobias responded that PEPFAR has probably emphasized focus countries too much, when, in fact, $4 billion has been set aside for other countries too. The Caribbean is not being overlooked. There was a meeting recently looking at programs the region is implementing using available U.S. funding. It's a question of finding a balance between the initial concept of this program, which was to ensure that we did not engage in an inch-deep 5,000-miles-wide effort at the same time we know we need to find ways to address needs all over the world. Note that the emergency plan is currently focused on more than 100 countries, 15 of which have been singled out for more resources because they account for about 50 percent of the infections in the world. There are things we can do to encourage other donors and the Global Fund. Vietnam is the 15th country.

What about Zimbabwe, where the average life span is now about 34 years?

Ambassador Tobias noted that Zimbabwe is not a focus country, but he met recently with the U.S. Government team there, and it is doing a better job than most of the focus countries in integrating various efforts. In particular, there is good cooperation between CDC and USAID.

Why is this year's World AIDS Day focusing on women's issues once again? Are we making special efforts to tie into the treatment part of PEPFAR?

Ambassador Tobias acknowledged that the President's plan has gained a great deal from its predecessor, the PMTPC program, which is now integrated into the President's plan. Clearly one objective is that the most effective orphan program we can have is keeping the mother alive.

Dr. Sullivan thanked Ambassador Tobias for his leadership.

International Subcommittee Chair Mason noted that PACHA had foresight in passing a resolution last year encouraging the same safety and efficacy standards for drugs used in the PEPFAR program as are used in the United States.

Presentation topic: The Cost of Treating Chronically Ill AIDS Patients: A Doomsday Scenario
Presenter: Mr. Jeremiah Norris, Senior Fellow, Hudson Institute, Washington, DC

Mr. Norris noted he was supposed to discuss WHO and drug listing and de-listing. But it is time to think the unthinkable. Mr. Norris noted that WHO had relied on copy drugs from India for its plan to treat 3 million AIDS patients by 2005 at an estimated cost of

$5.5 billion, but since then, several of these drugs have been withdrawn. Now all seven of the drugs being supplied for the WHO plan by Ranbaxy have been withdrawn due to failure to prove bioequivalency.

WHO has focused on those immediately needing treatment. But neither that organization nor the World Bank has studied the cost of various future scenarios. Most likely, Mr. Norris said, there will be a number of chronically sick people whose needs cannot be funded.

Mr. Norris has prepared cost breakdowns for three scenarios, specifically, first-line ARV treatment for 3 million by 2005 (the WHO plan); first-line ARV treatment for 8 million in 2010; and combined first- and second-line treatments for 11.5 million people from 2004 to 2010.

Before noting the costs of each of these scenarios, Mr. Norris showed a slide discussing transaction costs. Say, for example, that your total budget is $7 billion. For a program of the type under general discussion, you incur costs within that of 10 percent for conveyance, insurance, and freight. That gives you $6.3 billion to work with. Then you subtract 24 percent of that for import duties/taxes/customs, giving you $4.8 billion to work with. But then you incur 2 percent of that for procurement agency fees, in-country transport, storage distribution, wastage/pilferage, and so on, so in the end, your grand total available funding to actually get AIDS drugs for patients is $3.84 billion, out of a starting point of $7 billion.

Mr. Norris commented that this is a big price to pay for transactions. He noted that Congressman McDermott had done a study that showed of every dollar intended for the patient outside the Beltway, 53 cents stayed inside the Beltway, and the rest entered the door of various countries' Ministers of Health but there was no reliable accounting of what came back out.

In the first scenario, first-line ARV treatment for 3 million in 2005 (the WHO plan), Mr. Norris estimated the number of HIV/AIDS victims at 49 million. The number to be treated under this scenario is, however, 3 million, the ARV drug price per person per year for which would be $389. If one adds transport costs of 10 percent to that, and an estimated 15 percent for import duties, taxes, and transfer fees, then another 10 percent for estimated storage and distribution fees, the actual product price is $525/person, or $1.6 billion to treat 3 million, not including medical infrastructure costs estimated at a factor of 3 over that—$4.8 billion. (Estimates provided by Doctors Without Borders.)

If one runs these kinds of costs through the second scenario, ARV treatment for 8 million in the year 2010, the total product costs plus all the transaction costs add up to $4.6 billion, not including medical infrastructure costs estimated at a factor, again, of 3 over the price or $13.8 billion.

In the third scenario, the "doomsday" scenario, where you combine first- and second-line treatment costs over the next 6 years, the total cost of treating 11.5 million patients climbs to $94.6 billion.

Mr. Norris said his numbers might be too high, but he did not include the costs of other factors, such as pillaging, substandard products, administrative overhead, care of orphans, or the costs of treating AIDS-related TB and/or malaria.

His conclusion was that organizations engaged in treating AIDS patients worldwide have an obligation to look at these numbers and come up with their own.

Question and Answer Period

A related *Lancet* article quoted lower numbers. Also, we've seen that lower priced drugs, copy drugs included, can sometimes work. Your comment?

Mr. Norris responded that he would send to PACHA a Hudson Institute commentary to the *Lancet* article. He said the study referred to by the article was too small to "tell us anything."

At present, PACHA is trying to understand preliminary data on MTCT and NV and resistance. There may be resistance that confers to NV as well as to some other drugs. Is this an important economic discussion to have at this point? What would be the cost-effectiveness of putting a group together to purchase patent rights from primarily U.S.-based pharmaceuticals?

Mr. Norris noted he is not an economist, but even at zero price for drugs, "we don't know what the medical infrastructure costs will be." They will, however, overwhelm any price.

In your estimates, are you accounting for support services, testing for resistance, or treatment for side effects?

Mr. Norris responded no to each question. What has been lost in the argument is discussion about transaction costs. The World Bank didn't want to hear about this.

These costs are not sustainable over time, particularly when treating people for life. Is it critical for recipient countries to become economically stable and viable themselves?

Mr. Norris recommended the South African President's plan as the most comprehensive in the world because this leader knows he is in the AIDS struggle for life, so he has planned his funding accordingly. Operational costs for sustaining the program have been taken into account in the plan.

How do you prevent some of these transaction costs?

Mr. Norris replied, “If you find out, let me know. I was in USAID and the State Department, and these costs worried us a great deal. Americans are not tired of foreign aid. They’re tired of what happens to their dollars. That’s why they’re increasingly turning to private funds.”

Almost all of these estimates seem on the high side, including 100 million living with AIDS. I had heard 40 million. Then you’re adding 5 million/year.

Mr. Norris responded that the numbers keep shifting. We started last year with 42 million then that figure went down, then it went back up to 45 million. The Council on Foreign Relations estimates 100 million. “When China, India, and Russia kick in, we’ll be up there,” he added.

It was commented that almost all of our estimates of current prevalence are more likely to be over than under.

Mr. Norris responded that he hopes so, but a World Bank official last year said every estimate we’ve made is wrong.

It was commented that, regarding some of the other costs, such as duties, tariffs, and taxes, we should get countries to waive those costs. In terms of infrastructure costs, the average salary for people on the ground can be low, but your estimate seems to indicate 6-8 people supporting every 1 in care. And that seems high. Also, second- and third-line treatments are questionable everywhere in terms of risks and benefits. They will contribute extremely little in the treatment and control of HIV. In addition, there are no practical alternatives for the pharmaceutical prices coming out of industrialized countries, particularly the United States. These prices are based on research and development costs and what the companies think the market will bear. We should have our eyes on what the true incremental costs are of taking already developed drugs and creating a separate procurement system that does not include marketing costs, and so on.

Mr. Norris noted that there is some voluntary licensing between big pharmaceutical companies and firms abroad. What would be produced in South Africa under the mentorship of the patent holder are true quality drugs for the local market. He predicted more of this voluntary, not compulsory, licensing.

International Subcommittee Chair Mason noted that he has two resolutions, one on the need to monitor treatment outcomes, and one on international AIDS conferences. He announced that after discussion at lunch on international conferences, the Subcommittee will decide whether to move forward on the latter resolution.

Working Lunch—Bangkok and International Conference Discussion

International Subcommittee Chair Mason announced that the Subcommittee will formally put two motions on the table later, one on treatment monitoring and one on international

conferences. He noted that there may be a few modifications made to the resolution drafts already handed out.

Prevention Subcommittee Report

Prevention Subcommittee Chair Anita Smith thanked her Subcommittee. She noted that members met in September and also that some members stayed to listen in on the International Subcommittee meeting the next day. The presentations arranged by the Prevention Subcommittee for today reflect two issues of concern: the first speaker will talk about media and women's issues, then the remaining speakers will focus on issues related to reauthorization of the Ryan White CARE Act (RWCA), which the Prevention Subcommittee worked on with the Treatment and Care Subcommittee. She noted that Treatment and Care Subcommittee Chair Brent Tucker Minor participated in Prevention Subcommittee discussions of this issue through both meetings and phone calls.

Before introducing the first presenter, Ms. Smith noted that the Subcommittee would have two resolutions to present tomorrow, one on name reporting and the other on the RWCA reauthorization. She noted that there may be modifications to the resolutions before that time.

Ms. Smith then introduced Ms. Sharon I. Sopher as an Emmy award-winning television news and documentary journalist and producer who self-diagnosed her AIDS condition from information she found online. In 2001, Ms. Sopher launched a multimedia project called the HIV Goddesses: A Women's Wellness and Empowerment Project, the centerpiece of which is her documentary, "HIV Goddesses: Stories of Courage," which premiered in New York City earlier this fall.

Presentation topic: HIV Goddesses: Stories of Courage
Presenter: Ms. Sharon I. Sopher

Ms. Sopher noted that her exhibit is premiering today in Washington, DC, so she will speak from the heart and not from prepared remarks. In dealing with HIV/AIDS, "we're at war. Each of us chooses the weapon of our choice to slay the enemy, each trying to find spiritual strength and the intellectual ability to address an enemy who seems smarter than all of us put together." Ms. Sopher's hope is the HIV Goddesses project will touch us, as the Vietnam Memorial touched her during her first visit.

Ms. Sopher recalled when she worked with NBC and was primarily assigned disenfranchised issues, meaning Africa and women. This AIDS project has further reinforced her belief that the most important way to reach the American public is to take it to the grassroots level, person to person, woman to woman, community to community.

She has devised a Goddesses mobile that takes her project on the road because she can't fly. The mobile has inflatable screens. This is the way films are shown in Africa: You take the Cinema mobile to the bush, flip up a side of the truck, and everybody comes to see that movie.

Ms. Sopher noted that the Goddesses project is her first in America in 20 years. Like most journalists, she said, she would not know about AIDS in America unless she had it herself. “We’ve been conditioned by PR campaigns to connect AIDS to Africa and not to America,” she said. And this is one of the major reasons women in America are so vulnerable. That’s one of the reasons for her film, which will be shown during a reception in the Secretary’s Office later this evening as well as on World AIDS Day. She added that people like me and you and our health policy system have to help make links of AIDS to America for the American public.

Ms. Sopher recalled the circumstances of her illness. Back in 1995 she collapsed and was sent to Lenox Hospital in New York to the cardiac unit. No one could explain her dry cough, which never went away. It was the beginning of a series of infections, including mastitis. In 1996, her lymph system started getting inflamed. A lymph biopsy was performed, and she got a staph infection. It was the beginning of her awareness. She moved to Las Vegas for better air, then to Wisconsin, to be with her mother and sisters.

Finally, in Wisconsin, they saw that the lymph glands were huge, four times larger than they should be. Finally the medical system agreed there was something wrong. Ms. Sopher recounted spending 2 hours online to see that the information on HIV/AIDS was a perfect match for her symptoms. Then she realized she couldn’t possibly be the only woman in the United States having this experience. Being a journalist, she wanted information, and she wanted to end the silence. Ms. Sopher then showed a segment of a film entitled “Garden Songs: A Gift of Hope and Inspiration to Women Living with HIV in America.”

Ms. Sopher commented that having HIV/AIDS is a lonely experience, and that the stigma hasn’t been changed by any of the medical advances. Even today, so much prevention is about condoms and condoms in gay bars, although women are biologically vulnerable. Ms. Sopher called for an update of our knowledge of where the epidemic is. She said we stood by while the women in South Africa became an endangered species, and now we have to acknowledge that could happen in America. We have to inform all women. For example, who would have thought that the wife of the former Governor of New Jersey could possibly be at risk? Is men on the down low just a black phenomenon? There’s something so innately racist in America about how AIDS is presented, Ms. Sopher charged, and it puts women at even greater risk.

Ms. Sopher asked that AIDS be mainstreamed as a women’s health issue and not linger in the AIDS ghetto. She said she had received very little support from within the AIDS community. AIDS offices are often not women-friendly, she said. If this is put in the health arena, everything else that should be done will be very clear.

Ms. Sopher recalled the recent movie “Far from Heaven.” Publicity for the movie was all about empathy for the married man in his struggle for sexual identity, and not one word was said publicly about the risk to his wife. Someone has to start this dialogue. Ms. Sopher found that serial assaults by men positive with AIDS are not new nor unique: she

went online and found dozens of such stories around the world. Women aren't routinely tested even today, when the majority of infections come from heterosexual relations, "often with a man you think you're in a monogamous relationship with," Ms. Sopher said.

It's a human rights issue for women to be HIV-free. There's a lack of discussion about the accountability of men, she concluded.

Question and Answer Period

Ms. Smith noted that Ms. Sopher would be available later at a reception and showing of her film in the Secretary's Office.

Presentation topic: Evolution of California's HIV Reporting System
Presenter: Mr. Michael Montgomery, Chief, Office of AIDS, California Department of Health Services

Mr. Montgomery provided an historical perspective of the reporting system used in California, including several unsuccessful efforts to legislate AIDS reporting. Through the budget, the Governor in 2000 permitted development and implementation of a regulation to report HIV infection using a 17-digit code (a "code-based system"). A section of California State law encouraged the use of a code-based system because it "prohibits the release of HIV test results using identifying characteristics, except under certain circumstances."

California worked closely with the CDC on system development to respond to CDC concerns because the State wanted to be able to report its data to the CDC. Features of the system include that laboratories and health care providers must submit reports and that reports from labs can be followed up on by surveillance staff. System officials can and do unduplicate data between counties and States. The system uses a modified CDC case report form.

Mr. Montgomery showed how the code is constructed, including using the last four digits of the patient's Social Security number. This was controversial, but officials believe it was essential to prevent duplication of cases.

HIV-reporting exemptions in the State are:

- Publicly funded alternative testing sites
- Other anonymous or unlinked HIV testing programs
- Blood banks and plasma centers
- Blinded and/or unlinked seroprevalence studies.

In addition, there are plans to allow for blinded seroprevalence studies reporting.

Mr. Montgomery reported successes and challenges.

Successes are:

- Smooth implementation
- Reliable code and system
- All counties responsive
- Unduplication capacity
- No change in HIV testing patterns
- More than 35,000 unduplicated cases reported.

Challenges are:

- System is somewhat cumbersome and requires a lot of training, especially in the face of high turnover
- Increasing reporting backlog, particularly in Los Angeles County
- CDC is not accepting code-based cases
- Failure of providers to keep mandated cross-referring logs
- Funding limitations.

Recent developments include a performance review report that recommended names reporting, but this has not been endorsed yet by the Governor.

Mr. Montgomery then reported on data gathered by the State. His first slide showed the effect of HIV reporting on AIDS reporting—an increase of about 300 cases per month since the system was instituted. Cumulative totals of persons living with AIDS and persons living with HIV show that AIDS cases number 136,755; AIDS cases (living) total close to 58,000; and HIV cases (living) total about 35,000 in the State.

Methods of exposure data show that males living with AIDS as well as reported with HIV are predominantly men who have sex with men (MSM). Females living with AIDS and reported with HIV are predominantly being exposed through heterosexual contact. Black and Hispanic men as well as women are disproportionately affected as well. In addition, Los Angeles is the "epicenter" of the epidemic in California.

Testing patterns following implementation of the reporting system show no change in:

- Total number of HIV tests
- Number of positive HIV tests
- Number of tests by bisexuals, injecting drug users, persons with HIV-positive partners, and other risks
- Number of Hispanic, African American, Asian/Pacific Islander, Caucasian, or other races who test.

There has been a slight, gradual increase in the number of tests by MSM, possibly due to:

- Increasing risk among young MSM
- Improved targeting of this at-risk population
- Increasing attention paid to syphilis in urban centers.

There has been a slight, gradual decrease in the number of Caucasians testing, possibly due to improved targeting of at-risk populations.

Question and Answer Period

What happens if an individual does not have a Social Security number?

Mr. Montgomery said zeroes are entered instead.

How is the reporting system affected by HIPAA?

Mr. Montgomery said it's a public health exemption.

How does four-digit last-name coding work?

Mr. Montgomery explained that this part of the code is the first letter, then an algorithm of subsequent consonants. He also noted that when a person is diagnosed as an AIDS case, they are removed from the HIV database.

Dr. Yogev commented that he thinks California has a high percentage of unreported cases, perhaps more than half.

Mr. Montgomery noted that the State has had difficulty getting high-risk populations to test, and his office is trying many different strategies to combat the problem, including encouraging injecting drug users (IDUs) to come in to be tested for hepatitis C.

If California decides to switch to another reporting system, how long will it take to implement?

Mr. Montgomery said, hypothetically it could take a year. The mechanics won't be the problem but, rather, statutory language changes. "Our ultimate concern is that we have a system that encourages people to come in to get tested. What's key is that confidentiality is ensured, and with the present system, we're been successful with that."

A number of members noted that name-based reporting doesn't seem to create problems in the predominant number of States that use it.

Presentation topic: HIV/AIDS in New York State
Presenter: Guthrie S. Birkhead, M.D., M.P.H., Director, AIDS Institute, New York State Department of Health

Dr. Birkhead gave a presentation on:

- The HIV reporting system in New York State
- Evaluation of that system
- The RWCA.

Dr. Birkhead showed a slide that compared annual rates of death due to leading causes of death among persons 25-44 years of age in the United States from 1987 to 2001, and it

showed just how dramatic the rise and fall of AIDS deaths have been. He noted that, nonetheless, his State leads the Nation in cumulative AIDS cases and persons living with AIDS. With 6.6 percent of the U.S. population, New York has 19 percent of the cumulatively reported AIDS cases and 17 percent of the living AIDS cases. New York City, with 34.8 AIDS cases per 100,000, is surpassed only by the District of Columbia in per capita rate of AIDS cases.

The State still experiences about 2,000 AIDS death per year, "an incredible toll in any population," and there is a steady increase in those living with AIDS, with IDU cases higher in New York than in California, with spillover effect into the State's female population. Despite these facts, New York's funding levels have remained stable.

As of 2002, reported AIDS cases in the State by race/ethnicity showed black cases on a steady incline, Hispanic cases showing a slight decline, white cases showing a slight incline, and Asian/Pacific Islanders and Native American cases showing a very slight incline. In addition, in terms of exposure, the State is beginning to see a reversal of trends, where IDU cases are going down and MSM cases are going up. Nonetheless, the State does a good job of targeting prevention and health care services. To continue requires a great deal of knowledge about the many different threads of the epidemic.

Dr. Birkhead noted that AIDS surveillance alone is not sufficient. From a 1998 study, it was found that HIV cases were not declining. For example, among adolescents in the 25 States studied, there was a 3 percent AIDS case rate versus a 14 percent HIV infection rate; among African Americans, the rates were 45 percent against 57 percent; and in terms of heterosexual transmission, the rate was 12 percent against 18 percent.

If HIV surveillance data can be obtained, they would be very helpful in:

- Estimating the burden of HIV disease in the population
- Monitoring trends in the HIV epidemic and identifying populations at current risk
- Targeting HIV prevention and evaluating its effectiveness
- Allocating funds for health and social services
- Effective tracking of the epidemic.

In 1998, New York enacted a public health law on reporting and partner notification. In 2000, regulations went into effect requiring:

- Reporting of persons with HIV, HIV-related illness, and AIDS by name
- Reporting of sexual and needle-sharing partner names known to the medical provider or whom the infected person wishes to have notified
- Development of domestic violence screening protocol for each identified contact
- Maintenance of anonymous counseling and testing as an option.

Those who must report are physicians, nurse practitioners, midwives, and clinical labs, including blood banks; what must be reported are antibodies, viral load, and CD4 counts less than 500. The information that must be reported includes patient name and known sexual/needle-sharing partners.

New York has a secure data system, Dr. Birkhead maintained, even though it is fairly large, involving several hundreds of thousands of lab reports each year.

A look at data derived from the reporting system shows that HIV infection is on the rise among certain age and risk groups (ages 13-29, IDU and heterosexual contact, and among females and blacks). Dr. Birkhead commented that this points us in the direction of the epidemic. Black females are particularly affected among the living HIV/AIDS cases, constituting 56.6 percent of all female cases.

The State undertook a CDC-funded impact study for 3 years. The six major study components were to:

- Review the usefulness of the data collected
- Measure the impact of HIV reporting on HIV counseling and testing rates
- Survey groups at risk to determine knowledge and attitudes toward the law
- Use focus groups of HIV-positive individuals, service providers, and partner notification staff
- Survey as a sample of HIV counseling and testing providers
- Survey practicing physicians.

The State found that there had been a big increase in partners identified since the reporting system had been instituted. New identifications of positive partners also rose.

Against the concern that name-based reporting would cause individuals to avoid testing or medical care, the State found the law and its regulations had had minimal to no impact in a variety of settings. In addition, it was found that the availability of rapid testing has increased by 30 percent those coming in to be tested.

The study found that there was no evidence the law is deterring HIV testing among high-risk groups, and that attitudes toward the law, including partner notification, were generally good, with MSM more skeptical. It was found that the demand for counseling and testing services has stayed the same.

Dr. Birkhead noted that the study results will be published in the near future.

Turning to the RWCA, Dr. Birkhead gave an overview, and discussed reauthorization and ADAP.

New York State is a major beneficiary of the act as it is currently structured, Dr. Birkhead noted, and made the plea that major structural changes be avoided. New York is particularly concerned about:

- Consolidation of Titles I and II
- Elimination of the statewide component of the Title II-based funding formula
- Medicalization of the act, which would limit allowable services to medical/clinical services.

At present, through Titles I and II of the act, the State provides:

- Medical care
- Medications (ADAP) case management
- Treatment adherence support
- Mental health services
- Counseling (such as for substance abuse and risk reduction)
- Peer support
- Housing assistance
- Nutrition/meals
- Transportation
- Outreach for case finding and other supportive services.

New York's recommendations include:

- A separate ADAP allocation formula favoring States with waiting lists
- Revisions of the allocation formula to include cases of HIV, not just AIDS
- Increases in ADAP funds
- Continued funding of a range of health care and supportive services.

Since 1991, New York's receipt of total funds under the act has risen from about $250 million to $2 billion.

Question and Answer Period

How can we get the act to ensure access to medication for everyone who needs it?

Dr. Birkhead said his State proposes a formula that would recognize unmet need, yet not take funding from other States, like New York. That formula would require a separate ADAP funding allocation.

How did you get the reporting and partner notification law passed?

Dr. Birkhead noted that the proposal was very controversial, and that it took a year and a half to develop implementing regulations, with several cycles of public input.

Presentation topic: The Role of FDA in HIV Testing
Presenter: Elliot P. Cowan, Ph.D., Associate Director, Division of Emerging and Transfusion Transmitted Disease, Center for Biologics Evaluation and Research, Food and Drug Administration, U.S. Department of Health and Human Services

Dr. Cowan characterized FDA's role in HIV testing: it facilitates product development and approves safe and effective HIV tests and monitors the integrity of HIV tests. He characterized tests that are available for medical diagnosis and for blood and plasma donor screening. These screening tests detect antibodies, including those that detect HIV proteins, although these are being replaced by other tests that detect HIV nucleic acid (NAT). There are also supplemental tests—Western blots and immunofluorescent assays.

Dr. Cowan showed the effectiveness of donor screening, and noted that the period of time required to get test results has shrunk to 22 days for an antibody screen and 11 for an HIV RNA screen. He noted that early in the epidemic the risk of infection through transfusion was 1 in 100, but now it is 1 in 1.9 million. He projected that with new technology, the ratio will fall to 1 in 3 million.

Additional medical diagnostic tests are tests for prognosis and patient management and tests used as an aid in the diagnosis of HIV infection. Dr. Cowan noted the detuned assay as used by the CDC is an epidemiologic tool to determine recent infection. For individuals, he added, NAT is probably the best test to determine that.

Currently, there are three FDA-approved rapid tests. No special storage conditions or instrumentation are needed. The tests are easy to perform, with visual readout. The results are available within 20 minutes. All detect antibodies. Dr. Cowan showed how the OraQuick test works for detection of antibodies to HIV-1 and -2 in finger-stick whole blood, venipuncture whole blood, plasma, and oral fluid, the latter of which is the most recently approved test in this series.

More recently than that, FDA has approved the Trinity Biotech series—Uni-Gold—for detection of antibodies to HIV-1 in venipuncture whole blood, serum, and plasma.

Dr. Cowan characterized the sensitivity performance of rapid HIV tests. He noted that OraQuick's oral fluid test is a bit less sensitive at 99.32 percent than the others. He noted that patients on HAART can get false negatives using the oral fluid. About 550 people were involved in the sensitivity survey.

Dr. Cowan then discussed the Clinical Laboratory Improvement Amendments (CLIA) waiver, meant to expand access to rapid HIV tests. The CLIA waiver now extends to the OraQuick test for whole blood and oral fluid and the Uni-Gold test with venipuncture whole blood. It permits fewer laboratory restrictions and notification of preliminary results without need to recontact the person tested.

At present, rapid HIV test reactive results are treated mostly as preliminary positive results. Dr. Cowan explained that all reactive results must be confirmed using an appropriate supplemental test. He noted that his office is working with the supplemental test manufacturers to change their labeling so that these tests can be used with the rapid test. He noted that screening test results are highly accurate, but reactive test results should be confirmed through supplemental testing. And he noted that State laws may preclude interpretation of results as a preliminary positive result.

Sale of rapid HIV tests is restricted to clinical laboratories; the test is approved for use only by an agent of a clinical laboratory; and test subjects must receive an information pamphlet and pre- and posttest counseling. The tests are not approved for use to screen blood or tissue donors.

A current hot potato is how certain restrictions apply to the CLIA waiver. These include the fact that CLIA-waived test entities must:

- Enroll in a CLIA program
- Obtain a certificate of waiver
- Pay a biennial fee
- Follow manufacturers' instructions
- Meet State requirements.

In addition, the sponsor must also apply for the CLIA waiver after initial approval is received and by providing studies to demonstrate that the device is simple and accurate in the hands of intended users.

At present, the following rapid tests are waived under CLIA:

- OraQuick for use with whole blood
- OraQuick for use with oral fluid
- Uni-Gold for use with venipuncture whole blood
- Uni-Gold for use with finger-stick whole blood.

Dr. Cowan noted that sales and use restrictions still apply to CLIA-waived rapid HIV tests. He also noted that FDA works quite closely with other agencies, particularly the CDC, on waiver considerations and training.

Current rapid test issues include whether a second rapid test could be used to confirm results of the first "on the spot," obviating the need for supplemental testing by Western blot, IFA, or NAT. Also, availability of a rapid HIV test that can distinguish between HIV-1 and -2 antibodies to aid in part in measuring the prevalence of HIV-2. Another issue is self-testing using rapid tests, which "will take a lot of discussion." Some countries still ban home tests. Dr. Cowan feels self-testing using rapid tests is probably inevitable.

In summary, the present and future of HIV testing includes the following perspectives:

- FDA sees advances in HIV testing as a public health priority.
- Excellent HIV tests are available, making it easier than ever to be tested.
- FDA is working closely with manufacturers to facilitate development of new tests and of promising new technologies to make it increasingly easy for more people to be tested in a greater number of environments and to assist small manufacturers.

Question and Answer Period

Why is FDA accepting the supplemental test of Western blot versus other tests that are better?

Dr. Cowan noted that the Western blot is currently the gold standard, but that FDA is waiting for data on two rapid tests that might work as well. Then formal studies will need to be done, and an advisory committee will need to consider the matter.

It was mentioned that two relevant studies have been done, one in the District of Columbia and one in Texas, but Dr. Cowan said he believes these studies predate approval of the current rapid tests and that further studies will be needed involving the current products.

There was discussion on OraQuick test results and how long they might take. Dr. Sweeney said the package insert says 20-40 minutes, but she has heard of one case where there was a confirmed positive in 40 minutes. Dr. Cowan responded that according to the company data, there are no cases in which specimens were nonreactive at 20 minutes but then became reactive at 40.

Asked about the advent of home tests, Dr. Cowan said FDA will open that subject for public discussion at the relevant FDA advisory committee. He noted that at present, home test kits can be found for sale on the Internet and that FDA is trying to block their sale, as they are illegal.

It was mentioned that more counseling guidelines might be needed given the advent of rapid tests, as the quick results can cause intense reactions. Dr. Cowan noted that after the approval of the first OraQuick test, the *Washington Post* carried a major article about the impact on Whitman-Walker counselors.

It was suggested that FDA not explore confirming results through use of exactly the same rapid test. Dr. Cowan reassured PACHA he is looking at a different test that contains different antigens. He reiterated that studies are also needed.

Presentation topic: Update on the HIV/AIDS Epidemic in the United States
Presenter: Robert S. Janssen, M.D., Director, Divisions of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Dr. Janssen began by discussing incidence and prevalence, the former as the number of new HIV infections occurring each year, and the latter as the total number of people living with HIV or AIDS each year. He noted that CDC has initiated an incidence surveillance system.

Under incidence, the estimated number of new HIV infections annually in the United States looked flat through 2000, but this will be informed by the new surveillance system. In 32 States, the annual number of HIV/AIDS cases by transmission category saw a 17 percent increase in 2002 in MSM cases; however, other transmission categories seem stable. The concern now is, given the rise in the number of persons living with AIDS, does this represent increased incidence? Dr. Janssen said the CDC thinks it might.

In short, incidence trends are stable or possibly increasing in some groups, possibly MSM, and prevalence is constantly increasing. In light of this, the CDC has launched new prevention initiatives to:

- Make voluntary HIV testing a routine part of medical care
- Implant new models for diagnosing HIV infections outside medical settings
- Prevent new infections by working with persons diagnosed with HIV and their partners
- Further decrease perinatal HIV transmission.

Awareness of serostatus among persons with HIV:

- The number infected is between 850,000 and 950,000 nationwide—most likely in the upper boundary now
- The number unaware of their HIV infection ranges from 180,000 to 280,000.

The roughly 25 percent of people with HIV who are unaware of their infection account for approximately 55 percent of new infections. The 75 percent who are aware account for about 45 percent of new infections. This reinforces the need for prevention services for those living with HIV. Late-testing surveillance data from 2000-2003 indicates, also, that of the 70,233 persons diagnosed with HIV in this time period, 37 percent developed AIDS within a year of an HIV-positive test.

CDC's approaches for diagnosing more infections include:

- Increasing diagnoses in current venues
- New venues
- New technologies.

At present, in current venues (CDC-funded sites), the number of tests reported and the number of HIV-positive test results reported are stable. "Rapid tests are giving us the same prevalence overall, except in some pockets," Dr. Janssen explained. One result of these data is that CDC is now working with public health departments to encourage more testing in areas where the most positive results are appearing.

In addition, new venue demonstration projects funded for a total of $23 million through 2005 are underway to:

- Develop models and demonstrate feasibility of implementing AHP strategies
- Develop and support seven demonstration projects in 32 sites, including 9 health departments, 17 community-based organizations, and 6 university-based medical providers.

HIV-testing demonstration projects are designed to provide:

- Routine HIV testing in medical settings
- Rapid HIV testing in jails
- Rapid HIV testing in nonmedical settings
- Partner counseling and referral using rapid HIV tests
- Connections with social networks.

Demonstration projects involving partner counseling, testing, and referral and social networks have turned up three-fold higher HIV-positive test results than the Nation as a whole. In addition, CDC may be looking in the future toward more work with high-

prevalence hospitals. The Cook County Hospital's Emergency Department (ED) in Chicago has been using OraQuick testing since October 2002. The result is that 62 percent of patients accepted HIV testing, 98 percent received their test results, 2.4 percent of new HIV-positive individuals turned up for test results and counseling, and 80 percent of them entered HIV care in a median of 18 days. In addition, the number of HIV tests ordered by ED providers increased from 5 to 29 per month.

In terms of new technologies, Dr. Janssen deferred to Dr. Cowan's presentation, but noted that the CDC had engaged in procurement and distribution of 250,000 OraQuick test kits in 2003—167 shipments to 108 health departments and community-based organizations (CBOs) in 36 States. Consequently, 1.4 percent of 22,811 person tested were found to be HIV-positive. An additional 105,200 tests kits were shipped in 2004 to 73 health departments and CBOs in 22 States.

One hope is that rapid testing will improve the number of people who receive their results, and some preliminary data show this is the case.

The CDC does have concern about the use of the rapid test in nonmedical settings, so it is now helping with training.

Key recommendations regarding individuals living with HIV/AIDS unknowingly include:

- Screening for risk behaviors, STDs, and pregnancy
- Prevention message and counseling
- Partner notification.

CDC now has six Prevention in Care Settings demonstration sites where provider training has been completed.

Question and Answer Period

It's well to identify those who are positive, but once they are identified, will we provide care, treatment, and support?

Dr. Janssen said the CDC has published guidelines on what services it expects to be available for newly identified individuals and has worked with HRSA on how much money will be needed to support those services. He asked PACHA to ask HRSA directly for the estimated cost. In terms of posttest counseling, the CDC recommends that it not be abbreviated. It should be the same as counseling on cancer or some other chronic disease.

What kind of incentives do you offer to individuals to come and get tested?

Dr. Janssen said sometimes movie or theater tickets are offered in exchange for individuals asking their friends to come in and get tested, but not in exchange for a positive test.

Concern was expressed about the 75 percent who know they are infected contributing to further infection—45 percent of the new cases. Aren't people who are positive less likely to infect other people? Also, what is the CDC's program for mobilizing community leaders?

Dr. Janssen responded that when individuals know they are infected, they are less likely to transmit. There is an approximate 68 percent reduction in risk behavior when people learn they are infected. In terms of the community leadership alliance: In 1999 to 2000, the CDC launched the alliance, and is now revising it to take on new partners and also to target the activities of the partners to become more in line with current programs. For example, to advance prevention, the CDC is working with the pharmaceutical companies on how to efficiently get information to physicians. Those companies have good access.

How were CBOs affected in terms of funding when CDC began its new initiatives?

Dr. Janssen noted that the directly funded CBO program is a supplemental program where 50-60 percent lose their funding upon refunding. A number of State departments follow up and put out announcements that then allow those CBOs to get picked up. With the Minority AIDS Initiative, the CDC tries to build capacity, then to encourage these CBOs to find funding streams other than CDC. "We're in the process of evaluating this initiative, asking the question, were we actually able to build capacity," Dr. Janssen said, adding that the review should be completed by next spring.

It was commented that RWCA should get more funding for prevention, especially given the CDC estimates of those who seem not to know they are infected and go on to infect others.

Dr. Janssen said he's comfortable with the figures that indicate the majority of new infections are being transmitted by those who don't know they are infected.

It was noted that the Prevention Subcommittee has discussed the need for a more coherent HIV prevention program to emerge from the RWCA reauthorization. This includes physicians who are uncomfortable with assessing levels of risk among their patients. Dr. Janssen agreed that "we all struggle with individuals who are diagnosed, show up in the ER with pneumonia, get medicine, leave, then show up with pneumonia again a year later. That's a very challenging population. The CDC is trying to reach it through its directly funded CBO program."

Dr. Sullivan thanked Dr. Janssen for his presentation and asked him to comment on how the incidence of infection has remained stable since 1994. Dr. Janssen responded that this is a complex epidemic; it's really a bunch of epidemics, some of which have come under control, while others have not. The CDC has slides that it has stopped showing because they indicate that although incidence level remains the same, there are surges that appear as spreading lights across the country. In terms of prevention programs, "as we get better data, we will be able to engage behavioral interventions that are about 30-40 percent

effective." If people who learn of their infection reduce their risk behavior and the number of people who don't know they are infected declines, one would assume that the number of new infections should decline. "But we'll have to wait to see. People who are getting infected now have multiple comorbidity: they're substance abusers, they're depressed. At the CDC we don't deal with substance abuse."

Adjournment

Dr. Sullivan characterized the presentations and questions raised as excellent and he thanked the Subcommittees and their Chairs.

Presidential Advisory Council on HIV and AIDS (PACHA)
Twenty-Fifth Meeting
Hubert Humphrey Building
200 Independence Avenue, S.W., Room 800
Washington, DC 20201

November 9 and 10, 2004

Day Two

Welcome Remarks

PACHA Chair Dr. Louis Sullivan outlined the agenda: The morning will be devoted to reports and presentations by the Treatment and Care Subcommittee, then to public comments. Lunch will be a working session, where Subcommittees will get together to discuss proposed resolutions. Then the Council will reconvene in the afternoon for motions on Subcommittee resolutions and voting.

Dr. Sullivan noted that Dr. David Reznik would be standing in for Brent Tucker Minor as Treatment and Care Subcommittee Chair.

Treatment and Care Subcommittee

Dr. Reznik introduced Dr. Rodney Whitlock to provide a congressional perspective on the Ryan White CARE Act (RWCA) reauthorization.

Presentation topic: U.S. House of Representatives' Perspective on Reauthorization
Presenter: Dr. Rodney Whitlock, Deputy Chief of Staff to Congressman Charles Norwood (R-GA)

Dr. Whitlock will walk PACHA through a general perspective on the reauthorization process. This will involve a little politics and a little policy. Then he will be open to questions, although he wants to learn from PACHA, too.

Since spring, he has talked to as many people as possible about the direction of reauthorization, and changes. That's all caught up in politics, he said, but at least now we know who will be the President. On the U.S. Senate side, it is not clear who the chair of the relevant committee will be. It may be Michael Enzi (R-WY), but then again Judd Gregg (R-NH) may not be leaving as chair. The committee staff really can't talk to their House counterparts until they know.

On the House side, the relevant committee, Energy and Commerce, is chaired by Joe Barton (R-TX), and Dr. Norwood will play a role in it. Dr. Whitlock said he's not sure very many Representatives know where to start on the issues. They do need to get up to

speed, however, because “we need to get the reauthorization done.” It will be interesting to see the role Senator-elect and former PACHA Co-Chair Dr. Tom Coburn (R-OK) plays in the reauthorization. Dr. Whitlock said he has great admiration for Dr. Coburn, and noted that he was deeply involved in the last reauthorization.

On the policy side, the most important consideration will be money. Every program out there will be engaged in a battle for scarce resources. Dr. Whitlock said he thinks the prescription drug plan will not go smoothly. He noted Dr. Norwood voted against it, out of concern about the cost, which will be more than was thought. He predicted that everything will get squeezed—Title 7, Title 8, Medicaid, home health, and so on.

This means that when one looks at reauthorization of RWCA, the battle will be between the ideal available resources. There may be some “very difficult” prioritization decisions. It is too early to see how they will play.

Dr. Whitlock predicts several major items will be discussed in Congress.

First, the RWCA model is evolving. It began as a palliative care act, but it is now moving toward maintenance or a chronic care model. Do we know enough about the direction of the epidemic to do what the Institute of Medicine (IOM) suggested? To look at core services, reduce flexibility, and mandate services?

Dr. Whitlock noted: “We aren’t even close to being able to describe core services as well as pay for them. When we get there, we will have reached the time for difficult decisions.”

Second, there is the issue of regional variation. Dr. Norwood is from Georgia, and he will be intensely interested in what is available for Georgia and the Southeast and whether it will address patients’ needs there.

Third, maintenance of effort will be discussed. Dr. Whitlock said he is quite certain this is in light of concerns about other health programs being squeezed. In Georgia, the Governor is having a hard time finding money. That will happen in other States, too.

In conclusion, Dr. Whitlock emphasized that many Representatives don’t really know much about RWCA or how important it is. Many of them are Republicans. Dr. Whitlock urged advocates to help Congress—particularly majority Members of Congress—understand what the act has done and how it has made a difference.

Questions and Answers

Dr. Reznik asked what other steps PACHA could take in the reauthorization process.

Dr. Whitlock responded that he would like to know from PACHA how extensive its recommendations will be. He can guarantee that PACHA recommendations will be

listened to. He can't guarantee acceptance, but he urged PACHA to take advantage of a huge opportunity to guide the process.

Dr. Reznik noted that today the Council would be taking up a fairly general motion on reauthorization. He said he hoped the Council would consider more specific statements and getting something very quickly to DHHS Secretary Tommy Thompson, the President, and Members of Congress.

Two questions: President Bush provided 10 States with $20 million to help with AIDS Drug Assistance Program (ADAP) waiting lists, like the one in North Carolina. The waiting list is gone, but come March, will additional monies still be available? In addition, when we talk about core services, is it understood that we need supportive care?

Dr. Whitlock addressed the second question first, noting that the IOM report "fell flat on its face because you can't talk about entitlement with the current political makeup of the White House and Congress and have people take you seriously." It is unfortunate that the report didn't get as much attention as it should have because it could have served an important educational role. He then asked how PACHA members would describe the weakness in the ADAP program as it is now structured. Why do we find States with shortfalls?

PACHA member responses were:

- States have different resources; some have more than others.
- We're aggressively reaching out to bring more people into care, and that requires more funds.
- We're continually upgrading the medications needed to treat people with HIV. That success is one reason the program costs more.
- People are living longer with HIV, and then they become susceptible to the other health conditions that come with age.
- A commitment was made. It should not be ended.
- The budget was prepared for what was known—AIDS patients, not HIV patients. Centers for Disease Control and Prevention (CDC) figures are wrong by a factor of 2, if not more.
- There are different opinions on when to start treatment and what to treat. These affect local and State Government numbers.

Dr. Whitlock commented that it seems budgets are not anticipating need. Is this because of issues in the program's structure? Like not accounting for HIV cases? Where do we need to be in the next round so that we don't end up in a crisis mode? We need to be straight about what we anticipate and how much it will cost. The problems you're outlining, he said, need to be addressed in reauthorization.

It was commented that more and more people are asking if Ryan White is an entitlement. Money will get tighter as the Government tries to deal with the deficit. At the community level, what we hear from physicians and others is that they will support RWCA as long as

it delivers what it's supposed to, so it seems that support is dependent on some kind of performance outcomes or evaluations. Sometimes the patient's inability to comply, due to, for example, mental illness or substance abuse, is a problem.

Dr. Whitlock observed that in an ideal world, we wouldn't have RWCA because we'd have cures or less costly treatments. But we're not there and we won't be in the near future. Is this the last reauthorization? The next to last? That's a good question. When the treatment of HIV/AIDS has evolved to become similar to treating, for example, multiple sclerosis, then the question of the program's necessity will be challenged, but we're not there yet. It will be interesting to see how these issues are raised this time around. Congress needs to hear that the program is working. The fact that HIV-positive people are staying alive is not as obvious as HIV-positive people dying.

Dr. Whitlock further observed that the policy arena doesn't deal well with issues involving such topics as end-of-life issues or what resources we're putting into people whose potential success is uncertain.

Rev. Edwin Sanders commented that he is concerned that something similar to reconstruction of the act is needed. The Council has been heavily focused on the impact the disease is having on African Americans in general and women in particular. When you consider women, you have to look at their role as primary caregivers to children, and that alone shapes the kind of care and services provided by RWCA, he said. The act must address the need where it exists.

Dr. Whitlock responded that he doesn't personally believe in the sanctity of the act's titles as they are currently structured. But it is not clear to him at present whether "blowing open the titles and looking at a complete restructuring makes sense" in terms of getting reauthorization accomplished quickly, "before monetary issues overwhelm the act completely." It may not be wise to create more controversy than necessary in order to get some relatively discrete changes.

It was commented that an analysis should be conducted to make sure that what is done is responsive.

Dr. Whitlock said he thinks that involves core services, but how much can be done remains to be seen.

Ms. Debbie Rock commented that it frightens her to think Congress doesn't understand the needs of women, teenagers, and children in this epidemic. If it doesn't see their needs and allocate resources accordingly, HIV/AIDS will still be treated as something separate, something shameful, when in fact people are dying.

Dr. Whitlock said making that point is an important part of the next reauthorization. We have to make the case. When we talk about core services, that comes back to what should we be doing for everyone, period.

It was observed that the key issues seem to be outcomes, accountability, fiscal responsibility, and entitlement. What stands out is the concept of an evolving model of care. The current act was set up on the palliative model. Now we need a new model. We're trying to mainstream HIV/AIDS, but we also have the urgency of new cases coming in juxtaposed to a failing health care system. In the United States, maintenance costs $15,000 to $20,000 per year per patient, but in Africa, it's only $1,000 per year per patient. And Africa has better adherence and a better model of patient care than we do. How do we bridge this gap?

Dr. Whitlock predicted that we will continue to battle between return on investment, and pharmaceutical research and prices, particularly when the Government is paying. If the Government is paying the bills, it's only a matter of time before we delve more deeply into how much drugs cost. Doctors understand how the fee structure works. The pharmaceutical industry will learn, too. The day will come.

Dr. Reznik commented that initial drug pricing is closer to $10,000 per year per patient, that we do have RWCA outcome measures, and that the act works.

Mr. Don Sneed commented that for every white male who dies of AIDS, six black men die, and that for every white female who dies of AIDS, 23 black women die. He has concluded that something is broken somewhere. Something is wrong in terms of prevention. We need to have restructuring to make the act more functional and responsive, he said. Some cities receive direct funds from the CDC. Perhaps that program should be expanded to achieve better outcomes.

Mr. Sneed also noted that the current system keeps those living with AIDS dependent, not independent.

Dr. Whitlock agreed that the transition points back to work not handled well. From the political perspective, however, such issues move the act into other jurisdictions. This might make reauthorization too complicated to deal with.

Dr. Beny Primm said he thinks that Congress is not paying attention to the Council's recommendations.

Presentation topic: Ryan White CARE Act Reauthorization Process and ADAP
Presenter: Dr. Marty McGeein, Senior Advisor, Assistant Secretary for Planning and Evaluation (ASPE), U.S. Department of Health and Human Services (DHHS)

Dr. McGeein sits on the RWCA Working Group. She will discuss the group's work. The Working Group was formed to examine what works and what can be improved in the act. It has broad representation from DHHS, including representatives from the budget, legislative, and legal sides of the Department, as well as representatives of the Health Resources and Services Administration (HRSA).

The group's charge from President Bush is to focus on primary health services, flexibility, and accountability from grantees.

The Working Group is reviewing source documents, the IOM studies, proposals from advocacy organizations, and recommendations from the CDC/HRSA Advisory Committee. The group received a good briefing from FAB, which represents more than 70 organizations. In addition, the group has traveled outside the Beltway "to get the real story of who provides care." Dr. McGeein and her staff have also attended a number of meetings like this one to get that perspective.

The Working Group has learned that:

- RWCA has problems, but they are not terminal. Some want to simply put more money behind its programs.
- There is great concern about the variability of the act across regions, which has to do with ADAP and the variable quality of Medicaid.
- Many are concerned about capacity, and the anticipated surge in infected patients, thanks to the CDC initiatives.

The group's questions are:

- How do we maintain patients, given the cost?
- What are barriers to care?
- Will the act be medicalized?
- What is the cost-effectiveness of the act?

On the last point, Dr. McGeein said, there are no studies that look at costs vs. benefits of the act, and those studies are needed. Congress might want to look at accountability.

Are there appropriate and adequate data for such studies? Dr. McGeein said it is understood that DHHS may need to pay for better client data from community-based organizations (CBOs).

The group's next focus will be to finish its analyses. Once all issues have been examined, the group's findings will move upward in the Department.

Questions and Answers

Dr. Sullivan observed that AIDS is a war half-won. Members of Congress and others don't realize the urgent need to continue the war because they think it's over. We've had success, but it is far from complete, he said. The common mode of infection now is heterosexual sex. Critical too is that there are many who don't know they are infected and are spreading the disease. This is not like heart disease or diabetes; this is a public contagion. When we engaged in the effort to double National Institutes of Health (NIH) funding, economic studies were conducted that showed how longer life expectancy was well worth what we were paying into the medical health system. Congress is looking only

at what is immediately before it. The net contribution of improvement in people's lives needs to be taken into account, as well as the net return to the Nation.

Dr. McGeein commented that it's going to be a tough year. She recalled that the most effective lobbying statement she ever read was that every $1 spent for prenatal care saved the system $13. Cost-effectiveness is really cost-benefit. It would be interesting and helpful if the models used in the IOM study could look back, not just to the future.

Dr. Yogev commented that, in this epidemic, the power has shifted to people who don't have power. Nearly 100 percent of his patients are on Medicaid. At his institution doctors who have more than 50 percent Medicaid patients are gently asked to bring in more patients with insurance. The issue is broader than cost-benefit. It is a social issue. We have to speak for people who have no voice. How do we do that?

Dr. McGeein agreed the power has shifted. The initially affected population pulled together. The gradient is different now. The gifted congressional delegation from Illinois would love to hear what Dr. Yogev just said. But it may be beyond the scope of the RWCA.

Dr. Cheryll Bowers-Stephens commented that an argument could be made that the RWCA is an entitlement. A cost-benefit analysis is needed. Given Louisiana's current state of fiscal affairs, costs could shift to the uninsured and to Medicaid if the act is not reauthorized.

Dr. McGeein noted that when one uses the word "entitlement" in this case, it has to do with the fact that the act is a discretionary program.

Are we talking about primary care services or primary health care?

Dr. McGeein said that primary care services mean primary health care as far as she is concerned.

Break

Treatment and Care Subcommittee Report (Continued)

Dr. Reznik said the Subcommittee would bring two resolutions to the afternoon session, one on reauthorization of RWCA and one on the use of name reporting.

Public Comment

Dr. Sullivan outlined the rules for public comment. As each individual is called, he or she is to give their name and affiliation, then end their comments in 3 minutes. One-minute warnings will be given.

Dr. Sullivan called Carl Schmid of the AIDS Institute.

Mr. Schmid read a short statement that focused on troubling trends and policy development for low-income and uninsured people living with HIV/AIDS (PLWHA) in America. He said funding for programs such as RWCA and ADAP is not keeping pace with growing demand. ADAP still faces a shortage of some $200 million this year, and States are limiting access to medications by increasing eligibility requirements and limiting drugs on their formularies and the number of prescriptions each patient can receive. He noted that those who are eligible for both Medicaid and Medicare will lose their Medicaid drug coverage on January 1, 2006, and it is not yet clear whether the 60,000 PLWHA will receive guaranteed and consistent access to the full range of all necessary medications. Therefore, such patients should be deemed a special population. Mr. Schmid also endorsed the IOM proposal that an entitlement-based financing structure be created to allow access to essential services for all low-income HIV-positive individuals.

Dr. Sullivan called Mary Hess, president of Minority Health Care Communications, Inc.

Ms. Hess said her firm is a nonprofit that provides medical education. The company underwrites all of its conferences with other funds so that professionals can attend them at low cost or for free. Ms. Hess worked in the drug industry for 15 years. Now she wants to see the industry reach out to the community in an authentic, genuine, and organic way to support those who need it, rather than use overt marketing tactics to develop their markets. Ms. Hess said private and public partnerships are the wave of the future. She has worked, for example, with pharmaceutical companies to find leaders in communities for the companies to work with. She counsels the companies to be frank and honest with community leaders and give them technical assistance in the fight against HIV/AIDS.

Dr. Sullivan called Consuelo Celestine of Minority Health Care Communications, Inc.

Ms. Celestine is a licensed practical nurse and director of community relations and promotion with her company. As a nurse in New York City for 25 years, she has seen the face of AIDS change. She proposed more funding should go to prolong the life and care of the PLWHA who are 50 years of age and older.

Dr. Sullivan called Laura Hanen of the National Alliance of State and Territorial AIDS Directors (NASTAD).

Ms. Hanen is the director of government relations for NASTAD. She said Congress is interested in fixing ADAP because it continues to be in crisis. She said it is important for PACHA to remember that RWCA is just one piece of the puzzle. Medicaid has a significant impact, and so do Medicare and the prescription drug act. She suggested that PACHA look closely at the cost-benefit analyses in the IOM report. We have a duty to get those studies out there, she said. If cost-shifting is in the works, it needs to be acknowledged that Medicaid is under significant strain, so a number of States might very well try to cost-shift toward ADAP as opposed to away from it. Flat funding is a problem

also and has been for more than a decade. Finally, if we are to have high-quality surveillance, we need more resources at the State level.

Dr. Sullivan called Katherine Dennison of the Whitman-Walker Clinic. Dr. Barbara Craven came to the microphone as a replacement, from the Carl Vogel Center. Dr. Sullivan told her to proceed; she had informed staff beforehand of the substitution.

Dr. Craven read a short statement about the benefits and importance of nutrition in HIV/AIDS care plans. In particular, Dr. Craven proposed that medical nutrition therapy be mandated by RWCA or another appropriate health care program, as endorsed by the American Dietetic Association. Specifically, she called for:

- Nutrition intervention as part of the primary care plan of all PLWHAs under the act or any other Government-funded program that supports care for the uninsured or underinsured HIV-positive individual.
- Nutrition interventions to be administered at the onset of diagnosis to help decrease the overall costs of other medical care.
- Specific nutrition interventions to be administered by a qualified registered dietitian or other licensed nutrition professional.
- Assurances that a qualified registered dietitian or licensed nutrition professional is available to serve at all primary care settings for people with HIV/AIDS.
- Specification that nutrition intervention be administered as often as necessary during a grant year to support an individual's overall health and quality of life.
- Assurances that ongoing provision of basic good quality food includes fresh produce to all RWCA-qualified or individuals who are HIV-positive.
- Assurances of provision of vitamins and supplements that support increased immune function and prevent or reverse metabolic changes and complications, wasting, and weight loss associated with HIV disease.

Dr. Sullivan called Dr. Rena Boss-Victoria.

Dr. Boss-Victoria is an advocate from Oregon State University, a health practitioner who works in the community. She has conducted studies with individuals and their families who are infected and affected. She is concerned about how to address the epidemic from family perspectives. Youth do not know what the risk factors are. If they do, they confront forces larger than their behavior. Therefore, there must be programs to strongly and purposefully engage youth and women in planning services meant for them.

Dr. Sullivan called Susan Wyche Muhammad.

Ms. Wyche Muhammad manages a capacity-building project for a CBO in Region II of DHHS. She commented on the expenditure of funds to combat global HIV/AIDS. She said she applauded the international programs, but "there are not enough dollars for our fight. I see every day many small CBOs really making a difference but having to close their doors due to lack of dollars. We aren't seeing the true face of HIV/AIDS in this

country. Providers need to pay attention to everyone coming into their offices to get the true perspective."

Dr. Sullivan called Anna Pavlova.

Ms. Pavlova is from the American Soybean Association. She said soybeans can provide people around the globe with basic protein. Her organization has been active working internationally on prevention and treatment of HIV/AIDS through a program called "World Initiative for Soy in Human Health," private voluntary organizations, the World Food Program, and the private sector in the United States and other countries. The impact of nutrition is underestimated in policy decisions, she said. She encouraged learning about the results of programs that deal with nutrition and malnutrition among HIV/AIDS populations for evidence to enable us to better address the pandemic in timely and cost-effective ways. Specifically of interest are programs that use nutrition to:

- Support the effectiveness of medications
- Reduce the risk of mother-to-child transmission (MTCT)
- Reduce risky behavior.

Break

Dr. Sullivan thanked all who made public comments and asked Mr. Joe Grogan to announce room assignments for Subcommittees to convene and work on their resolutions through lunch. He asked Dr. Primm to leave his proxy with his Subcommittee chair.

Rev. Sanders said he was outraged by the cost of delivery and asked to submit a resolution about it.

Mr. Grogan said he would consult with DHHS on whether a new resolution could be offered to PACHA at this stage.

Dr. Sullivan adjourned the Council for preparatory work.

Working Lunch

Dr. Sullivan reconvened PACHA for Subcommittee reports. He asked International Subcommittee Chair Abner Mason to go first.

International Subcommittee Report and Resolutions

Mr. Mason announced the tabling of the resolution on international conferences in order to obtain more information. He announced that another resolution, on the prevention of MTCT, which was tabled at a previous meeting, would remain tabled but taken up in the future.

Mr. Mason then read the draft resolution on the need to monitor treatment outcomes.

Presidential Advisory Council on HIV and AIDS
International Subcommittee

Draft Motion

Resolution on the Need to Monitor Treatment Outcomes

WHEREAS, the President's Emergency Plan For AIDS Relief (PEPFAR) focuses on providing effective treatment to people infected with HIV, and

WHEREAS, the President's Emergency Plan will be implemented in the 15 focus countries at the same time that the Global Fund for AIDS, Malaria, and Tuberculosis, and the World Health Organization will also be providing treatment to those infected with HIV in the 15 focus countries and other countries, and

WHEREAS, many other public and private organizations will also be providing treatment in the 15 focus countries as well as other countries, and

WHEREAS, the need to know as soon as possible if treatment regimens are effective is critical if we are to avoid the development of drug resistance and insure the most effective treatment regimens are known to all providers, and

WHEREAS, the Office of the Global AIDS Coordinator has the financial and technical resources to convene and support an ongoing international effort to monitor treatment outcomes,

BE IT HEREBY RESOLVED that PACHA recommends that the President instruct the Office of the Global AIDS Coordinator to work with other appropriate national and international agencies and providers of treatment services to establish a Treatment Effectiveness Monitoring Group whose primary function would be to provide the Coordinator and the public with up-to-date information on the effectiveness of HIV treatment regimens, including but not limited to those treatment programs funded by the Office of the Global AIDS Coordinator.

Discussion

Dr. Franklyn Judson asked who was going to do this.

Mr. Mason read the last paragraph of the resolution.

Specifically, Mr. Mason noted that the President would instruct the Coordinator, adding that the Coordinator has the resources and the purview to monitor effectiveness. He added the resolution does not specify how long the effort would last.

There was no further discussion.

Motion on the Resolution/Vote

The motion was moved and seconded. Dr. Sullivan asked for all those in favor of the motion to say "Aye." The motion carried by voice vote with no "Nays" and no "Abstentions."

Treatment and Care Subcommittee Report and Resolutions

Treatment and Care Subcommittee Chair Reznik said the Subcommittee's draft resolution on RWCA had been changed. The new draft reads as follows:

Presidential Advisory Council on HIV and AIDS
Treatment and Care Subcommittee

Draft Motion

Ryan White CARE Act Reauthorization Resolution

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

WHEREAS, the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act provides primary care, treatment, and essential support services to approximately 533,000 underserved PLWHA, and

WHEREAS, the Ryan White CARE Act has achieved its primary goal of providing comprehensive care to people who would not otherwise have been able to access it, with 50 percent of clients living below the Federal poverty line, more than 90 percent with no private health insurance, and almost two-thirds who are racial and ethnic minorities, then

BE IT RESOLVED that the Presidential Advisory Council on HIV and AIDS supports the reauthorization of the Ryan White CARE Act, and

BE IT FURTHER RESOLVED that the Secretary of the Department of Health and Human Services and the President of the United States work closely with members of Congress to ensure timely reauthorization of the Ryan White CARE Act in 2005 bearing in mind the following principles:

1. Federal resources should focus on ensuring that all underserved HIV-positive Americans have access to a core set of services that includes primary medical care, medications, case management, oral health, mental health/substance abuse

treatment, and support services that foster adherence to life-sustaining medications and allow people to stay in care.
2. HIV/AIDS care, treatment, and prevention should be guided by sound public health strategies and based on current evidence-based knowledge.
3. Federal resources should provide greater flexibility to target Ryan White CARE Act resources to better address areas of greatest need, especially emerging communities and the chronically underserved.
4. Federal resources should strengthen the Minority AIDS Initiative, focus general program funding to improve infrastructure and expand capacity in minority communities, and fund minority-serving providers.
5. Federal resources should ensure the integration of HIV prevention services into primary care.
6. Federal resources should ensure accountability for all providers of Ryan White CARE Act-funded services.

Motion on the Resolution

The motion was moved and seconded.

Discussion

Mr. Sneed expressed concern about number 4, "fund minority-service providers," because people could see this as minority money.

Dr. Judson agreed. Further, he added, the only true majority in the United States is women.

Mr. Sneed proposed ending number 4 with "minority communities."

Ms. Rock didn't accept the change.

Rev. Sanders said the Council does have to be wary of putting proposals in jeopardy of not being funded; however, this resolution is fine the way it is.

Dr. Sullivan summarized: Mr. Sneed's amendment died due to objection.

Vote

By voice vote, the resolution passed as offered with no "Nays" and two "Abstentions."

Prevention Subcommittee Report and Resolutions

Prevention Subcommittee Chair Anita Smith said the Subcommittee's only resolution is on HIV reporting, and the draft being submitted to PACHA this afternoon is largely the same, with some additional language in the final paragraph.

The resolution reads as follows:

Presidential Advisory Council on HIV and AIDS
Prevention and Treatment and Care Subcommittees
HIV Reporting

Draft Motion

WHEREAS, timely and accurate data are essential elements to the development of sound public health policies, and

WHEREAS, the reporting of AIDS cases has been required for many years in all States and Territories in the United States, and

WHEREAS, the use of such data has been critical in tracking disease trends, monitoring health outcomes, and allocating resources, and

WHEREAS, there is an inherent need for uniformity in data reports to ensure greater accuracy, more relevant comparisons, and less duplication of reported cases, and

WHEREAS, the use of HIV data has been shown to reflect current trends better than AIDS data,

BE IT RESOLVED that PACHA urge the President and the Secretary of the Department of Health and Human Services to work with the Centers for Disease Control and the States and Territories to develop data systems that report on HIV cases, and

BE IT FURTHER RESOLVED that HIV name reporting cases become the standard for data reporting in regard to HIV/AIDS in all States and Territories that receive Ryan White CARE Act funding.

Motion on the Resolution/Vote

There was a motion on the resolution, and it was seconded. There was no discussion. Dr. Sullivan asked for a voice vote, and the "Ayes" had it unanimously.

Dr. Sullivan characterized this as one of PACHA's best meetings. He thanked the members and the chairs of all three Subcommittees. He noted that PACHA deals with some very complex issues, but the Council is making significant progress. Some of the problems are due to its success. He thanked the staff.

Rev. Sanders revisited the question of resolution procedures and what happens to resolutions when they leave PACHA.

Mr. Grogan said as soon as PACHA acts, he informally notifies the AIDS Office in the White House, and officially notifies the White House through the Secretary's Office. He noted that he is also on the Ryan White Working Group, so he carries PACHA resolutions there, too, and takes the opportunity to represent the Council's views.

Ms. Rock noted that World AIDS Day is again focused on youth and women, although this time PACHA didn't recommend it. PACHA should be on record noting that we agree with this focus.

Motion on World AIDS Day Focus/Vote

Ms. Mildred Freeman suggested that the record reflect PACHA's support for the decision to make women and youth a focus. She moved that "We support the decision for women and youth to be the focus of World AIDS Day." This was seconded, amended slightly, and passed unanimously.

Dr. Sullivan noted there had been some concern after the Vice Presidential debates that Vice President Dick Cheney seemed unaware of the high incidence of HIV/AIDS among African American women. He reported that he contacted officials in DHHS and was reassured that they were busy making the Vice President aware. In the heat of the campaign, it was not appropriate for PACHA to comment, especially when efforts were already underway to provide appropriate information.

Dr. Sullivan said, "In one sense, I think, Cheney was being honest. A number of men in the same situation would be honest by saying they were unaware."

Ms. Karen Ivantic-Doucette wondered how members might better communicate with one another and advance the work. She would like to see PACHA become more proactive and visionary.

Dr. Sullivan said he was open to ideas about how to do that.

Dr. Sweeney said she may not able to make Subcommittee meetings, but they should be held anyway. She also noted that the Prevention Subcommittee has a conference call almost every Friday that helps busy members stay in communication.

Ms. Rock added that the Subcommittee chair, Ms. Smith, asked Subcommittee members to think very early on about what they wanted to bring to the table; the Subcommittee discussed those ideas and is still discussing some of them.

Ms. Ivantic-Doucette asked that Subcommittee chairs inform everyone what they are working on so that other members can comment if they wish to. The Subcommittee chairs agreed.

Ms. Smith noted that it was great for the Prevention and Treatment and Care Subcommittees to work together, and she hoped it would continue.

Dr. Sullivan thanked everyone for their helpful suggestions.

Dr. Judson said Rev. Sanders spoke for all for us when he expressed the desire for PACHA to be heard at the highest levels. He said PACHA can use moral authority to get through to those in power and also identify specific actions, bills, and other changes PACHA thinks need to be made. To be effective, motions have to be short, concise, and readable, with terms that are easily understood. Also, Mr. Grogan should be asked to periodically report to us exactly what has happened to our advice and actions. Did what we say get where it needed to go, has it been considered, and what was the response?

Dr. Sullivan concurred that it is very appropriate for the Council as a whole to request a response.

Rev. Sanders observed that PACHA has had at least four major victories since he has been a member: the global AIDS initiative, PEPFAR, ADAP, and the waiver. All of these actions are to the President's credit.

Ms. Lisa Shoemaker said she wants to make sure PACHA does not forget two things: First, the fact that people are living and working with HIV/AIDS still needs to get high profile in the United States, and individuals need to be encouraged to be tested, as they are in other countries. Second, remember that there are people with AIDS, like her, who can't work full-time. For some people, it's because they are in the trial period with Social Security disability; for others, their bodies simply won't let them. She said she is on a waiting list in Michigan for medicines that would otherwise be taken away from her. She also noted that she can't get married. It's scary out there. It's no party being poor.

Dr. Sullivan said these topics should be placed on a subsequent meeting agenda.

Dr. Judson noted that in States where there is sufficient political support, you can have an income that's three to four times the poverty level and still maintain qualifications for ADAP. Colorado went to three times the poverty level for that very purpose, to try not to penalize those who want to go back to work.

Mr. Grogan said he will bring this up to the appropriate DHHS committee, although he's not sure which one this will be. He did note that the DHHS committee on trafficking and women recently did research on this issue and how it affects national HIV/AIDS rates. Internationally, there is an almost direct correlation between lack of support for women, children, and families with high levels of prostitution. He will share the information he has with International Subcommittee Chair Mason and Subcommittee members Dr. Jane

Hu and Dr. Edward C. Green. Dr. Hu and Dr. Green will show a draft resolution they are working on to Mr. Grogan.

Rev. Sanders asked if PACHA could revisit the concept of a White House summit at its next meeting. PACHA has passed the resolution, and now it needs to be moved forward. Mr. Grogan said he has already called the White House about it, postelection, and he will do so again.

Dr. Judson commented that PACHA needs to discuss what drives multiple concurrent partners during the most infectious periods. Sometimes people are dying of AIDS, and yet trying to keep themselves alive through prostitution. It's exposure behavior regardless of who does it, so we need to get to the fundamental need to reduce exposure. That's what's got to be changed.

Dr. Sullivan indicated it was time to wind the meeting down. He invited everyone to think about more topics, and send them to Mr. Grogan.

Mr. Grogan noted that the next tentative dates for full PACHA meetings are February 7 and 8 and June 20 and 21, 2005. He said these are not set in stone, so if members have problems with those dates, please send him an e-mail within the next few days. He asked that Subcommittee chairs come up with dates in advance of those dates for their own meetings.

Addressing Dr. Sullivan, Rev. Sanders said all of PACHA owes him thanks and congratulations. "Your leadership has been profound."

Adjournment

Dr. Sullivan adjourned the meeting.