Presidential Advisory Council on HIV/AIDS
Twentieth Meeting

June 21-22, 2002
The Wyndham City Center Hotel
Washington, DC

Minutes

Members Present:

Thomas A. Coburn, M.D., Co-Chair
Louis W. Sullivan, M.D., Co-Chair
Stuart C. Burden
Philip P. Burgess, R.Ph., M.B.A.
Joseph A. Christina
James P. Driscoll
Vera Franklin
Mildred Freeman
John F. Galbraith
Cynthia A. Gomez, Ph.D.
Cheryl-Ann Hall
Karen Ivantic-Doucette, M.S.N., F.N.P., A.C.R.N.
Joseph Jennings
Rashida Jolley
Caya B. Lewis, M.P.H.
Abner Mason
Sandra S. McDonald
Joe S. McIlhaney, M.D.
Hank McKinnell, Ph.D.
Brent Tucker Minor
Dandrick Moton
Nathan M. Nickerson, R.N., M.S.N.
John A. Perez
Debbie Rock
Rev. Edwin Sanders II
Prem Sharma, D.D.S.
Lisa Mai Shoemaker
Anita Smith
M. Monica Sweeney, M.D., M.P.H.

Members Not Present:

Hon. Ronald V. Dellums
Ingrid M. Duran
Mary Fisher
Katryna Gholston

Friday, June 21, 2002
Morning General Council Session

Opening Remarks

Co-Chair Louis Sullivan noted that the Hon. Ronald Dellums was unexpectedly unable to attend this meeting. Dr. Sullivan extended his congratulations to Dr. Sharma, who will receive the William John Jeeves [sp] award, the highest recognition given by the American College of Dentists, at that group's annual congregation in October in New Orleans.

Dr. Sullivan explained that he would preside over most Council business today and Co-Chair Thomas Coburn would preside tomorrow, switching as necessary. On the subject of rapid testing and oral testing, Dr. Sullivan recused himself because he has served as an advisor to Orasure. Dr. Coburn will chair during that time.

Dr. Coburn welcomed the Council and noted he looks forward to a successful meeting.

Dr. Sullivan reminded Council members that Executive Director Patricia Ware requires all members to complete and return their ethics forms.

Dr. Sullivan called for review of the minutes from the last Council meeting. Mr. Burden noted that he had recommended a course of action, and although no action was taken as a result, he requested that the minutes reflect his recommendation ($1 billion in international funds for AIDS). The minutes were so amended. Mr. Minor moved to approved the minutes; Dr. Sharma seconded. The minutes from the last Council meeting were approved as amended.

Short-Term Solutions to ADAP Shortage

Dr. Sullivan recognized Dr. Coburn, who opened the discussion regarding the continued shortage of funding in AIDS Drug Assistance Program (ADAP) by inviting Council members to discuss possible options and recommendations the Council could make between now and start of the next fiscal year (a period of about 5 months). Several pharmaceutical companies have contributed money and product to several programs. In addition, there is approximately $200-300K in unspent Ryan White CARE Act (RWCA) money this year, but these funds are not available to the ADAP. There are some states (e.g., certain areas of Florida) where an excess of monies from other programs is being sent to their ADAP fund. Dr. Coburn stated that the Council Chairs are open to any ideas for action or recommendation.

Dr. Hank McKinnell noted that his company, Pfizer, instituted a pricing freeze, which was followed by Roche & Abbott, who announced a 2-year pricing freeze; Bristol-Myers (1 year); and Glaxo Wellcome (2 years).

Dr. Driscoll noted that it would be beneficial if the Council were able to persuade the administration to put ADAP higher within administrative priorities. He recommended that the Council prepare a letter to President Bush urging such. Congress, Dr. Driscoll said, needs a signal from the White House that ADAP funding needs to be better addressed.

Mr. Burgess noted that his organization, Florida AIDS Action (a recipient of ADAP funds), is asking pharmaceutical companies to come down to half price for AIDS drugs. Considering that the RWCA is administered under the U.S. Public Health Service, there should be some negotiating power. While appreciative that several major pharmaceutical companies have frozen their prices, the Council should be tougher in negotiations.

Brent Minor noted that many states have limited formularies, so that, even in places where funds are available, many states are still not able to obtain certain drugs. Mr. Minor suggested this issue be part of the discussion. He said there seem to be two tracks on which to proceed: one pursuing more Federal funding (petitioning Congress and the White House administration), and the other working with pharmaceutical companies. Mr. Minor said that a letter from the Council to both entities would be the most sensible route, and recommended that a subcommittee draft a letter to be reviewed and approved by the Council.

Dr. Coburn stated that an important piece of every Government program is to plan for careful oversight so that monies, whether for prevention, care, housing, or medications, are spent wisely and efficiently. Enough funding currently exists to be applied to ADAP; the third piece of the equation is efficiency and oversight: the ability to improve purchasing power.

Dr. Sullivan asked what other actions can be suggested, beyond the pricing freezes undertaken by the pharmaceutical companies. Mr. Minor agreed that the pricing freezes should be recognized as such; the next step might be to invite pharmaceutical industry representatives to address the Council and to discuss whether they can reduce drug prices—and if so, why? and if not, why not?

The Council's requests need to be based in reality: pharmaceutical representatives may be able to offer the Council insights into what is practical and logical. A simple request to cut all drug prices in half might sound good, but not be practical or achievable.

Dr. Coburn cautioned against creating an impression that the pharmaceutical industry has not been doing a great deal to help with the epidemic, when they have provided a great deal of product for indigent persons without reimbursement. Unfortunately, some people are on waiting lists, and some cannot get the medications they need even with ADAP assistance; it is important that such situations do not occur in the United States. Dr. Coburn noted that the President accepts the priority of ADAP funding, even though the need was not clear to him at the time the last budget was formulated.

Dr. McIlhaney stated that there are also health care providers who are unaware of the ways they can access drugs for patients. He suggested it might be appropriate for the Council to ask the American Medical Association (AMA) and the Centers for Disease Control and Prevention (CDC) to create an information campaign on how to access drugs. Dr. McIlhaney asked whether Dr. Coburn was suggesting that the Council should recommend additional oversight on the expenditure of ADAP funds. Dr. Coburn replied that he was not; rather, there is ongoing oversight at DHHS right now, from which a final report is due soon.

Mr. Burgess noted that each state has its own way of administering its ADAP program. Several states cannot provide services because of how the programs are structured. The Council should look at variances between the states, study best practices, determine which states work best, and share this information with the other states. Mr. Burgess noted there is also a problem with patients moving from one state to another. He asked whether there should be a separate task force to investigate this problem.

Dr. McKinnell noted that ADAP programs are difficult to navigate. The antitrust laws prohibit pharmaceutical companies from publicizing their drug donation programs. However, he noted, Pharmaceutical Research and Manufacturing Association (PhRMA) is creating a Web site that will link to all the pharmaceutical companies' sites and provide information on their donations. This should be ready in 2 to 3 months. Dr. McKinnell said the Council might recommend this process be accelerated.

Ms. Ivantic-Doucette stated that the Council should look at State funds as well as Federal funds. Wisconsin, for example, is a low prevalence state with a limited formulary; yet the State put additional ADAP money into the program to avoid a shortfall. Another point to consider regarding medication donations is the waste in the medications prescribed now—whether paid for by insurance companies or Title 19—for example, patients who receive a month's worth of meds and subsequently have a change in prescription. There is no "drug return protocol" to deal with such situations. Dr. Coburn noted that a Federal law prohibits drug returns.

It was also noted that the RWCA has a 3 percent set-aside for states in trouble; it may be possible to target more money in that set-aside. While some states like Wisconsin are dealing with the situation, others are having more difficulties. The task is to find a way to get funds into the neediest states. It was agreed that there are three pieces to the problem: Federal funding, the pharmaceuticals industry, and the elimination of waste/setting priorities. Any successful approach will involve all three pieces.

It was noted that the Council talked briefly at its last meeting about decreasing the burden in applying for Medicaid waivers. Maine will soon be coming online with this; is there a way to

fast-track other states that are interested in Medicaid waivers? Dr. Coburn noted this was part of the Council's earlier recommendations, to which there has not yet been a response from the White House.

Mildred Freedman suggested having shortfall states publicly announce their shortfalls and ask for assistance in the last quarter of the fiscal year. The public and the state legislatures need to be made aware of the shortfalls. Rev. Sanders questioned whether it is appropriate to petition elected State officials to assist with a Federal funding gap. Dr Sullivan stated that this is an appropriate action for individual citizens to undertake; however, it would be difficult and awkward to get the weight of the Council behind such a move.

Ms. McDonald noted that, as more people are tested and identified as HIV-positive, the shortfall will continue to get worse. The Council should therefore start thinking about longer-term strategies as well.

Dr. Sullivan asked the Council for a consensus that the suggestions offered here be incorporated into a letter of recommendation to be sent to the President. The Council agreed on this course of action.

RAPID TESTING

Dr. Bernard Branson of the National Centers for Disease Control and Prevention spoke first, providing an overview and description of rapid testing, to summarize the public health need, to illustrate difficult concepts regarding the test's predictive value, and to review its current usage.

There are currently an estimated 850,000 to 900,000 HIV-infected persons in the United States, and an estimated 40,000 new infections per year. The CDC estimates that 25 percent of HIV-positive persons do not know they are infected. Standard testing, with centralized labs and complex equipment suitable for high volume testing, is time consuming and technically demanding. After explaining the steps required, Dr. Branson noted that the results from an ELISA (enzyme-linked immunosorbent assay) test may not be known for a few days to even a week or two. By contrast, simple or rapid assays are done at the point of care and allow for same-day results. These tests can be run on small numbers at a time. SUDS, the only current rapid test available, is rapid (about 25 minutes) but not simple and tests serum, which requires a centrifuge. The test also has its shortcomings. The product Oraquick, under FDA review, is done with a finger stick, and the results can be read in 20 minutes. The test produces different results for positive and negative, as well as a separate result if the test was performed incorrectly.

The public health need for rapid testing is dire: the percentages of persons tested but not receiving their results are very high. There are several circumstances in which there is an immediate need (e.g., pregnant women). In addition, it is important to have rapid testing in outreach settings for people who do not typically access the health care system. At publicly funded sites with standard testing, 30 percent of people who test positive and 40 percent of those who test negative fail to return for their results, because it takes 1 to 2 weeks to get the results. In an STD (sexually transmitted disease) clinic, 79 percent of the positives got their results, but only half of these came back on their own; clinic staff had to find the rest.

By comparison, with rapid testing the CDC has found that 93 percent of tested persons received their results the same day. (Some people refuse to wait for even 20 minutes.) Also, 97 percent received preliminary rapid test results and came back for their Western blot results.

Dr. Branson noted graphically how many more people could have known their serostatus and thus represent an increase in individuals who might not have infected others. Given the fallibility of tests, The World Health Organization (WHO) recommends combinations of simple and rapid tests, confirming an initial positive result with a different test. CDC currently supports this globally for both volunteer HIV counseling and testing and to screen pregnant women. Other examples of where rapid testing makes a difference includes emergency rooms and clinics. Since 1994, emergency room and clinics in high incidence settings recommend screening for all patients. Studies have shown dramatic increases in HIV infection being identified when screening is done in emergency departments. The CDC is doing one other large screening test, in cooperation with the FDA, to screen pregnant women in labor who have not been tested ahead of time.

The CDC considers an increase in serostatus knowledge important; it is the second goal of its 5-year plan to increase from 70 to 95 percent the proportion of HIV-positive persons who know they are infected. Other goals are to increase the motivation of at-risk individuals to know their status, to decrease barriers to testing, and to improve access to voluntary client-centered counseling and testing.

Dr. Edward Baker, the Assistant Surgeon General, spoke on the Clinical Laboratories Improvement Act (CLIA). He noted that the CDC supports rapid testing as a major technological advancement that will save lives, noting that the issue of accuracy must be addressed. While no test is perfect, CLIA tries to improve the accuracy of testing. CLIA works closely with the Centers for Medicare and Medicaid Services (CMS; formerly the Health Care Finances Administration [HCFA]). CLIA's law applies to almost all facets of human testing. The CLIA standard is based on the complexity of the testing; the more complex, the more requirements are in place to ensure accuracy. The guiding principle is to ensure quality testing without interfering with access.

The complexity model is as follows:

- Simple and safe (waived): requires registration, staff must follow manufacturers' testing instructions
- Moderately complex: quality control and quality assurance measures, proficiency testing (PT), limited personnel, requires biennial inspections
- Highly complex: quality control and quality assurance measures, PT, stringent personnel, biennial inspections.

Simplicity is the crux of the issue: How simple does a test have to be? The responsibility for classifying testing protocols has been transferred to the Food and Drug Administration (FDA). In all, 3 percent of tests have been waived; 73 percent are considered moderately complex. If a test is approved by the FDA for home use, it is immediately waived. If DHHS determines that a test is simple and has an insignificant risk of erroneous result it receives a waiver (including those that employ simple, accurate methodologies with a negligible likelihood of erroneous result, or no unreasonable risk of harm to the patients if the result is incorrect).

It is important to think about the total testing process in terms of its simplicity: pre-analytical, analytical, and post-analytical. Limited public health testing is done in the nonprofit; such entities can conduct waived or moderately complex tests at multiple fixed sites (e.g., Michigan) under the oversight of one responsible party. A number of nontraditional sites have been certified for moderately complex testing, including rural clinics, correctional facilities, environmental labs,

health fairs, home health agencies, medical foundations, mobile units, nursing homes, physician office labs, schools, and student health services.

Dr. Judith Yost presented some studies from CMS and other sources on waived laboratories. As Dr. Baker stated, the intent of CLIA is to ensure accurate lab testing while maintaining access. There are currently 175,000 labs enrolled. CLIA dictates that waived tests are simple and accurate and have insignificant risks of erroneous results. About 94,000 (54 percent) of CLIA labs do *only* waived testing. CLIA does not distinguish between screening and diagnostic testing, and does not discriminate by location (the requirements focus only on complexity).

Dr. Yost said CMS is in support of quality, point-of-care rapid testing.

There is no routine oversight of waived tests, but there is a provision in CLIA to initiate oversight if needed. Waived labs have only one basic requirement: to follow the manufacturer's instructions. Therefore, it is important how each lab performs the test and how they ensure it is working properly.

In 1999-2000, pilot studies were performed in 500 waived labs. Approximately 50 percent of the labs had testing problems (e.g., no quality control, not following manufacturer's instructions, etc.). Additionally, based on the pilot studies in Colorado and Ohio, the Office of the Inspector General also did a study, as did the CDC CLIA staff. All studies found similar, problematic results. CMS selected eight additional states in which to visit waived labs to make sure the findings were not an aberration. Quality problems were again found in many of the 270 labs visited, although in Maryland, New York, Pennsylvania, and Idaho—states that have their own state lab licensure programs—the problems were fewer. The problems break down as follows:

The Office of Inspector General (OIG) study had similar findings.

CMS recommendations for improving the system include:

- Institute an education program for waived labs and validate its effectiveness;
- Compile existing education programs into a clearinghouse for the CLIA Web site;
- Survey a percentage of waived labs annually to gather additional data and provide education;
- Develop self-assessment tools for waived labs;
- Provide information on CLIA requirements to newly enrolled labs; and
- Work with testing system manufacturers to clarify instructions and to provide initial training following a sale.

Dr. Yost noted that issues are also exacerbated by turnover in lab personnel.

CLIA-regulated labs demonstrate improved performance over time due to the educational approach and oversight. CMS found that of those regulated labs visited biennially, 35 percent were also not following the most recent manufacturer's instructions. These significant findings have serious implications for patients. For example, in one lab that performed simple occult blood tests, staff were using expired reagents and not performing quality control checks. In one case, a diagnosis of GI cancer was delayed for this reason. Lab experts agree that any incorrectly done tests have the potential for some harm.

Dr. Yost discussed moderately complex tests v. waived tests (myths versus facts).

Quality assurance (QA) is ongoing (continuous quality improvement) to monitor the lab's overall quality of operation. CMS inspects labs routinely every 2 years. CLIA minimum standards provide a low cost and a low burden to laboratories. Technical assistance (TA) is available from CMS and state agencies. Ten years' worth of data shows that CLIA-regulated labs have improved and are doing well. The educational approach has improved performance in labs significantly. The problem rate has dropped from 35 percent to 9 percent. A New York study of HIV-positive patients showed an increased in access and earlier treatment/intervention.

The Blood Products Advisory Committee and one other advisory committee recommended that SUDS not be granted a CLIA waiver. Pre- and post analytical concerns have to be considered, including patient counseling, confirmatory testing, and public health reporting. HIV testing encompasses a broad spectrum of social and legal issues as well as public health issues. The SUDS test does not demonstrate minimal risk of harm; it is not always simple to perform, and it is not always accurate. As findings and concerns show, this is a truly complex issue, and deserves careful consideration.

Dr. Elliot Cowan discussed the FDA review and approval process for rapid HIV testing, including the timeline, the measures that FDA has taken to facilitate approval for new rapid tests, and a report of progress made.

Within FDA, all HIV tests are reviewed in the Center for Biologics and Research's Office of Blood Research and Review. Rapid tests are reviewed as Class III devices. Pre-market review is necessary to provide a reasonable assurance of safety and accuracy.

- The regulatory scheme he discussed was for a rapid HIV test to be used as an aid in diagnosis. Trials are conducted to determine effectiveness; the process requires the filing of an investigational device exemption application (IDE), per 21 CFR 812. Data accumulated in the course of the clinical trials is put into a pre-market approval application (PMA), per 21 CFR 814.

Dr. Cowen discussed the three-part process:

- For the IDE review, the decision must be made by the FDA within 30 calendar days following receipt of the application. If approved, clinical studies can proceed. If the application is deemed "not approvable," a new IDE submission needs to be filed.
- The timeline for approved IDEs is driven by the applicant: once studies are complete, the applicant assembles the study data for submission. FDA encourages pre-PMA meetings to help with this step.
- PMA review: the decision must be made within 180 calendar days of receipt of a completed PMA. There are four possible outcomes for the PMA review: "not approvable," "not approved," "approvable," and "approved." The first three require additional information and/or review.

An inspection of the manufacturer's facility provides evidence that the manufacturer has a quality system for the design, production, packaging, labeling, storage, installation, and servicing of finished medical devices (per 21 CFR 820). Inspection occurs after most review issues are resolved. The FDA determines whether the manufacturer is in compliance with regulations or not. This is a critical part of the process. As desirable as rapid tests are, the FDA and the public need to be assured of a reasonable certainty that the product will remain available as needed.

Dr. Cowen outlined the steps taken by the FDA to facilitate the review process for rapid HIV testing: rational standards for approval, simplified clinical trial requirements, and prioritizing review of rapid HIV test submissions. Since the FDA is prohibited from releasing any information related to test submissions, the discussion was limited to public health information and information authorized for release.

On 1 May, Orasure announced that Oraquick is approvable, but needs to submit product labeling and resolve some review issues.

In closing, Dr. Cowan said the FDA is committed to bringing safe and effective rapid tests to the market as quickly as possible. Through industry contacts, FDA has sought input and solutions regarding perceived barriers to obtaining pre-market approval.

Dr. Frances Pouch Downes, Director of the Public Health Laboratories in Michigan, spoke on the public health impact of rapid testing for infectious diseases. American Public Health Laboratories (APHL) labs have nearly 20 years of experience conducting HIV tests, developing testing guidances, etc. APHL labs have worked with the broader public health community to ensure services are available to the public. An increasing number of rapid care tests (including HIV, influenza, Lime disease, etc.) are being developed for use in emergency settings, physician offices, public health centers, and nontraditional sites. As has been noted, law provides exemptions for simple and safe test products with insignificant risk. When a test is granted a CLIA waiver, it can be performed by anyone in any setting. Proficiency testing, external controls, and oversight are not required. The only regulation is that manufacturer instructions be followed.

In Michigan, Dr. Downes noted, another option is used, a limited public health certificate, ensuring that non-lab professionals working in local health agencies can perform moderately complex and waived testing. The certificate allows for up to 15 waived and/or moderately complex tests to be performed by nurses and medical assistants, while trained professionals review the training and quality control measures. As new testing methods are developed, it is important that an appropriate system is in place to ensure quality. While APHL supports the use of rapid HIV tests and other rapid tests if they ensure reliability, many such tests are not sufficiently accurate. CLIA-waived tests should be sufficiently simple as to require no training, and they should be accurate. HIV and other rapid tests do not fall into this category. By contrast, in Michigan, 10 years of CMS surveys have rarely identified any deficiencies. This points to the need for appropriate training and oversight, reporting practices, etc.

Dr. Downes stated that the nature of rapid HIV testing requires the establishment of quality control and assurance procedures, which regulations for waivers do not include. Only simple, highly accurate tests should be appropriate for a CLIA waiver. APHL believes that rapid HIV tests are moderately complex in nature and should be performed under appropriate CLIA regulations for moderate complexity. High quality tests can be performed in STD clinics, etc., under a CLIA-limited public health testing certificate. Access to testing will not be compromised by using this certificate. APHL recommended that, whatever the complexity, data should be collected to determine how the test is performing and ask critical questions on access. APHL stands ready to work with leaders to assist with CLIA certificates, TA, and quality assurance.

Dr. Mark Loveless, Medical Epidemiologist and Director of the HIV/STD/TB Program of the Oregon Health Department, addressed the Council representing the National Alliance of State and Territorial AIDS Directors (NASTAD). Dr. Loveless noted he recently found out he is a CLIA-regulated lab director.

- Dr. Loveless spoke in favor of maximum access to HIV rapid tests, and of the critical importance of a CLIA waiver, which NASTAD supports for an extensive list of reasons, inclluding improving testing access and reducing disparities in the test's availability.

Dr. Loveless addressed a number of concerns and misconceptions regarding a CLIA waiver. (1) "HIV is a life-threatening disease that is too significant for a waived test." (the seriousness of the epidemic is the reason for widespread access to testing and other diseases that are life-threatening have waived test status); (2) "A waived test does not mean everybody's going to do it" (Widespread utilization is the goal of the industry); (3) "Too many false positives" (Evolving technology has dramatically reduced false positives); (4) "CLIA offers the only protection against the misuse of HIV rapid tests" (HIV testing is the most regulated and scrutinized medical lab test in use, CLIA is by no means the only HIV test regulatory process, and CLIA has no authority over issues such as the quality of test interpretation and subsequent patient education, counseling, and referral); (5) "There would be no safeguards that persons receive counseling and referral" (CLIA has no authority to ensure this post-test process and therefore does not have relevance); and (6) "There would be no oversight to ensure tests are performed correctly" (Newer technology minimizes the chance for error).

Regarding the "limited public health use" exception Dr. Downes discussed, Dr. Loveless stated this cannot be replicated in Oregon. Such an arrangement would increase the cost and complexity of the testing system without a documented benefit to the patients and testing sites.

In summary: NASTAD strongly supports a CLIA waiver for HIV rapid testing. NASTAD is committed to continuing high quality management of federally-funded HIV counseling and testing systems; they are also committed to working with public health labs and local lab directors to improve the quality and performance of CLIA-waived labs, whether doing HIV testing or not.

Questions and Answers on Rapid Testing and CLIA Requirements

A director of a CLIA-regulated complex lab noted that it is considered a quality problem if the piece of paper that came with the test is not sitting out next to the test during oversight. She asked what are the consequences of a failure in quality, noting that both waived and nonwaived tests need better oversight in the United States.

Dr. Joe McIlhaney asked Dr. Branson whether the CDC is able to do all the studies they need on rapid testing. Dr. Branson noted that because the test is not currently approved, it has to be treated as highly complex (with respect to sensitivity and specificity). As a result, the CDC cannot gather data on how the rapid test might work in a waived setting.

Rev. Edwin Sanders suggested that today's discussion should move toward specific recommendations, and that questions should be framed appropriately. He suggested one recommendation might be developing uniform guidelines for testing and quality control.

Dr. Monica Sweeney asked whether the push is to have a quick HIV test available at the local pharmacy (like pregnancy tests). Increasing the percentage of people who get HIV test results is important; however, even when somebody gets a negative result they see a counselor for information and interpretation. This service would not be available with a home test kit. Dr. Baker noted there are no applications for home use products at the present time. The distinction to be considered here is whether the CLIA requirements should be waived for lab use, which itself would entail no requirements for counseling and testing. Once the test is waived, it can be done

anywhere and by anyone. Dr. Cowan noted that a home *collection* product is currently available, but the results are read remotely.

Dr. Cynthia Gomez stated that the Council's primary purpose is to increase access. Today's disagreement is about how soon everyone can be comfortable with disseminating rapid testing in the best interest of the people. From all the information presented, Dr. Gomez said, sufficient risk was not demonstrated that would outweigh the benefits of CLIA-waived rapid testing. The risks have been known for a long time. The Council should discuss a timeline by which the country's labs would be comfortable implementing rapid testing safely and accurately. The various parties should work together to improve quality assurance at all times and in all locations. Dr. Downes suggested that the lab community is already in agreement, that rapid testing needs to be implemented now. Nonetheless, rapid testing can and should be done in settings where quality is assured. Dr. Downes said this can be done with many different options in many settings, not just the Michigan model discussed.

Dr. James Driscoll said that a CLIA waiver would considerably expand the market. It is startling, he said, that there are tests available in hundreds of countries but not the United States. With current testing available, everyone will be given other confirmatory tests; indeed, additional tests are in development that will allow two tests at once. Rather than 1 in 1000 false readings, the results will be closer to 1 in 100,000. He noted there are many places where people cannot afford medical care—underserved populations living at the margins of society. These people are being excluded; it is a barrier to health care.

Lisa Mai Shoemaker asked how hard it would be to ensure that those administering rapid tests would be certified. Dr. Branson responded that each state has its own certification regulations. There is no Federal provision for certifying people, for example, on administering Orasure tests.

Karen Ivantic-Doucette noted that rapid tests still check for the presence of antibodies, so there is still a window of inaccuracy immediately following infection. It is not clear that people understand this point: rapid testing serves no more purpose to the very recently infected than traditional testing. Dr. Coburn stated, however, that testing would be greatly beneficial to health care workers who have had exposure via an HIV-positive patient. He also stated that persons who do counseling and testing are well aware of the window period, and it is a standard part of the counseling technique in delivering negative results.

A council member asked whether any data exist on false negatives (e.g., how rapid tests compare with other tests on this point). Dr. Branson responded that since the CDC has been evaluating tests, some show no false negatives, while others do. An FDA decision will need to be made on this issue. However, Dr. Branson said, difficulty with false negatives arises only in extremely high prevalence populations (much higher than in the United States).

Stuart Burden asked whether the Council is comfortable with safeguards against abuses that can come with HIV positive tests, regarding discrimination in employment, immigration, travel, etc. There are no legal assurances against such discrimination. There is a greater stigma around HIV positivity than around the test itself. While the point was made people can be taught to administer the tests properly, that is very different from providing appropriate counseling. Dr. Baker responded that one consideration CDC gives in waiving a test for any circumstance is to create a series of scenarios in which false results can be used improperly. Secondly, he said, it is important to note that once a test is waived, it is practically unheard of to "unwaive" it.

Debbie Rock said the Council is putting barriers in its own way. A lot of the testing being discussed will be in places where states and community-based organizations (CBOs) are doing collaborative efforts. In Baltimore, for example, Ms. Rock collaborated with Johns Hopkins University (JHU); they took 6 months to train the Department of Social Services on HIV education. This is a point of entry for many at-risk populations. Ms. Rock said this setup has been working well: JHU does the testing and her outreach staff walk the patients through. The point is to get high-risk persons accessing medical care quicker, and working collaboratively can facilitate that goal.

Nathan Nickerson reminded the Council that a CLIA waiver status speaks to who can perform the test and in what settings; it does not refer in any way to the counseling and testing context of the test. If a CLIA waiver is granted, states can still structure their own requirements for counseling and testing. Dr. Baker reinforced the point, noting that if rapid testing were approved as moderately complex, the tester would have to be trained and have a high school education, and there would be quality assurance measures. CLIA-waived rapid testing would be appropriate in a voluntary counseling and testing setting, but there are cost implications for doing this. Basically, performing more testing (and counseling) will require more resources. Dr. Branson said this also affects how results are given out. Very often, the person who administers the test is different from the person who gives the results. In a waived setting, the same person would more often do both.

Dr. Yost noted that not all states have requirements for counseling and testing or oversight. There are about 12 states that have their own lab programs, but many states defer to CLIA or other organizations.

Sandra McDonald suggested the Council should return to the "human" part of HIV. With approximately 950,000 HIV-positive Americans, of which perhaps a third do not know their status, it is imperative, she said, that every tool possible is utilized to access these people, find out their status and refer them for care.

Brent Minor said it is very hard not to be persuaded by rapid testing. It is important, he said, to ensure that counseling and testing is as good and well researched as the test itself. A lot of work has already been done on that side. The benefits include seeing more HIV-negative persons and giving them valuable information as well as to those who are HIV positive. Mr. Minor agreed with Dr. Loveless that "normalizing" HIV testing in society is a great and positive thing; such a stigma exists about getting tested—some people don't even want their clinician to know.

Ms. Shoemaker noted it is important for people to get tested whether they are high-risk or not. The epidemic affects everyone. She said that until improved testing comes, the Council should push on with rapid testing.

Dr. Gomez stated that the main reason for this test is the high percentage of patients who do not get their results. Issues of counseling and testing continue to be important in terms of quality, even under current testing mechanisms; these issues need to be addressed generally, irrespective of any one test's waived status. Of most importance is getting more people to agree to be tested and stay for their results. Dr. Gomez noted that she brings hundred of people into her lab (with the assistance of CBOs) who would not ever go into a clinical care setting. Being able to provide test results before the individual leaves the room is an incredible opportunity.

Philip Burgess noted that pharmacists have been very involved in dealing with HIV infection; they are among the most readily available professionals to assist the community. Pharmacists interact with customers—they know the drugs, the latency periods, etc., and can play a vital role

in providing counseling. Mr. Burgess said he strongly supports getting rapid testing fully implemented.

Mr. Burden reiterated that there is potential for misuse and abuse of test results; he recommended that the Council reaffirm its insistence on privacy and confidentiality safeguards. One Council member responded that there are laws in existence in all 50 states that address privacy and confidentiality concerns.

Vera Franklin noted that rapid testing would be extremely beneficial to Native American communities, where social and logistical barriers prevent most people from returning for their HIV test results.

Dr. Sullivan thanked all Council members and guests for their contributions to the discussion.

REMARKS TO THE COUNCIL

Eve Slater
Assistant Secretary of Health, U.S. Public Health Service

Dr. Sullivan then introduced Dr. Eve Slater, who was appointed Assistant Secretary of Health in February; prior to that, she worked for Merck handling external policy and corporate affairs. On behalf of Secretary Tommy Thompson and the Administration, Dr. Slater expressed her gratitude to the Council for dedicating their time and service, their collective experience, and their intellect. She noted her informal comments today would address where departmental policies are with respect to HIV/AIDS. The Department's priorities include:

- Reduction of HIV incidence as rapidly as possible to as low a level as possible (ideally targeting a reduction of 50 percent by 2005;
- To engage the maximum number of HIV-positive persons into the health care system as early as possible;
- To provide, whenever feasible, resources directly to people living with HIV/AIDS (PLWH/A) so overhead is reduced, as are disparities;
- To integrate domestic and global efforts as much as possible; and
- To strengthen the scientific base of all agencies dealing with HIV/AIDS.

Dr. Slater asked the Council to consider how the Department's objectives can be reached. She said that President Bush is pragmatic; he wants to rebuild infrastructure to deliver services—hence the Healthy Community Innovation Initiative. Various communities throughout the United States will be targeted to rebuild local health care delivery systems; it is the Department's job to facilitate implementation of community programs, study best practices and models that work, and replicate the successes. Dr. Slater also noted the President is committed to doubling the NIH budget to $2.7 billion, much of which is targeted toward vaccine research.

In her current position, Dr. Slater and her colleagues have a series of small, low-budget offices with the responsibility of developing HIV policies across agencies. Deputy Secretary Claude Allen has also reviewed the trans-agency plan, which will soon be formulated as deliverable to Secretary Thompson. This plan is an attempt to overview the Federal monies being spent on HIV/AIDS across all agencies and to ensure that as many of the dollars as possible get to the patients that actually need them. Dr. Slater said she will be convening a work group that will systematically review the objectives and funding within each agency and look toward eliminating redundancies. Although the term "management review" often evokes suspicion, Dr. Slater said

the presumption is that the monies will not leave the HIV field, but rather be targeted more efficiently. It is not only HIV programs that will be considered in this "one-agency" review; the Secretary has merely designated HIV as the first.

The President has pledged a half billion dollars to the Global AIDS Fund. Dr. Slater said she is chagrined at the partisan commentary evoked about the fund. Everyone knows the money needs to be spent; and, in fact, this is nowhere near the amount that will be necessary in the long run. However, better infrastructure is needed, and the United States is in an evolving stage concerning global assistance. The President and the Secretary and everyone in HHS share concern for infected children: the estimates are 2.7 million children under 15 with HIV, and potentially 44 million orphans by 2010.

Afternoon Session

PANEL PRESENTATIONS: HIV/AIDS PREVENTION

Overview of Prevention Issues
Karen Ivantic-Doucette, M.S.N., F.N.P., ACRN
Marquette University College of Nursing

Ms. Ivantic-Doucette stated there are many things the Council agrees upon, but what constitutes prevention is not one of them. At the International Conference on AIDS in Durban 2 years ago, Dr. Peter Piot stated that the global prevention effort requires every person, public or private, coming from every arena—heath, education, policy, economics—to begin dealing with prevention issues. Perhaps this year as the Barcelona conference approaches, the community can report it is closer to a consensus on prevention.

Ms. Ivantic-Doucette said she focuses on breaking out of the traditional ways of thinking of prevention, and considers diagnosis and treatment as part of prevention. Normally one thinks of three layers of prevention: Primary (stopping the onset), secondary (testing and diagnosis), and tertiary (treatment and prevention of complications).

Treatment includes antiretroviral therapy (ARTs) as well as strategies or medications for tuberculosis (TB). Any use of medicine can translate into prevention. An example of primary and tertiary prevention together is perinatal transmission prevention, which is primary prevention for the infant and tertiary for the mother. Perinatal prevention also has another level: reducing the social problem of orphans, so it is a kind of preventive care for families.

With respect to primary prevention, the keystone has been education, defined as the sum of all influences that collectively determine knowledge, beliefs, and behaviors. There are two domains of learning: the cognitive domain (intellectual knowledge) and the affective domain; the latter is the "feeling domain," subject to attitudes and beliefs. For example, a person may have a cognitive understanding of condoms and their use in prevention, but also have affective barriers resulting from religious dogma or a disbelief in their efficacy.

Ms. Ivantic-Doucette noted that malnutrition is the primary cause of immunosuppression. Access to basic health care is another important factor (e.g., gynecological care). A final factor is policy guidance. Policy and regulations are not often thought of as prevention, but a survey of the health care field demonstrates that the crisis shortage of health care professionals is exacerbated by the number of persons unwilling to work with PLWH/A—despite advances in postexposure prophylaxis (PEP) for needle stick occurrences, etc. Policy becomes part of the prevention picture

when the CDC writes guidelines, sets up a PEP hotline, etc., thereby reducing both fear and the risk of new infections among health care workers.

Diagnosis Is Prevention
Franklyn Judson, M.D.
Director, Denver Public Health Department
Dr. Judson was involved with the first reported case of AIDS in Colorado in May 1982. His department is heavily involved in clinical care, prevention research, and policy and law development. Over the 20 years since the first Colorado case, the department has conducted half of all publicly funded HIV counseling and testing in Colorado. The staff currently manages about 1,200 PLWH/A, or about half of those in treatment for HIV in Denver.

Dr. Judson reviewed some fundamentals of what drives epidemics. The HIV epidemic is simply another very serious communicable disease. Whether any such disease advances or not depends on how infectious it is (and whether it varies at different stages of its natural history); how long the infection is transmissible; and, for sexually transmitted diseases (STDs), the numbers of partners and rates of partner change. The spread of the epidemic is primarily a function of multiple concurrent sexual partners or injection drug use (IDU) partners during the early and highly infectious stages of the disease. During the first weeks or months of infection, HIV may be 100 to 1,000 times more communicable than it is later on. In dealing with the problem of multiple, concurrent partners, early diagnosis, early treatment, and early behavioral change are very important.

Dr. Judson said there was an informal, unfounded, non-governmental intervention that was incredibly effective: “fear of AIDS.” Nothing was more effective in changing behavior. It worked best on those at greatest risk at the time, namely, educated gay men in the developed world. The result was a decline in new infection rates of 15 to 20 percent per year, totaling a more than 95 percent reduction in new incidence rates, as well as a parallel drop in the rates of other STDs in the same population.

Having a test that allows identification of exposure is an important step in the control of any epidemic; yet rather than make the tests widely available to everyone, some states (e.g., New York), under pressure from “activists,” began to write laws restricting the use of the HIV tests. Supply and access were limited; the result was that many people were denied the use of this key diagnostic test, sometimes for years.

The next logical step was to confidentially report infections, keeping natural history statistics. It was imperative that results be kept completely confidential and private. Colorado moved to become the first state requiring confidential reporting of all HIV tests in 1985. At this point, the State was no longer evaluating the epidemic solely by doing an AIDS body count. By 1987, HIV reporting regulations were turning into laws. At present, between 36 and 40 states have HIV reporting laws.

Between 1986 and 1995, partly for political reasons, the emphasis on Government-funded HIV counseling and testing programs was on counseling. This is fine if counseling is shown to be the most effective part of the intervention; but that is probably not true. Dr. Judson said that there is little evidence that information dissemination is effective in changing behavior. As far back as 1985, a random sampling revealed that people knew what AIDS was and how it was transmitted.

One issue to consider is the extent to which knowing one’s status affects behavior. For negative tests, the evidence is mixed on whether behavior becomes less or more risky. For positives,

almost all studies show an elimination of denial and a change of behavior. The duty to warn (partner notification, etc.) comes into play. This duty applies first to patients, then to the health care providers, then to public health entities.

Since 1995, the country has had both Government-funded counseling and testing programs and RWCA treatment programs. Early diagnosis can only have positive benefits; it leads to early intervention, which benefits the PLWH/A's partners and society. There is currently a change in the approach of Government and the public health arena to prevention in the age of treatment. The old method was an oddity: by comparison, public health entities never sought out all people negative for TB and counseled them on staying that way, while ignoring the TB-positives. Now, public health is trying to work prevention back into patient care, making sure PLWH/A take on the responsibility of preventing transmission.

Treatment Is Prevention
Federico Cruz-Uribe, M.D.
Director of Health and Health Officer, Tacoma-Pierce Health Department
Dr. Cruz-Uribe discussed how his health department combined communicable disease approaches with new treatment modalities. Tacoma-Pierce is the second largest county in Washington State, with a population of 715,000. There have been slightly more than 1,200 cases of HIV since tracking started. The epidemic is following the national trend: the bulk of cases is still men who have sex with men (MSM), but prevalence is increasing in communities of color and women. Like many local health departments, Tacoma-Pierce suffered hardships in funding. Ten years ago there was a serious budgetary problem and a resulting loss of public confidence and credibility; Dr. Cruz-Uribe was hired to redefine how the department did its work. The vision he instituted was to get back to basics: to focus their limited resources on primary prevention and disease control.

The department shifted significant resources toward prevention; it had been the safety net for indigent care in the county. The department put together a business strategy and structure for a disease control system. Dr. Cruz-Uribe developed relationships with private providers, asking them to be proactive in disease control; instead of just occasional reporting, providers were asked to test, treat, and report. This allowed the department to do more prevention and to ensure comprehensive clinical services were being provided in the community. As a result, the capacity for indigent care in the county has nearly tripled.

Dr. Cruz-Uribe stated that HIV should be treated like any communicable disease, the theme used for the entire process of the Tacoma-Pierce Health Department's restructuring. New policies were developed that helped target and access high-risk populations that typically did not get tested: injecting drug users (IDUs), persons with multiple sexual partners, etc. The department is implementing an ongoing case management system; as with other communicable diseases, the health care system works with patients until they are no longer infected (which means an ongoing relationship for HIV cases).

It has been a major challenge to work with the private sector, which had previously ignored the public health department. The critical piece was getting providers to test patients and report, and getting them active at managing patients with HIV infection. Surveillance, ongoing intervention, and treatment were also important: the department committed to having structures in place to ensure that each important step was met with every HIV patient. Most health departments do surveillance and outreach, but Tacoma-Pierce added an element they learned from the pharmaceutical companies: establishing a cadre of senior public health nurses who function as public health representatives, selling public health to private providers. This team visits

practitioners every 90 days. The first message centers on reporting, that is, making sure everyone is aware of treatment protocols and encouraging active involvement in prevention campaigns.

The State of Washington got involved late with the epidemic. Tacoma-Pierce County passed a reporting and partner notification requirement 2 years before the State did. The County board also instituted a policy for an early intervention/case management program. This helped get people into care and monitoring. More important from a prevention standpoint is behavioral changes. Case managers stay with their patients as long as they live in the county.

The department had trouble accessing persons with multiple sexual partners and pregnant women. The county board passed a regulation that physicians confronting symptoms of any STD were required to offer HIV testing. The county is currently looking at a policy to have HIV testing be part of plea bargains.

Dr. Cruz-Uribe then discussed directly observed therapy. Treatment failures lead to dramatic increases in cost; as a result, the health department looked at using videophone equipment to connect with patients. No more than 5 minutes with a patient every day is needed to ensure compliance. This program has been very popular and is much easier on staff than traditional home visits. Although the program is only 6 months old, private providers who have treatment failures have been referring patients to the department, resulting in a remarkable turnaround in lowering viral loads to undetectable.

Monica Sweeney, M.D., M.P.H.
Vice President for Medical Affairs, Bedford-Stuyvesant Federal Health Center
Dr. Sweeney framed her remarks in the context of the "Baby AIDS Bill," the focus of which was perinatal prevention: the infant was the primary prevention target (secondary prevention for the mother). Treatment extended through the prenatal, birth, and infant care periods. In New York City, a cohort of 843 infants were followed for about 2 years (1994–96). The transmission rate was 13 percent for treated infants, and 26 percent for nontreated infants. In 1995, another study of 943 infants showed a transmission rate of 6.3.

From 1987 to 1997, New York State had the highest number of pediatric AIDS cases. In the same decade, testing was ongoing as a blinded study with those infants. The mothers were not informed that the tests were being done, and results were not given to anyone. In 1993, a state assemblywoman, Nettie Mayerson, drafted legislation to unblind the testing, a move which AIDS activists fought on the grounds that it would prevent women from coming in for treatment. When one mother took home a baby that was later diagnosed with full-blown AIDS, there was a media uproar, which helped fuel Mayerson's bill. In 1996, Governor George Pataki signed the bill into law. The bill provides for routine counseling for pregnant women. It does not force testing, but a woman who refuses testing must sign her name to that refusal. In addition, all babies need to be tested when born, with or without the mother's consent. The mother or guardian is given the test results. Also in the bill is language requiring referrals to be made for positive women and infants.

Dr. Sweeney said that in the center where she works, counseling is done for all women and only two refused testing last year. One woman insisted she had just been tested and the results were pending; the other simply did not want to know. More than 99 percent of the pregnant women in New York State are now tested.

The *New York Post* called this the "Infant AIDS Miracle." Governor Pataki stated in 1993 he wanted to reduce the infection rate in newborn infants to below 5 percent. The "Baby AIDS Bill" resulted in a reduction from 25 percent to 3.5 percent. It is considered a major success.

Dr. Sweeney said that she and Nettie Mayerson also worked on name reporting, partner notification, and contact legislation. It is surprising, she said, that only 38 or 40 states have reporting.

Another issue where treatment needs to be more aggressive is injection drug use and sex with IDUs. IDUs are driving the epidemic in New York City. Most children born with AIDS now are the result of injection drug use by their parents. There are currently three states with compulsory testing for children: results have to be given to their parents or guardians. A bill has been introduced in Congress, which looks much like the New York State bill, to have all pregnant women counseled and tested. It has been recommended that this be a requirement for Federal funding for prenatal care.

Education Is Prevention
Ann Peterson, M.D.
Assistant Administrator for USAID Bureau for Global Health
Dr. Peterson noted that in places where same-day testing is available, clinicians have found that twice as many people are willing to come in and be tested. She then noted that roughly 70 percent of USAID (U.S. Agency for International Development) funds are focused on programs that stress the ABC approach: Abstinence, Be faithful, and Condoms. She saw her first AIDS case in Zaire in 1982; months later, she saw a second one in Stonybrook, New York. She did her first prevention work in Kenya. It is important to note, she said, that knowledge does not automatically equal behavior change and prevention. In Kenya, 85 to 89 percent of the people know about HIV; the medical community, however, is reluctant to discuss the problem, even with U.S. outreach and education workers. It is not clear what can be done to remedy this barrier. Clearly, expansion of the epidemic needs to be arrested, and that means changing behaviors. Treatment alone will not prevent new infection. One key piece is to have the right data that are appropriate to the audience and are thus important to tailoring education efforts. Citing statistics that women tend to become HIV positive at 20 to 24 years old, while men are 30 to 39 years old, she noted that behavior change is challenging. Youth is a key focus, especially internationally.

Dr. Peterson spoke of Uganda as a success story. She noted that clinicians there measure new infections in 16- to 19-year-olds; the overall prevalence lags slightly behind this particular population. Prevention efforts in Uganda focus on three behaviors: delay in the onset of sexual activity (one to two years); a reduced number of partners; and condom use, complementary to the other two behaviors. The reported number of partners has changed as a result: 30 percent of the married population in one small village in Uganda had one partner besides spouse; another 30 percent had two to four partners. However, in the early to mid 1980s, only 10 percent of this population was completely faithful. Education was part of prevention efforts long before testing was ready, and behaviors were already starting to change.

Condom use was a factor in the changed behavior, seen in specific populations such as urban sex workers. Other factors that lead to behavioral changes include strong political leadership; the openness of public discourse; concerned efforts to reduce HIV stigma; the involvement of grassroots community organizations, schools, CBOs, and PLWH/A. Clear messages have been sent, for example, “zero-grazing,” which means putting a stake in the ground and allowing a cow to graze only within the length of the rope. These efforts are not just in schools; partner reduction is promoted in adults as well, and these efforts also serve to protect youth.

While mass media can be a factor in changing social norms, it has been found that interpersonal communication is more effective. Dr. Peterson exhibited a slide in which a “sugar daddy” leers at

a teenage girl; she noted she has shown this slide to boys and asked what their responsibility is to their sisters, girlfriends, etc. This actually made them think about important questions. Talking in small groups works well; the difficulty comes when education efforts need to be scaled up.

USAID is working to maintain the priority of prevention efforts, expanding to new groups, and making sure messages are appropriately balanced. The agency is trying to finalize reliable, measurable indicators for the A and the B of the ABC approach. Success stories are starting to be seen, and USAID will look to what can be learned. The government of Haiti wants to know from U.S. agencies what worked in Uganda. USAID needs to analyze the results, learn from the data, and disseminate and adapt successful programs: to replicate successes.

Comprehensive Sex Education
Dorothy Mann
Executive Director, Family Planning Council, Philadelphia
Ms. Mann stated that her organization maintains 85 clinic locations, providing a range of community-based HIV and STD services, screening and treatment, as well as administering Title IV RWCA funds for Women, Infants, Children, and Youth (WICY). Ms. Mann also chairs the Government Affairs Committee board of directors, is involved with AIDS Alliance, and served on the CDC Advisory Committee on HIV, STD, and TB prevention.

Ms. Mann noted the AIDS Alliance and other organizations worked successfully to ensure the reauthorized CARE Act in 2000. Different groups working together on controversial issues ended up doing very important work by compromising and listening to each other.

Ms. Mann said her remarks are not just about comprehensive sex education, or abstinence education; too often, people working on prevention education find themselves in camps using buzzwords, but the fundamental goal is the same: to stop the spread of the epidemic and preserve the health of youth. This is far more important than ideological arguments. Ms. Mann argued that accurate information must be made available to the nation's youth about maintaining their health and avoiding risks.
Of the estimated 40,000 new HIV infections each year, half are among 18- to 24-year-olds. Ms. Mann noted that the U.S. teen birth rate has declined, despite the old conventional wisdom that nothing could be done about teen pregnancy until poverty was solved. Yet while the country has not "solved poverty," important strides have been made in reducing teen birth rates. Nonetheless, the U.S. rate of teen pregnancy is still the highest in the developed world by far, as is the rate of HIV infection.

Ms. Mann addressed sexual behavior in young people: 65 percent report having had sex by the age of 18; by 19, the figure is 80 percent. Ms. Mann said these facts call for a broad approach to educating youth about sex, to ensure they grow into physically and mentally healthy adults. It is critical to give them accurate and comprehensive information about prevention. Federally funded abstinence programs teach youth that a monogamous heterosexual relation within marriage is the norm and is expected of them. This is a noble goal, but the reality is that the average age at which people marry is currently 27 for men and 25 for women. It is not realistic to expect single persons of such age to remain abstinent until marriage. Abstinence-only sex education programs also fail to acknowledge that there are gay and lesbian youth who legally can never marry. Programs that rely solely on abstinence fall short of realistically addressing the needs of the majority of U.S. youth. Rarely does a "one size fits all" approach reach everyone.

It is generally felt that encouraging young people to delay sexual initiation is appropriate and wise; the data are clear that youth who delay sexual initiation have fewer partners and are less

likely to contract HIV and other STDs (or to have an unplanned pregnancy). Ms. Mann noted that education efforts in Philadelphia high schools discuss abstinence and delaying initiation (as the only way to be 100 percent safe); however, the fundamental difference in the approach of abstinence-based education acknowledges that many teenagers can and will be sexually active before marriage.

Ms. Mann argued that sex education approaches must be based on sound evidence that enjoys a scientific consensus. For example, abstinence-based programs teach that, for those who choose to have sex, condoms will protect them against HIV. There is a scientific consensus on the usefulness of condoms as a preventive measure. Conversely, there seems to be no scientific consensus that sex outside of marriage is psychologically damaging.

Some proponents of abstinence-only education maintain that high teen pregnancy rates are the result of comprehensive sex education; however, there are no data to support this assertion. Indeed, studies show that comprehensive sex education—even condom distribution—does not induce earlier sexual initiation. The pregnancy and STD rates were virtually identical across controls. It may be that the increasing HIV rate in youth is the result of increased screening.

Comprehensive abstinence-based education is attuned to the vast majority of public opinion: a poll by the Kaiser Family Foundation found that 81 percent of Americans believe that sex-ed programs should teach about contraception.

Regarding the moral debate that underlies this discussion, young and old people frequently make choices that many do not agree with or engage in behaviors many do not approve of, yet they cannot be abandoned. America's values do not permit throwing people away. Those working in HIV prevention remain engaged: educating, persuading, and informing. Ms. Mann said her deepest concern about abstinence-only programs is that they may abandon those who behave outside their lines—gay and lesbian youth, and the sexually active. A medically accurate curriculum that promotes abstinence but includes other pieces is the best approach to saving young people's lives.

Ms. Mann noted she had five recommendations, which she would provide in writing.

Abstinence Education
Joe S. McIlhaney, M.D.
President, The Medical Institute for Sexual Health

Dr. McIlhaney's presentation was titled "Sexual Abstinence and Monogamy: Exploring Co-Interventions for the HIV Pandemic." He noted that one problem with the debate on sex education is that people often take sides, with each side characterizing the other inappropriately. Some people immediately react badly to mention of "abstinence"; indeed, there are ongoing efforts to devise a new term for it.

Dr. McIlhaney stated that, among his OB/GYN patients, none has ever reported having been warned that her sexual activity could result in sterility. Consistent 100 percent condom use has only 85 percent efficacy, and condom use is often less than consistent. The most optimistic study data is from the Saracco study of 1993, in which 56 percent of respondents reported using condoms consistently. (The cohort was monogamous adults, some serodiscordant, who knew they were in a study.) Condoms are much less effective against diseases more infectious than HIV (e.g., herpes, gonorrhea, and chlamydia), for the last of which they offer only a 55 percent risk reduction. Further, they offer no risk reduction for human papillomavirus (HPV) infection. STD infection also increases susceptibility to HIV.

The fact remains, Dr. McIlhaney said, that condoms have a limited role and a limited effectiveness, which could help explain the continued spread of the epidemic. Even given optimism regarding consistent condom use, co-interventions are needed.

The single greatest risk for STD/HIV infection is an increased number of lifetime partners. Monogamous sexual activity between two uninfected partners prevents both from becoming infected. Even if one is infected from a previous relationship, monogamy allows only one other person to become infected, hampering the spread of the epidemic. Avoiding sexual activity until entering a lifetime sexual relationship offers the greatest hope of an STD- and HIV-free lifetime monogamy.

Dr. McIlhaney cited a study that compared women who became sexually active later in life to those who started earlier: women who started sexual activity before 16 had more lifetime sexual partners by far than whose who delayed initiation.

Regarding safer sex programs (also called dual-message programs), no curriculum based on these messages has been shown to decrease pregnancy or STD rates. The outcomes usually measured are: reduced frequency of sex, reduced number of partners, and increased contraception use. By contrast, modern abstinence programs are much more sophisticated; they use modern learning theories. Furthermore, they *do* teach about condoms and contraceptives using accurate data on rates of success.

Dr. McIlhaney cited the ADD health report on virginity pledges: 15 percent of girls and 10 percent of boys have taken an abstinence pledge. In another site, the "Not me, not now" program has reduced teen pregnancy rates from 63.4 to 49.5 per 1,000 girls.

Uganda has had success in reversing its HIV epidemic. This is a stand-out achievement; Paul DeLay has said what is happening in Uganda is almost a miracle. It is the responsibility of the PACHA to thoroughly understand the implications of its efforts with respect to sex education programs. HIV was entrenched in Uganda as early as 1980; 18 of 60 military officers tested were infected in 1986. President Museveni started the ABC program; his speeches emphasized abstinence until marriage. As a result, the HIV rate dropped among women, despite the fact that Ugandans never really took to using condoms. By far the most striking feature of the success in Uganda is the drastic reduction in multiple sexual partners. Other positive trends include a decline in MSM multi-partnering; the increase in age of female sexual initiation; and higher marriage rates for women. Dr. McIlhaney said that the fact that some people do not or cannot get married is not grounds to ignore important evidence that promoting marriage, fidelity, and abstinence has worked.

Dr. McIlhaney closed with the quote: "When two elephants fight, it's the grass that gets hurt." When HIV prevention advocates fight over such issues, he said, it's the kids that get hurt. He suggested that as the Council reviews the available data together, it will find the best way to proceed.

Sex Education Funding
Maggie Wynne
Legislative Analyst, Office of the Assistant Secretary for Legislation, DHHS
Ms. Wynne provided a breakdown of Federal efforts toward HIV prevention. The General Accounting Office (GAO) identified nine different Government departments, with most of the

HIV efforts concentrated in DHHS. Ms. Wynne broke this information down into abstinence-only efforts versus other prevention efforts.

Much of the federally funded work in abstinence education has been congressionally earmarked; all of this has been directed toward adolescents (e.g., Title X of the Public Health Service [PHS] Act in the early 1980s). The "Adolescent Family Life Act" has abstinence as one minor part. Only $2 million per year was spent on abstinence education until the late 1990s. The annual spending is now about $12 million. In 1996, Congress passed the Welfare Reform law, which includes a Title V program on abstinence, providing for a State grant program at $50 million distributed over 5 years. (One State, California, does not accept this money.) This program inserted a definition of abstinence education, defining it by eight elements, often referred to as A through H: abstinence until marriage; no mixed-message programs. This is also a matching grant program; the State has to match $3 for every $4 Federal dollars.

In addition, community-based abstinence programs were put into place just recently. Last year the funding was $20 million (to a fraction of the 360 applicants); this year, due to significant interest, funding has doubled. The President and Secretary Thompson supported $73 million for this year's budget. The family planning/sex education program has different earmarks, particularly with respect to sex-ed per se: much of this work takes place in medical settings (programs in clinics or in schools). The bulk of this is from the Title X Family Planning Program; this fiscal year (FY) the allocation was $266 million, comprising one-third for adolescents. The bulk of this funding comes from Medicaid. Federal funds provide 90 percent of Medicaid family planning funding; the States provide 10 percent.

The 1996 Welfare Reform law also provided for pregnancy prevention efforts; States get $16.5 billion annually, 1.4 percent of which (about $230 million) is for pregnancy prevention. Social Services Block Grants provide another $1.7 billion, of which $42 million is for pregnancy prevention. The General Accounting Office (GAO) identified about 27 programs (CDC has others). Of the many health programs and education programs in DHHS, only 2 of the 27 are abstinence-only; the others provider broader prevention messages.

Council Discussion of Prevention Issues

Mr. Nickerson commented on abstinence versus comprehensive sex education. One presenter made the point that condom use requires 100 percent adherence in order to be effective; Mr. Nickerson suggested that abstinence requires 100 percent adherence as well. He said that every bit of information is important. The disparities in philosophy between the presentations were not as pronounced as they are in the political and ideological world at large. Mr. Nickerson asked whether it is true that Federal funding policies of the Bush administration prohibit any discussion of condoms. Ms. Wynne replied discussion of condoms is not prohibited. It is prohibited, within abstinence-only programs funded by the Government, to promote their use. One Council member stated that condom use can only be discussed in terms of ineffectiveness. Dr. McIlhaney disagreed: people do and can talk about contraceptives.

Dr. Coburn noted he has made a similar observation to that made by Mr. Nickerson: that people on different sides of the issue say essentially the same thing. However, there is a lack of trust now because the sides are so polarized. The other issue to consider, Dr. Coburn said, is that of "informed consent"; one presenter, for example, made a statement that "condoms prevent HIV transmission," without any qualification. He said American youth can hear everything sex educators want to tell them about condoms, but the information needs to be the truth, and the truth in this case is that condoms have an 85 percent success rate even when used 100 percent of

the time. It is also true that delaying onset of sexual activity is a key factor in decreasing the lifetime number of sexual partners. Dr. Coburn said if everyone could agree on that one point, transmission of STDs in the United States could be reduced by two-thirds. He also noted he teaches about condoms in all education efforts, but only after teaching about the other pieces. Dr. McIlhaney agreed, arguing that, for both heterosexual and homosexual youth, neither should be having sex as adolescents. Marriage is not even a factor to consider at that age.

Ms. Mann stated this is exactly the kind of constructive dialog the Council needs on the issue. She agreed with Dr. Coburn that all information given to youth should be accurate. She noted her organization provides accurate information on birth control methods (comparing different techniques). She noted, however, that she has tried to access abstinence-only funding, and found it was unavailable to programs that do not dictate to youths, "You must be abstinent until marriage." The rigidity of this message (or "sex outside of marriage is harmful") is problematic.

Ms. Rock stated that she is a licensed child care provider; in her state there is a law that prohibits an adult with a communicable disease from working in a child care environment. This provides a legal framework for discrimination. Ms. Rock said she asked 3 years ago for public policymakers in her state to rescind this law. In this context, she asked Dr. Cruz-Uribe what he meant by saying that HIV is just like any communicable disease. Dr. Cruz-Uribe responded that such a law doesn't exist in his state, and he certainly would not support it. He said he suspects that law was written in the early stages of the epidemic.

Mr. Nickerson said that a lot depends on how people process the information they receive. If the only information given to someone about condoms is that they don't work, he asked, what is the takeaway message for a young person who is simply not receptive to an abstinence-only message?

Dr. Coburn reminded the Council that Federal abstinence money is tiny in comparison to other sex education monies available. Also, educators can talk about the effectiveness and ineffectiveness of condoms. Dr. Coburn said he wrote the law, and that grantees are talking about effectiveness and ineffectiveness. The issue of concern here is that there has not yet been a good study on the efficacy of abstinence-only education in the United States. This effort should be given a fair try based on preliminary results.

Mr. Burden stated that this is good news, and that the message needs to be disseminated to the community; at least some Council members were misinformed. Mr. Burden noted that almost all the presenters on rapid testing stated, "No test is perfect"; in the same context, certainly condoms aren't perfect either.

Mr. Burden requested donating the rest of his discussion time to the recommendations Ms. Mann did not have time to enumerate in her presentation. Ms. Mann listed some:

- Strengthen Federal funding for sex education programs requiring that all information disseminated is medically accurate.
- Give states more flexibility in using abstinence money.
- Support HIV prevention for school-age children with the proviso that curricula are medically accurate.
- Provide more and better training for parents, to educate them on the normal sexual development of their children and how to be better parents.

PANEL PRESENTATIONS: INTERNATIONAL ISSUES

DHHS Global Health Issues
William Steiger
Special Assistant to the Secretary for Global Health, DHHS

Mr. Steiger provided an update on the Global AIDS Fund. As of the last PACHA meeting, the fund had just received proposals and was in the process of reviewing them. In all, 385 proposals were received from 101 countries, totaling 1.15 billion in requests. Of these, 145 proposals met the eligibility criteria. The review panel was composed of 17 independent experts, who rated proposals according to several criteria and forwarded their recommendations to the Global Fund board at their April meeting. Secretary Thompson represented the United States. The fund agreed to support 40 proposals in the short term, over 2 years, for a total of $378 million. Grants were made for a 2-year period with a chance to renew to ensure that program milestones and accountability criteria are met. The Fund also approved an additional 18 proposals for another $238 million. The totals are $616 million for 58 programs in approximately 42 countries. This summer, the Fund will ask for additional information from many of the proposals that were funded. (Only one of the 58 approved proposals was judged to need no further adjustments—a malaria program in Tanzania.) Within the next month, the Fund will issue a second call for proposals (and will also entertain reapplied proposals from the first round that needed extensive reworking). The majority (53 percent) of the funding is going to combat HIV/AIDS.

In April, Richard Feecham was selected as Executive Director of the Fund. He will come on board sometime in July, but has begun working with the Fund's secretariat, many of whom are on loan from institutions in several governments. The Fund has issued a number of recruiting announcements. (Council members are encouraged to contact the fund (www.globalfundatm.org) for job announcements in grants management, financial arrangements, communications, and outreach.) The Fund's secretariat has been small, and as a result they have had trouble getting accurate information out on a timely basis. At a September board meeting, the Fund will make some policy decisions around governance issues: making the board more transparent and efficient; how to monitor and evaluate grantees; outcome-based disbursement of future funding, fiduciary arrangements (the World Bank is the trustee, but down-flow is not yet settled); resource mobilization, etc.

Regarding the Fund's financial stability, public and private partnerships have pledged a total of about $2 billion. At this point, $443 million of that money is on deposit at the World Bank, including $250 million from the United States. Another $50 million is outstanding, equally shared by DHHS and USAID. Dr. Peterson has been instrumental in getting this money moved into the World Bank. An important consideration is that the U.S. share of cash on hand is above 60 percent. Other donors are talking about paying for administrative costs; the United States certainly does not want to shoulder the entire bill for administrative costs. For calendar year 2002, $770 million is available for disbursement; for 2003, $450 million; for 2004, $150 million. The Fund will have to recapitalize itself within the next year or so. Mr. Steiger said he and his colleagues are confident they can fund this and the next grant cycle without a problem. They also expect good things of Dr. Feecham, who met last week with Secretaries Thompson, Powell, and O'Neill. The Fund is impressed with the steps Dr. Feecham has taken in terms of staffing and policy.

The United States is the only nation or institution that has submitted a second pledge to the Fund; President Bush will encourage his colleagues to step up and commit more for Years 3 and 4 of the Fund's life.

Mr. Steiger discussed the mother-to-child prevention initiative. President Bush announced a major initiative to expand the scale and scope of prevention efforts around the world: $500 million new dollars over next several years. The $200 million for FY2002 and FY2003 are in congressional appropriations and are not yet signed; in addition to this, the President has committed to donating $300 million in new funding for the future. To give a sense of scale: the annual budget of the Elizabeth Glaser Pediatric AIDS Foundation—the main private sector partner—is about $10 million in grants, or one-fiftieth the resources being committed here. Perhaps $50-$75 million is being spent in much of the developing world. Mr. Bush's initiative is certainly an exponential increase. The initiative entails both secular and faith-based organizations, NGOs, cooperative agreements with governments. Funding is earmarked for eight sub-Saharan countries: Botswana, Côte D'Ivoire, Ethiopia, Kenya, Mozambique, Rwanda, South Africa, and Uganda; funding is also going to Guyana, Haiti, and Trinidad, and, in 2004, Namibia, Tanzania, Zambia, and one other country. It is no accident that the countries listed are those with the highest seroprevalence. The desired impact, when the program is fully rolled out, is the treatment of one million mothers per year and the reduction of transmission by 40 percent in these countries.

The mother-infant program will focus on treatment for mothers and infants, and on building capacity to prevent perinatal transmission. The programs will be based on existing programs in the public and private sectors. The programs will also provide care for families and education on prevention. Some more highly developed countries will have comprehensive therapy; where less infrastructure exists, the focus will be on short-course therapy (e.g., Navirapine and/or AZT to mother and child). Two innovative pieces are also included: a hospital and clinic twinning program, matching a number of U.S. hospitals with counterparts overseas; and a travel program in supported clinics to build capacity and train native health care workers. This is a major step forward in international AIDS programming.

Mr. Steiger noted that Sec. Thompson will be leading a delegation of senior U.S. officials—including Dr. Sullivan, Dr. Coburn, Dr. Slater, Scott Evertz, Dr. Biato, Claude Allen, and Mr. Steiger—to the International Conference on AIDS in Barcelona. The Secretary will present at the conference, with Dr. Feecham and the director of the WHO, on increasing and enriching public/private partnerships.

CDC – Global Initiatives
Julie Gerberding, M.D., M.P.H.
Acting Deputy Director for Science and Public Health, DHHS
Dr. Gerberding noted she started her internship almost exactly 21 years ago today: the year the first AIDS patients were detected. In the years since, the epidemic has become one of the biggest health problems the world has ever faced. What is really new about AIDS, she said, is the medical knowledge that has come out of it: the amazing discoveries made in molecular biology over the last two decades. The other news is that 500,000 new cases are predicted per year. In reflecting on what is really known about prevention, Dr. Gerberding said, there are some lessons or recommendations to take back to CDC:

- Evaluate the research portfolio: ensure that ongoing research adequately addresses the problems.
- Look at how to improve access to diagnosis and treatment. Now that drug treatments are prolonging lives, it is a tragedy that the intervention potential has been missed. Step back and take a pragmatic and objective look at what programs are supporting and identify which strategies are truly reducing incidence.

- Look to expand on what works; document the "return on the investment," and reinvest. The HIV research and care community needs to admit that some attempted strategies do not work.

The Global AIDS program is exemplary in terms of following this framework. It is not certain yet to what extent program goals succeed, but there are lessons to be learned from Thailand, Senegal, and other successes.

Dr. Eugene McCray
Director, Global AIDS Program, National Center for HIV, STD, and TB Prevention
Dr. McCray distributed a map of 25 countries in which the Global AIDS Program (GAP) is currently operating: 17 in Africa, 5 in Asian, and 3 in South America. The GAP is very new; it first received emergency funding in July 1999—a $35 million appropriation of emergency funds for programs in 14 countries. This funding has increased to approximately $144 million this fiscal year; GAP is slated for level funding in FY2003.

The GAP Program Model entails Surveillance; Primary Prevention; Care and Treatment; and Capacity and Infrastructure development underlying all other areas (labs, information systems, monitoring and evaluation, training and technical assistance, etc.).

The process for establishing a GAP program starts with working with USAID on eligibility criteria (involving prevalence and the country's political commitment; whether there is already a GAP presence there); and a needs assessment (entailing a 2- to 4-week visit). The GAP assistance plan is based on priorities identified through a dialog with the host country. The most frequently expressed needs are around surveillance, voluntary counseling and testing, improving care for PLWH/A, strengthening lab capacity, perinatal prevention, and training for all these activities.

CDC staff members are currently assigned to 19 of the 25 GAP countries; it is hoped that staff will be assigned to an additional 5 countries by the end of 2002. Of the current projects, 18 technical strategies have been developed; 25 countrywide program assessments have been conducted; and 19 GAP country Program Plans have been developed.

A number of mechanisms help with the GAP's work, such as collaboration with many partners (USAID is main partner in most countries). GAP also works closely with HRSA, and Department of State, and the National Institute on Drug Abuse (NIDA). Cooperative agreements exist with a number of partners, and 46 awards have been made to domestic and international organizations including AHPL and NASTAD.

One concrete example of a successful GAP program is Botswana, where CDC has a presence. Botswana is one of the top four hardest hit African counties: 39 percent of the native women are HIV positive. The estimated life expectancy was 70 years; now it is 39. GAP is involved in several major program areas: working closely with the government to implement a "Know your status" campaign to ensure that 100 percent of Botswanans are tested; setting up voluntary testing sites in each district; mother-to-child transmission prevention; and working with State and Defense Departments to add counseling units to all maternal and child health clinics. In addition, a media campaign is underway to effect behavioral change, using the national broadcast system to run a radio series with AIDS-related information. GAP is working closely with an NGO called Population Services International, as well as a large youth NGO called YOHO, which targets 15- to 29-year-olds. Other efforts include peer outreach; CDC support drama groups; door-to-door education; and condom distribution. Comprehensive care and treatment efforts in Botswana include supporting Isoniazid Preventive Therapy for TB (IPT).

Monitoring and evaluation are also strong components in which many partners are engaged; this has been adopted and is being implemented in many GAP program countries.

Dr. McCray discussed future challenges. The GAP has grown very quickly, and has had to respond both to demands placed by partners in the United States and by non-GAP countries interested in their support. The GAP needs to be intelligent in planning for future growth, and needs to meet demands in a reasonable way. The CDC has a reputation for providing high-quality TA, the goal of which is to have programs increase their capacity to do their own work; to increase communications and to communicate effectively within and without DHHS so people will know what the GAP is doing, how to access services, and how the GAP works internationally. The GAP also needs to establish priorities and planning systems, and to review and evaluate them on annual basis. Changes need to be dynamic whenever possible; at present the focus is on hands-on training and TA—recruiting and training locally. However, as the epidemic matures, the GAP's role may change significantly to a more advisory capacity.

DHHS Caribbean Visit
Cheryl-Anne Hall
Sunset Park Family Health Center Network, Brooklyn, New York
In June 2001 [?], Secretary Thompson learned about the dramatic increase in the number of Caribbean nationals seeking HIV treatment in New York, especially in Brooklyn. As much as 30 percent of the population may be positive but have not been tested. Ministers have shared the difficulties they have had in arresting the spread of HIV in the Caribbean. Secretary Thompson promised at that meeting that he would convene a follow-up meeting in the Caribbean; Ms. Hall said she was invited as part of his delegation, which includes USAID, Scott Evertz, and other DHHS representative. The group convened in Guyana on April 20. The day was spent developing strategy, and culminated in the signing of a pan-Caribbean partnership agreement. Sec. Thompson deployed staff from the CDC and other agencies to Haiti to provide assistance and to help develop infrastructure, and to provide technical assistance to help with their proposal to the Global AIDS Fund (which was not approved in the first cycle).

Ms. Hall noted the WHO has been attempting to stop recruitment of nurses from the Caribbean; many countries are recruiting nurses there. Many of the recruited nurses serve as providers of health care in rural areas in their host countries, but this leaves a dearth of qualified nurses in the Caribbean.

Following President Bush's mother-to-child prevention program announcement, Sec. Thompson agreed to hold a follow-up meeting and promised to continue to work on behalf of the Caribbean nations.

Panel Discussion of International Issues

Dr. Sharma noted that the success in Uganda has been quite apparent; he asked Dr. McCray if those methods are being applied in Botswana and elsewhere in Africa. Dr. McCray responded that this is so: one thing they tried to do (partners in the CDC, USAID, and United Nations Joint Programme on HIV/AIDS [UNAIDS]) is to look at successes in Uganda and elsewhere and document best practices. Uganda was a perfect example: they began very early in the epidemic to encourage people to know their status. Voluntary counseling and testing was championed in Uganda, even before the GAP existed.

Dr. Sweeney noted that there have been efforts to educate mothers as well as young men and young women; yet one image shown today depicted a "sugar daddy" and teenage girl, denoting sexual predation. Dr. Sweeney asked if any efforts have been made to target that group of men, who are a common problem both in Africa and in inner cities in United States. Dr. McCray responded that this was a piece of population-based education, targeted primarily at educating young women. There are also some programs targeted at men, although in Africa, in general, it is not easy to access men. However, because people are interested in the media campaign, one approach is to access men through the women. It is a difficult process because many clinics are not perceived to be very male-friendly.

Mr. Burden said he fully supported the public/private partnerships that have been mentioned, and asked Mr. Steiger for word of the new initiative last year, between Rockefeller and others called MCHT (Mother-to-Child Transmission Plus). Mr. Steiger said this is clearly a potential partner to look toward, and said that such initiatives are good to build on rather than "reinventing the wheel."

Dr. McKinnell reported having seen impressive work going on in every country he visited in Africa: several U.S. Government agencies, foreign governments, and local governments had initiatives. There were 1,600 NGOs operating in Uganda. Dr. McKinnell asked when there will be accurate data on how much money is being spent, how many people are being tested, and what is the cost per test and per treatment. Mr. Steiger responded that these are President Bush's questions as well, and the Global AIDS Fund is in the process of developing ways to measure these things. They are asking potential partners to work in ways they have not done before. There is a lot to learn, Mr. Steiger said, but this is precisely the kind of accountability that is needed.

Ms. Ivantic-Doucette thanked the various participants for their collaboration in these efforts. She noted she has been working with the CDC and USAID for years to push to train new nurses, as well as on the hospital twinning project. The absence of nurses from developing countries is another layer of complication. Recruited nurses from the Caribbean and elsewhere are filling the U.S. shortage but leaving a gap in developing countries. Ms. Ivantic-Doucette also a caveat about praising the work in Botswana: this nation has a population of 1.4 million people, is rich in resources and has less poverty than other African nations. It does not compare to a large, more complex, and poorer country. Mr. Steiger noted the Global AIDS Fund is concerned about the nursing shortage internationally. The Secretary has been focused on nursing education and expanding the pool domestically to combat the problem.

Dr. McCray stated that the Global AIDS Program is doing everything it can to make sure everybody understands that this is a 10- or 20-year proposition, not just a project for the next 2 or 3 years.

Announcements from Executive Director

Ms. Ware asked members to complete their activities disclosure forms. She stated that members who do not return this form would not be permitted to attend further meetings. She also asked Council members to complete and return to her or to her assistant their 2002 annual ethics training form. She noted the Council would review ethics issues tomorrow morning. She also said that the event on Monday with Secretary of State Colin Powell is not an official PACHA event; the Council cannot pay member expenses for those who choose to stay in Washington to attend. To such persons, Ms. Ware offered registration forms.

The proceedings adjourned at 4:49 p.m.

June 22, 2002
Morning Session

Dr. Coburn called the meeting to order. He noted the Council had a productive session yesterday, and outlined the schedule for today. Following Ms. Ware's presentation of some ethics training issues, the floor will be opened for discussion. There will be a period of time for public comment, after which any final business can be conducted.

ETHICS ISSUES

Ms. Ware noted that most Council members received ethics training in the Council's first meeting; for those who have not had training, this is a very important Federal requirement.

Ms. Ware reminded the Council that no member can represent him or herself as a PACHA member when expressing individual opinions. Unless there is a consensus on the Council, individual members cannot state an opinion as a stated member of the Council. Even if a member does not explicitly state he or she is speaking on behalf of PACHA, if introduced as a PACHA member, the assumption (e.g., on the part of the press) will be that he or she is representing the Council. This is important to keep in mind as many members travel to Barcelona. As an example of consensus, Ms. Ware cited the Council's decision about increasing funding for ADAP; members are free to relate the Council's unanimous recommendations regarding ADAP.

Ms. Ware also discussed members' conversations with Government officials. No member can discuss any issues with Federal employees without going through PACHA. In one recent situation, a Federal employee called one of the Co-Chairs to ask to speak at this meeting. Ms Ware stated that Federal employees need to arrange to speak through her office only. Dr. Coburn qualified this issue by stating that PACHA members still have every right to have discussions with Federal employee, but only with the verbal disclaimer that they are not speaking on behalf of PACHA.

Ms. Ware noted that there should always be a PACHA staff person present at subcommittee meetings; meetings conducted by conference call should be arranged through and attended by someone from the PACHA office. When a member receives questions from the press or public, Ms. Ware said, they can always contact her or her staff. Serving on this Council does not prohibit members from functioning within their agencies and organizations as normal. For example, one member wrote an article and sent it to Ms. Ware for clearance because he listed his position as a PACHA member. It was decided in this case that the gentleman use his private (organizational) title first, thus not to represent himself as speaking for PACHA.

Ms. Ware said any member questions on these issues should be directed to her. Dr. Coburn further advised the Council to request a written response from Ethics if they feel something is questionable.

One member asked what represents an official PACHA position; Ms. Ware responded any issue that has been voted on or on which consensus has been reached. These issues will always be listed in the minutes and transcripts. Mr. Burden noted this is an important point: to be sure which items have reached consensus and which are still in discussion would be good to review as a matter of course in the meetings. Dr. Coburn agreed that a review of the consensus point should be done for every discussion.

Ms. Ware shared her recent activities with the Council. She noted she has traveled across the country extensively talking about the President's HIV agenda. She has attended board meetings to update many people on PACHA activities and answer questions, in the process developing respect for the work the Council is trying to accomplish. She has met with pharmaceutical company representatives to develop a rapport and to let them know what the Council is doing. She has met with organizational and Government officials, who now understand that PACHA is serious about its assignment. Ms. Ware stated she has two new assistants on staff: Dr. Elizabeth Onjoro and Gail Wilkins. Now that Ms. Ware has support staff, she said she hoped communication and information dissemination to the Council would be quicker.

Regarding Federal regulations on travel, Ms. Ware urged Council members to be patient and to continue to contact her as needed. Ms. Ware will attempt to find a way to help members do what they need to do.

Ms. Ware addressed members unable to sign the document attesting that they had been briefed on ethics because they were not at the last meeting; statements are needed on how these members receive this briefing. PACHA staff asked Ethics to do a makeup briefing, but no one was available during this meeting. Those who were unable to attend the last meeting have regulations in their notebooks; perhaps a conference call can be arranged with an Ethics person on the line. It is not sufficient to attest merely to having read the regulations; nor will previous briefing (i.e., from the previous Council) suffice, inasmuch as regulations have recently changed. The information presented today by Ms. Ware may be enough of an update, but this is not certain; Ms. Ware said she would let the Council know next week.

Dr. Coburn noted that, because he cannot operate on a short timetable, proposed dates for next year's meetings will be sent out soon. Council members are asked to communicate back on their preferred dates. If feedback is not received, the Co-Chairs will decide the schedule based on their own availability. In any case, by October's meeting a complete schedule for next year will be available. Dr. Coburn said he also hopes to build a better-structured organization that will allow members to bring their thoughts and assets from their organizations.

Ms. Ware noted the Council's August meeting was canceled due to budget considerations. Dr. Coburn noted the August meeting was an extra meeting anyway, and was based on extra budget money that subsequently disappeared. Still, should the Council need to communicate in the meantime, it can certainly be done (e.g., via e-mail). The next meeting will therefore be October 24 and 25. At least two meetings will be scheduled for next year, possibly three.

Ms. Ware asked members to share their Barcelona schedules with her so that she can plan a reception for one evening.

Open Council Discussion

Dr. Coburn commended Ms. Ware for the variety and balance of yesterday's panel discussion. He stated that the Council will not close out anyone's input; everyone will be heard. Dr. Coburn gave the floor to Ms. Ware to discuss a subject she believed the Council missed during yesterday's session.

Ms. Ware stated that she has been neutral and objective in running the Council; however, the issue of marriage received insufficient discussion during yesterday's prevention presentations. She stated she has a few thoughts on marriage as related to abstinence funding and the criteria for funding. Ms. Ware stated she spent hours with the first lady of Uganda in an attempt to generate

and achieve a cultural paradigm shift; as a result, the people of Uganda changed their way of thinking about sex and marriage. This is apparently what Congress was trying to achieve in putting the A through H criteria on sex education monies. The literature is replete with data indicating that young people do better when they are raised in households with two biological parents. It has been seen, particularly in African American communities, that when families break down, the children suffer: there is more drug use and abuse, more teen pregnancy, etc. This is not to say that every child in a two-biological parent household will do well, but it does speak to the astronomical risks for broken homes.

Ms. Ware said the emphasis must be on solid families: marriage, monogamy, more black men back in their homes as loving husbands and fathers. Society must help its young from an early age to understand the importance of this and thereby acquire the qualities it takes to grow and to develop lifelong, committed relationships. Going from one broken sexual relationship to another impedes the ability to commit, to bond, and to trust. This is what the Million Man March and the Million Family March were about.

Dr. Gomez spoke on a point of order: The Council is supposed to hear issues, and members should have the ability to express opinions. Yesterday, however, there was a cutting off of some people's opinions, while Co-Chair Coburn interjected his own opinions. Dr. Gomez stated she was dissatisfied with a process that did not allow full expression of some opinions while seeming to preference others.

Dr. Coburn responded by noted he was not chairing the meeting yesterday in which he expressed his opinions; rather, he participated outspokenly as a PACHA member. In addition, Dr. Coburn noted he has deferred to Ms. Ware this morning because she saw an area she did not feel was adequately covered. There has been an attempt to ensure a balance. Dr. Coburn noted also that the Council agreed yesterday that delaying sexual activity was an important message. Nevertheless, he said, criticisms on process will be noted and attended to when he sits as chair.

Karen Ivantic-Doucette noted she was in Uganda when the constitution was written and the marriage law was passed. Uganda, which had had polygamy for centuries, went to a one man/one woman system. [?] said it is too early to know whether marriage in Uganda will decrease HIV rates; what it has done, on the other hand, is to outlaw polygamous households with no social sequali. Although it was the right move, [?] said, people should be cautious in applying the Ugandan model in the United States: Uganda has different concepts of prevention and a very different society. Furthermore, the marriage law has served to disempower the women in Uganda. Prevention researchers are trying to figure out how to provide social modeling to young people. The most important bases of behavior are the modeling learned before age of 6; that whole component is not being addressed here.

Ms. Ware said there is also a public health issue to be considered. It is clear that one risk factor for any STD is multiple sexual partners. There is also a protective factor in communities with two-parent households. The Ugandan experience limited the practice of having multiple sexual partners.

Caya Lewis spoke to underscore the previous comments on Council process. The Council must have time for discussion and contemplation, she said; after 10 presentations yesterday, the Council entertained only about 3 questions. Ms. Lewis also noted she is looking forward to getting agendas earlier and being able to provide suggestions and feedback as to who will present at Council meetings. Because the discussion yesterday was curtailed, Ms. Lewis said, more information is needed on comprehensive sex education, including results of studies. Some

studies, for example, have shown that kids who get abstinence-only education use condoms a third less than those who receive comprehensive sex education. This constitutes an additional health risk. As researchers try to limit partners and delay the onset of sexual activity, those in the public health arena need to talk about the social reality, which is that the majority of young people do have sex before leaving high school. When abstinence fails, they need all the information. Ms. Lewis said she looks forward to talking further with Dr. Coburn about the legislation, in light of Ms. Mann's stated inability to get Federal monies for comprehensive sex education. Right now, the legislation seems to stipulate that people may not stray from the A through H criteria.

Dr. Coburn stated that no presenter was scheduled this morning specifically because the Council clearly needed time for discussion. He said he would talk with Co-Chair Sullivan about allotting more time for discussion following each presentation or series of presentations. The Council is not perfect, Dr. Coburn said, but he is working to improve it.

Joseph Jennings introduced himself and noted that he lectures to motivate kids. He said many young people are making decisions about their lives based on a lack of information. There is a tendency to think that kids are stupid or cannot make up their own minds. He said he has talked to 6 million kids in 15 years, imparting the message that they have the right to do anything they want, as long as they understand there is a price they have to pay for their actions. He urged the Council to present youth with all the available information. In the black community there is a particular lack of information; it is 500-year-old information that conditions the community, resulting in so much sex and so many babies.

Mr. Perez echoed Dr. Gomez's concerns about Council process. The Council needs to speak to the Chairs on practical recommendations and work to arrange the agenda to allow for full discussion of issues.

Ms. Rock suggested that the human side of PLWH/A issues was missing from yesterday's presentations. Teenagers, she said, speak well and will tell researchers what they do and do not do. Some teenagers, for example, report that their parents introduced them to drugs. Ms. Rock stated she would like to hear more from consumers, and from the people who work in the counseling and testing field, including those doing rapid testing. It would benefit the Council and the FDA to hear the human side of these issues.

Mr. Ware said these concerns were duly noted. She explained that, of all the invitations to present to the Council, very few persons could show up to present on Saturday, so all presentations were scheduled for Friday. Today's meeting was left today open specifically to engage in discussion. While this arrangement is not ideal—inasmuch as the presenters are not present today to hear the discussion—Ms. Ware noted that the FDA sent someone to take notes. The intention of the meeting's setup was not to limit dialog.

Dr. Sweeney recommended switching the meeting schedule back to Thursday and Friday if people cannot attend on Saturdays. Didactic lectures and panel presentations should be broken up and followed with discussion. Ms. Ware noted she tried to schedule for Thursday and Friday; however, these were the only two consecutive dates on which the Co-Chairs were both free. It is clear, Ms. Ware said, that the Council really should meet on weekdays. Dr. Coburn agreed that there was never an intention to hold regular Saturday meetings.

Mr. Minor said that the issue of changing behaviors is really the discussion that must happen here—not just about setting up rules, but a real behavioral shift, with its difficulties and its

benefits. He noted he is in full agreement with the importance of changing behaviors; however, some of the language used yesterday—notably, "unhealthy homes" and "marriage as the preferred option"—is problematic. Mr. Minor asked how this language applies to an 18-year-old or to Mr. Minor himself as a gay man. He said the Council must consider gay and lesbian youth and not marginalize them. The GLBT community must be part of the cultural paradigm being striven for.

Dr. Sharma said he would also like to echo the recommendations that more time be allotted for discussion. The Council's first meeting in March was instructive; there was a good structure to the presentations. This Council represent a variety of views; Dr. Sharma said he would like the Council to focus more on what its charge is. There are 35 different views in this room, and agreement on everything cannot happen, but the Council must focus on what can be done to minimize the impact of the AIDS epidemic.

Ms. McDonald said that the discussions have been enlightening, and concurred with Dr. Sharma that the Council must agree to disagree on certain points. Ms. McDonald said she does not prefer abstinence-only education because it is labeling and exclusive. She noted that, despite the extensive discussion about adolescents, there are none present. Adolescent voices are needed to explain what it means to them when they are told that abstinence is the only option. Ms. McDonald recommended bringing in "MTV people," and looking at the broader culture in which sex is hot or important for young people. She stated that she is not interested in making recommendations that are doomed to failure before they leave the room.

Dr. Driscoll echoed the concerns that the Council needs to keep GLBT youth central to the deliberations. Not only are gay people not able to marry, he said, there are many other reasons for both homosexuals and heterosexuals not to want to marry. There is a tremendous legal angle, Dr. Driscoll said, which is "as bad as being a doctor." The important thing is to encourage stable partnerships. The Council and the community need to be flexible on this point: the important thing is limiting partners and opportunities for infection.

Ms. Franklin stated she has appreciated all the comments so far. She noted she has gone from executive director of an HIV program to a tribal leader; in the latter role, she said, she can impact her community in a different way. Ms. Franklin said that, after listening to the discussion yesterday and today, it all begins with commitment. She noted that her personal experience has shown that it absolutely makes a difference for children to have two parents. Ms. Franklin said she truly appreciates being on this Council and listening to all points of view.

Dr. Coburn said it is important the Council remember there are two members selected especially because they are young people. He encouraged these members to speak and be heard.

Mr. Jennings asked, in light of Mr. Minor's comments and self-identification, whether the Council is now focused on gay HIV issues. It was his understanding, he said, that the Council is not pushing an agenda, and wondered if the discussion of gay issues is consistent with Council boundaries and rules. Dr. Coburn responded that the Council is a diverse group of people, each bringing a different set of experiences, values, etc., whether black, white, Latino, gay, straight, etc. He added that the Council decided at its first meeting not to squelch any issues. The Council shares one desire: to make recommendations that will ensure that the next person does not get HIV. Dr. Coburn stated he is a conservative, hard-nosed Republican congressman. Yet the Council is going to try to build consensus on important issues, with the power of diversity behind its decisions. Mr. Jennings asked, given the conflicting views on marriage as a part of the social foundation and the fact that homosexuals cannot legally marry, whether the Council should seek

an answer to that issue. Dr. Coburn said that the Council would not; HIV is the focus of discussion. While there are many impacting tangential issues, it is the Council's goal to prevent the next person from getting HIV. Mr. Jennings opined that all the Council's rules should be on the table.

Ms. Lewis said this is an opportune time to bring up a process point, with respect to talking about building consensus and speaking up as active participants. Ms. Lewis said she had issues with the process by which the Council's first set of recommendations to the President was developed. Because the first set of recommendations were developed post-meeting and sent around on e-mail, the response seems to have been limited. This is not an ideal consensus process, she said. Dr. Coburn responded that not everyone used "reply all" in response to the e-mailed recommendations, but several members sent responses to the Co-Chairs. Not many negative comments were received. In the future, Chairs should recommend that all members reply to the entire Council. Dr. Coburn stated also that a committee of 35 members cannot collaboratively draft an entire letter.

Ms. Lewis agreed that e-mails should go to the entire Council so everyone can react. It is also important to the consensus process, she said, that when ideas or feedback are incorporated into a Council document, the membership needs to see a revised version before it is made final. Dr. Coburn responded in defense of the Chairs' position, noting that he and Dr. Sullivan were instructed to get the letter out quickly. The Council developed six or seven goals, based on which the Chairs developed a draft, distributed it, received comments, revised the letter, and sent it; as a result they communicated the intent of the Council to the President's administration. Ms. Lewis responded that it is not her desire to send out recommendations, no matter how quickly or how slowly, that are not constructed under a valid consensus process. She stated she hoped this situation will improve now that the subcommittees are functional.

Dr. Coburn offered one cautionary note: striving for 100 percent consensus leaves a committee with nothing. He insisted that this committee must accomplish something or else it will be disbanded. There are issues to be dealt with more important than anyone's particular agenda. As Co-Chair, Dr. Coburn said, he will help to build the best consensus achievable; if some disagree with the results, that is what America is all about. The fact is, HIV infections are still increasing in the United States; the measure of whether of not this Council is effective is whether infection rates are lowered.

Dandrick Moton noted he is the director of a community youth group started in Arkansas in 1991 and that he is not an expert on HIV/AIDS, but has read up on the subject. As a guest speaker at an Arkansas AIDS conference, he made front-page news. He cited an analogy his mother made regarding teaching young people about "healthy choices": he said the truth he teaches young people is like a safety net—it will catch all the people who do not make those healthy choices (i.e., the sexually active).

Ms. Shoemaker reminded the Council that she and several other members are consumers and can offer personal information on what it is like to live with HIV. She stated there has been too much talk for the last 20 years; of primary concern is that the Council is an advisory board and needs to have the tools to put out there in the communities. As a Council, it is important for each part to work together. Ms. Shoemaker said that "we are all human beings"; the disease affects every single person.

[One member] asked whether a response has been received from the President regarding the Council's first set of recommendations. Dr. Coburn responded that there has been no word from

Scott Evertz of the Office of National AIDS Policy. Dr. Coburn received a fax from a presidential aide; it is not clear whether this is meant as formal response, but it is not satisfactory. Dr. Coburn said he intends to clarify the intent from the White House before distributing the fax. [The Council member] opined that someone from ONAP needs to attend PACHA meetings—if not Mr. Evertz, then a designee.

Rashida Jolley asked the Council to consider further involvement of youth in Council meetings.

Dr. McKinnell reminded the Council of one simple fact: since the Council convened yesterday, there have been 30,000 new HIV infections worldwide. He stated there has been too much politics being discussed; the focus should be on practical, workable solutions.

Mr. Nickerson said he hopes the Council will not approach HIV like drug use[?]. Evaluation has demonstrated that prevention efforts primarily reach low-risk youth. The Council really needs to think about who is at risk: certain populations have been disproportionately affected. Mr. Nickerson noted that the word gay was not even used in Council until today. There has been no mention of needles in prevention discussions, although needles have been in the picture since the epidemic started. It is important to concentrate on where the infections exist.

Dr. Sweeney noted that she talked about IDUs in yesterday's presentation. Drug use is certainly driving the epidemic in certain populations. She noted she distributed articles this morning from MMWR and HRSA on drug use and how it drives the epidemic. She recommended that the topic be further discussed in the prevention committee.

Ms. Ivantic-Doucette brought up another issue raised yesterday: the linking of diagnosis and treatment to prevention. When regulations around interventions are developed, she said, they are broken into the areas of primary prevention, diagnosis, and care and treatment. This has limited how people can implement new programs. Even new monies from the Minority AIDS Initiative have actually served to exclude minorities from receiving quality care. She asked the Council to talk about the way prevention has been interpreted, to rethink the use of care and treatment monies, and to consider new, creative interventions. Dr. Coburn recommended working on such issues in the prevention committee.

Follow-up Discussion on Rapid Testing

Dr. Coburn called for a Council consensus on rapid testing. He asked whether the Council should formulate this as a recommendation, and if so, how.

Dr. McKinnell noted he does not care whether rapid testing receives a CLIA waiver or is designated moderately complex. The urgent thing is to get it out quickly and widely. Mr. Burgess said that, clearly, allowing rapid testing to be waived will increase access. He recommended waiving it.

Dr. Driscoll noted there is an apparent contradiction for the United States to push for rapid testing throughout the world and denying it to African Americans and other Americans here. When a highly beneficial drug is approved, by comparison, obviously its advocates want it approved for broad usage; the alternative is Viracept approved for last-ditch efforts. Dr. McKinnell countered that the Council should not get bogged down in the process of telling the FDA how to do its job, and recommended letting the President decide on the issue.

Ms. Ware reminded the Council that the FDA representative wanted to make it clear that discussion of the CLIA waiver will not hinder the approval of rapid testing. It was his estimation that it would take no more than 3 weeks after approval to determine whether or not CLIA regulations will be waived. CMS will set regulations for how rapid tests will be used; FDA will then determine whether CLIA will be waived.

Dr. Sweeney noted that the prevention committee met this morning and decided on a recommendation that the full Council urge approval and a CLIA waiver for rapid testing. Rapid testing should be made available as soon as possible, maintaining all confidentiality and counseling and testing guidelines applicable to existing tests. This recommendation was motioned and seconded.

Dr. McKinnell noted there are several FDA advisory committees that have recommended otherwise. He said he would much rather focus on the outcome; working on the details of how to get there leads to a morass that is more appropriate to the President or the Secretary of DHHS. While he agrees that rapid testing should be immediately and broadly accessible, Ms. McKinnell recommends that the Council not urge a CLIA waiver.

Dr. Sweeney noted the prevention committee engaged in extensive discussion this morning and determined that increased availability of rapid testing is a part of the reason for recommending a waiver. Mr. Nickerson agreed that this strategy would provide wide access. It may be the case that a moderately complex rating would not impede access, but that is unclear. Mr. Nickerson said he supports a recommendation to waive CLIA requirements.

Dr. Gomez said that the Council has been given enough information to make an informed decision and assume a position. While the Council has been told the lack of a CLIA waiver will not be a barrier, several of the presenters yesterday disagreed. Dr. Gomez said she feels the Council is meant specifically to recommended “waived” versus “non-waived.”

The Council’s vote was held momentarily for a process question: will the full Council reconvene following committee meetings this afternoon? The answer was no.

The vote for the proposed recommendation was carried unanimously.

PUBLIC COMMENT

Dr. Coburn noted that each member of the public will be limited to five minutes.

Mary Hess
Ms. Hess is President of Minority Health Care Communications, a nonprofit TA and marketing organization whose goal is to help nonprofit organizations reach pharmaceutical allies more successfully. Ms. Hess said her career has always been focused on pharmaceuticals in HIV and cancer. She has attended many meetings with pharmaceutical companies (Bristol Myers Squibb, etc.). While she had not intended on making public comment, Ms. Hess said, Council members should be aware that Oraquick is not an oral fluid test: it is a whole blood test requiring a finger stick, collection with a lancet and a blood loop. It also has multiple steps. A CLIA waiver would enable people with no background in multiple-step lab processes to administer this test. As a former employee of Orasure, Ms. Hess said she strongly believes in rapid testing, but Oraquick is not based on the same testing process. She recommended arranging a product demonstration with Orasure management.

Ms. Hess's second recommendation, related to prevention messages and the continuing concerns about reaching the target constituencies with prevention messages, is to create an "ad council working group" with a voluntary membership comprised of various marketing experts and marketing staff from the pharmaceutical companies currently working on HIV (Glaxo Wellcome, Bristol Myers Squibb, Smith Kline, etc.) to participate collaboratively with a CBO membership to develop prevention messages. Ms. Hess said she would be willing to help create an infrastructure for such a project.

Dr. Geneviève Flanvielle
Dr. Flanvielle noted that, with respect to rapid testing, the Council selected a limited range of persons to speak. In considering a topic like rapid tests, everyone involved in the debate should speak, providing all the information needed to make a decision.

As an openly gay, unmarried woman, Dr. Flanvielle said, her 10-year relationship was truly a marriage in the full definition of the word. She recommended that the Council use the term "relationship" not "marriage." The important thing is the quality of the relationship. Dr. Flanvielle said that "ethics, principles, and values" are the key words that children and adolescents need to be taught. It is not the logistics of a relationship, but its quality, that matters. She recommended teaching values: what is appropriate and what is not. Youth should be taught that abstinence is better; however, if they are sexually active, they need to know to use condoms. Youth should be taught the whole truth. Dr. Flanvielle noted that 3 or 4 years ago in a prevention convention in Los Angeles, with 5,000 attendees, there was only one session on ethics. It was attended by 10 people, 7 of whom were educators. Youth expect to be led; adults should lead by teaching values, ethics, and principles.

Dr. Eugene Capello
Dr. Capello, who is the Executive Director of Florida AIDS Action and works with the University of South Florida College of Medicine, said the research community had the foresight to create a structure with lifesaving medications for AIDS. Within Title II of the Ryan White CARE Act, ADAP completes this function; however, some states have waiting lists, including Florida, where there is great concern about ADAP. Dr. Capello applauded the Council for its recommendation that the President address the issue; emergency allocations are needed to fund ADAP in FY 2002 and 2003.

Regarding rapid testing, Dr. Capello thanked the Council for the recommendation just passed, including a CLIA waiver. This is an important tool for outreach workers to reach the most difficult-to-reach populations, such as sex workers, the homeless, and chronic IDUs. One story from Tampa reported on a outreach person searching 8 months to find a lost positive. Dr. Capello asked how many new infections that positive might have caused in that time. Rapid testing in a counseling and testing context, with immediate entry into treatment, will assist in reaching the key goal of the CARE Act. Dr. Capello thanked the Council for its leadership and commitment.

Frederica Wilson
Ms. Wilson noted she came to convince the Council to do what it has already done, that is, recommend approval of rapid testing. Ms. Wilson is the State Representative for District 104 in North Miami, Florida; she is also founder and Executive Director of 5,000 Role Models of Excellence, a mentoring program in Miami-Dade County public schools. Dealing with African Americans, this program involves 10,000 children and 15,000 men who serve as mentors. Ms. Wilson said the HIV rapid tests, with properly trained and supervised outreach workers, will be an incredible tool. Too many HIV-positive persons do not return for their test results and may be infecting many others in the meantime. Unreceived results also become a burden to the agency

trying to find the PLWH and get them into care. African Americans and other disproportionately affected populations have been statistically less likely to return for their results. Florida has the number 1, 3, and 4 cities for HIV infection rates in the United States. During the past session, Ms. Wilson said, she had a victory in passing a difficult bill that deals with the testing of inmates on release from prison. Governor Jeb Bush signed the bill in May. The bill states that, 60 days prior to release, each inmate in Florida will be tested for HIV/AIDS; if positive, they will be counseled, medicated, and linked to care in the city of their relocation. Ms. Wilson thanked the Council for its time and commitment to this cause.

Regarding youth prevention: With child statistics rising on a daily basis, and with teenage mothers and fathers in the public schools across the county, Ms. Wilson said, these is no such thing as an abstinence-only curriculum. HIV infection rates in youth need to be addressed. Young people are not "cookie cutter" people.

Frederick Wright
Mr. Wright noted he is happy to celebrate the fact that he is alive; in part because of people like the Council members standing up for people like Mr. Wright. As a moderate Republican, Mr. Wright commended President Bush's work on the global AIDS issue. He noted that in the Christian faith, Jesus was clear on the point of feeding all his children; he did not distinguish between 12, 20, or 55 years old. Mr. Wright said Africa's problems stem from its having been so long exploited by imperialists from other countries, including the United States. Mr. Wright noted that Haiti has been occupied three different times; history shows that, as capitalism pushes other societies, they have cultural problems. Mr. Wright said Americans, especially as Christians, have the responsibility to address these problems.

Mr. Wright said the World Health Organization should provide more money for global HIV. Two years ago, Sandy Thurman said that $30 billion will be needed to address AIDS globally; yet there is only $1 billion available. Mr. Wright asked the Council to recommend that President Bush put more money into the Global AIDS Fund. He also noted that the G7 is meeting today, and the United States should urge Great Britain and other G7 nations to support the Fund. Last year, Terry Anderson called global AIDS "industrial genocide." Mr. Wright said he hoped a cure is found soon and this Council can be disbanded, but for the time being, he hopes to convince all leaders on this Council to lean toward more money for global AIDS.

Marcia Martin
Ms. Martin referred the Council to a quote from Secretary Thompson, stating that the danger of HIV "is getting worse. The worst mistake we can make right now is to let our guard down, for AIDS is still a wretched killer and too many lives are at stake." Sec. Thompson was quoted in the book "Fiscal Year 2003 HIV/AIDS Appropriations Recommendations," published by the National Organizations Responding to AIDS (NORA). Ms. Martin said she had some concerns that she hoped the Council would think about as they decide the direction in which to proceed. For example, she asked the Council to stop thinking in terms of "instead of" and always think "in addition to." The HIV community has been stuck with "this *or* that" for 20 years.

Having worked in the Federal Government for 8 years, Ms. Martin said, simply getting more money is not the answer. In discussing prevention, there are many options: condoms, needles, abstinence: no one is paying attention to the practical applications. AIDS Action is thinking about how to participate in the national conversation. It is a totally different environment from what it was 20 years ago. Strategies need to be updated; it may be time for the "old folks" to get out of the way if they are still working from old ideas. Ms. Martin provided a few newer ideas for consideration:

- Prescriptions for prevention: prevention plans should be different for different people. If marriage is claimed as an effective tool, then gay marriage would be just as effective. This can be researched and tested. Ms. Martin noted she cannot speak to what a 14-year-old needs to know about HIV, but this information should be tailored, as compared, for example, to what a 37-year-old needs to know.
- "Can you package it?" Ms. Martin asked how to ensure that care is available to everyone—regardless of how it is financed. A goal of this Council and the community must be to assure that care is available for all PLWH.
- Communities can help. Communities have always done some of the best work around the epidemic. It has been the communities that built the initial response to the epidemic; Government needs to support these communities.

Ms. Martin praised the Council's diversity and said this is an example of "in addition to" rather than "instead of." She said the HIV bureaucracy knows more now than 20 years ago about effective prescriptions for prevention, but it still has not given itself permission to write them.

Closing Comments

Ms. Ware thanked all the public speakers.

Ms. Ware also announced that Ethics has decided that Council members who have not received an ethics briefing will be permitted to sign their ethics forms attesting that they have read and understood the printed materials.

ADDITIONAL COUNCIL DISCUSSION

Council staff distributed copies of notes from the June 21 discussion regarding the ADAP shortage. Dr. Coburn noted he asked Mr. Minor and Dr. McKinnell to look at options. Dr. Coburn noted they have had discussions with the Appropriations Committee on next year's ADAP budget; the purpose right now is to alleviate the extreme shortage for this fiscal year. Knowing how such things have worked in the past, Dr. Coburn said, it will be very difficult to get results from the Government in the next 4 months. The Council is therefore asked to consider what can be done in conjunction with Pharma in terms of non-Government strategies.

Dr. Coburn noted that any ideas from yesterday's discussion asking for Government action should be communicated to the White House, while the Council, the pharmaceutical companies, and other entities should do what they can. For example, there is no reason the AMA and specialty medical associations cannot send out information on how to access programs outside of ADAP, as recommended. Dr. Coburn said he hoped the Treatment Committee will be responsive to these recommendations. There are approximately 1,300 people on waiting lists in the United States (although, Dr. Driscoll said, it is hard to get exact statistics at any one time—there are close to 500 in North Carolina alone). Dr. Coburn asked the committee to understand that, in terms of Federal authorizing legislation interfacing with State regulations, just putting more money into ADAP may not solve the problems. In some cases money may be sent to States not suffering an ADAP shortage because of better State-level participation. A better response and a smarter, more refined process are needed in the short term.

Dr. Sweeney asked to be reminded about the recommendation yesterday when someone put together a reference for all mechanisms for accessing care programs across the United States; Dr. McKinnell stated that a Web site listing such resources will soon be online.

Dr. Driscoll suggested that the Council send a letter to the White House, and empower Ms. Ware or designee to seek a meeting on the subject of that letter with White House staff member Aaron Phelps.

[WHO?] explained that some States have really good models and manage their money well; those models need to be shared with or replicated in the shortfall states. In addition, because this is the fourth quarter of the fiscal year, emergency funding is needed to get the shortfall states through the crisis. Dr. Coburn said this is an excellent suggestion, but the Council needs to consider how to carry it out. He said that the emergency bill in Congress right now has no additional ADAP money in it.

Mr. Nickerson stated that, although short-term solutions are needed at present, the Council needs to consider the entire ADAP model as appropriate for dealing with a long-term disease. Part of the problem may be the simplicity of the model. Dr. Coburn agreed, and said the next generation of drugs will only exacerbate that problem.

Dr. Driscoll suggesting looking at RWCA States that are in trouble. He recommended authorizing Ms. Ware to continue discussions with WHO to see what can be done about putting more targeted money into troubled states.

Dr. Coburn asked whether the Council could depend, on a regular basis, on the Treatment Committee to determine appropriate courses of action and get recommendations to the Executive Director. Mr. Minor noted that the Treatment Committee will be meeting at noon today and can begin work on this immediately. He suggested that the committee draft a response and send it to Ms. Ware and the Co-Chairs. Dr. Coburn explained that he does not believe the situation permits a full Council review of the Treatment Committee's recommendations, given the dire need to inform State medical associations on how to access drugs outside of ADAP; he therefore asked the Council to trust the Treatment Committee to draft recommendations.

Ms. Ware cautioned that Council members cannot interact directly with State agencies: all communications need to come through the PACHA office.

Dr. Gomez moved, and Ms. Rock seconded, to grant the Treatment Committee authority to execute recommendations to go to the Co-Chair and thereafter be sent off as appropriate.

Mr. Minor brought to the Council's attention the letter from Paul Kawata of National Minority AIDS Council (NMAC) that was distributed this morning, regarding an interactive session at the U.S. Conference on AIDS (USCA) between PACHA and conference attendees. The idea is to have an opportunity for this Council to go to USCA and listen. The majority of people who attend and who are served by the attending agencies are people of color. Attending will be executive directors, case managers, and front-line providers. Mr. Minor noted he was not asking that PACHA pay for the conference or associated travel expenses; however, as a number of members will be attending anyway, the thought is to serve as members of PACHA in the public view. Mr. Minor said it is a key part of Council members' job to hear what is being said in the community and bring it back to the Council. USCA represents a great opportunity to say to the community, "We want to hear you."

Dr. Sullivan noted he will have to check whether he can rearrange his schedule to attend the USCA; he recently accepted an invitation to lecture at a university on the same evening as the scheduled session. In general, however, he said the Council should respond to this invitation, and

if he is unable to attend, that is all the more reason other Council members should go. Dr. Sullivan noted the Council has a very limited budget; if members can attend on their own budgets, that would be excellent.

Ms. McDonald said this would be a great occasion for PACHA to step up and hear front-line stories. Since several members are already planning to attend, the Council can make a decent showing.

Dr. Coburn noted he has a conflict that cannot be resolved during the USCA, but said that it is a great idea for Council representatives to attend and listen to conference participants. He cautioned, however, that listening is all such members can do in this context; members cannot expound on PACHA policy or opinion. He asked for a showing of which members will be attending; eight members so identified.

Mr. Minor noted that Mr. Kawata has already designated the time and date for this "town hall meeting." He said the idea is to document all comments and distribute them to the Council, so if the Co-Chairs cannot attend, at least they will see the comments.

Dr. Coburn called for a motion to authorize this action, with the understanding that members will not be put in a position in which they have to respond to public comments or questions. Ms. McDonald so moved, and Mr. Perez seconded. Discussion on the motion followed:

Ms. Rock recommended alerting NMAC in writing in advance of the USCA that Council members cannot respond on behalf of the PACHA. Dr. Coburn assured the Council that there will be appropriate interaction between the PACHA executive staff and Mr. Kawata to that effect, making sure to satisfy both parties and observe ethical concerns. Mr. Minor noted he has already informed Mr. Kawata that whatever was agreed upon by the Council would have to go through Ms. Ware's office.

Dr. Coburn called for a vote; the motion passed unanimously.

Dr. Sullivan related to the full Council his comment to the International Committee yesterday, regarding President Bush's $500 million initiative on global AIDS. Although this pledge is just a start in dealing with the global AIDS crisis, Dr. Sullivan suggested that the Council start by sending a letter of commendation to the White House, and noted that more money is needed. The Council's role, he said, is not only to criticize when it disagrees but also to commend when it agrees. Mr. Perez agreed with Dr. Sullivan's recommendation, and asked if it were appropriate to attach a secondary request for a formal response to the last set of Council recommendations.

The Council discussed the pros and cons of including both positive and negative feedback in the same letter. Dr. Sullivan noted he has received many comments about the absence of a representative from the Office of National AIDS Policy. It is important for such a person to attend to ensure communication from this Council back to the White House.

Mr. Burden asked whether it would be appropriate to set a target for international AIDS funding from the United States. Dr. Sullivan explained why he discourages this idea: the President has a whole range of issues he needs to deal with. If PACHA were to establish a target, Dr. Sullivan said, he would be concerned about it becoming a bone of contention; he would rather leave it open to future communication and discussion. The point right now is to recognize the first step of $500 million and to note that additional funding is needed. Mr. Burden said his concern is that

only the commendation section of such a letter would be read, and the section on insufficiency would not be noted.

Mr. Nickerson noted that *The Washington Post* ran several editorials yesterday observing that public perception is that the $500 million should be spent this year rather than spread over 3 years. The letter to the President needs to speak to the need for more money. Mr. Nickerson said there was definitely a process that was interrupted in Mr. Bush's allocation of funds. Dr. Coburn cautioned that the Council does not know what took place behind the scenes regarding that allocation, and therefore cannot speak of such in the letter. The previous PACHA pointed out that infrastructure is one of the most important pieces. Dr. Coburn said the Council cannot be made a political football between the press and the White House. Mr. Nickerson stated this was not his intention, but suggested the Council should express its enthusiasm for more international AIDS funding. Dr Sullivan began suggesting language: "We recognize that the allocation will not solve the global crisis…"

Ms. Ivantic-Doucette recommended framing the letter in terms of leadership on the issue. The letter can include discussion of the need for ONAP's visible leadership to continue supporting the President.

Abner Mason said it is appropriate to send a letter commending the President; it is a dramatic step, the import of which is not always recognized by the Council because the issues are so large and complex. It would be a shame to miss the opportunity to say to the President, "That's the kind of leadership we want," and to pledge the Council's continued commitment to work with the Administration on implementation. In addition, Mr. Mason said, the Council should send separately a letter on the other identified issues (e.g., requesting a response to the previous recommendations or the participation of ONAP). The commendation letter, he said, should be stand-alone. Dr. Sullivan said this recommendation is acceptable.

Dr. Driscoll suggested that any communication to the President should discuss the number of AIDS cases rather than the number of dollars recommended. The Council should target numbers of people to be helped in period of time, not how much should be spent.

Dr. McKinnell moved to draft a letter to the President, and Dr. McIlhaney seconded. Discussion on the motion followed:

Mr. Perez asked for clarification that the Council will draft a letter of commendation only, and offered a friendly amendment asking for a separate letter to ask for a response to the previous Council recommendations. Dr. Coburn gave his personal assurance that he will seek and garner a response from somebody in White House on the previous recommendations. He then called for a vote; the motion passed unanimously.

Ms. Ware noted that the intention is not to reconvene as a full Council, but to have committee chairs report back to the plenary via e-mail. She stated that there will be a more thorough agenda for the October meeting, and said she hopes the subcommittees will be able to meet by conference call in the meantime.

One Council member recommended putting any major items for action or a vote on the agendas ahead of time. Regarding public comment, today the Council heard comments on issues that had already been voted on; it would be more appropriate to hear from the public before a vote. Dr. Coburn added it may be possible to gather public comment before the Council even convenes, and publish this comment in advance.

Ms. Rock noted that members of two different populations—the deaf and hearing impaired, and seniors—asked her to convey to the Council that their populations are not getting appropriate HIV services. The deaf sometimes have communications problem with clinicians, especially those that cannot write in English.

Dr. McKinnell stated that committee conference calls are a good idea, but the committee chairs need guidance on budget matters. Dr. Coburn assured the Council that the Chairs will ensure committee members are so guided. Ms. Ware noted that a line item exists for conference calls; she will look at the budget to see how many calls it will support, for how many people, and for how long.

Ms. Ware noted there has been a recommendation to record the committee meetings and include minutes along with the plenary session minutes. Dr. Coburn noted that this would entail three transcribers; Ms. Ware suggested that each committee designate someone to take notes. Dr. Gomez requested that a staff member be designated for all committee conference call; Dr. Coburn agreed that there should be a designated staff person on all conference calls. Dr. Coburn also said support staff should be appointed to take committee minutes. Ms. Ware will arrange for support staff to attend this afternoon's committee meetings and take notes.

Ms. McDonald asked whether substance abuse will be one of the main points of the next meeting, and volunteered to help coordinate presentations on the topic. Dr. Coburn offered his thanks.

Dr. Coburn thanked the members for their service and commitment. He said the Chairs' goal is improvement in each and every meeting.

Ms. Ware reminded everyone that committee meetings are not open to the public.