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THE HEALTH RESOURCES AND SERVICES ADMINISTRATION

and

CENTERS FOR DISEASE CONTROL AND PREVENTION

convene the

CDC/HRSA ADVISORY COMMITTEE ON HIV AND STD PREVENTION AND TREATMENT

Rockville, MD
November 18 – 19, 2004

Record of the Proceedings

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Members in Attendance

A. Cornelius Baker
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Robert Fullilove, Ph.D.
Fernando Garcia, M.D.
Gale Grant, M.A., C.P.P.
Dennis Leoutsakas, Ph.D.
Thomas Liberti
Dorothy Mann
John Martin, Ph.D.
Jean Flatly McGuire, Ph.D.
Freda McKissic Bush, M.D.
Jesse Milan, Jr., J.D.
Donna Sweet, M.D.
Antonia Villaruel, Ph.D.

Members Not in Attendance

Renee Austin
David Farabee, Ph.D.
Loretta Sweet Jermott, Ph.D.
Judy Goforth Parker, Ph.D, R.N.
Carmen Zorrilla, M.D.

Designated Federal Officials

Ronald Valdiserri, M.D., M.P.H.
Executive Secretary (CDC)

Deborah Parham Hopson, Ph.D., R.N. (HRSA)

Federal Liaisons

Beverly Watts Davis, SAMHSA
Jay Epstein, FDA
William Grace, NIH
Joe Razes, CMS
Daniel Simpson, IHS
Joseph Grogan, Executive Director, PACHA

Presenters

Laura Cheever, M.D., Sc.M. (HRSA)
Janet Cleveland, M.S. (CDC)
Janet Collins, Ph.D. (CDC)
Susan DeLisle, M.D. (CDC)
Kevin Delaney, M.P.H., (CDC)
Nancy Dubler, LLB, Montefiore Medical Center
Robert Janssen, M.D. (CDC)
Jeffrey Levi, Ph.D., George Washington University School of Public Health
Gordon Mansergh, Ph.D. (CDC)
Greg Millet, M.P.H. (CDC)
Mary Vienna, R.N., M.G.A. (HRSA)

Introductions and Welcome

The CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment (CHAC) held their bi-annual meeting in Rockville, Maryland on November 18 – 19, 2004. CHAC Co-Chairs Jesse Milan, Jr., J.D., and Robert Fullilove, Ed.D., welcomed committee members and public observers to the meeting. Mr. Milan mentioned that long-time committee member Judy Goforth Parker, Ph.D., R.N., had just completed shoulder surgery and that the committee hoped for her speedy recovery.

Executive Secretary Ron Valdiserri, M.D., M.P.H., Deputy Director of the National Center for HIV, STD, & TB Prevention (NCHSTP), also welcomed participants and reminded them that the meeting was open to the public and that any comments made would become a matter of public record. He then welcomed new committee members:

• Renee Austin, a Health Educator from California;
• Dorothy Brewster Lee, M.D., MPH., a senior Technical Advisor for HIV/AIDS with the Catholic Relief Services in Baltimore, Maryland;
• Fernando Garcia, M.D., Medical Director of the Valley AIDS Council in Harlingen, Texas; and
• Carmen Zorilla, M.D., a Professor of Obstetrics and Gynecology at the University of Puerto Rico School of Medicine.

Dr. Valdiserri referred committee members to their packets for information on their roles as special government employees. Members were asked to attend a lunchtime briefing on their responsibilities related to this designation.

Also on hand representing HRSA was Laura Cheever, M.D., Sc.M., Chief Medical Officer for the HIV/AIDS Bureau (HAB), who announced that HAB Associate Administrator Deborah Parham Hopson, Ph.D, R.N., would be arriving later in the morning to participate in the meeting. Dr. Cheever sent regards from HRSA Administrator Elizabeth Duke, Ph.D., who would be unable to attend.

As a first point of order, Mr. Milan asked the group to accept the minutes from the previous meeting, which would be reviewed and adopted later in the day. Donna Sweet, M.D., moved to accept the minutes and Jean Flatly McGuire, Ph.D., seconded the motion.

Shelley Gordon, Senior Public Health Analyst, distributed information on the terms of service for all members. Dr. Valdiserri asked members whose terms were expiring to attend the spring meeting, at which they would be formally thanked and acknowledged for their service to the committee.

NCHSTP Director's Report

Janet Collins, Ph.D., Acting Director for the National Center for HIV, STD and TB Prevention (NCHSTP), gave an update on the Center's activities.

First she outlined some personnel changes:

• Thena Durham, Deputy Director for Policy, would be retiring in February after 30 years with CDC as research microbiologist;
• Dr. Eugene McCray, Director of the Global AIDS Program would be joining the Office of Global Health;
• Dr. Tim Mastro was appointed Acting Director of CDC's Global AIDS Program; and
• Dr. Ida Onorato has joined the NCHSTP Office of the Associate Director for Science.

Dr. Collins said CDC is continuing to seek applicants for the NCHSTP Director position and invited committee members to make recommendations.

With respect to the Congressional budget, Dr. Collins said that the government is operating under a continuing resolution (CR). The House bill offers a $5 million increase for fertility prevention and level funding for domestic HIV programs. In conjunction with appropriations discussions, House members have lauded CDC for its implementation of the Advancing HIV Prevention (AHP) initiative.

The Senate is proposing level funding for domestic HIV/AIDS programs. Also being proposed are $158.5 million for STDs and $140.5 million for TB programs, the latter of which reflects a $3.2 million increase. GAP would receive $119 million.

Dr. Collins provided an update on CDC's Futures Initiative, which has been undertaken by the agency to assess ways in which restructuring might promote enhanced performance, program integration, and greater efficiency. Under the Initiative, the agency has developed a new organizational chart that contains six coordinating centers, as well as Offices of the Chief Operating Officer, Science, Public Health Practice Improvement, Enterprise Communication, Strategy and Innovation, Workforce Development, a Washington office, and Chief of Staff. The heads of all Offices and Coordinating Centers report directly to CDC Director Dr. Julie Gerberding.

The Office of Enterprise-Wide Communication will be responsible for message management, media relations and coordination of communication activities in the event of emergencies. The Office of Strategy and Innovation will conduct forecasting, strategy development, goals development and management, policy analysis and health equity promotion.

Dr. Collins provided information on the agency's effort to update its content review guidelines. CDC published a draft set of guidelines in June 2004, from which it received nearly 5000 comments from across the country. The agency is reviewing the comments and will publish final guidelines in Spring 2005.

Comments focused on use of health department panels, sign off by accountable health officials, uncertainty about the review process for national organizations, review of Web-based materials, and matching of title and content of instructional materials.

Dr. McGuire asked how CDC would prioritize its HIV and STD activities in the context of the new structure. Dr. Valdiserri mentioned that Dr. Mitch McCohen**,** Director, Coordinating Center for Infectious Diseases, would be giving a more in-depth presentation on the new structure at the spring meeting.

Dr. McGuire voiced concern over the public perception that CDC is limiting the explicitness and openness of prevention interventions, and said the CHAC could help the agency vet some of the issues. “I think it’s good notice to us to work to convey what is actually intended with the guidelines,” said Dr. Collins.
Thomas Liberti, The Florida State AIDS Director, said that the previous guidelines had been effective. “Why the revision?” he asked. Dr. Collins responded that the intent was not to disrupt what is working in the current system, but to look at potential enhancements. She invited the CHAC to weigh in. Mr. Liberti and Dr. McGuire agreed to take the lead in providing feedback to the agency.

Update – HRSA’s HIV Care and Support Programs (Including ADAP Update on New Funding)

Dr. Parham Hopson gave an update on personnel changes in the Bureau:

• Dr. Jose Morales is new Director of the Division of Community-Based Programs;
• Michael Evanson is the new Deputy Director of the Division;
• Dr. Deborah Willis-Fillinger is the AETC Branch Chief;
• Celia Hayes has become the Deputy Director of the Division of Training and Technical Assistance;
• Claude Franklin has been named Executive Officer of HAB; and
• Richard Moore is the Chief of the Office of Program Support.

One major organizational change has been the merging of the Office of Science and Epidemiology and the Office of Program and Policy Development to create the new Division of Science and Policy. The Division’s Interim Director is Joan Holloway, who is also HAB’s Director, Community Relations.

Dr. Parham Hopson moved the discussion to the budget. On June 23, 2004, the President allocated $20 million to the AIDS Drug Assistance Program (ADAP) for the purposes of removing 1700 people from program waiting lists in 10 states. The grant was awarded to Chronomed Script Pharmacy for mail-order prescriptions. To date, 917 prescriptions have been filled and 417 patients are now receiving medications.

HAB has signed six new technical assistance cooperative agreements with the Academy for Educational Development, the Cities Advocating an Emergency AIDS Response Coalition, Emory University, the Health and Disability Workgroup at Boston University and the National Minority AIDS Council.

In September, HAB co-sponsored a meeting to facilitate collaboration among the national training centers funded by CDC, HRSA, the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Department of Health and Human Services’ (HHS’) Office of Family Planning. The outcome of the meeting was the development of collaborative workplans to address training needs around CDC’s AHP initiative, and to foster greater coordination of limited resources.

In August, 2004, HRSA held a Ryan White Grantee Meeting that was attended by more than 2300 participants. Evaluations of the meeting indicate that the conference was successful.

HAB continues to work on its development of reauthorization recommendations for the Department. Dr. Parham Hopson acknowledged Marty McGeein, a Senior Advisor in the HHS Office of the Assistant Secretary for Planning and Evaluation, who is coordinating the Departments efforts on reauthorization.

Freda McKissic Bush, M.D., asked about the potential of the ADAP emergency funding to reach those who are still not receiving medications. Dr. Parham Hopson emphasized that the needs of all 1700 persons would be met. Mr. Liberti asked what happens after the $20 million is spent. Dr. Parham Hopson responded that HAB is in discussions with the Department to address the issue, adding "we do not want to take people off waiting lists just to have them return." She said that one possibility might be to roll the initiative into the larger program. Meanwhile, the President has proposed a $35 million increase for ADAP.

Mr. Milan referred to a letter sent by the CHAC to the Secretary in May, outlining concerns about access to ADAPs in light of AHP implementation. To date, the Secretary has not scheduled a meeting with committee members. Mr. Milan asked both HRSA and CDC staff to take their concerns to the Secretary.

ADAP Ethical Issues

Jeffrey Levi, Ph.D., of the George Washington University School of Public Health & Health Services, presented a paper he had developed with Nancy Neveloff Dubler, LLB, of the Montefiore Medical Center to examine ethical issues related to the rationing of care in ADAP programs. Their work had been commissioned by HAB to understand current dynamics within ADAP and to explore the ethics of medication distribution. Dr. Parham Hopson explained that the Bureau would be using the information in part to develop technical assistance tools and best practice models for grantees. She emphasized the importance of ADAP flexibility given changes to Medicaid programs in the States.

As background, Dr. Levi discussed a number of factors coming together to create a crisis in the ADAP program:

• An increased demand for CARE Act services;
• A rise in HIV infection rates;
• Fewer AIDS-related deaths;
• Medicaid cutbacks, and decreased incidence of the kinds of disabilities that would qualify a person with HIV for Medicaid;
• Higher medication costs; and
• Flat/reduced funding for the CARE Act.

State variations in the program have also created a disparity in access. While most States enroll participants who are living with incomes at 100% - 200% of poverty, there are others that set their eligibility requirements higher. Additionally, there is no national formulary, and States are using a variety of cost-cutting strategies to conserve limited resources.

In terms of rationing resources, States must maximize existing resources and consider the use of approaches such as sliding scale fees for those who are able to contribute. Dr. Levi added that in a rationing scenario, the legitimacy of the process is critical, and any approach must include client input.

In rationing resources, he emphasized that four ethical principles must be followed:

• Wise stewardship of resources;
• Equal treatment of clients who are similarly situated;
• Fair access rules; and
• Respect for patient autonomy/needs, which in some sense is lost in the rationing process.

Regarding rationing, it might be effective to establish a potential hierarchy for medication access. Those receiving medications would be in the top tier. Next might be pregnant women, with the goal of preventing vertical transmission and with an obligation to continue treatment after a baby's birth. Third might be treatment-naïve patients that meet HHS guidelines for treatment. Individuals in this group could be subject to income eligibility and co-pays.

A final group, added Dr. Levi, would be other claimants as possible.

Dr. Levi said, " We are asking a lot of the CARE Act to mitigate decisions made 40 – 50 years ago about poverty-based health care programs. That being said, it would be important to examine what else the CARE Act can do to get at these discrepancies."

Dr. Fullilove asked what the data says about people moving to receive better care and medications. Dr. Levi said there is anecdotal evidence indicating that some people do move, and Mr. Liberti added that in some Florida counties as much as 10% of clients come from other States including New York, California, and Georgia.

Next the group asked about purchasing insurance. Richard Conviser, Ph.D., a Senior Health Scientist in HAB's Division of Science and Policy, stated that grantees were previously able to use CARE Act funds to purchase COBRA, which resulted in substantial cost savings. Since 1999, CARE Act grantees have also been able to use ADAP funds to purchase new private health insurance policies for people living with HIV/AIDS. A HAB report issued in 2003 (*Closing the Gap: Financing Health Insurance with ADAP Funds, A Cost Comparison Analysis*) has shown that such insurance purchase is cost-effective. However, added Dr. Conviser, in some States it's hard to get the ADAP program involved in insurance purchase because of limited staff time, and in others, there are no high-risk insurance pools. In still others, State laws prohibit the use of Federal funds to buy insurance.

Mr. Liberti said insurance continuation programs have been successful in Florida, where the state receives $7.00 worth of care for every dollar spent.

Dr. Sweet made a motion commending HRSA for their efforts on the issue and urging them to craft related technical assistance projects. Dr. McGuire seconded the motion and it passed unanimously

Presentation of Recommendations from the CARE Act Reauthorization Workgroup

The CHAC Workgroup on CARE Act Reauthorization presented its recommendations on resource distribution issues related to the CARE Act. The process of developing the recommendations involved CHAC discussions, public input, and HRSA data runs examining the potential impact of changes to Title I and II formulas.

In crafting recommendations, the workgroup adhered to a set of guiding principles, which called for them to consider what they had learned from public meetings on reauthorization, promote long-term equity in CARE Act funding distribution, promote the evolution of the CARE Act to a chronic disease program, reduce historic distribution imbalances, acknowledge that new approaches will cause increases and decreases in jurisdictions and promote system-wide improvement without jurisdictional prejudice.

Mr. Milan made a motion to adopt the recommendations for discussion. The motion was seconded and the entire group agreed to accept it. Following that, the group began discussion of each individual recommendation.

1) Funding Formulas

Draft Recommendation
Eligibility for Title I and funding under Titles I and II should be based on a formula that uses the U.S. Public Health Service (PHS) measurement of advanced HIV disease (i.e., currently a CD4 count of 350 or fewer). The CARE Act should authorize HRSA to incorporate these PHS measurements into their system for allocating resources.

Discussion
The first recommendations spurred the most discussion out of all four. It was explained that the 350 marker was recommended in an effort to move past AIDS reporting, which workgroup members saw as an outdated approach given the current epidemic, and to accommodate some kind of HIV reporting in the absence of a uniform, nationwide surveillance system. Workgroup members acknowledged that the current system does not count cases according to a 350 marker and would require some alterations.

Dr. Valdiserri said there would be a number of complexities related to the implementation of the recommendation, and were it to be approved, CDC would have to come back to the committee to further discuss what that would entail. A. Cornelius Baker, Executive Director of the Washington, DC-based Whitman Walker Clinic, argued for the use of an advanced HIV disease marker, rather than just an HIV surveillance system. He said that because minorities tend to get diagnosed in the later stages of HIV, a surveillance system would not result in the adequate flow of dollars into areas where they would seek care.

Dr. McGuire voiced concern that the recommendation was “fatally flawed” given the current limitations of data collections systems and was unconvinced that it would change resource distribution in a beneficial way.

Mr. Baker suggested that using a 350 marker would urge jurisdictions to test people and get them into care earlier, as opposed the current system using AIDS cases, which, he argued, rewards jurisdictions for not getting people into care sooner.

Renee Austin asked for some language in the rationale to acknowledge that the recommendation could not be implemented in conjunction with the current data reporting system. The workgroup added statements to indicate that their recommendation could not be implemented under the nation's current data collection system and would create an additional burden on States. Further language recommended that CDC and HRSA consult with States and other stakeholders in the implementation of the recommendation.

There was confusion regarding the word "eligibility" and clarification that it referred only to a jurisdiction's or entity's eligibility for funding, not individual's eligibility for services. There was a suggestion to amend the language at the beginning of the first sentence to read "Eligibility for Title EMA status and funding under Titles I and II should be …" The revision was accepted by the workgroup and the revised recommendation was put forth for a vote.

A motion was made and seconded to adopt the revised recommendation. Nine members voted to approve the recommendation, one voted against it, and one abstained from voting.

Final Recommendation
Eligibility for Title EMA status and funding under Titles I and II should be based on a formula that uses the U.S. Public Health Service (PHS) measurement of advanced HIV disease (i.e., currently a CD4 count of 350 or fewer). The CARE Act should authorize HRSA to incorporate these PHS measurements into their system for allocating resources.

2) Increase Formula Portion of Title I

Draft Recommendation
Increase the formula portion of Title I to 75 percent and make 25 percent of the total Title I award available for supplemental funding.

Discussion
Mr. Liberti explained that the recommendation would result in a loss of funding for some jurisdictions, an increase in funding for others. The recommendation was made in the best interest of patients around the country, and the eventual elimination of "hold-harmless" provisions would ultimately help achieve greater equity in funding distribution. It was also noted that a larger proportion of formula funding would result in greater program stability at the local level by decreasing year-to-year fluctuations in funding.

Following no additional discussion or questions from the committee, a motion to approve the recommendation was made and seconded to accept the recommendation. The motion passed by a unanimous vote.

Final Recommendation
Increase the formula portion of Title I to 75 percent and make 25 percent of the total Title I award available for supplemental funding. Current hold harmless provisions should apply only to the supplemental portion of the award.

3) New ADAP Awards Process

Draft Recommendation
Twenty percent of all increases in Title II ADAP funding above the FY2004 funding level should be distributed through a newly created, separate supplemental awards process. These supplemental awards should be distributed using HRSA-defined criteria to meet emerging unmet need and should not be subject to Section 2618(H) of the CARE Act.

The CARE Act should authorize HRSA to develop a mechanism for allowing a temporary reduced federal-state match requirement, for these new supplemental funds only, when the chief elected official of a state can demonstrate economic difficulty and demonstrated hardship in meeting the current federal-state match requirement. HRSA should have the authority to grant a reduced federal-state match on an annual basis. Each year, the chief elected official of a state must be required to demonstrate economic difficulty and hardship in order to receive a reduced federal-state match.

Discussion
Mr. Liberti mentioned that the recommendation would give HRSA more flexibility in managing the ADAP program and States would benefit from receiving allocations that better reflect their needs. Further, the recommendation would enable jurisdictions to forego the match requirement, provided they offer an acceptable explanation subject to HRSA approval.

A motion was made and seconded to approve the first part of the recommendation. The motion was approved by a unanimous vote. A motion was then made and seconded to approve the second part of the recommendation. The motion was approved by unanimous vote.

Final Recommendation
Twenty percent of all increases in Title II ADAP funding above the FY2004 funding level should be distributed through a newly created, separate supplemental awards process. These supplemental awards should be distributed using HRSA-defined criteria to meet emerging unmet need and should not be subject to Section 2618(H) of the CARE Act.

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4) IOM Care and Service Model

Draft Recommendation
We join the Institute of Medicine in recommending the creation of a Federal entitlement program to provide care and services for low-income Americans living with HIV disease, as proposed in the Institute of Medicine report, *Public Financing and Delivery of HIV Care: Securing the Legacy of Ryan White*.

Discussion
There was some concern that in supporting this recommendation, the committee would counter its earlier recommendation in support of the current CARE Act Title structure. This spurred some discussion as to whether the recommendation should be included as part of the committee's package of recommendations for CARE Act reauthorization. Dr. Sweet suggested maybe removing the recommendation from the package and adopting it as a separate resolution.

The workgroup agreed to withdraw the recommendation from the reauthorization package, and vote on it as a separate recommendation.

Final Recommendation
The recommendation was removed from the reauthorization package.

Following discussion and adoption of the reauthorization recommendations, a motion was then made and seconded to adopt the following resolution:

> "We join the Institute of Medicine in recommending the creation of a Federal entitlement program to provide care and services for low-income Americans living with HIV disease, as proposed in the Institute of Medicine report, *Public Financing and Delivery of HIV Care: Securing the Legacy of Ryan White*.

The motion passed by a vote of 9 to 2.

Medicare Part D – Update and Impact on the CARE Act

Joe Razes, the HIV/AIDS Coordinator for the Disabled and Elderly Health Programs Group at the Centers for Medicare & Medicaid Services (CMS) and Mary Vienna, Chief Nurse for HAB, gave a presentation on Medicare's new prescription drug benefit. Administered by CMS, an agency that is the largest payer of healthcare for persons living with HIV disease, the new program currently offers discount cards to Medicare beneficiaries, and will institute a prescription drug benefit by 2006.

Those with HIV qualify for Medicare largely by becoming disabled and remaining so for two years. Of the approximately 60,000 – 80,000 beneficiaries with HIV/AIDS, 70 - 85% also qualify for Medicaid. These "dual eligibles" are largely poor and in the end

stages of AIDS. Their benefits vary based on where they live, so they often rely on ADAP to supplement their Medicaid formularies.

The Medicare Modernization Act (MMA) of 2003, also known as Medicare Part D, goes into effect on January 1, 2006, with enrollment beginning in November 2005. Each beneficiary can choose between a stand-alone drug benefit plan, or a managed care plan that includes a prescription benefit. CMS is promoting the latter. The average monthly premium is expected to be about $35, with adjustments being made on an annual basis based on cost-sharing and other factors.

Beneficiaries will have to pay 100% of a $250 deductible, 25% of covered Part D drug costs between $251 - $2250, 100% of covered Part D drug costs from $2251 - $5100, and an annual out-of-pocket threshold of $3,600, after which catastrophic coverage will go into effect, which will require beneficiaries to pay 5% of costs or a $2 /$5 co-pay, whichever is greater.

With regard to subsidies for low-income beneficiaries, those who are dually eligible, receiving SSI, or living at or below 150% of the Federal Poverty Level (FPL) and have no more than $6000 in assets for a single person and $9000 in assets as a couple will be eligible to have their premiums fully subsidized, and they won't face the "donut hole" that requires 100% payment of covered Part D medication costs between $2251 and $5100. These beneficiaries will be required to make co-pays of $2 for generic drugs and $5 for brand-name drugs.

Partial subsidization would be available to singles living below 150% FPL with $10,000 in assets, and couples at the same income level with $20,000 in assets. In these cases, there would be a sliding-scale premium, $50 deductible, 15% co-pay of costs up to the annual out-of-pocket threshold, and drug co-pays of $2 for generic drugs and $5 for brand name drugs.

Mr. Razes emphasized the complexity of the new program and said that one of the biggest challenges in promoting the drug benefit will be trying to explain how it works to both those who will administer it and those who will use it. CMS will have a large outreach component to help people understand and transition to the new program.

Those who are dually eligible will now receive all medications solely through Medicare. The availability of certain HIV/AIDS drugs will depend on the Medicare plan available in the area. CMS has contracted with U.S. Pharmacopoeia to design a model formulary for all plans. Medicare plans can put together their own formularies, as long as they demonstrate to CMS that they have drugs in each category and class. CMS will not approve for participation in Medicare any plans that have policies discouraging enrollment.

Ms. Vienna explained that because the "majority of the benefit is written in the law, there is a limit to what CMS can do." While the law is "good news" for Medicare beneficiaries that previously assumed all costs for their medications, said Ms. Vienna, there are some concerns about the impact on CARE Act clients, as well as others. As an example, she said that the new program will make Medicare a secondary payer, which is a major change from how the program has functioned previously. What this means is that supplemental insurance policies will be billed first, and Medicare will fill in the gaps.

The law prohibits the government from requiring specific drugs to be covered and leaves it up to the individual plans to determine formularies. Additionally, there is no allowance for third-party payments as a means of covering the cost associated with the "donut hole." This includes payments from ADAP programs. In addition, drugs not covered by the plan do not count toward the catastrophic limit, regardless of whether they are necessary or not. This means there is no clear way for clients to access medications if they can't cover the co-pay.

Also, said Ms. Vienna, the law prohibits appeals from other than the Part D beneficiary if a plan does not cover a drug, a serious concern for those with advanced HIV/AIDS, dementia, substance abuse issues and some mental health conditions. Another concern stems from a plan's prerogative to change formularies once beneficiaries are locked in, a "fundamental issue for beneficiaries," stressed Ms. Vienna.

She added that it will also be important to see how the tension between drug companies and health plans plays out, the former being likely to push for availability of more drugs on formularies and the latter likely to limit drug availability to increase their bargaining power in receiving lower drug prices.

Ms. Vienna highlighted some of the challenges for beneficiaries:

- Whether or not to enroll in 2006, if they have a choice, knowing that they will face penalties for delayed enrollment;
- Determining if they are eligible for participation in a low-income subsidy program;
- Selecting the best option from a range of plans;
- Dealing with the consequences of choosing a plan that does not provide the needed benefits; and
- Tracking total out-of-pocket prescription costs to qualify for the catastrophic benefit.

Mr. Baker thanked CMS and HRSA for jointly presenting on such an important topic. He asked how out-of-pocket expenses would be covered for beneficiaries who do not have the money to pay them? Also, how will multi-combination drugs be classified within the two-tier system? Finally, if a person needs to change their regimen to use drugs that are not on a formulary, how will a plan deal with that need?

Ms. Vienna responded that charitable donations can be used to pay for out-of-pocket costs, and acknowledged that the issue of combinations and classifications is a tough one. Mr. Liberti stated that there are 5000 dually eligible individuals with HIV/AIDS in Florida that are currently receiving their medications from Medicaid and do not, for the most part, require case management services. "I don't think they'll be able to maneuver through what you described and I don't know how our case managers will absorb these clients to help them get through the new system," he said.

Individuals who are dually eligible, explained Ms. Vienna, will automatically be enrolled in a plan if they don't select one. ADAPs can cover Medicare beneficiaries, but if programs are forced to make choices between a Medicare beneficiary with limited access to HIV medications and an uninsured individual, which will they choose?"

Mr. Baker voiced frustration at having heard about money being appropriated to address the problem of ADAP waiting lists at the same time that Congress has passed legislation that might significantly limit access to necessary medications for some people with HIV/AIDS. He further added that it was unrealistic to think that charitable organizations could pick up the slack.

Mr. Razes said he believed there would be technical changes to the law to address some of these concerns. Christopher Bates, Acting Director of the Office of HIV/AIDS Policy, urged greater activism around the issue in HHS and stronger education efforts with local officials and communities about the "full-scale impact of this program."

Dr. McGuire said that in terms of a formulary, HIV/AIDS beneficiaries would probably need to choose a higher-than-average cost plan. She expressed frustration at not knowing whether it was worthwhile to make comments to the Secretary or the Administration on the issue.

Dennis Leoutsakas, Ph.D., urged the committee to take action and Mr. Milan concurred, saying "I feel very odd not having this committee say something because of our responsibility for the continuum of care." He suggested appointment of a short-term workgroup to develop a motion or strategy for the full committee to consider the following day. It was agreed that Dr. McGuire, Mr. Liberti, Mr. Baker, and Dr. Leoutsakas would participate in the workgroup.

Before breaking for lunch, Dr. Valdiserri mentioned the upcoming teleconference on HIV and flu shots. He said that further information was available at www.cdc.gov/hiv/dhap, and thanked HRSA for their support in marketing the event.

Update from the Division Of HIV/AIDS Prevention (DHAP)

Robert Janssen, M.D., DHAP Acting Director, reported that CDC now has 2003 surveillance data, which show an increase in the number of individuals living with AIDS and a minimal increase in the number of AIDS cases. He said he thought the latter number was related more to reporting issues than to actual increases.

Annual rates of male HIV/AIDS cases are unchanged for all races, while the rates for African American men continue to be disproportionately high. There has been a slight decline in AIDS cases among African American women, but they are still higher than other groups.

The data show a significant decline in IDU-related cases, but a 10% increase since 2000 in risk associated with MSM. The biggest increases, said Dr. Janssen, are in the Hispanic MSM population.

The take-home message is that trends appear to be flat and disparities in case rates among racial and ethnic communities remain.

As of October 2004, HIV reporting has been implemented in all States. A behavioral surveillance system is in place, and this year CDC will be looking at MSM. The agency has funded 25 cities and expects data next spring.

With regard to CDC's investigation into an HIV outbreak among black MSM college students in North Carolina, the agency will commit $1.4 million over two years to implement the popular opinion leaders survey. CDC will also do a survey at Historically Black Colleges and Universities, and will conduct a risk assessment of African American women in North Carolina.

On the research front, CDC is conducting clinical trials with heterosexual men and women in Botswana to test the capacity of Tenofovir to prevent HIV transmission. A similar trial is being conducted in Thailand with IDUs.

Facts sheets on recently implemented trials will soon be on the CDC Web site, and the agency will be holding a consultation to discuss next steps if the trial results are positive.

Update from the Division of Sexually Transmitted Diseases

Acting Division Director of STD Prevention Susan DeLisle, ARNP, MPH, presented data on gonorrhea and chlamydia rates in the U.S. Ms. DeLisle said that CDC estimates more than 3 million infections occur annually and contribute to more than 50% of the cases of preventable infertility.

In the U.S. chlamydia is really a disease of young people, mostly those in their late teens to mid-20s. In men in particular, chlamydia rates are highest among those 20 – 25.

Gonorrhea exhibits the same patterns in terms of age, and data records striking racial disparities. Among African American girls ages 15-19, 2700 of every 100,000 are infected with gonorrhea.

In 1988, the Division implemented an infertility prevention project aimed at reducing chlamydia infection rates. The program began as a pilot project in family planning clinics, and resulted in a 51% decline in infections over three years. In 2003, the project received $27.8 million to support screening activities in family planning clinics, STD clinics, correctional institutions, and school-based and teen clinics.

Some of the challenges in screening include level or increased chlamydia rates in some areas, as well as low gonorrhea rates that in some ways make it difficult to justify continuance of broad-based screening efforts.

Future activities will focus on:

• Improving partner management, including the use of partner-delivered therapy and therapy delivered through pharmacies via a voucher system, both of which have shown promise;
• Expanding public and private screening, to include a health disparities prevention collaborative that focuses on system-level quality improvement and the expansion of public sector screening in non-clinical sites on populations exhibiting high prevalence;

• Increasing the level of female re-screening in the private and public sectors, as well as in non-clinical and non-traditional sites;
• Screening of males, including development of a strategy and guidelines; and
• Re-focusing of resources to achieve the greatest impact, which will include re-directing resources from gonorrhea programs and revising chlamydia screening guidelines.

Dr. McKissic Bush asked about the litigation potential and dosing schedules for the Tenofovir trials. Dr. Janssen said participants were receiving once-a-day dosing. There is little data on the drug's impact on those who do not have HIV. If approved by the Food and Drug Administration (FDA), there will be a five-month observation period to assess any adverse effects. "[Tenofovir] is fairly a benign drug," said Dr. Janssen, "but it has created problems in individuals with neuropathy."

Dr. McKissic Bush asked how CDC decides on trial subjects without HIV. Dr. Janssen said that people volunteer and Dr. Valdiserri added that all trials require informed consent. In Botswana, the trial is enrolling 18 – 35 year olds.

Fernando Garcia, M.D., said that his clients engage in high-risk behaviors due to the availability of drugs to treat HIV. Dr. Janssen replied that in looking at vaccines, researchers look carefully to determine at what point risk behavior might overshadow the efficacy of the vaccine under study. He added that models show if you double risk behavior, you negate the efficacy of the vaccine.

Dorothy Brewster-Lee, M.D., M.P.H., asked Dr. Janssen about CDC's definition of "high-risk heterosexuals." He responded that the definition is based on factors such as the number of sex partners and evidence of drug use.

Dr. McGuire asked what made CDC choose Tenofovir. Dr. Janssen said it was PMPA, worked well in early trials, is well absorbed, only has to be taken once a day and has a long half-life. She then asked him to report on the value of current HIV data. He said that on the whole it provides a better profile of the epidemic, but in certain jurisdictions it does not yet provide much information. He added that the system needs time to produce valuable data.

Dr. Janssen said he'd provide the committee with more information on minority recruitment for the Tenofovir trials. He clarified that MSM that use crystal methamphetamine are categorized by CDC under the risk category of MSM if they do not inject the drug, and as MSM/IDU if they do.

In response to a question about the LGV outbreak in the Netherlands, Ms. DeLisle stated that reported cases in the U.S. are low but that the agency is monitoring the situation. Further, CDC has a listing of labs that test for LGV posted on its Web site.

In response to a question, Ms. DeLisle said that CDC is working with professional medical associations to disseminate information about its fertility prevention efforts.

Dr. McKissic Bush asked for recommendations for working with partners. Ms. DeLisle responded that there are a variety of models she could offer.

In closing, Dr. Janssen said CDC data would reflect de-duplication of HIV/AIDS cases in a year. Mr. Liberti also asked about funding for jail and prison testing programs. Hazel Dean, NCHSTP Associate Director for Health Disparities, said that the corrections demonstration projects had ended in September, and while they were beneficial, no additional funding had been allocated. CDC will conduct a data review and consider how to fund additional programs.

Rapid Testing Update

Kevin Delaney, M.P.H. an epidemiologist in DHAP gave an update on Rapid Testing, a critical aspect of CDC's AHP initiative. Currently there are four rapid HIV tests available in the U.S.:

- Oraquick Advance;
- Uni-Gold Recombigen;
- Multispot; and
- Reveal G2.

The last two are not approved for use outside of laboratory settings. Most of CDC's rapid test experience is with Oraquick, as it was the first test to be approved and to receive a CLIA waiver. From 2003 – 2004, 527,775 test kits were shipped to 137 health departments and community-based organizations in 36 states. From September 2003 – June 2004, more than 116, 000 people were tested using OraQuick, 1.5% of which tested positive for HIV.

CDC maintains a Web site on rapid testing, which receives about 9,000 hits per month. The agency conducts training in OraQuick for providers and trainers. From 2003 – 2004, 1002 providers and 36 trainers were trained on how to conduct the test, related counseling, safe disposal of biohazardous materials and quality assurance activities.

CDC has funded demonstration projects in jails, social networks, medical settings and non-medical settings to assess the feasibility of rapid testing models. The awards were made in 2003 and data collection was begun in Spring 2004. CDC is still collecting data from demonstration sites.

Post-marketing surveillance of OraQuick has revealed that is it being implemented in variety of settings, such as bath houses, clubs, and mobile vans, as well as in traditional counseling and testing sites and STD clinics. The data also show that in 21 cases the test has returned false positive results, and in at least five cases, HIV-infected individuals were incorrectly informed that an OraQuick result was a false positive, as a result of a false negative Enzyme Immunoassay (EIA) and failure to perform the recommended Western Blot confirmation. This emphasizes both the effectiveness of the rapid test and the importance of the confirmatory test in certain situations.

In 2005, CDC plans to:

- Make additional bulk purchases of OraQuick;
- Conduct more provider-focused and train-the-trainer trainings;

• Summarize and report on the results of the demonstration projects;
• Continue post-marketing surveillance efforts; and
• Monitor the performance of other FDA-approved tests.

Mr. Baker asked how CDC responds to the tension of testing as many people as possible vs. finding those who are HIV-positive. Dr. Janssen said the agency is moving toward more targeted testing, but is also doing non-targeted testing to reach high-risk people. He added that demonstration projects would help CDC develop guidelines and identify best practices.

Mr. Baker said that Whitman Walker is testing the sensitivity of OraQuick for detecting acute infections. Dr. Janssen explained that many HIV false positives are due to fact that OraQuick is often more sensitive to a recent infection than the current diagnostic algorithm. CDC is funding studies to examine the effectiveness of nucleic acid amplification testing (NAAT) to detect acute infections, as well as studies to evaluate other alternatives to the current diagnostic algorithm of EIA and Western Blot.

Dr. Garcia expressed concerns about false positives and added that in his experience, many doctors do not have the training to conduct the test properly and deliver the right results. Mr. Delaney responded that the likelihood of the test resulting in a false positive is low, unless an individual is in the process of seroconversion. At the same time, CDC guidelines stipulate a confirmatory test. Dr. Garcia said that Texas had difficulty getting testing laboratories to perform all necessary confirmatory tests.

The group urged greater CDC outreach to the private sector. Mr. Liberti spoke about the effectiveness of using the rapid test in Florida, and said funding had prevented wider implementation.

Adoption of minutes

Before recessing for the day, the committee made a motion to approve the minutes from its May meeting. The motion to approve was made by Dr. Sweet, then seconded, and approved by 10 of the members, with one member abstaining.

Following the vote, the Co-Chairs recessed the meeting at 5:10 p.m

November 19, 2004

Committee Special Order to address Medicare Prescription Drug Benefit

The committee began the morning with a presentation from the workgroup formed on Day 1 to address issues related to the Medicare prescription drug benefit. Dr. McGuire said that the group recommended sending a letter to the Secretary to request a meeting, which would reference the previous letter sent by the committee and communicate the urgency of addressing the issue of HIV medication access for those who rely on publicly funded programs, given the changes in Medicare, the implementation of AHP and recent budgetary crises around the ADAPs.

The workgroup explained that a meeting with the Secretary would serve to:

• Identify agreed-upon projections of HIV-positive individuals in need of drug access / payment options as a result of Federal initiatives and expanding need;
• Determine the relative roles of the three agencies (HRSA, CDC, CMS) in terms of tracking the level of need;
• Determine the relative roles of CMS and HRSA in planning for coverage, and
• Specifically address the immediate problems posed by the Medicare drug benefit.

Also, given the urgency of the situation, the workgroup suggested including the following recommendations to the Secretary.

- Assure that people with HIV are considered a special population eligible for full formulary coverage under the Medicare Modernization Act.
- Assure that people with HIV do not face additional out-of-pocket charges associated with an above-average cost plan.
- Assure that HIV-positive Medicare beneficiaries (who are not dually eligible for Medicare and Medicaid) are not at risk for interruption of their coverage.
- Provide an extension of the mandatory enrollment period (November 2005 – January 2006) to assure the successful transition of individuals who are dually eligible.
- Assure extensive education and outreach to HIV-positive beneficiaries and their representatives on the new benefits plan.

Dr. Leoutsakas made a motion to discuss the recommendation. Mr. Baker seconded the motion.

After minimal discussion, the group unanimously passed the special order to draft a letter to the Secretary and request that he meet with committee co-chairs within 30 days of the date of the letter.

Interaction Between Crystal Methamphetamine Use and HIV and STDs

Gordon Mansergh, Ph.D., of DHAP discussed CDC efforts to address the growing links between the use of crystal methamphetamine and HIV infection in MSM. He explained that while the drug has been around since World War II, the current epidemic started in the 1990s.

Data suggests that use of the drug is relatively common, especially among MSM. Further its use is consistently associated with high risk sex. Use of the drug before sex is linked to unprotected receptive anal (URA) sex among MSM, including sex between discordant partners.

According to research conducted in San Francisco and New York in 2001, HIV-positive users of the drug are twice as likely to have URA with HIV-negative partners, 2.3 times as likely to have URA with partners whose status they don't know, and 4.3 times as likely to have sex with positive partners than HIV-positive persons who do not use the drug.

Some of the reasons MSM report using the drug include enhancement of sexual pleasure, to get high, to "party," to relieve boredom and to cope with negative emotions. A study conducted in Seattle in the mid-1990s found that party circuits, baths and sex clubs, transgender social groups, and young adult groups provide forums and networks for use of the drug. A fifth group includes self-medicating HIV-positive individuals who are often homeless, injection drug users and depressed. In summary, the motivations and context for MSM using the drug is generally social and/or sexual.

Dr. Mansergh provided materials from some community campaigns to address the issue in San Francisco and New York. He said that communities have been taking action to increase public awareness about the link between the use of crystal methamphetamine and HIV/STD transmission.

CDC is also taking steps to address the issue, including convening a consultation in January 2005 to examine current efforts and develop recommendations for research, programs and policy. DHAP is also funding a behavioral intervention study in Chicago, Los Angeles, New York and San Francisco that uses group cognitive behavioral therapy and experiential exercises to reduce risk. Behavioral surveillance is being conducted through various data collection systems.

CDC's STD program is also supporting efforts in California, Arizona, Illinois and Washington to promote community awareness and train disease intervention specialists to work more effectively with MSM on the issue. Funding is being provided to support local-level task forces and expanded screening in non-traditional sites.

CDC will continue to work with other agencies and partners to develop effective programs and policies related to the problem.

Dr. Garcia urged CDC to include border communities in its efforts. Dorothy Mann, Executive Director of Philadelphia's Family Planning Council, asked who to contact in

her city to find out the extent of the problem locally. She was directed to contact her State Alcohol and Drug Abuse Director. Dr. Fullilove also suggested that she speak to the police.

Mr. Baker commended CDC for following up on the committee's request for this type of data. He said that this is a growing concern among health centers that serve gay communities and that several of the leaders of major gay and lesbian health centers had written Dr. Gerberding and SAMHSA's Administrator Charles Currie to urge their collaboration in responding to the problem.

He also reported some changing trends in the east, where five out of six people who come for treatment at Whitman Walker are crystal methamphetamine addicts. He said that use is increasing among blacks and Latinos, and in Boston there have been reported increases in drug use among gay women.

The group raised the issue of whether crystal use leads to HIV infection or vice versa. Dr. Mansergh discussed the need for greater research on the topic, as there could be subgroups in both directions. Dr. Fullilove mentioned that in doing research on cocaine use in the 1990s, he uncovered the concept of "chemical foreplay" — the use of drugs to enhance sexual pleasure. Dr. Mansergh said that research should consider crystal use among MSM in the context of drug use in general.

Mr. Milan suggested the CHAC urge the Secretary to immediately establish a coordinated strategy to address crystal methamphetamine use in MSM populations, specifically as it relates to HIV transmission. Mr. Baker made the motion, Dr. Leoutsakas seconded the motion and the committee approved it by unanimous vote.

Finally, it was agreed that the CHAC would send two representatives to the January consultation. Dr. McGuire, Mr. Liberti, Dr. Leoutsakas, Mr. Milan, and Dr. Fullilove volunteered to be among those chosen to attend.

Men on the Down Low: More Questions Than Answers

"'Down low (DL)' is a culturally specific term in the black community related to heterosexually identified men who have sex with men without the knowledge of female partners" explained Greg Millet, M.P.H., of DHAP.

"These men allegedly shun the mainstream gay culture, and in general have casual male partners and steady female partners," he added.

Mr. Millet presented other alleged characteristics of this population, such as having unprotected sex with female partners while either not being aware of their HIV status or not disclosing their status.

The term originated in the early 90s in the black community and made its way into rap lyrics, popular television shows and other media venues. In 2003, CDC began to report on the phenomenon and its implications for HIV transmission.

Earlier this year, J.L. King released *Men on the DL,* in which he illuminated some of the thinking of DL individuals, and highlighted the challenges of designing prevention programs that meet their needs. For the most part, there is little data on this population related to either behavior or infection rates. Most data on black MSM focuses on gay-identified men, not heterosexually identified bisexually active men.

Mr. Millet says the publicity surrounding the issue has raised controversy in the black community, particularly related to infection of women by male partners on the DL.

Some studies, said Mr. Millet, have estimated levels of bisexual activity, such as a study conducted by Wohl in 2002 that looked at heterosexually identified men who have sex with men, but provided no data on sex with female partners. Another study conducted with over 5000 HIV-positive men of all races suggested that more gay or bisexually active MSM report having sex with women than straight MSM. While the Internet is one of the only places where DL men meet and congregate, few prevention studies focus on this venue as a way to gather and disseminate information.

It is clear that further qualitative and quantitative studies of this population are needed to develop effective prevention interventions. Studies should address the contextual factors of HIV risk for DL men and determine their risk for HIV in comparison to other black men. Further studies should compare the sexual risks of black HIV-positive heterosexually active men, bisexually active men and homosexually active men.

Dr. Garcia emphasized that there designed primarily for gay white men Hispanics who engage in DL activity. Mr. Baker added that in his program, they use the term "bi-curious" so as to avoid "ghettoizing" the practice and not reinforce negative stereotypes of sexuality. He urged CDC to articulate and think about new ways to outreach to black men who have sex with men without institutionalizing a negative terminology.

Mr. Millet countered that many men identify with the term and don't consider it pejorative. As scientists, he said, it is important to identify what risks are associated with men who do identify with the term. He agreed with the need to be sensitive the variety of meanings that people associate with the term.

Mr. Baker suggested that the entire black sexual experience has become dominated by the DL issue, and asked if the concern is primarily how the practice affects black women.

Mr. Millet referenced an article coming out in March that looks at the debate. Mr. Milan asked how to encourage research that engages individuals who are ambivalent about their sexual orientation, given that public school policies discourage discussions of sexual orientation at the same time that young people are engaging in sexual activity.

CDC is conducting seven studies on DL and risk behaviors. Dr. Valdiserri emphasized that the issue is important programmatically, and at a minimum, a major take-home message for HIV prevention is that not all MSM identify themselves as gay.

Ms. Mann said she runs a program for HIV-infected women and children who are angry and frustrated with DL men. “If you want to know why women stay in relationships where a male partner is not monogamous, look at domestic violence literature,” she suggested. “Further, if there are programs out there, I’d like to know about them.”

Mr. Millet admitted the thorniness of the issue, saying that women can be as easily victimized as men. For its part, CDC is taking a two-prong approach, funding both programs and epidemiological studies to get a better handle on what is happening in the DL community.

Public Comment

(see attached for full texts of public comment by: Marsha Martin, Executive Director of AIDS Action; Leo Rennie, Director of Prevention Programs for NASTAD; and Carl Schmid, Director of Federal Affairs for the AIDS Institute)

Agenda Items and Dates for Next Meeting

Ms. Paulette Ford-Knights of CDC will circulate potential dates for the next meeting in Atlanta in May. Suggested agenda items for the next meeting included:

- Update on CDC and HRSA global activities;
- Update on the CDC consultation on crystal methamphetamine;
- An update on the CHAC’s Reauthorization recommendations; and
- An update on the CDC assessment of African American women in North Carolina.

Mr. Milan formally thanked Dr. Fullilove for his participation and said he would be recognized at the next CHAC meeting. Additionally, Mr. Milan acknowledged outgoing CHAC members Mr. Baker, Ms. Mann, Gale Grant, M.A., C.P.P., and Antonia Villarruel, Ph.D., and said that they would continue to serve as members until their replacements were named. He thanked them for their service and invited them to the next CHAC meeting where they would be formally recognized.

Mr. Milan asked for a motion to adjourn the meeting. The motion was made, seconded and the meeting was adjourned at 11:40 a.m.