

**Presidential Advisory Council on HIV/AIDS
Twenty-first Meeting**

January 30-31, 2003
Hubert H. Humphrey Building
Washington, DC

Minutes

Members Present:

Thomas A. Coburn, M.D., Co-Chair
Louis W. Sullivan, M.D., Co-Chair
Rosa M. Biaggi, M.P.H., M.P.A.
Jacqueline Clements
James P. Driscoll, Ph.D.
Mildred Freeman
David Greer
Cheryl-Anne Hall
Janice Hu, Ph.D.
Karen Ivantic-Doucette, M.S.N., F.N.P.,
ACRN
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
David Reznik, D.D.S., M.S.
Debbie Rock
Rev. Edwin Sanders II
Prem Sharma, D.D.S., M.S.
Anita Smith
Don Sneed
M. Monica Sweeney, M.D., M.P.H.

Members Not Present:

Ingrid M. Duran
Mary Fisher

Vera Franklin
John F. Galbraith
Katrinya Gholston
Lisa Mai Shoemaker

**Thursday, January 30, 2003
Morning Session**

Opening Remarks

Co-Chair, Dr. Louis Sullivan welcomed all Council members and representatives of the press to the meeting. He noted that he would be leaving the session for 3 hours to participate in a March of Dimes event, but that his co-chair would preside during that time.

Co-Chair, Dr. Tom Coburn welcomed past and new Council members and forecast an active Council meeting. He expressed hope that this Council would accomplish what has not been accomplished to date.

Dr. Joseph O'Neil, Director of the White House Office on National AIDS Policy (ONAP), greeted the Council for the first time in this capacity. He said that he wanted to

put the Council's work in context and help members realize that they are advising the Administration at a historic time in the HIV/AIDS epidemic. President Bush takes the Council's work very seriously, he continued, and has expressed the desire to meet with members tomorrow to voice this commitment. The Council will be present also at the President's address to a larger group concerning AIDS here and abroad. Although some see the State of the Union endorsement for AIDS funding as amazing, Dr. O'Neil stated that the President's remarks were wonderful but not surprising, and consistent with the Administration's attitude.

The Council's job is several-fold. The Government needs to be kept honest, and the Council can accomplish this task as it is best done: in the spirit of good will. Members must be visionary, must keep their eyes on the forest but see the horizon. Members need to ask the important questions: Why are infections not decreasing? Why are people still waiting for medications? This is a truly historic time in the epidemic, and the Administration is passionately seeking new answers.

Ms. Rock applauded the commitment to global AIDS funding but questioned delays in funding of domestic programs, specifically, the Omnibus Bill and Health Resources and Services Administration (HRSA) funds for client services. Dr. O'Neil acknowledged that funding is only a piece of what is essentially a political matter. The Council will not be doing its job if it says only "more money"; everyone needs to be accountable. Dr. Coburn added that this year there are 19,900 matters and \$280 billion worth of "pork" to help members of Congress and having nothing to do with health, included in the Omnibus Bill. The cynical view, he said, is to see this as "members acting like politicians instead of like statesmen."

Remarks: Claude A. Allen, Deputy Secretary of Health and Human Services

Dr. Allen welcomed the Council to the Department of Health and Human Services (HHS) on behalf of Secretary Tommy Thompson and the Department. He thanked members for their roles in fighting against HIV/AIDS and paid special tribute to the co-chairs and to Pat Ware, Executive Director of the Council. He stated that he is honored to fulfill the charge he has been given by the President and the Secretary to pay close attention to this issue, which has critical personal significance for him as the father, brother, and uncle of African American women, the population group with the fastest growing rate of new infections.

Dr. Allen proceeded with a brief update on the Department's activities since the last Council meeting. Making sure that people know their HIV status is critical. To help in this part of the battle, Secretary Thompson has approved use of the rapid HIV diagnostic test kit, which gives results with close to 99.6 percent accuracy in 20 minutes. With the short time needed for results, clients can seek counseling and treatment immediately.

The President has led the fight to double the research budget at the National Institutes of Health (NIH), and the Administration is focused on the issue of health disparities among minority populations here in the United States. The President plans to double the capacity

of the Community and Migrant Health Centers, which provide HIV/AIDS care to the poorest and most vulnerable populations. The current network of 3,300 sites serving 11 million low-income clients will expand by 260 new and improved centers serving an additional 1.25 million persons. A 5-year initiative to expand access to health services for rural and inner-city areas will ultimately fund 1,200 sites serving 22 million people each year.

Dr. Allen reflected on the 20-year fight against HIV/AIDS at the Department and observed that HHS officials need to step back and take a look at where they are and where they need to go to end this disease. If the Department were a country, with its more than 300 programs and a \$450 billion budget, it would rank as the sixth largest in the world. In order to deal with the magnitude of the situation, the Secretary has put together an HIV/AIDS Management Coordination Team, comprised of senior officials from all agencies that deal with HIV/AIDS. The team's purpose is to ensure that resources are being spent wisely and grants are being used to fight the disease and not to support bureaucracy; it does not have an audit function.

The Deputy Secretary reviewed the specific provisions for HIV/AIDS made in the State of the Union address and marveled at the amount of time given to the issue. (Details of the President's plan appear in Dr. Allen's written remarks, which were made available to Council members.)

Dr. Allen described his own journeys to Africa and the "shining example" he found in Uganda, where the spread of HIV is dropping and coming under control, thanks largely to the tireless efforts of the First Lady of Uganda and her message to youth of ABC. Abstinence until marriage is the best policy for youth, Being faithful in a mutually monogamous relationship is key, and Condoms, used consistently and correctly, can reduce the risk of HIV/AIDS for those who engage in risky behavior. Uganda is the only nation in Africa with a growing rate of life expectancy.

Dr. Allen urged Council members and all others in the United States who labor in the HIV/AIDS field to keep Uganda and its success in mind. International programs must always respect the cultures and traditions of other countries and not just provide the "American" solution, which has not even been very successful here. At the same time, much can be learned from other nations. HIV/AIDS is a tough issue, the speaker concluded, and the Department appreciates the courage of Council members who have chosen to participate in finding solutions and developing ideas to deal with it.

Dr. Sweeney questioned why this country has no way for best practices to receive national exposure and implementation. She gave as an example the success of New York State in reducing vertical transmission of HIV. Dr. Allen cited three possible explanations. First, certain system problems have existed in the Department, which basically is many systems (HRSA, NIH, etc.) that rarely communicate with each other. These barriers are being torn down, he stated, and agencies are being forced to talk across their boundaries. A demonstration program will model the process. Second, a national forum has not been provided to show how best practices can be replicated and translated

into application. Third, agencies with best practices often have not kept track records of how they conceived and developed their best practices, which would be extremely helpful. Dr. O’Neil added that some States are taking unorthodox means to get the word out on their successes; Dr. Antonia Novello, who will speak on Friday, will discuss the situation in her State of New York.

Dr. McIlhaney asked if data are available on how Uganda is accomplishing its success and how this approach can be replicated. Dr. Allen remembered seeing posters in Ethiopia that mentioned condoms but also conveyed the ABC message. In Uganda, the effort decreased the number of partners and increased the age of sexual debut for girls. We must be willing to take these steps, he stated.

Dr. Sharma queried how U.S. interests can be sure that money is not misused, in faith-based projects, for example. In Africa, Dr. Allen said, the Department is working with the U.S. Agency for International Development (USAID) to ensure respect and level the playing field. Smaller faith-based players will be involved through the Compassionate Capital Fund, which will be extended internationally.

Update of PACHA Activities

International Conference on HIV/AIDS—Barcelona, Spain

Dr. Driscoll reported that the HIV/AIDS community seems to be moving toward reconciliation since the protests in Barcelona. Rapid testing has been a major success; in talking with Secretary Thompson and Deputy Secretary Allen, he found that the consensus is that people came together. Regarding the issue of treatment versus prevention, people are moving beyond conflict here and realizing that the two are symbiotic: one cannot be addressed without addressing the other. Pilot programs in resource-poor countries *are* possible and feasible, and the best intelligence and resources need to be applied to the job. Generics are more available, and not-for-profits are working. An annual cost of \$300 per person for HIV treatment is becoming possible.

Ms. Ivantic-Doucette commented that she sensed a divisive advocacy in the beginning in Barcelona, rather than a feeling of unity. During the International Committee’s meeting with Secretary Thompson, he was incredibly compassionate in “owning” U.S. leadership in the effort. He was going to outline steps for U.S. participation before he was booed off stage. Her perception is that there is a fundamental tiredness in the HIV/AIDS community that has been working at this for so long; its members need to be reenergized.

Dr. McKinnell agreed that there is a basic fatigue in the activist community, but international and Government participants now “get it.” Fifty percent of patients on antiretroviral therapy (ART) now will exhaust their options in 5 years, and new compounds will be needed. If virus loads are suppressed to zero, it could take 70 years to eradicate HIV. This is a tricky situation.

With regard to the multisectoral “getting it,” Ms. Ivantic-Doucette counseled that it may be wise to start thinking along the lines of ABCD, with D for Development. All the poverties that drive the epidemic need to be looked at: economic, access, mental health, and others.

Mr. Mason noted “lots of support” for the Global Fund, which is “the group that will make the difference.” The Fund had expected more money from President Bush.

United States Conference on AIDS (USCA)

Mr. Sneed found USCA helpful, especially as a means for new staff to learn skills and gain exposure. Affinity groups profited as well. Noting the booring of people who disagreed with each other, he advocated maintaining respect in sorting out differences.

Ms. McDonald, a charter member of the National Minority AIDS Council (NMAC), said she has attended many USCA gatherings and always comes away with the experience of seeing “little bitty people doing *huge* things.”

New Members of Presidential Advisory Council on HIV/AIDS

Ms. Ware asked the seven newly sworn members of the Council to introduce themselves. Rosa Biaggi, Jacqueline Clements, David Greer, Janice Hu, Brent Minor, David Reznik, and Don Sneed reviewed their backgrounds and current experiences as members of the HIV/AIDS community.

Discussion of PACHA’s Vision and Goals

Dr. Coburn began the discussion by characterizing the Council’s vision as being so successful that it is not needed. Its goal is to limit and destroy this disease. A subgoal is to leave politics outside. Dr. Coburn has been very pleased with his meetings with President Bush and senior staff at CDC and other agencies. Nevertheless, the bureaucracy has to “crank it out,” and doctors and other professionals do not want the rapid test. In China, a 10-minute urine test is 99 percent accurate; in Africa (Benin), a staged rapid test is 100 percent accurate. Neither test is allowed in the United States.

Dr. Coburn affirmed that the Council’s job is to advise Secretary Thompson. He expressed his extreme pleasure in Dr. O’Neil, who took a 50 percent pay cut to take the position of ONAP Director, and advised Council members that only he and Co-Chair Sullivan speak for the Council. If individual members are questioned by the press, they speak only for themselves and must stress that point.

Mr. Minor responded to Dr. Coburn’s request for suggestions on how to approach the issues with the view that the Council should be the eyes and ears of the Administration in helping to address today’s issues in a more effective manner. When the Ryan White CARE Act was funded in 1990, a different group of patients was being treated. Our delivery systems and funding mechanisms need to be adjusted to meet current needs. We

need to evolve with the epidemic, be more nimble in delivering services, and listen “outside the Beltway.”

Mr. Sneed called for a serious look at how medications are being prescribed for AIDS patients. The AIDS Drug Assistance Program (ADAP) is basically bankrupt, he said, because of overuse. All patients don’t need highly active antiretroviral treatment (HAART) or all the other drugs that doctors keep changing them to. Dr. Coburn suggested that Mr. Sneed might want to change from the Prevention Committee to the Care and Treatment Committee.

Ms. Freeman proposed endorsing the ABC program used in Uganda. Dr. Coburn replied: “I teach abstinence” and went on to state that CDC will be releasing some horrible data on the prevalence of HIV/AIDS in this country. His own personal experience includes delivering 290 babies last year, 270 of them to indigent patients, one of whom was an 11-year-old girl. These mothers basically had no knowledge, no praise, no self-worth, and no alternative.

Dr. McKinnell suggested four categories of Council activity: (1) set a goal (e.g., an AIDS-free generation by 2020); (2) prevention (bring on the fight, and make a recommendation); (3) treatment (specifically, the crisis in funding); and (4) research (the ultimate answer is technology, but the Food and Drug Administration [FDA] won’t allow the research to get the answers).

Dr. Driscoll urged going where consensus exists but nothing is being done (e.g., rapid testing, delay of sexual debut, or limiting partners and teaching monogamy).

Dr. Sweeney asked members to consider a few matters. HIV/AIDS is surrounded by complacency; people think they can take a pill and they’ll be all right. Why aren’t successful models being replicated? Examples include testing in prisons and lessons from abroad, such as the 10-minute urine test. Spending 90 percent of time and effort on treatment and 10 percent on prevention doesn’t make sense. Everyone talks about a vaccine, but consider the records for other vaccines. Only 20 percent of at-risk teens have received the hepatitis-B vaccine, and influenza vaccine has a dismal pattern of use. People won’t come to get a vaccine.

Rev. Sanders offered two points. First, he is always amazed that the HIV/AIDS community doesn’t go beyond the biomedical into the socioeconomic issues that influence and are the backdrop for HIV and AIDS. It has been found that the people who don’t take their HIV/AIDS medications don’t take any other prescribed medications either. Problems would still exist even if all the medications that are needed were available. Second, the Council wants to follow the position of being faithful to what the scientists tell us about this disease, and not take a political position.

Discussion moved to future meetings of the Council. Dr. Coburn reported that the Council operates on a limited budget of about \$400,000, including staff expenses. The next meeting should be protracted; Committees could go away and then come back

together. He prefers weekend meetings, so that he doesn't have to leave his practice. Dr. Sweeney spoke to the Council's losing momentum when members stay apart too long. Ms. McDonald asked about requesting more money, and Dr. Coburn said that he had asked repeatedly for an accounting of how the money in the Council budget is spent, but no one will give him that accounting.

Dr. McIlhaney urged the Council to think in terms of advocating, to *not* accept the current situation and to look everywhere to see how it can be changed, to follow it to death and *do it*. Dr. Coburn added that if contact tracing and partner notification are not instituted in the U.S. public health system, the problem of HIV/AIDS will never be solved. He implored members to "do everything we know how to do"—with courageous leadership based on love, and reported being moved to tears by President Bush's description of how initiatives will have an impact on real lives.

Afternoon Session

Public Comments and Council Response

Before hearing from the seven representatives of the public, Ms. Ware asked Council members to be sure to enter the names of any other organizations they may have joined on form 450 and to complete the foreign activities questionnaire as well.

Dr. Sullivan welcomed members of the public and invited speakers to begin.

Jackie Walker, ACLU Prison Project

Ms. Walker found it encouraging to see an ex-offender, Mr. Sneed, on the Council. She noted that 17 percent of people with AIDS go through the prison system and that 2 percent of all the people in prison have HIV. The annual report on hepatitis-C, HIV/AIDS, and the prison system is now available at the Web site of the National Criminal Justice Reference Service: <www.ncjrs.org>. Regarding testing, 20 States do mandatory testing, 3 States do voluntary testing, and the Federal prisons test only on release. Ms. Walker offered her view that education and prevention are more important than testing. She stated that she is available to the Council as a resource on HIV/AIDS, tuberculosis, and the prison system.

Mr. Sneed asked Ms. Walker if she thinks mandatory testing 6 months out of prison is a good idea. She replied that she doesn't think such testing is necessarily a good use of resources. A more worthy expense would be the video produced by a California group that addresses women partnering with men coming out of prison and provides honest talk about what they did in prison.

Dr. Sweeney asked if any State has developed an effective model for quarantining prisoners until their HIV status is known. Ms. Walker said that this kind of reporting is not done, so that she doesn't know. Alabama has entry and exit testing and segregates

HIV-positive prisoners, but 48 States have abandoned the practice. New York has a great system, as do Louisiana and California, but this type of research is not done.

David Oxley, Orasure Technologies

Mr. Oxley spoke briefly, expressing his small-business firm's appreciation for the Council's efforts in behalf of rapid testing. Orasure has submitted its CLIA waiver to the FDA and awaits a positive response.

Gene Copello, Florida AIDS Action

Dr. Copello spoke as a member of the Steering Committee of the Southern AIDS Coalition. He provided Council members with copies of the November 2002 draft *Southern States Manifesto on HIV/AIDS and STDs in the South: A Call to Action*, a document that led to two regional conferences and to the formation of the Coalition. He summarized the key points of the *Manifesto*:

- ?? The changing face of HIV/AIDS as an epidemic that is increasingly rural, female, African American, and heterosexual is strongly affecting the South, which has the largest proportion of persons living with AIDS when compared with other geographic regions of the United States.
- ?? The health care infrastructure in the South is inadequate to support HIV/AIDS prevention and care programs. Growing waiting lists for ADAP programs across the region complicate the situation.
- ?? Evidence shows that people living with AIDS often return to their southern hometowns for family support, but much of the Federal funding is distributed based on where they were diagnosed. This has a tremendous impact on communities already lacking access to basic health care.

The *Manifesto* recommends that current Federal funding streams and appropriations levels for HIV/AIDS and STD programs be increased and that Federal resources be distributed in such a manner as to ensure all at-risk individuals in the South—and across the Nation—access to at least minimal prevention, diagnosis, and treatment services.

Considerable discussion followed Dr. Copello's presentation. Rev. Sanders noted that the points made in the *Southern Manifesto* have been seen over and over, but reallocation or restructuring to make resources follow the epidemic has not happened. Institutional forces have been built around this epidemic that don't make the best use of resources. Dr. Coburn stated that the last Ryan White legislation provides funding based on prevalence, but that CDC did not trace the epidemic. Where the infection is going is important, not where it has been. The resource problem is true in the South because of low income and long history, but Uganda addressed the problem through leadership, even without infrastructure and without resources. Rev. Sanders added that perhaps a nontraditional infrastructure can be used if a traditional one is not available.

Dr. Coburn revealed that CDC does blind testing, unethically, without telling the infected patients they are infected, similar to the notorious Tuskegee syphilis tests. As of last month, he stated, two blind tests were still running. CDC has historically traced this

epidemic through blind tests, random blood tests. When he was a Member of Congress and Chair of the Health Committee 2 years ago, Dr. Coburn put a halt to blind tests on newborns, but two other blind tests continue.

Dr. McKinnell stated that this matter should go to the Secretary immediately as a serious ethical problem. Dr. Sullivan suggested a request to the Secretary about what response has been made to the *Southern Manifesto* and what plans exist for the future. Dr. Sullivan then summarized the issues of CDC testing and notification and declared that the Council needs some resolution on this: the Council needs to have a CDC representative come before the Council to present its justification for these practices, ideally at its next meeting.

Thena Durham, Deputy Director of CDC's National Center for HIV, STD, and TB Prevention, spoke from the audience. HIV/AIDS is different, she stated; this is a State-based surveillance issue. Blinded testing is an epidemiological tactic developed where no treatment is available. CDC does not collect identifiers for any testing; all its information is blinded. The most recent example is West Nile virus, which indicates only palliative care. Ms. Durham offered to relay the Council's concern to Dr. Jaffe at CDC.

Dr. Sullivan expressed his appreciation but stated that the Council would like to have Dr. Jaffe or Dr. Gerberding appear before the Council to explain their reasons for blinding. Dr. McKinnell noted that this really gets to the politics of HIV; if we were doing random screening of brains and one had a brain tumor, he said, I would want to find that person. Dr. Coburn added that infected individuals can be identified without jeopardizing their families; the real reason CDC is doing this is because they don't have good numbers. Ms. Ivantic-Doucette contributed her experience as a provider for 450 patients. Many of these women continue risky behavior without telling their partners, and sometimes she needs blind tests to see what is happening in her client base. It is the patient's right to inform the partner, she stated.

Dr. Sullivan urged Council members to reserve this discussion until they hear from CDC. He also cautioned that the Council's concern should be couched in terms suggesting that CDC procedures "would *appear* to be unethical." Ms. Lewis added that members should always consider ethical issues regarding testing as they deliberate. Mr. Nickerson put in a last word as a local health provider. "HIV exceptionalism" has pertained to other diseases as well, he said, and blind surveillance can be the key to seeing where pockets of disease exist.

Dr. Coburn ended the discussion with his view that "once you have a treatment, you *cannot* do blind testing."

Michael Harris, MF Harris Research

Mr. Harris, president of a small biotech start-up company, presented his research on the Dark Horse Project, a study of immune response using air and mixed gases under

hyperbaric conditions. He stated that his findings warrant further investigation of the method in relation to HIV and AIDS.

Ann Pozen, National Association for Victims of Transfusion-Acquired AIDS

Dr. Pozen addressed the absence of any financial relief for victims of transfusion-acquired AIDS, while the Ricky Ray Hemophilia Relief Fund of 1998 has provided one-time payments of \$100,000 to hemophiliacs who have contracted AIDS or their families. A bill supporting Dr. Pozen's concern was introduced in the House and Senate during the 107th Congress, and she would like it reintroduced and passed.

Dr. Sullivan asked how many transfusion-infected individuals this involves. Dr. Pozen replied that no surveillance was done on this patient group, but a math model prepared by CDC estimates that about 12,000 persons were infected between 1981 and 1985. Most of them have died or their heirs are not eligible, but those eligible under the Steve Grissom Act would be compensated at \$100,000 per infection for medical bills and lost income of both the infected patient and the breadwinner who had to take care of the patient. The final cost of the Ricky Ray Fund was \$750 million, which might be comparable to the cost of the proposed compensation.

Bill Arnold, ADAP Working Group

Mr. Arnold testified that the greatest weakness in the AIDS treatment situation is access to ADAPs. If ADAPs are not funded, this last-resource source will be lost. Drug companies represent the only additional resource, but the paperwork involved can be prohibitive. The speaker pleaded with the Council to consider the plight of the 7,000 or 8,000 individuals who need this funding.

Ms. Ivantic-Doucette noted the formulary limitations in some States as a problem, but asked what ADAP has done regarding nonmedical issues. Mr. Arnold replied that every ADAP is reviewing its procedures with its board, medical officers, and other relevant entities. Prescription issues exist within the medical community, and formularies depend on funding and budgets, particularly State budgets.

Dr. Driscoll reported that at the Fair Pricing Coalition Act meeting, some drug companies had taken price cuts back by lowering the rebates they had offered to ADAP in New York. Drug companies had been asked to freeze prices to all public payers, but then the Consumer Price Index (CPI) kicks in and there is little net advantage. The CPI will adjust the rebate advantage in New York and Texas.

Dr. Coburn stated that he manages but does not treat HIV patients because of the strict protocols now in effect. Money can be wasted if doctors don't know what they're doing. Dr. Sweeney commented on the strict protocols on treating with cocktails and that a provider needs a certain volume of patients before being eligible for consideration as an "expert." Experts can be nurse practitioners, physician assistants, and other non-M.D.

providers. When protocols are followed and experts provide treatment, much better results are accomplished.

Mr. Sneed noted that patients are often put on drugs that they do not understand or know how to adhere to. Pharmaceutical firms spend a fortune trying to get doctors to put patients on their brands, and patients need to educate themselves to be able to turn down medications. The structural problems of ADAP also need to be studied.

Father Edward Phillips, Diocese of Nairobi

Father Phillips sought to share some key points from his experiences in Africa. First, AIDS is destroying the entire family system in Africa. Second, in the English-speaking countries, health care for AIDS is provided primarily by faith-based organizations (FBOs), but these groups are not invited to the government table. In Kenya, FBOs provide 71 percent of such health care; in Nigeria, 60 percent; and in South Africa, 64 percent. Third, the family system and good governance constitute the basics of success in the AIDS war. Mother-to-child transmission must be prevented, and antiretroviral therapy must be provided for mother, child, husband, friend, every element of the family system. Then good governance must ensure that funds for ART are going to that purpose and not out of the country through corruption into Swiss banking systems.

Report on Visit of CSIS Task Force on HIV/AIDS to China, January 13-17, 2003

Dr. Sullivan introduced fellow members of the Center for Strategic and International Studies (CSIS) who participated in a visit to China to meet with senior health officials. These officials have are about where U.S. health officials were in the early 1990s regarding HIV/AIDS. Former U.S. Ambassador to China J. Stapleton Roy and Dr. Sullivan led the delegation to Beijing. Dr. Bates Gill, the CSIS Freeman Chair in China Studies, and Dr. J. Stephen Morrison, Executive Director of the CSIS Task Force on HIV/AIDS and Director of the CSIS Africa Program, organized the group's work with the Chinese Ministry of Health.

Ambassador Roy acknowledged that his participation in the delegation was based on his China connection rather than on any technological expertise. The Chinese are aware of their limitations in this area of public health, and the Minister of Health not only spent several hours with the group but also accepted Senator Bill Frist's (R-TN) invitation to come back to the United States to study nongovernmental organizations (NGOs) and other approaches to dealing with HIV/AIDS. China had no NGOs in 1995 but is now forming such groups.

China is at risk of a generalized HIV/AIDS epidemic that could mirror the situation in sub-Saharan Africa. By 2010 the virus could infect between 10 and 20 million Chinese. Because the blood supply all across China is contaminated, HIV could spread to 1.3 billion people. The United States has strong humanitarian and national security interests for keeping the situation in China from reaching catastrophic levels. Chinese officials have taken moves to confront the looming catastrophe that they are not equipped to

handle, and U.S. officials plan to advise them on how public-private partnerships and other mechanisms can be utilized.

Dr. Morrison specified the threat in China as an HIV breakout from affected clusters to the general population. China and India comprise the front line of suppressing a major HIV/AIDS breakout globally. Action must be taken to preempt this potential crisis.

The speaker sounded a few cautionary notes regarding China's ability to act in its own behalf in the face of a generalized HIV/AIDS epidemic.

- ?? Insufficient political will and financial commitment to deal with it are found at senior and provincial levels.
- ?? The country lacks public health care capacity. China has only 50 to 100 doctors trained in HIV.
- ?? Poor baseline data and assessment capacity are found. Probably 1 to 1.5 million infections exist, but only 30,000 have been diagnosed.
- ?? Lack of awareness is critical; only 55 percent of the population know about HIV.
- ?? Bureaucratic and political obstacles exist; little communication is seen between bureaus and offices.
- ?? The national budgetary commitment is \$62 million annually.

Dr. Gill enumerated several issue areas that the United States can bring forward and that he hopes the Council will support:

- ?? The importance of senior-level contact and leadership dialogue between China and the United States (Chinese Government levels above the Ministry of Health have difficulty committing);
- ?? Funding and expansion of technical assistance on the ground in China by agencies such as NIH, CDC, USAID, and the Department of Labor (training, planning, and budgeting are needed for the rural populations most affected in China; 120 million "floating population" are cut off from systems);
- ?? Assistance to China regarding a trans-bureaucratic coordinating mechanism (the Global AIDS Fund turned down such a proposal this week); and
- ?? Increased diplomatic energy directed toward relations with China in order to assist the country more effectively.

Finally, the United States should be at least doubling its current \$5 million financial commitment to China.

In response to questions from Council members, Dr. Sullivan and his associates further described the situation in China. Fully 80 percent of the population in China is in rural areas rather than in cities, which presents a very different scenario than in the United States. The lack of infrastructure is thus critical. The HIV-infected population is mostly male, 70 percent are injection drug users (IDUs), and the fastest growing mode of infection is heterosexual contact. China's statistical base is woefully inadequate in this matter. No national blood-testing program exists, and stigmas are the same as experienced in the United States. The United States has a strong health system. China's is flimsy at best, and its infrastructure is comparable to that of Africa. Health professionals in this country have developed incredible experience in the past 10 years. China is right at

the point where an epidemic could be stopped if intervention is implemented, but if the top levels don't respond, a crisis is imminent.

Dr. Jane Hu, founder and chair of the China Foundation and a member of the Presidential Advisory Council, gave additional insights. The China Foundation has been working in the densely populated and extremely poor rural areas with blood sellers, IDUs, and sex workers. The group estimates that 20 million persons may be infected. AIDS in China will affect the United States in more ways than AIDS in Africa does, because the United States and China are major trade partners. Dr. Hu believes that the window of opportunity for averting the impending crisis is only 3 or 4 years. She believes that President Bush would be the most powerful person to convince the Chinese leadership, from the top down, that China needs a national movement to stem the spread of AIDS.

Ms. McDonald proposed that the Council make a recommendation to the Secretary and to the President that these matters in China receive immediate attention. After referring the study of China as well as Russia, India, and Burma/Myanmar (all highly volatile areas for epidemic explosion, per Dr. Sharma) to the International Committee, Dr. Sullivan called for a vote. The China recommendation received unanimous approval.

Dr. Sullivan then stated that he had to return to Atlanta and that Dr. Coburn would preside over the remainder of the Council meeting.

Wrap-up

Ms. Ware announced that the Council will be able to have three meetings a year, and that she has suggested planning them over Friday-Monday periods. She asked Council members to check their calendars and send her available dates in June/July and in October. She noted that the co-chairs will need to be more effective in communicating with members.

Regarding Council funding, Ms. Ware explained that the ONAP budget is handled through NIH and that its consulting firm does not give her a running total of what they have spent, although she keeps trying to get this information. "Maybe we need to change consulting firms," she stated. PACHA funding goes through Health and Human Services.

Mr. Minor stated that he wanted to thank Pat Ware and the co-chairs for handling the public comments so well.

Minutes of the last Council meeting were unanimously approved.

The meeting adjourned at 5:20 p.m.

Friday, January 31, 2003
Morning Session

Opening Remarks

Dr. Coburn called the meeting to order and introduced the first speaker.

Disparities in HIV/AIDS Health Care

Health Resources and Services Administration (HRSA)

Deborah Parham, Ph.D., R.N.

Associate Administrator, HIV/AIDS Bureau

Dr. Parham proposed to focus on three aspects of disparities in HIV/AIDS health care: how disparities came to be such a central issue, how these disparities are reflected in the people served through the Ryan White programs, and how disparities can be reduced both in access to care and in the health status of people being served.

In the early days, when AIDS progressed rapidly and unchecked among white gay men in urban areas, it caused poverty and dependency. People lost their jobs and thus their health insurance. Disenfranchisement from the health care system *because* of poverty and its associated problems was not the primary force separating people from services. This has all changed. Over the past decade, AIDS has spread most rapidly among people least able to fight it: injection drug users, minorities and minority subpopulations (women, gay men), homeless individuals, and persons in prisons and jails. When these populations came into care, they suffered from the stigma of race, ethnicity, and sexual orientation. Many did not have health insurance, many were living in poverty before they became HIV-positive, and many presented with high rates of comorbidities like mental illness and addiction.

One survey reported that people living with HIV in care over a 6-month period in 1996 were *half* as likely to be employed as the general population, *half* as likely to have household income above the 25th percentile, and *half* as likely to have private insurance. More recent data show that almost 70 percent of AIDS cases reported in 2001 were among minorities, and more than 81 percent of cases among women were among minorities. Even with the vast resources that the United States has mobilized, every 13 minutes, someone in this country is infected with HIV. Every 13 minutes, someone else is diagnosed with AIDS. Every 34 minutes, another person dies from it. Based on 2001 data, one in four of those contracting HIV this year will be under age 21. Seven in 10 of AIDS diagnoses and deaths will be among racial or ethnic minorities.

The Ryan White CARE Act community of providers sees about 533,000 people each year. The proportion of clients who are racial and ethnic minorities continues to increase; today 70 percent fall within this group. The CARE Act is the payer of last resort (i.e., Ryan White funds can be used when people without private insurance and personal resources have essential needs that are not met by Medicaid, SSI, and other components

of the public “safety net”). Disparities in access to health care are often reflected in the health status of people entering care at Ryan White-funded sites. Among new Title III clients in 2001 (funding for early intervention services), only 51 percent had no symptoms of HIV disease, 25 percent were already living with an AIDS-defining condition, and another 24 percent had conditions symptomatic of HIV disease.

To the huge question for the Ryan White community—and for all providers—of whether disparities in access to care and in health status can be corrected, Dr. Parham answered a resounding Yes. To do so, energies need to be focused in two areas: people must get into care as soon as possible after they become HIV positive, and providers must work toward reducing disparities in health status once people have entered care. This is really what the Ryan White program is all about. On average, patients are better off receiving care at a Ryan White-funded site than elsewhere. Providers improve patient chances by taking care of the whole person, meaning shelter, treatment for comorbidities, proper diet, and other aspects of life that threaten compliance with a complicated regimen of treatment. When providers address the multiple problems associated with AIDS and when they look at people’s needs as they relate to staying in care over time, they can stop disparities in health care. This reality is reflected in the lives of hundreds of thousands of people who are alive and thriving because they have received access to the services to make it all possible.

The text of Dr. Parham’s remarks was made available to Council members.

Office of Minority Health

Nathan Stinson, Jr., Ph.D., M.D., M.P.H.

Deputy Assistant Secretary for Health (Minority Health)

Dr. Stinson outlined the five strategies that his Office employs in its focus on AIDS, which was chosen as a priority because the science exists and money was already being spent on the disease. The strategic approaches reflect how the Department of Health and Human Services does its work.

1. Policy: the always important foundation.
2. Enhancing the science base: The Office collects racial and ethnic data and finds that the cost of doing surveys, questionnaires, and other data-gathering tasks is a hard sell. New clinical programs and treatment approaches are easily marketed.
3. Partnerships: This strategy receives much lip service, but real partners are needed to work in unison for the common goal. The Office is seeking to establish partnerships with State Minority Health Offices. In South Carolina, all migrant health camps have been identified, and the State has conducted HIV assessments of all clients.

4. Linkage to services: The Office acknowledges that people who get sick will need services from beginning to end, and thus it gives grants to community organizations that provide services and do prevention work.
5. Strategic communications: To enable the replication of approaches that the Office knows will work, culled-out examples must be shared with communities. Here the Office walks a fine line. Some messages convey things the individual can do, but they must be presented in such a way that they don't blame the individual for the problem but instead encourage that person to be receptive to the message.

Dr. Stinson revealed that the Office of Minority Health receives free radio time from the ABC Radio Urban Network in exchange for public service messages that are broadcast over the network's 200-odd stations. The current focus is on the "Take a Loved One to the Doctor" message, which it is hoped will help establish a day in September when listeners will do just that. The Office also is working with Hispanic radio stations.

Regarding best practices, Dr. Stinson avowed that *equal care equals equal outcome*. The best must be replicated once people enter the health system. (Note: Later in the meeting, Dr. McKinnell stated that *equal equals equal* is only half right: doctor and patient behaviors determine outcomes.)

Community Representative

Deborah Dimon, R.N., B.S.N., M.P.H.
Alexandria, Virginia, Health Department

Ms. Dimon has been involved in the planning and delivery of HIV/AIDS services for low-income under- and uninsured persons living in Alexandria City for the past 12 years. She spoke of the challenges inherent in connecting with clients and supporting their adherence to primary HIV medical care, treatment regimens, and other services. Several factors contribute to the lack or irregularity of client connection to care. In addition to the denial and distancing that may characterize the client's initial reaction to receiving an HIV-positive diagnosis, a litany of fears also comes into play: fear of death, of being reported, of becoming a statistic, of becoming labeled, of facing discrimination, of losing employment, of being deported, of losing or damaging relationships with family and friends. Some people lack trust in the Western medical model of care and/or public services. Others believe that HIV was manufactured by the "powers that be" and subsequently mistrust the treatment developed by the same. Younger persons are receiving a diagnosis that demands consistent and routine medical care during a stage of life when one normally enjoys good health. Adolescents have expressed feelings of being misunderstood by an older generation of providers. Families may have so many priorities to juggle that health care takes a back seat. Persons from racial minorities have found it difficult to relate to providers from different backgrounds, and others living with HIV do not always feel an uninfected provider can meet them on common ground. Persons living with HIV in prison often choose not to disclose their status for fear of having their confidentiality compromised and experiencing the subsequent fallout. Language and

cultural barriers present new challenges in connecting and providing services for a growing number of multicultural residents living with HIV.

Clients sometimes perceive the treatment prescribed in long-term management of the infection as too difficult to follow, requiring too many pills, demanding too much consistency, causing unwanted side effects, possibly exposing one's status to household members or coworkers, and providing a daily reminder of an infection that has no cure. There are misunderstandings that treatment controls infectiousness and that being infected means only having to take a few pills a day. Significant psychosocial conditions also diminish the ability to connect and remain adherent to care.

In an attempt to meet these challenges, facilitate access, and support adherence, in 1992 the Alexandria Health Department implemented a case management model. Public health nurse case management, enhanced by close collaboration with a consumer advocate, was tied to the existing primary HIV care services. Collaborations were developed with a minority community-based service organization and with the Alexandria Detention Center, Alexandria Mental Health/Mental Retardation and Substance Abuse Services, INOVA Alexandria Hospital, and other nonprofit AIDS and social service organizations.

The Department has provided primary medical care at one of its four sites, the Flora Krause Casey Health Center, since the beginning of the epidemic. HIV pre- and posttest counseling services are provided at all the sites, and persons testing positive for HIV receive partner counseling and referral services. They are then directly linked to the Casey Health Center for comprehensive primary HIV medical care, case management, dental care, drug assistance, nutrition counseling, and supplements. Health counselors also work with inmates at the Detention Center prior to their release.

Adding an adjunctive consumer advocate to medical care and case management providers has served as a bridge to enhance connection to services and peer support for adherence to medical monitoring and treatment. The groundwork laid by the Department's first consumer advocate, Eddie Ross, was instrumental in developing the consumer advocate role and in exemplifying the key qualities needed in this role. Eddie Ross was from the community and was living with HIV; through his understanding, communication, education, and simple caring for fellow consumers, he maintained the human element in the system of care.

Despite the dedicated team of physicians, nurses, and consumer advocates, however, challenges outside of the Department's control continue to impede connections and adherence to care. The original minority community-based organization (CBO) that provided the consumer advocate services withdrew from its role as the sole minority HIV service provider in Alexandria. The absence of organizations willing to adopt this responsibility led to direct employment of consumer advocates by the Department. Positive Livin' has emerged as an exciting alternative, but concerns exist that competition for limited funding may diminish collaborative efforts. Funding changes for mental health and substance abuse services, housing and residential treatment facility shortages, increased unemployment, and the general economic downturn have all complicated social

stability for consumers. Nevertheless, the team continues its efforts, and there are still many success stories to share.

Community Representative

Mari Parr

Positive Livin'

Ms. Parr, the new Executive Director of Positive Livin', a minority community-based organization in southeast Fairfax County (Alexandria City), served as a case supervisor and project manager with black populations for 6 years. In seeking to determine how her organization can reach out to minorities and get them to help get the message on HIV/AIDS out, she spoke with consumer clients. Three major concerns were revealed: (1) distrust of the system after incarceration; (2) the issue of being accepted, particularly if one is still drinking and not taking care of him/herself; and (3) upset and amazement that people still don't know about "the bug": the HIV virus. The third client stated that he wanted to be a part of it, that he would make a difference because he could say, "Look at me!" This would represent his first chance to be connected. Many blacks can't trust the system and consequently seek comfort in a nonjudgmental environment. Consumer advocates can provide this security.

Ms. Parr acknowledged that new minority CBOs face problems, too, among them funding and proving themselves to seasoned providers. These small minority groups are also part of this puzzle along with their potential clients.

Dr. Coburn ended this portion by quoting Martin Luther King, Jr.: "To change someone, you need to love them." Not just say it, Dr. Coburn added, but show it by actions.

Members of the Council departed at 9:30 a.m. to meet with President Bush and returned to the Humphrey Building at approximately 12:30 p.m.

Afternoon Session

Discussion of Committee recommendations continued after lunch; they are summarized in the Committee reports. Dr. Coburn interrupted this discussion when Dr. Joseph O'Neil and Dr. Claude Allen arrived. He thanked Dr. O'Neil for the confidence the President has in his work; Dr. Coburn has known him since the Co-Chair has been at the White House and is happy to have others see what a wonderful human being he is.

Dr. Allen reported that the Department of Health and Human Services (HHS) has received the application for the rapid-test CLIA waiver, an event that can triple if not quadruple testing stations. His chief concern is that HHS have the manpower to do all it is charged to do. Secretary Tommy Thompson's role as chair of the Global AIDS Fund will also add to the responsibilities of HHS. Consequently, Patricia Ware, Executive Director for PACHA, has been asked to come to HHS to be Special Assistant to Deputy Secretary for Health Allen, working in the areas of women's health and minority health.

Josephine Robinson will take over immediately as Acting Director of the Presidential Advisory Council.

Dr. O'Neil cited the "great time" he and Ms. Ware had working together at Jackson Place, and termed losing her to HHS as the "cloud" on this whole situation. Ms. Ware then addressed the group, stating that she had enjoyed working with all the members of the Council and that she is pleased the group is so diverse. The Co-Chairs had worked hard behind the scenes to make that happen. Discussion of Committee recommendations was delayed until scheduled speakers had completed their remarks.

Public Health Model: New York State
Antonia C. Novello, M.D., M.P.H., Dr.P.H.
New York State Commissioner of Health

Dr. Novello expressed her pleasure at being back in Washington and with the Council and her eagerness to show members "how to do it right." If it can work in New York, she stated, it can work anywhere.

New York State has a population of 19 million (2.3 million of whom were not born there) and citizens who speak 167 languages. The State has 18 percent of AIDS cases nationwide. Of the 149,341 cases reported through December 2001, 43 percent are in the black community, 29 percent in the Hispanic community, and 27 percent among whites.

New York spends \$2.2 billion in Federal and State funding on its response to HIV/AIDS. This response includes prevention (education, counseling, and testing), the continuum of health care (primary care, hospital, home care, nursing care, case management, medications [ADAP], and managed care under HIV Special Needs Plans), support services (housing, transportation, nutrition, permanency planning, and peer support), and harm reduction: syringe access and exchange, partner notification, prenatal and newborn testing and treatment, and focus on communities of color. This focus includes partnerships with CBOs serving persons of color. Two programs focus exclusively on developing leadership and providing services within communities of color: the Community Development Initiative (CDI) and Multiple Service Agencies (MSAs). The State builds partnerships among CBOs and faith-based organizations (FBOs) and provides financial support to FBOs to provide HIV education and services. Under Project WAVE (War Against the Virus Escalating), minority radio stations provide free air time to promote HIV counseling and testing events.

Since 1985, New York has provided free, anonymous HIV pre- and posttest counseling and HIV antibody testing. The 66 State-operated sites in 24 counties include walk-in and evening clinics in high-risk areas. Individuals who test positive are given partner notification assistance and referrals to medical and support services. The State is developing HIV Special Needs Plans (SNPs) as a unique feature of its Medicaid managed care program. SNPs will be comprehensive networks of primary care physicians specializing in HIV as well as enhanced managed care services such as treatment adherence support, HIV case management, and linkages to other support services. The

first SNP, HealthFirst, will begin voluntary enrollment in April 2003. Initially the six SNPs now working toward certification will serve Medicaid-eligible, HIV-positive persons in New York City, Long Island, and Westchester County.

The HIV Reporting and Partner Notification Law that took effect in New York on June 1, 2000, seeks to develop a highly secure and confidential reporting system that collects and maintains complete, accurate, unduplicated information on all HIV/AIDS cases in the State. This system monitors recent trends in AIDS cases, new HIV infections, and emerging subepidemics. Physicians and others authorized to order HIV-related tests, including nurse practitioners, physician assistants, nurse midwives, coroners, and medical examiners, report these data along with laboratories and blood and tissue banks that conduct testing. Data reported include initial cases of HIV diagnosis, HIV illness, and AIDS; names of known contacts and others the patient wishes to notify, and status of such notifications; and results of domestic violence screening. Sensitivity here is crucial: notification is delayed if a threat of domestic violence exists. New York is the only State that has had no breach of confidentiality.

New York State has had notable success in reducing perinatal transmission of HIV. By emphasizing prenatal HIV counseling and testing, newborn testing as a safety net, training of physicians, and technical assistance to hospitals, the public health system has dramatically reduced the number of HIV-positive women delivering and the number of cases of mother-to-child transmission when women delivering are HIV-positive. The percentage of women aware of their HIV status before delivery has increased exponentially. (These and other aspects of New York State's approach are explored in fuller detail in Dr. Novello's PowerPoint presentation, which is available to Council members.)

The State's harm reduction initiatives include a syringe exchange program begun in 1992 and offered in 13 individual programs across the State. More than 100,000 clients have been served in the past 10 years at sites ranging from storefronts, mobile vans, and street sites to hospital-based locations. An independent evaluation conducted by Beth Israel Medical Center found that new infections had been reduced by at least 50 percent.

A second primary prevention program, the Expanded Syringe Access Demonstration Program, allows syringes to be sold or furnished to persons age 18 and over without a prescription. More than 2,400 pharmacies are registered to distribute such syringes, with the provision that they must offer information on the closest substance abuse treatment center and instructions on safe disposal of syringes. An independent evaluation was due to the State Legislature in January 2003.

Dr. Novello encouraged Council members to learn more about HIV/AIDS statistics, programs, and services in New York State by accessing the State Web site (www.health.state.ny.us) and clicking on the HIV/AIDS icon on the home page.

International Model: Haiti
Jim Yong Kim, M.D., Ph.D.

Partners in Health, Harvard Medical School

In the absence of Dr. Joia Mukherjee, who was attending the Global AIDS Fund meeting in Geneva, Dr. Kim presented an overview of the Haiti Model. An infectious disease physician and anthropologist, he began by asking a common question: Why introduce antiretrovirals (ARVs) into resource-poor settings? “Because they are effective and they will reduce suffering, mortality, and transmission,” began his answer. The conventional wisdom argues against this position: ARVs in poor countries fall victim to lack of infrastructure and prohibitive costs of drugs. But the language of sustainable programs, endorsed by President Bush, suggests options. Prevention and treatment go hand in hand. Operational research cannot be conducted if there are no operations.

Haiti is the poorest country in the Western Hemisphere and the highest in HIV prevalence. Its public health care system has collapsed. Landless peasants travel to Port-au-Prince in search of work and return to their villages with HIV infection. Since 1998, highly active antiretroviral treatment (HAART) has been offered in Haiti, thanks to recycling and donations. The directly observed therapy (DOT) approach has been coupled with HAART, serving as a safeguard on the money invested in treatment. DOT originated in Tanzania and was instituted by doctors treating patients with tuberculosis, who would observe the patients taking their medications. It has had an extremely successful record, particularly in prison systems, and basically pays for social systems support.

Drug procurement has to be front and center of any HIV/AIDS work in Haiti. The biggest challenges to scale-up there include creation of coalitions to expand and harmonize prevention and care services. The goal of new initiatives such as the Global AIDS Fund is to adopt the CHIPS (complex health intervention in poor settings) strategy that will allow providers to confront challenges appropriately. Basic health services must be provided before individual diseases can be attacked. By focusing on HIV, providers create the focus on developing health systems, which has never been done before.

As President Bush has stated, saying that because someone is poor, he won't get treated is part of our primitive past.

Historical Overview on Research, Care, Treatment, and Prevention **Robert R. Redfield, M.D.** **Director of Clinical Care and Research** **Institute of Human Virology, University of Maryland at Baltimore**

Dr. Redfield recalled his 20-year, career-long involvement in HIV/AIDS work. During that time, he has seen unparalleled advancement that has changed AIDS from a devastating illness with a 10-month survival rate to a chronic disease whose sufferers are often able to have a normal, natural lifetime. Nevertheless, many in the United States still fail therapy, and sub-Saharan Africa still has decreasing life expectancy.

Today the HIV epidemic is treatable and preventable, yet despite remarkable advancements in treatment and the prevention of complications associated with HIV infection, the epidemic continues. Despite unprecedented scientific advancement (largely by the U.S. Public Health Service), HIV has transitioned from a local infection in the late 1970s to a global pandemic whose impact on the world will soon be measured by its causation of global economic and political instability.

Dr. Redfield posed an opening thought to Council members: If an efficacious preventive HIV vaccine could be deployed today worldwide, would this prevent the economic and social destabilization of sub-Saharan Africa? If not, what would?

Six areas of focus are indicated:

1. Durable treatment is a primary prevention strategy.
2. Antiretroviral (ARV) resistance has critical consequences.
3. Sustainable success requires resources to develop, implement, and evaluate new treatment strategies.
4. An unchecked HIV epidemic in our Nation has the potential to increase racial health care disparity.
5. Our Nation should aggressively and successfully empower resource-limited countries to implement sustainable HIV antiretroviral treatment (ART) programs and reverse the widening health care gap and its economic and security consequences.
6. Developing new treatment priorities for resource-poor and resource-limited areas should be a U.S. scientific priority.

The impact of ART in the United States has several elements:

- ?? Major impact on mortality of advanced HIV infection
- ?? Major impact of morbidity secondary to HIV infection
- ?? Evidence of health care disparity related to mortality among blacks
- ?? Significant treatment failure in experienced clinics secondary to the development of drug resistance
- ?? Significant “swings” in consensus recommendation related to use of ART
- ?? Increased morbidity and mortality secondary to drug-induced toxicities
- ?? Increased transmission of ARV drug-resistant virus.

Dr. Redfield traced the evolution of HIV/AIDS treatment through multiple mainstream approaches, noting that he has many patients who have lost all treatment options. The current mainstream treatment strategy includes these elements:

- ?? Sequential combination chemotherapy (rational ART sequencing based on concerns of cross-resistance)
- ?? Preservation of future treatment options
- ?? Maximized adherence via reducing pill burden and dosing interval
- ?? Expanded use of viral load monitoring
- ?? Use of resistance testing in selected clinical settings (viral rebound, new infection) to steer drug selection
- ?? Delayed use of ART (due to high risk of viral failure and toxicity).

The consequences of implementing this strategy include the following:

- ?? Greater than 30 percent of patients in treatment with drug resistance
- ?? Increase in patients requiring deep salvage regimen
- ?? Increase in primary infection with resistance virus
- ?? Recognition of significant toxicity, particularly of principal investigators (PIs)
- ?? Increase in morbidity and mortality from drug toxicity
- ?? Changes in consensus treatment recommendation: delay treatment.

Dr. Redfield advised that the United States has provided the learning curve for the world. No other Nation need do the same.

The lack of durability in clinical cohort studies is shown in certain 1-year ART failure rates: Baltimore, 63 percent; Cleveland, 53 percent; San Francisco, 50 percent; and Amsterdam, 40 percent. The transmission of HIV-resistant virus has changed from 3.4 percent in the 1995-98 period to 12.4 percent in 1999-2000. There is a growing population of treatment-experienced patients with multidrug-resistant virus.

Impatience for progress is a driving factor in the search for successful treatment. This impatience has many faces:

- ?? Desire of HIV-infected population to be treated
- ?? Desire of biomedical community to treat
- ?? Lack of significant debate about consensus treatment recommendations
- ?? Poor understanding of *in vivo* HIV replication treatment goals despite decision to use ART
- ?? Lack of significant public health debate on the impact of premature use of ART on future control of the HIV epidemic.

Progress toward sustainable therapy can be made by acknowledging the reasons for viral failure. These include premature wide-scale introduction of suboptimal ART, limited public health debate about long-term implications for both patients treated and future patients, the high adherence threshold (90-percent adherence equals 50-percent treatment failure in 1 year), and limited development of adequate treatment support systems prior to introduction of treatment. A portfolio of treatment support structure choices is needed; this is a critical funding issue that the Presidential Advisory Council can influence. Knowledge, skills, and equipment need to be imported to deal with this situation.

Dr. Redfield acknowledged that many in the gay community developed drug resistance because they volunteered to help researchers in the beginning. Two epidemics are possible: one that is treatable, and one that is less treatable because of lower drug adherence in poor communities. There is real concern about the potential for drug resistance to have a disproportional impact on the urban poor and the potential, if unchecked, to lead to increased racial health care disparity. HIV infection could become biologically entrenched in one population.

The HIV/AIDS community needs to reevaluate risk reduction and prevention messages in light of increased ARV resistance. It needs to emphasize the development and implementation of successful secondary prevention programs. It needs to develop and implement new treatment support systems that enable patients to be successfully treated for the long term. All the system's financial flexibility is being sucked into drugs; there is reluctance to invest in treatment support, yet long-term durable therapy is critical.

Dr. Redfield expanded on the potential for growing health care disparity at home. In Maryland, 85 percent of HIV clients are black, and 2 percent of all blacks are infected. In his own clinic, not one black has been cured. He sees women in their 40s with lung cancer; one-third of those infected don't know they're infected. New acute infections need to be diagnosed; infrastructures need to be strengthened. Dr. Redfield specified some of the characteristics of the domestic health care disparity:

- ?? Differential penetration of the HIV epidemic in the U.S. population
- ?? Differential impact of ART on mortality
- ?? Potential for increased comorbidity and disease outcome (renal disease, hepatic disease)
- ?? Potential to increase current cancer disparity
- ?? Potential for differential penetration of multidrug-resistant virus
- ?? Potential for disparity to become biologically entrenched
- ?? Potential for increased racial tension over outcome of AIDS epidemic in sub-Saharan Africa.

Treatment must be embraced as a key component of the overall prevention effort. Early diagnosis must be enhanced to include acute HIV infection (i.e., high viral load). Increasing evidence shows that treatment during acute infection is of benefit to the patient. The North Carolina STAT program found that 10 percent of new diagnoses were seronegative acute infection. Public health capacity must be increased to provide greater opportunity for early diagnosis, especially during acute infection, and the effectiveness of the public health system in actively engaging and retaining persons living with HIV into care and treatment must be improved. Increased standard-of-care thresholds are indicated for long-term durable viral suppression via the development and implementation of improved treatment support systems for care delivery. Resources and new initiatives must be targeted that are designed to address and revert the potential impact of HIV infection on increasing health care disparity in the United States.

Leadership and proportional response are what was missing, stated Dr. Redfield. This week, he concluded, President Bush supplied them both.

Dr. Redfield moved on to a discussion of ART in Africa and the growing health care disparity abroad, evidenced and caused by the following factors:

- ?? Accelerated natural history
- ?? Declining life expectancy
- ?? Unilateral access to specific ARV drugs
- ?? Western biomedical research priorities
- ?? U.S. and European "experts" driving local therapeutic guidelines

- ?? Limited local leadership
- ?? Transition of HIV epidemic from health crisis to cause of economic and political instability.

Western researchers and health care providers need to be humble in Africa and to avoid transferring U.S. methods and strategy to African Nations. An African strategy is needed, not a transplanted U.S. strategy. Translating the current Western approach on sequential combination drug treatment is the wrong approach. Instead, the optimal profile of ARV drugs to be used in Africa must be defined. Next steps include the following:

- ?? Define a realistic role for diagnostic testing in management
- ?? Develop an African ART strategy
- ?? Focus on operational therapeutic research in resource-poor and resource-limited countries and validate success before wide-scale application
- ?? Make development of products with proper profile for use in resource-limited countries a priority
- ?? Recognize that we have one chance to get it right. If significant viral resistance emerges (as in the United States and Brazil), this is a signal for ART; if the reverse, the course of events unfolding in Africa will be lost.

Finally, global health will be the defining issue of U.S. foreign policy in the next century. We don't need to solve every world health problem, but certain goals for ART are inescapable:

- ?? Reverse the impact of the HIV epidemic on declining life expectancy in affected countries
- ?? Reverse the tragic trends of increasing numbers of HIV-related orphans
- ?? Reverse the trend of loss of key members of work forces of local industry and teachers
- ?? Minimize the impact on local government and global economics
- ?? Avert the development of economic and political instability in sub-Saharan Africa and avert the spread of instability to other regions of the world.

Dr. Redfield offered some closing thoughts on the subjects under discussion. What will be our Nation's legacy related to the HIV epidemic? Will we close or widen the world's health care gap? (His) belief is that greater success will come for all if the power of science can be refocused to the development of treatments capable of causing sustainable improvements in health worldwide.

Now is a time of great opportunity to affect the transition of the HIV epidemic from a health pandemic to a factor critical to global economic and political stability. Whatever course of action is taken will have historical consequences and shape our world and the 21st century. If successful, the introduction of ART in sub-Saharan Africa could be the beginning of an era of better global health with broad economic and political stability consequences. If unsuccessful, progressive widening of the health and economic gaps and growing global political instability should be anticipated.

Council members welcomed Dr. Redfield's remarks, and he said that a copy would be made available to the Council.

Discussion focused on the need for a treatment support system. Ms. Ivantic-Doucette noted that Western love of technology/drugs is outspending available funds, and people are reluctant to spend money on interrelationships with patients. She asked if funding direct treatment should be considered. Dr. Redfield stated that funding should come through Ryan White funds. Providers need to "get it"; patients used to be blamed if drugs (given too soon) failed. Now a new paradigm is needed: a new treatment support system, perhaps intensive at first and then eased up. This is now a chronic disease model, and patients always have to be given a chance to change.

Dr. Coburn noted that giving people a drug and sending them out the door is not treating patients; they need support to be adherent. Regarding whether the best drugs should be given first, Dr. Redfield observed that certain alternatives can be durable and that high-mutation-threshold drugs are being developed. In his practice, he said, providers are aggressive and treat early but not before establishing "friendships" with the patients.

Update on Global AIDS Fund
Terrell Halaska
Deputy Chief of Staff for Policy

Ms. Halaska reported on the meeting of the Global Fund to Fight AIDS, Tuberculosis, and Malaria just completed in Geneva. As the elected Chair of the Fund, Secretary Tommy Thompson, representing the U.S. Government, will direct meetings and focus on the efficiency of the Fund. The Board elected Dr. Suwit Wibulpolprasert of Thailand as Vice Chair. The United States has provided 48 percent of the Fund's funding to date. Projects in Africa received 60 percent of the Fund's grant awards, with 10 percent each going to proposals from India and other countries. AIDS-specific projects received 60 percent of funding, malaria-specific 20 percent, tuberculosis-specific 15 percent, and a combination about 2 percent. The Fund's next meeting in June will take place in Geneva, and an October meeting will be held in Thailand.

Update on USAID Programs
Connie Carrino
Division Director on HIV/AIDS

Ms. Carrino briefed Council members on the activities of the U.S. Agency for International Development (USAID) program on HIV/AIDS. Last year's budget totaled \$510 million, with \$75 million going to the Global Fund and \$435 million toward bilateral spending in 50 countries. Her work in HIV/AIDS began in 1991, when there was no targeted funding and she went to New Delhi as a diplomatic courier in order to work in the field. Tremendous progress has been made since then, and USAID funds programs from prevention through care that seek to prevent infections, provide care, and provide support to families and communities.

Programs in Africa are often work-based. USAID provides “food for AIDS,” \$10 million directed toward AIDS-related famine. Tuberculosis is the leading cause of death in countries with USAID support, and prevention *is* critical in controlling AIDS. USAID endorses the ABC combined program for prevention. Sexual transmission accounts for 80 percent of AIDS worldwide, and even girls at sexual debut do not control their agreement. ABC is important. Another prevention program supported by the Bush Administration focuses on mother-to-child transmission.

Children on the Brink, a 1997 report, introduced the subject of AIDS orphans, another target of concern. Children do best when they are reared within a family and within a community. Working in the community is an important part of USAID efforts. Scaling up means scaling out into the community, enlisting the support especially of FBOs; to encourage this support, USAID is providing small grants for small groups under the Administration’s faith-based initiative. USAID Administrator Andrew Natzios is keen on this initiative, and projects are being pursued in Uganda, Ghana, and Cambodia, among others. Ms. Carrino thanked the Council for its support of the Administration on the FBO initiative; Mr. Nickerson clarified that the Council had included FBOs as one of several categories of partners.

Dr. McIlhaney spoke to the issue of women’s rights, noting that a USAID report states that young men are as moved by this issue as are young women. Nevertheless, replied Ms. Carrino, in countries like Chad girls are married off at the age of 12 or 13, often to much older men.

Ms. Lewis asked how USAID women’s health and reproductive health programs are conducted in partnership with FBOs. In mother-to-child prevention efforts, programs promote understanding of family planning after the baby is born, and STD prevention and treatment are included as well in community programs. Regarding the mother-to-child initiative, Ms. Carrino reported that all 14 countries have done assessments and set up team structures at the top. They will then prepare proposals for 3-year plans, some starting with mother-to-child transmission and others continuing efforts already in place. Each government is basically doing its country’s program.

Ms. Ivantic-Doucette questioned whether USAID funds for infrastructure can be used to purchase drugs. Ms. Carrino noted that her agency is working closely with other agencies, and that all are looking at trade-offs, using generics overseas, for example. Dr. McKinnell offered that no patents apply to the 14 countries involved, so there would be no problem with generic drugs. The Accelerated Access Initiative addresses this situation.

Wrap-up

Dr. Coburn stated that Council members will receive a letter asking about available dates in late spring/early summer and in early fall for the next two Council meetings. He noted that it is important for Dr. Sullivan, who has a particularly demanding schedule, to be able to be present.

In the Council's work in advising on policy, it is important to present both sides of an argument. Dr. Coburn asked that if members wish to communicate a position to other members, they should first send their position to Dr. Coburn and Dr. Sullivan, along with opposing views on their argument. For example, he cited, Dr. Kim and Dr. Redfield were on opposite sides of their issue.

Mr. Mason questioned whether a press release on the Council's work during this meeting would be appropriate. Dr. Coburn replied that he had found that in Washington, if you talk about what you do, you get a lot less done. He thinks that the Council should walk quietly and give its best advice to the President. Talking about oneself is what D.C. does, but it is not a good policy.

Both Dr. Coburn and Ms. Ware addressed the issue of contact of Council members with the press. Council members are private individuals, not representatives of the Council. They speak only for themselves. Regarding AIDS, however, this will never come through. The press will connect members with the Council, no matter what they say. It is therefore wise to say only what the Council has completely endorsed. The press is not interested in what happened; they want only members' reactions and thoughts about issues and to provoke controversy. Council members are only advisors, not news makers, but the Council hit two home runs today: the CLIA waiver is as important as anything the Council has done in the past 2 years. Members are accountable only to the President.

Dr. Driscoll suggested that the Council formally thank the President for meeting with its members. Dr. Coburn stated that he would prepare such a message and post it for members' review.

Ms. McDonald proposed that the Council thank Pat Ware for all her hard work on behalf of members, meeting arrangements, and other matters. She stated that the group would like to offer flowers to Ms. Ware, but few seemed aware of the changes about to happen.

The meeting adjourned at 5:05 p.m.