PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

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THIRTIETH MEETING

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TUESDAY,
JUNE 20, 2006

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The above-entitled matter convened at 9:00 a.m. in Room 800 of the Hubert Humphrey Building, 200 Independence Avenue, S.W., Washington, D.C., Louis Sullivan, M.D., Co-Chair, presiding.

COUNCIL MEMBERS PRESENT:

LOUIS SULLIVAN, M.D.	Co-Chair
TROY BENAVIDEZ	Member
ROBERT BOLLINGER, M.D., M.P.H.	Member
JACQUELINE S. CLEMENTS, B.S.	Member
EDWARD GREEN, Ph.D.	Member
ALAN HOLMER, B.A., J.D.	Member
JANE HU, Ph.D.	Member
FRANKLYN JUDSON, M.D., M.P.H.	Member
SANDRA McDONALD	Member
JOE McILHANEY, M.D.	Member
ROBERT REDFIELD, M.D.	Member
DAVID REZNIK, D.D.S.	Member
M. MONICA SWEENEY, M.D., M.P.H.	Member
RAM YOGEV, M.D.	Member

PACHA STAFF PRESENT:

JOSEPH GROGAN, Esq.	Executive Director
DANA CEASAR	Program Assistant

PRESENTERS:

MICHAEL SAAG, M.D., Professor of Medicine, Director, University of Alabama at Birmingham

MYRON S. COHEN, M.D., J. Herbert Bate Professor of Medicine, Microbiology, and Immunology and Epidemiology Director, UNC Center for Infectious Diseases, UNC Chapel Hill

I-N-D-E-X

M-O-R-N-I-N-G S-E-S-S-I-O-N

9:03 a.m.

CO-CHAIR SULLIVAN: Let's try and get started because we would like to adhere to our time schedule for the meeting today. One thing I failed to mention yesterday, but I'm sure all of the Council members will agree with me. I congratulated Joe Grogan and his staff for the book that was put together for our meeting.

(Applause.)

EXEC. DIRECTOR GROGAN: Thank you but I wish -- I can't take any credit for that. It was really Dana who put this all together and she did a fantastic job.

(Applause.)

CO-CHAIR SULLIVAN: Certainly excellent, very good papers and good biographical sketches. So thank you very much for this very fitting for the 25th year of this epidemic. We also had some very good discussions and presentations yesterday and I'm sure that will continue through to today. Our session this morning will be presided over by the

Chair of our Treatment and Care Committee, Dr. Reznik. So, David, we'll let you go forth.

MEMBER REZNIK: Good morning, everyone. We have some people that are awake. Today we're going to cover a couple of very important issues and our first speaker, which is actually an honor for me to introduce him, I think it's our first speaker, let me make sure, is Michael Saag. Michael Saag graduated from the University of Louisville with his medical degree and then did a residency in infectious disease in molecular virology at UAB or University of Alabama at Birmingham.

During his fellowship training, actually while a fellow, Dr. Saag conceived a concept of a comprehensive HIV outpatient clinic dedicated to the provision of comprehensive care in conjunction with the conduct of high quality clinical trials, basic science and clinical outcomes research. This is as a fellow. So that is really very unusual. At least in today's world, it's a little bit unusual. Since he established the clinic, Dr. Saag has participated in studies of antiretroviral therapy as well as novel

treatments for opportunistic infections.

Some of his articles include the description of the first use of viral load in clinical practice, the first description of rapid dynamics of viral replication, the first guidelines for the use of viral load in the practice, the first proof of concept of fusion inhibitors as a therapeutic option and also making available many antiretrovirals that were only available through research trials.

In the early days of the epidemic, many of our patients in Atlanta actually took the trip to Birmingham to see Dr. Saag to get access to care. And I believe it was last year one of our community group had a survival project to honor Dr. Saag for his commitment not just to people in Birmingham but to the people in Atlanta and around the country.

As many of you know, my partner was sick earlier, all of last year, and when things came down to a crisis, we have a wonderful medical director at Program, Dr. Jeff Linnox. I called up Dr. Saag because things were getting to the point where I

needed to contact the brains and people that also have the compassion and the two doctors got together and I can happily say that my partner is doing much better. Truly a great person, dedicated to dealing with this disease and facing the problems as they are emerging, it is my privilege and honor to introduce Michael Saag.

(Applause.)

DR. SAAG: Thank you very much. I'm going to speak from here if that's okay and I'm going to take only about 20 to 25 minutes and leave time for discussion because I know that a lot of you have ideas as well. But the thesis of what I want to talk about is care, HIV care delivery and while you may think that this is an exaggeration that in my opinion is an emerging crisis in care, there really is, and I think by the end of my remarks, you'll hopefully see what I'm trying to say.

So we'll start with our clinic in Birmingham, and what you're looking at is a Kaplan Myer survival plot and to sort of walk you through this, this is eight years worth of data. These are

data from HAART Era and just to translate this for you, if someone shows up with a CD4 count greater 200, the majority of them, this is the top two bars, are alive eight years later. If they show up a CD4 count less than 200 at initial presentation, don't start the HAART regimen until after a CD4 count of 200 and if they're between 50 and 199, that's their line, and if they're less than 50, that's where they go. So that up to almost half of the patients who show up with a CD4 count less than 50 in the HAART ERA are dead eight years later still today.

The next slide shows you, in our clinic, the median CD4 count of someone showing up for care. It speaks for itself. This is in today's world with all that we know about HIV, all the messages that are out, everything that you've been dealing with personally at whatever level you're at, the median CD4 count of patients. Look at 2003. A hundred was the median CD4 count of someone showing up in our clinic referred for care. What it means is that people who are infected with HIV at least in my part of the world, and I think it's a lot of the United

States, are infected and don't know it and they don't seek care until they get sick.

So the take-home point is kind of obvious. Mortality is much higher when patients diagnosed late. The majority of newly diagnosed patients are diagnosed late. The exception to this are pregnant women. The median CD4 count of a pregnant woman seen in our clinic is 400. Why is that? We have universal opt-out testing for women. So? Universal opt-out testing is needed.

Now 20 years ago, I would not have been saying that. Fifteen years ago, I would not. I've been on the other side. Why? Because 15 or 20 years ago, all we had to offer somebody who was diagnosed HIV positive, all we had to offer them, was discrimination.

Now there is still discrimination, unfortunately, but at least we have therapy and we have a way to keep people alive and in my opinion, if you can get somebody into to care, especially early, and you treat them, it's like diabetes. Yes, there are complications of treatment. Yes, there are

complications of disease, but the majority of people will live for decades, and I'm talking into the 70s, 80s and 90s. So that it's a public health point that we should testing, or at least offering testing, with appropriate counseling to everyone and if they choose not to be tested, that's their decision. But I would say anyone who has ever been sexually active in their life should be tested at least once.

Now, that's the background. Let me segue into another study out of our clinic, and this is a cost study that was published a couple months ago in *Clinical infectious Diseases*. What we wanted to do was to determine the annual health care expenditures for HIV stratified by CD4 count.

Now this has been modeled a lot, but this is actual data from actual utilization of our clinic. We described the cost components of health care, medications, labs, hospital, etc. to analyze the effect of the changing CD4 count on expenditures. We took our database out of our clinic that we captured data since 1988 on every patient and this was looking at mainly the year 2001 and established care January

1994.

In 1999, we had a pretty big change where we could start incorporating health care utilization which would include all these metrics. So once we started capturing that, then we could assign costs based on utilization.

So for inclusion criteria for this study, they had to be receiving their primary care at UAB. We have a lot of patients who are referred in from Atlanta or other places. But the only ones we included in the study were those actually came exclusively to UAB for their care. The baseline CD4 count had to be available and follow-up of at least once and for hospitalization for that one year period.

We took the actual utilization and assumed that every patient had Medicare insurance to create a level playing field. So everyone had Medicare and reimbursements were based on Medicare rates in Alabama, complete billing for all health care use, and that we collected 100 percent of whatever was charged. For medications, we simply

used average wholesale price. So we had every medication with a start and stop date and we could assign this.

This is the demographics. This has changed actually in our clinic since 2001-2002. The age is a little bit higher now, fortunately. It's about 42. At that time, there were about 40 percent blacks. Now it's about 50 percent. Men who have sex with men is now, in our clinic, about 48 or 49 percent, and most of the patients now of the last 300 patients referred to our clinic in the last year, 50 percent of them had no health insurance.

So these are the data, and what I'd like to do is, I'm going to walk you through this. Let's start with this first column and what you'll notice is that when the CD4 count is high, annual costs are low and when a CD4 count is low, annual costs are high. And it's pretty remarkable how almost linear that is, so that not only is somebody showing up late at higher risk of dying. They also cost more money and the overall average cost was about $18,600 per year.

If we look at the reason why the costs are higher late versus early, it's mostly in non antiretroviral medications and somewhat in hospitalization, but hospitalization which everybody focuses on really is only a small component of the overall cost of care even among those with less than 50 copies. If you take them as a group, it's only about eight or nine percent of the total health care expenditures. The take-home point here is that 75 percent of cost no matter how you slice it, no matter which CD4 count strata you're in, is medications. Seventy-five percent of cost is medications in any CD4 count strata you look at.

And then finally, look at this. If I charged accurately for a Level 3/Level 4 visit, everyone had insurance and I collected 100 percent, on average I would only collect for our clinic $360 per patient per year. For a 1,000 patient clinic, that's $360,000 a year to do everything, pay the doctors, nurses, reception, rent, utilities.

This is a statement about our health care delivery system and in HIV care in particular, you

can't make money. Why? Because the $359 per patient per year is assuming everyone has insurance and our collection rate is 100 percent. About 40 percent of our patients have no insurance. Our collection rate is about 40 percent. So in that year, our actual reimbursement from third parties, not counting Ryan White or anything else, was about $130,000 for that year total to our clinic.

The bottom line is you can't make it in clinical practice in HIV. And if you look around the country, a lot of the so-called boutique practices in New York, Los Angeles, San Francisco, they're dying. They aren't, those practices are going away and almost the majority, clearly the majority of patients who are seeking HIV care today are doing so through publicly-funded clinics around the country.

Let's look at this a little differently. So there is some good news in here. We simply asked the question, if you took at the six-month point in the study, you took the original CD4 strata they were in and asked the question, at six months later were they in the same strata or did they improve or did

they get worse, and that's what this graph shows. If we just focus on the this 50 to 199 group CD4, they started in this group. If they stayed the same, their annual costs were about $24,000 per patient per year. If they dropped to the less than 50 group, their costs jumped to here. But if their CD4 count went up to that group in the course of six months, their costs were lower and this was statistically different. That dropped about $6,000 less.

How do you get CD4 counts to up? Well, you treat them with antiretroviral therapy and this is just another way of showing that ARV therapy is cost effective. Good news.

But look at where the cost savings were. Most people would guess it was in hospitalization, and indeed, there's a big difference here. The antiretroviral therapy medicines costs is about the same and you might predict that, because you're only going to give so many drugs and that's what they cost. But most of the difference in cost was in the non antiretroviral medications. People got sick and they required foscarnet or cidofovir or whatever,

chemotherapy, and that's where the majority of the costs are and again to reiterate my point, the majority of the cost no matter how you slice it is in medications.

Look at this. This is my whine. This is us over here trying to make it, trying to get through day to day. So the conclusions are antiretroviral therapy is cost effective. Medications are the most expensive component and physician costs account for less than two percent of expenditures, even in the most optimal conditions and it's certainly much less than that.

So before I go further, I'll just ask the question. If you were a young physician coming up through training, would you choose to go into HIV medicine or would you choose to go into dermatology or would you choose to go into radiology or would you choose to go into some other specialty that pays a little more? Who in their right mind would choose this specialty? Which gets to the next question, where is the next wave of doctors going to come from who take care of HIV patients? Where is that going

to be? So that is one of the questions I want to have a discussion about with you guys when I get through. So that's Point 1.

Another point is when we think about Ryan White, the original authorization, think about that time versus now. In 1991 when that authorization legislation was first put through, people were dying of AIDS everywhere. There were no medicines to speak of, a few, but none worked very long. Patients were dying. So what did we have to do? We had to help people learn to live with disability and we had to help them die with dignity. And the Ryan White Act helped us do that.

Things are very different now. Patients, fortunately, aren't dying to the same degree. The Disability, we have people coming off of Disability and going back to work. The crisis right now as I see it isn't in providing even case management or social services like it was when this was first authorized. The crisis is in providing care, in providing health care.

So your group recently said this, "Every

American who needs HIV treatment and care should have access to it." Couldn't agree with you more. People who are HIV positive need essential medications. Absolutely true. Without the drugs providing care is difficult to impossible. True. True. True. But is that enough?

The policy implications or the provision of antiretroviral care and other essential medications means that we should be funding ADAP to a fuller extent. I've lived in a state that since the beginning had a waiting list, had a waiting list for medicines, an embarrassment to our state. But you know what? There hasn't been a single patient who has gone without medicines out of my clinic ever, not once. Not one time. Why? Because our Social Service work their tails off to apply for compassionate use programs when people don't have medicines and the pharmaceutical companies, fortunately, would provide those medicines on appeal. So there was a stop gap. Where is the stop gap for care if there is no physician, if there is no clinic?

The reality check. In our clinic, that's

why I showed you data from our clinic, so I could keep it simple. Our operating budget is $2.1 million a year for about 1,400 active patients. Third party payment, and this is generous, is $250,000 a year for care and another $250,000 a year for infusion therapy for those who are getting chemo and other things. Our Title III funding is $508,000 a year. That's been the same for the last seven years despite a 60 percent increase in our clinic patient load and last February I was told we were getting a five percent cut despite funding for seven years, despite clear documentation of increase in burden. Now that cut was changed to 2.5 percent cut in March or April, but it's still a cut.

It's hard to swallow that. It's hard to tell my providers, those social workers and other who are working their tails off every day, that I can't hire another person. I don't have another FTE to absorb the volume and what they're dealing with now as a side bar is a tragedy with Medicare Part D. Why? All the patients in our state who are Medicaid/Medicare co-insured in December got their

medicine through Medicaid. January 1, they got their medicines through Medicare Part D.

Here is what happens. Let's say they have eight prescriptions. They go to the pharmacy. They've enrolled in Medicare Part D. The pharmacy tells them, well, we can fill these five but three of these require prior authorization. They take their prescriptions back to us. We get on the phone. First, we have to figure out what plan they're in. It could be one of 14. Then they call the 1-800 number, get put on hold for 15 minutes and they're told, you dialed the wrong number. Call another one. Get put on hold another 15 minutes.

Then they say we're going to fax you a form. You fill out the form. Somebody has to. Fill out the form and that's a request for review. That form has to be signed by a physician. So the nurse has to go find the doctor and get him to sign that and fax it back in. They have 72 hours to respond. They send us another fax form which is actually the review. They have to go to the chart. They have to find out their insurance status. They have to find

out all this information, fill out another form, get the physician to sign it, send it back in. Seventy-two hours later, almost always it gets approved.

That process takes one of my health care providers 30 minutes to an hour per prescription per patient. I'm not exaggerating, and I have providers right now who are on the verge of quitting. If they quit, who do I replace them with? It is really devastating what's going on in our clinics right now and I see other doctors around the room who are listening to this nodding yes. So I'm not alone. This is what we're going through.

So the key points, mortality is higher when the patients are diagnosed late. I've told you that. The majority of people show up late. Many patients don't know it. Universal opt-out testing. But with more universal testing, I'm predicting, at least in my neck of the woods a 25 to 50 percent increase in patient volume. That's good that we're finding people who need care, hopefully earlier. But here is the question; who is going to take care of these folks? So with the new Ryan White

Reauthorization, we're getting rid of waiting lists and I"m afraid we're going to replace them with waiting lines. Where are people going to get care? Where is it going to come from? Who is going to do it?

We're about maxed out and I'll show you this quote. This is from this month, Laurie Dill. Trained at UAB, running something called Montgomery AIDS Outreach, a Title III recipient. Let's just read it together. Medical Director, this guy, her co-medical director, Larry Williams, resigned from MAO on 6/7. "I, Laurie, will be the acting medical director while we recruit and hire a new medical director. We are currently actively looking to fill positions, a full-time medical director and a part-time physician to see patients mainly in our rural satellite clinics. As you know, MAO is a Ryan White funded agency. We currently have myself and two practitioners to provide staff. We have three clinics in Montgomery and Dothan and hold once or twice a month clinics in six other satellite clinics. We follow 1,000 patients in a 23-county area in

south central Alabama. Please contact me for other information."

What's her chance of finding another doc or doc and a half? This is happening today and the thing that concerns me is that this is probably news to a lot of you and it's because a lot of us in the trenches are so consumed with day-to-day function we don't have time to come to D.C. and talk. But a lot of us have changed that, at least I have, in the last several months.

So the policy implications. Funding of ADAPs for sure, but we do need a dramatic increase in funding to increase clinical capacity. Title III in my opinion from what I've observed has been largely ignored in the reauthorization. ADAP has been front and center. Every single thing I see coming out of D.C., ADAP, ADAP. Great.

What does ADAP do? It provides medicines for patients. How? By paying for them. But nobody went without before. So the beneficiaries are predominantly the pharmaceutical industry and the patients. Yes, they both will benefit. I'm not

saying that's bad or evil, but I'm saying it can't just be ADAP. It has to be a more comprehensive look at care.

So we need to do this by increasing Title III funding and provide incentives for younger docs to go into practice. We need to do something loan repayment. The HIVMA which I'm on the board of directors has put forward a proposal just to simply put in this some loan repayment for doctors who commit to HIV care. I don't know where the young doctors are going to come from.

We need creative solutions to encourage more doctors in advance to choose the skills to treat HIV, tuition reimbursements, insure adequate reimbursements for care. As we expand our clinical capacity to treat HIV positive Americans, we must not forget quality. HIVMA called for the Care Act for a portion, this was actually cut, from the bicameral, bipartisan legislation so far.

Seventy-five percent of care as we said are on core medical services. Good. That's good. If it were up to me, I'd say 95 percent, but I'll

take 75 percent. That's good. We have to put care first and require that ADAP programs cover a minimum of the formula. Okay. I like that. But there are no provisions to promote qualified careers, no significant increase here and no training incentives.

So this is what you guys said. We've already gone over this, but I would change that. "Provision of medication" should be "provision of care" and without qualified HIV care clinics, the drugs mean nothing. Nothing. The drugs don't mean anything unless somebody is there to monitor them and those of you who practice HIV medicine know that it is the most difficult type of practice you can possibly deal with.

A cardiologist gets paid $80 roughly for interpreting an EKG. Most docs when they finish medical school can do that mostly and in fact, the computer does it for you most of the time. Right? $80. What do I get for interpreting a complex resistance profile? Nothing. What do I get for filling out prior authorizations for an hour? Nothing. What do I get for fielding phone calls from

distraught patients who are having side effects of the medicines? Nothing. What do I get if I charge a Level 4 visit and get audited and only document a Level 3? Arrested for fraud.

This is what we're up against. So I'll turn it over to you and maybe we can think together about what types of solutions we can have and I'm sorry to bring you such a troubling message, but this is what's happening and this is the truth.

MEMBER REZNIK: Thank you, Dr. Saag. We'll take questions, but I do want to since you quoted from our Presidential Advisory Council blue book which I happen to keep with me at all times, one of our recommendations actually was creative solutions must be found to encourage more doctors, PAs, advanced nurse practitioners to choose to develop the skills necessary to treat HIV and included in that recommendation was to issue reimbursement for health care workers who choose HIV care in medically under-served areas, encouraging recognition of HIV care as a medical specialty, provide incentives for more nurses, physician

assistants, nurse practitioners and physicians to be certified through their appropriate associations, ensure adequate reimbursement for HIV care and promote programs to increase the diversity of health professionals trained in HIV care.

Now that may not have shown up in Reauthorization, but as long as I'm on the Council and I think I have a few months left we're going to definitely push that concept. I mean I think you make some great points, but I'm going to get off that little soapbox and see who has questions since I took over yesterday. Dr. Sweeney.

MEMBER SWEENEY: Thank you very much for that sobering message. I'm an internist practicing in Bedford Stuyvesant, Brooklyn and I work in a community health center and one of the strategies that some health centers are taking and I'm hoping to do in the future, all of the internists who work or are hired now have to agree to be trained to take care of HIV patients in one of our community health centers, so that eight people who are adult medicine docs, not just docs, they are mid levels as well, all

have to agree if they want to work in this particular center that I'm referring to to be trained in HIV.

Now that is a public institution in the truest sense. We have to take all comers regardless of their ability to pay and it's one of the ways that we integrate primary care and specialty care of HIV not only so that we have greater person power, but so that there is not the discrimination of having an HIV clinic and so if you go to that side of the room, somebody knows of the building, somebody knows. I was just wondering what you would think of that as a model to try and have more primary care physicians trained to be HIV specialists as part of their primary training.

DR. SAAG: I like the idea of training people. My experience has been that if people don't want to be there they'll find ways to circumvent. So unless you're self-selecting for people who want to be there and do HIV care, there could be a problem in universalizing that as a policy because people who don't want to go someplace won't go. They'll find a way to -- They'll vote with their feet. So training

people who want to be there is good, but I think the other issue is incentivizing them. Right?

I'm sure your clinic is publicly funded in New York and Brooklyn and everywhere there is much more money typically than in some other parts of the country. So that's good. So I assume your clinic is not running in the red. Right? So at least, you can pay the folks who are there and that's good. I think training is good and that's a nice idea.

MEMBER SWEENEY: I just want to follow it with you talked about the difficulty in treating patients with HIV because of the complexity of medications. But you know in many other specialties, internists and primary care physicians do much of the work-up, diagnosis and beginning treatment and you refer to a specialist when it becomes too complicated or to give you a program to follow and then they are followed concurrently with a specialist and a primary care physician. Why can't that be a model for treating patients with HIV?

DR. SAAG: It works on one critical assumption that I'm not sure is true and that is that

the competency of the primary provider is such that they understand the nuances of HIV care. It's not a cookbook formula even for starting therapy. I had a referral from a primary doc who thought they were doing a great job three weeks ago who diagnosed somebody in Pell City, Alabama, sent them to me on Combivir, monotherapy alone.

So I mean harm can be done. You have to assure that whoever's doing it is well trained, not just trained. And so there's a lot of harm that can be done. It's like somebody trying to give chemotherapy when they're not an oncologist and you're right. When you have to incorporate more people, absolutely, but the training has to be there too.

MEMBER REZNIK: Alan Holmer.

MEMBER HOLMER: Thanks for the powerful presentation. What portion of your patients are eligible for Medicare and in searching for solutions, is this a conversation that if Mark McClellan, the head of the Center for Medicare and Medicaid Services, who is an M.D. and a spectacular

individual, if he were here, are there solutions that we might be able to talk through with him? But first, what portion of your patients are eligible for Medicare?

DR. SAAG: Probably less than 20 percent and the reason is they have to be disabled for two years, etc. And even in our state, Medicaid is ridiculously hard to get. You have to be disabled earning less than $510 a month. And so most people who have worked and they get their disability check, it's over that $510. So the only person who are really going on Medicaid are people who are poor and have never worked or not worked much. It's hard in Alabama, but that Medicare/Medicaid is only a small portion. The majority of our folks, either they have private insurance or they are totally uninsured.

MEMBER HOLMER: Okay. And what portion would be totally uninsured would you guess?

DR. SAAG: About 30 to 40 percent and that's where the Ryan White CARE Act comes in.

MEMBER SWEENEY: Right.

MEMBER REZNIK: I do want to make a

suggestion and maybe, Dana, if we could get copies, enough copies of this available for the members because I would like you to look it over as possibly coming up with a motion this afternoon based on our recommendation that we had that we actually wrote last year. Next on the list is our Southern belle, Jackie Clements.

MEMBER CLEMENTS: Well, thank you, kind sir. Dr. Saag, I have more of a comment than a question. I worked with a Title III clinic that is experiencing just what you said. We have about 300 patients, two PAs that see them, one position we have had to replace three times in the last four years simply because it's a lot of work working with HIV patients and there are other places that they can go and get more of a reward other than that heart-felt thing.

The problem with it also is that it is very harmful to the patients to have to go through that many providers in so short a time. There is a connection that you make with your provider and they question the stability of the clinic. They question

how well their care is given and how much people care about them. So our consumers are really going through a hard time having to go through so many providers in such a short period of time

DR. SAAG: Has your patient volume increased over the last five years?

MEMBER CLEMENTS: Yes.

DR. SAAG: And has your funding from Ryan White increased?

MEMBER CLEMENTS: No.

MEMBER REZNIK: Dr. Redfield.

MEMBER REDFIELD: Mike, I want to thank you. I mean I think you brought a number of points to the table which I think unfortunately are more universal than people want to acknowledge and I think you're an extremely articulate spokesperson to bring to the forefront. Even in the State of Maryland which is regulated, our inpatient cost gets compensated by some mechanism I don't quite totally understand but I know that the hospital is not that upset about uninsured patients being hospitalized, although that obviously they're not really

enthusiastic about them being not hospitalized which I think is probably the wrong incentive.

I don't think any of us can make a clinical program function based on the revenues that we can generate. So this is complicated both for private practice but it's also complicated in the academic setting where you have clinical individuals that have to basically cover their salaries based on their clinical activity.

So I agree with your term. I don't like to overuse the word "crisis" but I think that there's been a lack of attention to health care delivery systems in general and there's clearly a lack of attention to how to stimulate and incentivize in effective way young people to go into AIDS medicine.

We've been trying to recruit African-American physicians now in our program proactively for about the last seven or eight years. We've been successful with several African physicians, one African-American physician. Next year, hopefully we'll have an outstanding young fellow who is African-American.

But as I've talked to many of the young physicians who wants to go into AIDS medicine when they have $100,000, $150,000 loan debt and they are looking at the fact that the only way I can pay them is if they can bring in the clinical revenue if they want to be a clinical person. The reality is like you, we have 40 percent uninsured rate. We have probably a 26 percent reimbursement rate and like you, we've had 40 percent increase in clinic visits last year and no increase in Ryan White funding, actually a cut and actually worse than that, a cut from the hospital from the ambulatory care support.

So I think you've hit something that's so universal. It may be less seen in some of the northern or high volume Ryan White or high financed Ryan White at this point, but it's going to be seen and I think it's something that needs to be really thought through. I think it's unreasonable to expect young physicians to go into a practice where they don't believe that they can be compensated to the point that they can pay back their loans and raise a family.

You and I went into it because we finished our fellowships. We were fellows. Everything else was full. It was a new thing. It was exciting. But I think you've hit it and I think when we get our nation, you and I may have disagreed about the advantage of early diagnosis before. I've always been an advocate of it because at least people would be denied the discrimination of unknowingly infecting someone who is special to them and getting optimal care based on diagnosis.

But clearly today, there's no doubt about it that diagnosis is key and we're about to see probably a 25 to 35 percent increase in people needing care. So I think much more aggressive creativity and it's not all the Federal Government. I think medical groups need to be accomplished.

We talked yesterday about Title III because I'm of a view, you know, I have 42 Ryan White grants in the state of Maryland and each one has to be reported monthly. So I'm writing two reports a day on average. I'm not sure that's the best utilization of our people to be writing monthly Ryan

White reports for 42 different grants. We unfortunately don't have a Title III grant which I think is the most comprehensive way to provide care and treatment.

So I think there's going to be both an increased need for support probably from multiple systems including the Federal Government but incentivizing young people to go into AIDS medicine in particular and for incentivizing young people in the south to go into AIDS medicine which is even another area that's even more complicated.

I think it's critical and I just want to thank you. I've read what you've written and obviously published. I read your letter and your memorandum. I think it's well thought through, it's fundamental and I think actually does require much more insightful urgent action. I think getting someone who is knowledgeable about health care economics in our nation to really sit down and think about this like McClellan and others, this is a serious issue and most of us are patching together care right now and I think patches are going to

break. I mean people can only work so long and not be compensated for what they do.

DR. SAAG: Sorry to interrupt, but there is one thing that I've thought about a lot and that is the sort of safety net that our country relies on to capture people when they fall into the cracks. The threads of that are made up solely of health care providers who give a damn. If they stop caring, there is no safety net.

They're the ones, they're social workers, our docs. When a patient comes back and says, "I have this prescription that was denied because I need prior authorization," if we just said, "Sorry," that's it. The system assumes that health care providers give a damn and if they stop giving a damn, God help us.

MEMBER REZNIK: Dr. Saag, before I take another question, you did an interview with NPR recently and you were asked a question about burnout. When I listened to it, you paused and I told Mike this on the way over here during that pause I came up with ten different possible ways that I would answer

the question. Because one of the issues that we're facing is that a lot of providers have been doing this for years. You've wanted the epidemic change and always wanted to know what was behind your pause and what do you think about our existing providers who have all of these forms to fill out who aren't getting reimbursed who now have to learn basically molecular virology in order to figure out proper treatments for patients? How do you think that impact is --

DR. SAAG: Real quickly, I mean for those of you -- Michelle Norris has invited me to the NPR studios just down the street and it was a really nice interview and she surprised me with the question actually. She said -- Oh, I was talking about provider burnout. I was referring to a lot of the health care providers in our clinic who I'm worried are going to leave and I can't replace and she turned a question on me and she said, "Well, are you burning out?" And I went "Whoa."

Then I thought to myself "Am I?" And I really did have to think and the answer is no. But

the fact that I had to stop and think says something, doesn't it? And like you and I were talking, maybe we're just getting tired. I mean this is fatiguing to fight this fight every day. But no, I'm not burned out yet.

MEMBER REZNIK: Me neither. Next is Dr. Judson.

MEMBER JUDSON: I think the realities of this are just staggering and gripping. I don't want to drag on but I was in Colorado involved with the very first cases and at one point our public clinic within our public hospital system, Denver Health and Hospitals, had seen or consulted on 50 percent of the AIDS patients in the state up until about 1992 or `93. I think the remarkable thing is the quality of the people who were drawn into this struggle from the very beginning and that they have stayed this long.

You are appropriately pessimistic. I guess looking back it was a remarkable effort and every year, I would ask the people who directed, we had directing our clinic when I was Director of Public Health and head of Infectious Diseases there,

is there anybody who we have not been able to provide the best treatment that we know over the past year and whether there were waiting lists or whatever else the challenges, most of these physicians could look back and say no, one way or another we haven't turned anybody away. We haven't denied them treatment we thought was important.

But we're clearly at the end of that. Something is going to break. We're still getting interest in some fellows, but I agree with you. That's just - the economic model isn't there to allow it to continue. With Medicaid disproportionate share, we've been able to hold up a health and hospital system where 44 percent of our patients don't pay, $220 million a year of unsponsored care. We're still in the black. We have been since we became a state authority, remarkable achievement, but it's just there`s going to be an end to that at some point.

I think the other side of it though is that we're not the only ones who are beginning to potentially burnout or age out. I think the public

appropriately, the taxpaying public, is beginning to look at AIDS like everybody out there either does know or should know what they need to know to prevent HIV infection and should our whole moral effort be based on how do we marshal the resources to continue to try to treat our way out of this epidemic, if we're not able to begin to show, I think, get off of this 40,000 new cases a year or accepting that status quo and proceed towards eventual elimination which I believe we have the means to do, I think the public support for things like Ryan White is going to wane. It's going to even get worse.

Lots of times people are saying that one out of eight woman will be subject to breast cancer and we're spending $3 to $4 billion a year or so on breast cancer which isn't preventable at this point by known means and we're spending $20 billion a year total, approaching $20 billion for HIV/AIDS. So I think in a resource constrained society, that's going to balance out.

So it brings us back to the purpose of PACHA and I think for many of us to get back into

making absolutely certain that all of the incentives not to get HIV infection are out there and all the disincentives to get HIV infection are out there and to begin to try to get back on track to the reduction in incidents that we saw for a period of ten years where we went from 170,000 or 180,000 cases a year at the peak down to the 40,000 or so. We're just not going to make it with treatment under economic models, medical models, anything else.

DR. SAAG: One question that I think remains to be answered and Dr. Cohen can address this maybe in his remarks is how much does treatment lead to prevention of transmission and my guess is it's a pretty significant impact, but we need to prove that.

MEMBER JUDSON: I think it's a significant impact but the estimates are that 50 to 60 percent of new cases are still coming from the 25 percent who are undetected and probably highly as we know disproportionally from the relatively new, highly infectious cases in the concurrent partners. It isn't possible I think to continue to maintain multiple concurrent partners during undetected early

infection. That's the pipeline.

MEMBER REZNIK: Thank you, Dr. Judson. Dr. McIlhaney.

MEMBER McILHANEY: In the meantime, first I agree with you, Frank, about the exhaustion of the taxpayer, but in the meantime, it's obviously just going to cost money in one way or another to solve that personnel problem.

The average debt I think for physicians coming out of medical school ranges about $75,000. Some of you may know more specifically than I do, but I think that's about what the kids are coming out of school with now.

CO-CHAIR SULLIVAN: I think it's over $100,000.

MEMBER McILHANEY: Is it over $100,000 now?

MEMBER CLEMENTS: Yes.

MEMBER McILHANEY: Okay. I thought I might be a little bit behind and so you know as compassionate as the young people may be finishing up medical school the reality is that they have that

debt weighing down on them. There's a model that I'm familiar with and it has to do with Christian Missions. As I understand in Africa, way over 50 percent of medical care there is provided by Christian missionaries and yet the number of young physicians who are willing to go do that was decreasing because of this debt thing and a friend of mine started an organization that started raising funds to pay off the debt for these kids when they finished medical school so they would be free to go on over and start mission work.

It seems to me that might be a model to be considered that we could pay the debt for young people that are willing to go into HIV work, provide them their residency funds and then require that they do HIV care for five years or something like this. So it's just a thought.

I think you're right. There needs to be some real creative thinking about what to do because it is compassionate work to do what you're doing and I congratulate you and Bob Redfield and the rest of the people here that are doing that, Monica, but you

just have to face the reality that people aren't going to do if they just flat can't do it because of financial problems.

DR. SAAG: Exactly.

MEMBER REZNIK: Dr. Yogev.

MEMBER YOGEV: I think you have raised the right point, but I think even you are late to raise the point of the crisis. It was there. It is there and in Chicago, there are two institutes and we are affecting the quality of the patient's right today because I know in Chicago there are three hospitals now that have a program and if you're uninsured, that basically does not allow you to admit a patient. You have to send him to the county hospital which are overwhelmed and the quality of treatment which was really good there is down and that's where are physicians are living and they have the best salaries by the way. So we are in the midst of a crisis and it's going to get worse.

Part of the population that I'm aware of that I'm sure you are dealing with a little bit is the adolescent. This is the second fastest growing

in our population of new cases. I cannot admit into my hospital. I have a quota without saying it and what's interesting even in the Medicaid issue if you reach the age of 18, you get Medicaid. But after 18, you have to be AIDS. So everything which you did to prevent AIDS now caused them not to get Medicaid or Medicare.

So we are producing a population of uninsured. We have the disease, the beginning, the spreading, whatever and I think it's about time to move into really a national approach to it and we should consider for example -- are in the crisis to develop category special and to recommend to our government of a special entity that you can come and you can go out of special area in medicine that are in crisis that you need people, if you need them in the emergency room, there would be funding from the government to supplement this entity. If we decide the HIV, we need to recommend that HIV should be identified.

I was a little bit disagreeing with you with all due respect that training is enough in HIV.

There are multiple studies and I'm sure you are aware of them that show that if you have less than 10 or 15 patients the quality of care you give them is not as good as if you have more.

DR. SAAG: I didn't mean to imply otherwise. I agree with that completely.

MEMBER YOGEV: I know, but it came out that training will be sufficient in the model.

DR. SAAG: No.

MEMBER YOGEV: It will not be sufficient. It will be sufficient to train the physician when to get the patient to the specialist, but those specialists should be identified and one issue would be to develop a system nationwide. You know countries who do it nationally are suffering less if you look at United Kingdom. I'm familiar with a system in Israel. The government is paying for those patients and removing a lot of the burden. So obviously, we'll never get to the government to pay for everything, but to develop this criteria that an entity like HIV will become preferred in whatever government, state will be paying on top of what you

suggested.

DR. SAAG: I agree with you. I didn't mean to imply otherwise.

MEMBER YOGEV: I'm sure.

DR. SAAG: Sorry.

MEMBER REZNIK: Next would be Dr. Redfield.

MEMBER REDFIELD: Mike, I want to come back and try to be a little creative in how we put this together because the only way we run a financially solid program at Maryland right now unfortunately is it's driven by partnership on the Schedule A's for the hospitalization side which is really the wrong way to do this because as long as there are undiagnosed people who come in with an average CD4 cell count under 200 like as in Alabama which unfortunately the case in the State of Maryland also, we're still going to have people unfortunately find out their diagnosis largely probably a third of them by being acutely admitted to a hospital.

I've tried to create models at Maryland of this concept of cost avoidance and this is why I

want to go back to McClellan and his group because if you take a clinic of 1,000 people based on Mike's numbers and you just switch their diagnosis from less than 50 to the greater than 350 for a clinic just with 1,000 patients you just saved on paper $23 million. My clinic you would save 4,000 patients. We'd save $92 million.

Now we are all of a sudden putting some money into a system and the problem with some of our health care finance situations is to look forward how we have cost avoidance. In other words, if we're looking for the current system to finance this, it's just going to keep going the way it's going. Schedule As, hospitalizations, are going to be driving the ability with outpatient clinics to work.

But one has to get more critical in looking at this. Now I couple that with my own view that I said about Ryan White. How do you do Ryan White funding? I'd like to link incentivizing Ryan White funding to those states to get the average CD4 cell count at the time of initial diagnosis going up. Those states that can do it at 250 or 350 or 400 I

add I think they shouldn't be penalized for that. They should be incentivized for that.

So again, I think there is a critical need to figure because truthfully if it's just, I hate to say this, compassion or just try to get people involved, I don't think we're going to get the momentum to get the investment in the care system that we need. We need a sustained investment to build primary care for HIV infection, one, because we now know this is a process that if you do it right at the beginning, you could have a good shot at living a natural lifetime. If you do it wrong at the beginning, you have a good shot of not living a natural lifetime and yet we also know that we're at a climate now that we're going to move to earlier diagnosis. There are ways to begin to go higher CD4 cell counts, try to make the economic argument to someone that's thinking 10, 20, 30 years that the capital that is being used in this in the long term is actually we're saving long-term health care costs which are substantial for this nation.

So I think someone has to look at it

because we're not talking about a band-aid here. We're talking about changing the financial hydraulics of what drives our investment in ambulatory HIV care at a federal level.

MEMBER REZNIK: Dr. Sullivan.

CO-CHAIR SULLIVAN: First of all, thank you very much for coming and brining us this message this morning because it's very dramatic and I think the discussion has been very good. I don't disagree with any of the things that you say. But the question is how do we dig ourselves out of this hole that we're in. That's going to be difficult because you talk to other areas of specialty, well, David knows that there was some NPR series on the news I think a few days ago. Some of you may have heard about the shortage, the crisis, in our nation's emergency rooms. So I think we will see that going around.

As I see it, we really have a situation where our leadership is really asleep at the wheel, Congress and the Administration. This is very different from what the situation was in the early

`50s. Those of you like me who are old enough to remember there were reports of a pending shortage of health manpower and Congress got busy and passed a lot of legislation so that now today we have one in three medical schools in the country today had its origin in the second half of the 20th century. We're graduating twice as many physicians today as we were graduating in 1950, 16,000 every year as opposed to 8,000 every year.

Interestingly enough, we thought at one point that we had overshot the mark. You may remember the GMENAC Report in 1977 that said we had overshot the mark. Well, today, we really are approaching where we were in 1950. We've had a nursing shortage for several years that we really haven't been able to get serious attention and resources to address. We now have a pending physician shortage. The Association of American Medical Colleges I believe about four months ago put out a paper indicating or proposing that medical schools should increase their class sizes by 30 percent to avoid a shortage.

So I guess what I'm thinking is this. We certainly need to concentrate and bring to the public's attention all of these issues about AIDS, but I think this really should be joined with other issues. We're not going to solve this issue simply by focusing on AIDS when you see how emergency rooms are overwhelmed, hospitals are, etc. and we have this pending shortage of health manpower. It seems to me we need to find ways to join with other organizations like the AAMC, the AMA, the Dental Associations, etc., to really say loudly to the American people we have a problem that needs to be addressed because I can assure you many people are totally unaware of this. Now I think we clearly need to bring the attention of the American people to this situation in AIDS, but I think to really get the kinds of situations that we need this has to become a real national concern.

We have an election coming up in two years. Health care is going to be on that agenda. This is the time to really find a way to join forces with others to really try and address that because if

this gets to be a real issue for the American people anyone who wants to be elected is going to have to address that.

So my suggestion is we need to certainly focus the attention of this council on the AIDS issue of the crisis that you have outlined so dramatically. But I think we also need to find ways to get allies and to join so that those emergency rooms that are overwhelmed, the rural communities that don't have physicians to really see some attention to their needs. So that certainly is an issue I think this council needs to be concerned about.

How do we really focus attention on getting solutions when they are short-term solutions to some of the issues here? But I think that's patchwork. I think we need to find a way to really address this. We did it as a country back in the `50s. We really are not doing it today.

The papers, The New York Times, has front page headlines about we to solve our nursing problem are really taking nurses from undeveloped countries and robbing them of their manpower. So we need to a

much better job. I think we need to find a way to make this a more coherent strategy.

Sorry. One other thing, I think Joe and Frank also made good points. We spend too little of our resources on prevention because if we don't really change that paradigm we really are 30 or 40 years from now going to be having the same kind of discussion. So we do need to really find ways to improve the health literacy of our citizens, change their health behavior.

I thought we have a very interesting discussion yesterday. At least I learned something about how the different social patterns in places like India and maybe China that maybe the epidemic will be different there. So I think we need to find ways to really increase the effort on health literacy of our population and prevention as well because without that, I think we're going to be spinning wheels. They may be larger wheels, but we still will be spinning wheels some decades from now. So that's my comment.

MEMBER REZNIK: We have time for two more

questions. Dr. Bollinger has been very patient and then Chris Bates.

MEMBER BOLLINGER: With apologies to Dr. Sullivan because I think his point was extremely important about a comprehensive and long-term approach to solving this problem, I want to move back to a more short term. One of the patches if you will and I apologize for that because I don't want to distract from the importance of your message, yesterday we heard from Marty McGeein about the reauthorization process. Now I'm not as intimately familiar with the process. Others here are, but it sounded pretty pessimistic about the logistics of the process, the funding that's being talked about for that. I didn't hear a lot that would really address some of the issues, the really important issues that you raised today.

One of the issues that occurred to me was actually brought up a few minutes ago by Bob Redfield and I wanted to ask a question and maybe some recommendations from you, Mike, about this. What he was talking about was incentivizing the process in a

way that rewards programs that save money and one of the ways to save money that you've outlined is to diagnose earlier, is to get people into care and good care earlier with a higher CD4 count and right the system does not. In fact, it sounds like there's a disincentive to that.

In my experience at Hopkins in Baltimore and I want to get back to that question. There are two steps to it. One is testing people and we've talked about the universal testing. The second is accessing the care. I want to talk about that second piece or ask you about that second piece because there are quite a few patients I've seen in Baltimore who I know have been diagnosed before they came to see me the first time. They have complicated lives. They're active drug users. They were tested in pregnancy four years ago and never accessed care when they could have benefitted.

So I think there are sort of two steps to this. We could provide universal testing, but what suggestions do you have about improving the access to care or linking care to those earlier access points

where we can actually get people into care at a more economically beneficial time?

DR. SAAG: Well, I don't know that I have a solution and since the time's running out, I'll just be very brief. I think that whatever testing is done has to be linked to care provision and that could be done out of physician offices with good referral connections to clinics or it can be done at the clinics themselves which are a little more difficult, although we've had a lot of success with rapid testing in our clinic itself and it's amazing how well that works and almost everyone who tests positive goes right into care.

But out-of-physician practices I think is where it needs to happen. I think free-standing testing is an option, but linking that to care is more difficult. So as a short answer, I would say that would be an approach.

MEMBER REZNIK: Thank you and Chris.

MR. BATES: Christopher Bates, office of AIDS Policy. Hi Mike.

DR. SAAG: Hi Chris.

MR. BATES: I'm really happy to see you here and to hear your comments this morning.

DR. SAAG: Thank you.

MR. BATES: I just have two comments that I think compliment some of what you said today. I've served on two panels, both in Philadelphia and Washington, D.C. attempting to try to recruit physicians and PAs to do this work and it's a bit disconcerting to after lengthy conversations, in-depth conversations with folks who were highly qualified that underneath their feeling really was hidden issues of stigma around working in this population, homophobia.

There was at least one woman in Philadelphia who just expressed to us that she was not interested in working with gay men or men who had sex. She was not interested in working with drug addicts in that her expectation coming out of medical school was to be working with a different kind of population. I think we can sweep that under the rug. We can't ignore that. This is not the same epidemic that manifested itself say in African countries and

other places around the world. Our domestic epidemic is a real one based in populations that are highly disinfranchised and undesired and are general populations. So I don't want us to miss that as a contributing factor to the recruitment.

Furthermore, I would also offer up that as I've traveled around the country speaking on behalf of the Administration and the Department about our concerns and needs for HIV what continues to challenge me is the absence of a serious educational dialogue between legislators, both at the state level and the Federal level, outside of the AIDS epidemic center. The states such as New York and Florida, Texas and California, have very aggressive and very engaged delegations both at the state and the Federal level who are participating in dialogues about policies and funding as it pertains to HIV. That is not the case and even in our 14 southern states right now, there are heavily impacted with new epidemics.

So we have some imbalances here that undermine clearly our capacity (1) to keep a focus what those challenges are on a very personal way on

the part of the legislatures. They don't understand what's even happening in their states. Many of them have not been to any of these provider offices or to clinics. They haven't seen this experience firsthand. So it doesn't mean the same and when talking heads and I don't mean to say that despairingly but when people from Washington, D.C. who are paid to lobby and paid to have these conversations professionally on the Hill I think it's not the same. It's not the same as seeing people from your district, people from your state, people who live down, who vote for you engage you in a conversation about the impact of this epidemic in a very personal, very natural way.

So I just wanted to offer those points up and then my last piece is it's not easy to identify people who don't want to come to terms with a potential HIV status. We have spent lots of time and money and hours training people to do outreach and going into very seedy and unsavory kinds of environments to connect with the most at-risk people if you will in our society and still with them

knowing often times that they have HIV. What's the incentive to come? They won't be able to get ADAP in some states. Some states they may wait up to nine months for their first medical appointment and even in other places, the opportunities in terms of choice of where to go and seek services so you have some anonymity, some sense of confidence around your HIV status not being exposed, it's just not available. So it's an either or. It is a highly complex environment we're in right now with lots of challenges on many levels of which funding is key but not central.

MEMBER REZNIK: Mike, if you would hang on one more second, Dr. Sweeney promised me she would have two sentences. I'm holding her to that.

MEMBER SWEENEY: Joe McIlhaney mentioned raising money to pay off loans for people who wanted to do certain kinds of work. One of the things I think we should do is just look at the National Health Service Corps and expand it. The model is already there and it works very successfully. Some of my prime, my greatest physicians, have come from

the National Health Service Corps. They meet their obligations and they stay on in the community health center if you make the environment right.

The other thing is there's another model that's used by the State Department called hardship pay. They pay special for doing special kinds of work in special kinds of environments. We can expand that. We can suggest that. We can't expand that. We can suggest it as a mechanism for getting people to do HIV care because as you've heard it described, it is special and hard.

And the other one is there is a shortage of physicians going forward, but there is also a great maldistribution and there is a model. I worked in Columbia, South America when I was doing an externship there. They have something that every physician who is going to get licensed to practice has to do time in what they call Rual. And so everyone, it's a privilege still in 2006 to be a physician. Pay for the privilege even if you're rich by doing some time working in populations that are health-power shortage areas. So there are lots of

models that we could look at to help while we're coming up with better solutions.

MEMBER REZNIK: Dr. Sweeney, if that was two sentences, they were too very long ones. But thank you. Dr. Saag, I want to thank you for taking the time out of your busy schedule to come and present to us.

(Applause.)

MEMBER REZNIK: For the members of the Council, please during your break or during lunchtime look at page 38 which is where we did have some recommendations on training medical professionals in quality assurance and hopefully we can come up with a motion today.

I'm running behind schedule so I have to introduce our next speaker who I think has to catch a plane. I'll do a brief introduction on Dr. Cohen who is the J. Herbert Bate Distinguished Professor of Medicine, Microbiology and Immunology and Public Health at the University of North Carolina at Chapel Hill. This has been a North Carolina few days.

You can see his bio which is pretty much

an incredible biography. He is the Director of the NIH STD Clinical Trials unit. He is Director of UNC Division of Infectious Disease and the UNC Center for Infectious Disease. Quite an incredible track record. Over 400 articles published. Much of Dr. Cohen's work has been conducted aboard especially in Malawi and the People's Republic of China. So if the members could come back to the table and the audience settle back down it's been a great honor to introduce Dr. Cohen.

(Discussion off the microphone.)

MEMBER REZNIK: Okay. Dr. Cohen is being gracious and is going to give us a five minute break. Did you all hear that in the back? You have five minutes.

(Whereupon, the foregoing matter went off the record at 10:18 a.m. and went back on the record at 10:29 a.m.)

MEMBER REZNIK: Okay. Good. That was a long five minute break. I've already introduced our next speaker. So without further adieu, we'll let him get his system in gear. Are you plugged in?

DR. COHEN: Maybe. Is this working now?

MEMBER REZNIK: There you go.

DR. COHEN: Okay. I think we're going to start. Is that correct? Let me indicate thank you for inviting me. I was in London yesterday. I've been living in London for awhile. So my jet lag is enormous. So we'll see how much disinhibition I have this morning. I got here. There was a thunderstorm. I got here like 2:00 a.m., slept for an hour, came over here and I've not quite an idea of how this is all going to turn out.

Let me say from listening and being in academics I was restrained for like an hour listening to Mike Saag and my colleague. Let me say that what we're going to talk about now is really prevention of HIV and I think one of the big issues without a doubt has been marrying prevention and treatment as several in this panel already said. It makes no sense to believe you can treat your way out of this problem without much more intensive prevention activities where we've not done a good job by any measure. We've not succeeded in prevention in the United

States and certainly not on a planetary level. So we have to hope for better strategies for the next 20 years.

Now I'm going to talk almost exclusively as a biologist, as a translational biologist. So I'm going to go slow and show slides and kind of explain where we think we are in terms of transmission understanding which leads us to prevention strategics. But let me say that there's not doubt in my mind in terms of physician recruitment and education and training that the person who goes into HIV medicine or the next generation has to be somebody who is interested in public health as well. The responsibility isn't just about knowing about the medications. The responsibility is understanding about the community and about the issues that surround HIV transmission.

And I think that if I was a fund raiser, there's no doubt. Why should somebody want to pay for HIV treatment instead of diabetes treatment as Dr. Sullivan kind of was alluding to? Well, the big issue here is this is a transmissible disease and the

more that the treatment and the activities that surround the treatments are wetted to prevention, the more it's totally different than all the other diseases on the plate of all the funders and I think it would be a tragedy not to end this dichotomy and make this an absolute commitment.

In the report that I participated in supported by the CDC, the IOM Report of 2000, *HIV Prevention in the United States: No Time to Waste*, there's a whole chapter devoted to prevention in the treatment setting and the obligation of the medical community to learn about preventions. So having said all that, this is really a prevention talk that I'm about to give.

I'm going to go faster with things that I think you've already talked about and the slow down when I think there are new ideas and there is no tradition of interrupting. Is that correct? There's a hesitation to interrupt, but I would prefer actually for this kind of a talk to be interrupted and Frank I know will be glad to interrupt. But I prefer to be interrupted because why go on if there's

something that makes no sense or that is so argument evoking and so controversial, why go forward? Why not just have the controversy right then?

So basically, this is the bottom line. This is a biological event. HIV, you don't get a little HIV or a lot of HIV. As far as we know, there is the transmission event and the transmission event is dependent on infectiousness and susceptibility. And we're really certain that the concentration of virus in the genital secretions or in the blood, but especially the genital secretions, are going to explain most transmission events and this is not rocket science. Most infectious disease depend on the inoculum. So we're very concerned about inoculum.

We're also concerned about viral phenotypic factors because we're reasonably certain that the type of HIV we have in the United States, clade B or Type B is not as contagious as some of the clades in other parts of the world. So while we see people living in other parts kind of mislabeled as misanthropic sexual people, a lot of this epidemic

has to do with biological disadvantage and we see that biological disadvantage at some level in terms of inoculum and phenotypic factors.

We see it played out even more aggressively in susceptibility. We know that about one out of 100 white people have a hereditary resistance factor to HIV. Resistance is very rare with people with color. We know that there is innate resistance in some white people and we know that there might be some people with acquired immune resistance which would help us to make vaccines. We'll get to that later.

So infectious and susceptibility equal a transmission event and if you're lucky, you don't have to a transmission event and if you're unlucky, you have a transmission event. Our job is of course to prevent this transmission event.

So this is kind of a starting point. Now I'm going to criticize this article heavily because it's just wrong and this is an article I wrote in `97. So as I attack the author, I want full -- If I'm attaching my friend, Ward Cates, it's because he

and I wrote this together.

We knew really with great certainly the transmission probability from mom to a baby and we knew the transmission probability from needle stick to the next person and we knew that because we have the mom and we have the baby and we knew that because we have the needle or the unit of blood and we have the subject who was exposed. So these numbers could be decided on with great accuracy and have been tremendously validated over the years.

But these sexual transmission numbers are an incredible mess and I won't tell you how we got into this mess, but that mess has helped give a bad message to people. That message that we've sent to people is that it takes thousands of episodes of intercourse for HIV to be transmitted and that really is not true basically. These numbers, and if there is time for the discussion, I can explain how we made such a mess out of this, but the methods we used confused the message and we used a set of methods in the late `80s, early 90s, that it made an incredible mess out of our understanding of HIV transmission.

Now how do I know this is such a mess? Well, look at my colleague, Audrey Pettifor, working in South Africa. She's doing a national survey in South Africa of boys and girls, males and females, and she sees a low prevalence in young people just as they are becoming sexually active. This right off the bat gets us into this whole needle stick argument and almost gets us away from it the idea that the whole HIV epidemic is being construed on the back of needle sticks just doesn't hold water.

So let's forget about that and let's say these people are now becoming sexually active and you see the young boys have a low prevalence sustained over a fairly long period of time, but these girls acquire HIV at an incredible rate. About one-third of the girls in South Africa by the time they reach 21 are HIV infected.

Now I would submit to you if that was going on in the United States, everything would stop in the United States. Somehow people are tolerating this or at least living through it in South Africa, but the bottom line is when you ask these girls how

many partners they have, are they having anal intercourse, how old are their partners, you don't find data different than the United States. We've done similar studies called Add Health in the United States and the data is not different in South Africa. So some different kind of events are going on in South Africa. We would argue that they are mostly biological than behavioral and that the transmission probably is not 3,000 episodes of intercourse. It's more like 20 or 30 episodes of intercourse. So the first shocking message is that HIV is not so inefficient.

And we know that most people on the planet have sex about eight to ten times a month until they started getting older. I'm not going to go into that too much. But if you look at the young people here 15 to 24 studies have been done in China, Chicago, France, England and there's all these books, most by a guy named Laumann called Sex in France and Sex in England and Sex in China and when you do very careful surveys you find out that people have sex about eight times, ten times a month. It's very

difficult then to get to 3,000 episodes of intercourse for most of us in this room, maybe even in a lifetime let alone in enough time to have a transmission event.

Then you see as you get older, we start lumping the numbers because sexual intercourse really gets reduced and I don't want to get too personal about this. But the number could get below the line. Actually if you extend this out because you're telling people not be sexually active. So it gets lower and lower and lower. But the point is that we don't think that the transmission probability is published throughout the `80s and early `90 are correct and we think some other better explanation is necessary.

And that leads us to the idea of amplified transmission. If the rates are too low, we think HIV transmission is intermittently amplified by increased general tract setting of HIV and an amplified transmission will help us to understand the epidemic and maybe allow us to redistribute some of our resources for prevention a little bit better.

So these are the ideas about amplified transmission. There are different sets of ideas. For infectiousness, we are very concerned about the stage of the disease, co-infections that might drive up the blood and general tract viral burden. STDs are a huge factor, classical STDs are a huge factor in the transmission probabilities and then genetic factors that might lead somebody to have a higher viral burden and remain more contagious over a longer period of time and I'll show you some data about that.

Susceptibility would depend on STDs, vaginal flora, mystical innate immunity and again genetic factor that we think we've only scratch the surface on. Only one or two genetic factors are understood in terms of susceptibility. Go on.

MEMBER BOLLINGER: Would circumcision go on the list?

DR. COHEN: Yes, circumcision would be on a prevention list.

MEMBER BOLLINGER: That's not a susceptibility factor?

DR. COHEN: It will come later. Thank you. So circumcision could be a susceptibility factor, but it will come up in our discussion of prevention. And so we think probably this slide is correct that the concentration of HIV in ejaculate will predict the probability of transmission depending on the number of endocervical receptors. We're able to measure all three things. We can collect ejaculate from people who are HIV infected and we can measure how much HIV there is. We can actually do biopsies of the endocervix and see how CCR5 receptors there and how many CD4 receptors there are and so on and so forth and we can calculate these curves and you see that the HIV transmission probability at an HIV copy number less than 1,000 copies per mil of semen is probably very close to zero, whereas the HIV transmission probability at about 100,000 copies in semen is probably about one in 300.

And when you get up to 1,000,000 copies of HIV in the semen or the female genital secretions, you're probably getting much closer to a transmission

probability of about one in 30. So if you have like numbers of chambers of guns to your head, if you use that metaphor, you can see it's not 1,000 chambers. It's not this message and I was kind of totally shocked to see the Minister of South Africa and I'm sure all of you in this room are familiar with this story having sex with so many newly infected and then quoting an article from the `90s saying he quote Nancy Padian's article which we think is wrong and said, "I read this article. It says that you need 1,000 episodes to get HIV infected. Therefore this was a low risk event for me." So that was the most misanthropic message I've ever heard sent. We think that this slide is correct.

We also think this is correct within reason and I'm going to come back to this slide a couple of times. So we think that someone's HIV negative here, they acquire HIV, they have ramp-up viremia and in this early window of viremia, they would be very contagious because of the very high general tract viral burden, maybe only 30 episodes of intercourse are necessary and then some people will

get very low copy numbers and those people might transmit at very low level. But then we suspect that as HIV infection advances people don't become so sick that they're not sexually active. They remain sexually active even unto being admitted to the emergency room with a low CD4 count. They might have been sexually active that day. So some percentage of patients with AIDS or people with AIDS will also transmit disease.

And we only have one piece of data about this but it's a very compelling piece of data. From the Rekai study (PH), there were 14,000 people who weren't really couples. They were assembled as couples later. So all 14,000 people were in a closed community and what they found was that in this Rekai study as they measured the transmission events that occurred in this closed population that 43 percent of the transmission events occurred at the earliest point in time that they could measure. So that meant that there were two negative people enrolled in the study and by the next time they measured both people were positive.

So obviously a third person got into that relationship. The two negatives both became positive and what we expect happened or suspect happened was that one person got acute HIV and they immediately transmitted it to their next partner allowing this event here.

Then in the Rekai study, almost no transmission events occurred in people with established HIV infection until people became much sicker and were very close to death. They remained sexually active and then about 16 to 20 percent of transmission occurred at the end of this window of time.

Now I just want to remind you that most of our HIV prevention efforts are focused on the middle of this curve, on people with established infection with fairly low CD4. We've had no, very little HIV prevention efforts in people with AIDS and I think the HHS has done a good job in trying to launch much more aggressive interventions here and we've certainly not done anything with acute infection for a whole bunch of reasons. So this is

kind of where we are and this is a very compelling study.

Can you all understand me at this rate of speed? Okay. Then I'm going to talk faster. So one issue here is about acute HIV infection. Now it's not to say even if it's true that almost half of all the infections are accruing because of acute HIV infection. It's not to say that we believe that suddenly this could become a giant public health maneuver. It is to say that it is something that we really need to understand in the next five, ten, fifteen years for a whole bunch of reasons that we might want to talk about later.

So we spend a lot of time trying to develop a way to diagnose acute HIV infection. Historically, people look for symptomatic subjects who are at risk and about half the subjects at risk have some sorts of signs snd symptoms when they acquire HIV infection. But the signs and symptoms are so vague you couldn't possibly separate them out. In an epidemic with 60 million people, less then 1,000 people with acute HIV infection have been found

by diagnosis which is kind of amazing.

MEMBER McILHANEY: Excuse me. Did you say it's not true to say that half of new infections occur in this early stage?

DR. COHEN: I think it's true to say -- No. I think if we go back to this slide we have one piece of data and that one piece of data is right here and it says that 43 percent, in this study, of all the HIV infections that were observed seemed to have occurred from the earliest stages of infection.

MEMBER McILHANEY: But did you say that it's not true to say that about 50 percent occur in the early stage?

DR. COHEN: Well, I wouldn't generalize it because we only have this one piece of data.

MEMBER McILHANEY: Okay.

DR. COHEN: In other words, if you were going to say I have a single study that shows that this might be important this is the study.

MEMBER McILHANEY: Okay.

DR. COHEN: But if you were going to try and extrapolate that to the whole planet, it would be

a problem.

MEMBER McILHANEY: Okay. I just want to be sure.

DR. COHEN: And I think -- I know we kind of oversold this a little bit. It's my group that's been doing this work and I think we've oversold it a little bit and I'm trying to be a little bit sensitive.

MEMBER McILHANEY: Yes. I understand what you're saying now. I just wanted to be sure.

DR. COHEN: No. Thank you. Other question before I go on? So the symptomatic idea is never going to work. So we tried another strategy and we intend to continue to pursue the strategy in the next couple of years. So here is the HIV negative person and this is actual data of people being followed in a blood bank. Sometimes people have what's called blip (PH) viremia. They may or may not go on to HIV. So this is very intriguing. We have about 12 people with this blip viremia and whether they all go onto HIV or not is not known.

But most people clearly when they get

exposed, then within two or three days after exposure they have ramp-up viremia and for reasons we don't understand completely there is tremendous and rapid replication and people achieve a peak of a million to a billion copies of HIV and as they're achieving that peak, they're antibody negative. So if you went to a clinical and said test me today, you would be at your most contagious of your whole life, but you would be antibody negative.

Now of course the antibody test can get better and better and better. But they can only get so good because the host requires several weeks to make antibodies. That's the rule of our species. So matter how good the antibody test gets. there's always going to be this window period of high contagion in an antibody negative person.

I should point out to you that it's during this window of time of rapid viral replication that the host is undergoing a terrible destruction and that is we're pretty sure now that CD4 memory cells, the central memory cells, living in the gut are all wiped out within two or three weeks. We have

this experience now kind of written in stone with monkeys where if you take a monkey and you infect him with HIV and you follow their gut lymphocytes in what's called the central memory pool, it's destroyed in weeks and now biopsies have been done a humans with very early and acute infection by again Danny Douek showing the same thing. This is terrible irreversible damage. So whatever CD4 you end up with after you recover from your acute infection, you never have the same number of CD4 cells available to you as before this gut pool is wiped out.

This inspires in us a desire to really think hard about trying to prevent this event. So if you're going to say to me how are you ever going to find all these people and why would you want to find them, one reason we want to find them is to protect these CD4 cells because this is the No. 1 devastating event that occurs during this window of time.

The other devastating event that we're pretty sure about is the integration of HIV into the genetic material of the host. So when you start out, your genome actually has a lot of retrovirus from

millions and millions of years of evolution. About six percent of the whole gene is retroviruses. But you don't have HIV incorporated in your genome and so in the very earliest days of HIV infection we can see a very small number of integrated events, but then after acute infection has transpired, we see a heavy dose of integrated events. The reason we can't cure HIV infection is because of the integrated DNA. So if we could deal with the integrated DNA, get it all out of integration or prevent it from ever being integrated, we could potentially cure this infection. So we have a lot of reasons to be interested in acute HIV infection, surveillance for instance, prevention and earlier treatment and so on and so forth.

Now I've argued that we can see a huge coy number and no antibody. So it's not a big leap of faith to do what the blood bankers do. So let's go back to `87 and almost everybody in this room was working in this field in `87. And you'll remember in `87 and Dr. Sullivan will remember this perfectly the transfusion field was in terrible trouble and we were

able to do antibodies to find contaminated units of blood but about eight or ten or 20 units of blood would slip the antibody testing and as soon as the PCR test was available for detection of HIV, every unit of blood in the country was submitted to a PCR test.

Now it's estimated by my friends in modeling that it costs about $80 million to find the last eight infected units of blood in the United States, but that had to be done in order to get people to feel that the blood supply was safe. That was really not an option.

With the blood supply people did was they did pooling and they took 100 samples and they put them all together and if everything was negative in 100 samples, they went on with their business. If one sample was positive in 100 samples, they would go back and break apart the whole blood and find the one infected person. This saves a lot of money since you're not paying $50 a test. You're doing $50 for 100 tests. And remember because of this ramp-up viremia, there's a lot of virus in the blood of

people with acute infection.

So the State of North Carolina led by Peter Leone who talked to you yesterday, he's the Medical Director for the state, they agreed to screen everyone in the State of North Carolina for acute infection. So we're going to look at all of our testing sites. We're going to find 563 people with new HIV infection detected by antibody. Those are over here and then we take all the negative samples. They go to a robot in Raleigh, North Carolina and the robot every day does 1,000 samples and when we do that we find 23 acute infections which seems like a small number, but that's five percent of all the infections detected in the State of North Carolina. For every one of those people with acute infection, we start finding a cluster and Peter talked to you yesterday about social networks from clusters. Right? So you see how powerful this becomes because of clustering and snowballing. So the state committed to this and many other states are looking into this for obvious reasons.

The copy numbers are important. Here is

the copy number of control subjects with established infection. We're looking at blood, not semen, but you see in the United States it's about 29,000 copies at set point and the acute infection patients it's about 210,000 copies in acute infection and then this guy has more than a million copies. So the transmission probability of this group is about one in 800 or one in 1,000. The transmission probability of this group is about one in 100 to one in 80. So we see a huge difference in the United States of these transmission probabilities as calculated from the data we collected.

And for every person we find with acute infection, we find a terrible thing really. They don't have one partner. We find three or four or five partners. And there are three universes for the partner. The partner can have established infection and they could have given their established infection to the person with the acute infection or the partner can have acute infection or the partner can be HIV negative. Of course, the partner who is HIV negative becomes an unbelievable prevention

effort for us to prevent a transmission event from occurring and the partner with established infection or acute infection also becomes important to the overall prevention strategies for our state.

And what's important is where do we find these people. So here are the testing sites, STD clinics, HIV testing sites, prisons and jails and other. Most of the testing in most states goes on in STD clinics and remember this is bias because we have opted in testing. This is less than half than all the people who have come to STD clinics in our state. So we don't know what happened to the other half of the people. We only know what happened to this half.

But we know that we find established infection, recent infection and acute infection mostly in STD clinics and as I'm going to tell you in a second, this isn't surprising because we think HIV transmission is primarily -- Well, first of all, HIV is another STD. So it's the same behaviors that lead to STDs lead to HIV and second, we think that much of HIV transmission is actually a two step process. It involves a classical STD as well as HIV.

But what's important here and now -- Is anybody here representing the CDC officially? Many of us are on a committee. Many of us are on the same committee where we've talked about this. I can't say enough times how I can't believe we can't get the STD clinics in the United States to work to do testing for every subject who goes into an STD clinic because this would be the biggest no-brainer way to find a huge number of people who don't know their status and to find people with acute infection and we've been telling the CDC this for at least five years and, Frank, you might want to comment on this.

MEMBER JUDSON: We're already doing it.

DR. COHEN: You personally have been doing it.

MEMBER JUDSON: Yes.

DR. COHEN: You're trying to do opt-testing on very client who comes to your STD clinics. But you realize nationally that's not the norm. That's not the national norm.

MEMBER JUDSON: I think it's a lot better.

DR. COHEN: The more it's done the better it is. Anyhow, this is a soapbox. My only soapbox for this morning is that --

CO-CHAIR SULLIVAN: Why has this CDC not responded to that?

DR. COHEN: Do you want -- This is just by sheer option and others in the room are on committees with me that work with the CDC. I think that first of all there's kind of an internal turmoil for many years about the STD branch how independent is it or how much does it report to the HIV branch. The HIV branch's interest in STD waxes and wanes. The kind of belief of the importance of STD, sometimes they believe they're important. Sometimes they're not so interested. So the two groups don't really work seamlessly in my opinion, STD and HIV groups. They should work more seamlessly. That's the first point.

The second point is the CDC gets like anything else it's an organization led by talented individuals who get on their kind of issue. So they've been very interested in emergency rooms in

the United States and I say, look. If you're going to test everybody in all the emergency rooms in the United States, you don't own the emergency rooms. It's a tremendous effort. But you own the, you don't own, but you support every public health STD clinic in the United States. So the energy necessary to do opt-out testing in the United States is very small, the catalytic energy compared to testing everybody in the emergency rooms.

But they've had this internal debate about emergency rooms versus STD clinics and this is just dragged on and on. I've gone to the CDC personally three times to give a talk like this to say test everybody in the United States.

Now to defend the CDC, they're trying to do opt-out testing. They're trying to get every STD clinic to lead towards opt-out testing. But I think a forceful statement from this committee would be helpful.

MEMBER JUDSON: Having started my career at the CDC and been involved with the CDC ever since, the problem isn't so much individuals at the CDC who

get into their own thing and want to protect their turf. I mean it is, but the primary problem is that Congressmen and Congress people like categorical programs. They like to have their name affixed to it. They want to see an outcome. They want to know where the money goes and that it's accountable.

So that some of the biggest attacks on the CDC have come when the CDC has attempted to use money for one project in another project area. So they drive it for TB, for respiratory distress syndrome, for anything.

DR. COHEN: Let me say I don't it's a turf. I don't think this is an issue of like some -- I think it's people's interest. If you're interested in herpes, you're interested in herpes. If you're interested in HIV, you're interested in HIV. Sometimes the people wouldn't necessarily see the connection as clearly we might want them to.

MEMBER JUDSON: It's like the silo thinking starts with Congress.

MEMBER McILHANEY: I'm on Dr. Gerberding's advisory committee and one thing you

pick up is that they feel like they obviously cannot mandate that all STD clinics in the United States do this because they don't control them like that and I think there's a little bit of paranoia about issuing proclamations that I think they're wrong about. I think they should do exactly what you're saying and I think sometimes they underestimate how much influence they'd have just saying all STD clinics should do this.

DR. COHEN: Right. Of course, they do -- First, I'm sensitive to what you said. But I do think they do issue proclamations all the time limited by money. They say if you don't meet this goal, we're not going to give you Title X money. That is their only control over the public health plus they provide public health advisors.

But also I don't think there's a tension here. The STD clinics would love leadership from the CDC. I can't imagine any STD clinic not being thrilled about being told if you do this is going to benefit the people of your community and your state.

MEMBER McILHANEY: I totally agree and

some of us keep pushing them to do what you're saying.

DR. COHEN: Okay.

CO-CHAIR SULLIVAN: Let me just say I think our Prevention Committee ought to look at this issue, because I do think that perhaps some support from this council might be helpful. I can understand CDC really battered from all side, etc. but it seems to me that one purpose that we could serve is to really point out to not only CDC but the members of Congress about the importance of this.

DR. COHEN: I can't see how you can -- If you tested all people who went to visits to STD clinics in the United States you would without doubt drastically increase the number of undetected people living in the United States.

MEMBER REZNIK: We'll come up with a motion at lunch. That's No. 3.

DR. COHEN: All right.

MEMBER REZNIK: I like fast. You talk fast. I write fast.

DR. COHEN: Let me keep going then. Do

STDs play a major role? There are tremendously compelling pieces of evidence that HSV-2 which is really an aggressive virus trying to fill up the entire planet. Right now, at least about 20 percent of Americans are HSV-2 infected. That number is almost certainly going to climb in the absence of some mystical intervention. So I think for many people HIV transmission looks like that HSV-2 is transmitted much more efficiently than HIV. Probably it just takes a few episodes, two or three episodes of intercourse for HSV-2 to be transmitted.

So an HSV-2 negative young person has their first encounter with an HSV-2 host. Now the HSV-2 infected host may not know they're HSV-2 infected. I"d say less than five percent of people have symptoms and signs that would lead to know their status. So they've unwittingly given HSV-2 to the partner. The HSV-2 causes endocervical and penile skin changes that render the host much more susceptible to infection. A really important abstract is going to be presented at the meeting in Toronto that were biopsies done on the women who had

recently acquired HSV-2 and demonstrating beautifully visibly how many more receptor cells there are and how many more receptor per cell.

So the first stage is HSV-2 transmission or maybe syphilis transmission or maybe gonorrhea transmission or maybe trichomonas transmission and then the next stage is HIV transmission not requiring 1,000 episodes of intercourse, now only requiring maybe not even 30 episodes of intercourse, maybe requiring only ten episodes of intercourse because of the tissue changes inspired by the classical STD.

So there is no doubt about this. What's gone wrong in the STD field is that the clinical trials the STD people have tried to do to demonstrate that intervening with STDs can prevent HIV transmission, those trials have failed miserably and that has caused tremendous policy consternation which is going to be played out at a WHO meeting on July 11, the big showdown between the policy people who don't want fund STDs as part of the HIV portfolio and the people who are saying that's insane. It's just that the trials didn't work out. It's not that STDs

aren't important. So this is kind of where we are with that issue right now and many of us are going to that policy showdown meeting.

So let's move to Africa just for fun because I want to show you something about transmission in Africa. I work a lot in Malawi. We've worked there since `90 and we worked there for a very specific reason. We wanted to see the effects of STDs on HIV transmission. If we're working in a U.S. clinic, we'd have to work for years to see a transmission event. But in Malawi, we're in a country of 10 million, 90 percent rural, about 15 percent adult prevalence but in the STD clinic we run, half the people are HIV infected. So one out of two people who come in are HIV infected.

Obviously, this is a human laboratory where we can learn things very quickly and we with the help of the U.S. Government and international funds built a research center called Tidziwe Center that we're extremely proud of. That's it in its construction.

And this is just a study that I want to

show you. It's published with about five other studies like this, but this is 1,361 men screened and 47 percent were antibody positive. So we take the antibody negative people and we say these are people who are going to be sent home. We say do you have acute HIV infection. What we found to our shock was about two percent of people have acute HIV infection which is a very high number. Bob Bollinger did the first study like this in India, very similar study and found more than one percent, greater than one percent. So Bob actually led the way. Let me give credit to you because it was a brilliant study using p24 I think.

So the point is this has been repeated over and over. If you go to STD clinics, you look at the negatives. You're going to find some acute infection and what's even more shocking is if you have a swollen gland and a general ulcer, exposure to sex and you're HIV negative you have about a ten percent chance of having acute HIV infection.

This is the viral burdens now in Africa. The antibody negative people have higher

concentrations than they would in the United States. Here's 150,000 copies at set point. So the Africans are managing to have much higher concentrations of the virus. Why? We don't know. But that increases the transmission probability. If you look at the acute infection patients, it's one million copies median. This is two billion and this is three billion of copies of HIV. So the median transmission probability in Malawi for the acute infection people is about one in 30 and this guy is 100 percent transmission probability.

So what am I saying? I'm getting you away from the `97 article that had one in 1,000 transmission and I'm saying that's not true. The transmission probability is going to be predicated by where you are in the disease and whether you have an STD and you shouldn't count on 1,000 episodes of intercourse before you acquire HIV. You should count on one episode of intercourse before you get HIV. It's a very different message than what we sent out in the published articles and not everybody agrees with this. So you're only hearing my opinion.

Here is an interesting unpublished piece of data. Now we're actually collecting semen in the clinic because we want to see what happens over time. The blood is in red and the yellow is semen and what happens is the blood is sustained, but the semen viral burden goes down precipitously after we treat the STD. So the maximum contagant for semen is only a few weeks. So this is a pretty interesting finding to us from a public health point of view in terms of how we're going to manage it.

MEMBER JUDSON: You're saying not everybody agrees with that. Who with an infectious disease background and who understands simple mathematics of transmission and inoculum would not agree with that?

DR. COHEN: Let's leave this. We have hours to go before we're done. Let me leave your question. We'll get to who might not agree with this and why people might not agree.

Okay. So now we come back to this slide and this is now we have to dissect this better. So I've kind of made my argument in the most aggressive

way I could make and now I'm going to break my argument apart and show you something a little different. I think it is true, this gets to Dr. McIlhaney's point, I think it is true that some substantial number of infections occur in the earliest days of infection. Whether it's ten percent, twenty percent or it's fifty percent, I don't know, but it's not a good time to be having unprotected intercourse with somebody.

And just because they told you I got tested last month, that ought to be a sign not to have sex with the person because why were they being tested last month? Obviously their risk behavior sent them to a clinic to be tested. So it's kind of interesting. Remember we had, I mean this goes back to the `80s and `90s, the whole idea that recent antibody testing sets the stage for a safe feeling. People were going to have a card to show you they were antibody tested, stamp it on their hand. Remember all this. Well, that actually to me would be a symptom that you really don't want to have sex with that person for obvious reasons because they

might have antibody negative acute HIV infection and be most likely to infect you.

Then we have this incredibly idealized vaccinated person or person who's called an elite controller who suppresses virus to few copies and no transmission events occur. This is not true. So this is what actually happens. Ramp-up viremia and then set point and only less than one percent of people who get HIV can do this. In fact, people spread their virus out over a whole spectrum of HIV concentrations. Now the person with the highest concentrations sustained at what's called set point. How you achieve set point we don't know. Is it genetic? Is it immunological? Is it virological?

All we know is at six months or nine months or a year into your infection, you've achieved some sort of state and if the state you achieve has a very high viral burden, then death is more rapid and transmission is more likely. But if you're lucky and you are lucky enough to have a very low concentration of virus in your blood, you're probably much less contagious and you certainly will live much longer.

Now there's a mathematician named Christophe Fraser, F-R-A-S-E-R, and he says that "the virus is seeking an optimal concentration" and what he means by that he thinks that the virus wants to spread to as many people as possible and the way that the virus can do that is to kill the fewest hosts possible. So what he says is that the virus is trying to achieve five logs in the blood of people. At five logs, the host lives many years and the host remains contagious enough to send the virus to the next person.

What's interesting about that five log deal is that the Africans generally sustain about five logs of virus. That is the most common set point, 4.9, 4.6. So Fraser obviously modeled this based on what he was seeing but it's an interesting kind of Darwinian evolutionary argument. So he doesn't believe that acute infection is important and he doesn't believe that AIDS is important. He certainly doesn't believe that most people get this low set point. He believes that all over the world where there's five logs, it's that five logs that's

really critical to sustaining this epidemic.

EXEC. DIRECTOR GROGAN: When you said the Africans are around five in contrast to what other?

DR. COHEN: U.S. are like 20,000.

EXEC. DIRECTOR GROGAN: And where in the U.S.?

DR. COHEN: About 18,000 to 20,000. So if you look at the U.S., I mean it depends on the person, but we've not -- If you took 1,000 U.S. people untreated in Bob's clinic in `90, most would not have 100,000 copies. Most would, I think, have 20 or 30.

MEMBER REDFIELD: When we looked at the Defense Department a number of years ago.

DR. COHEN: How many subjects?

MEMBER REDFIELD: It was a large number.

DR. COHEN: Thousands?

MEMBER REDFIELD: Yes, but it was the average viral load was between 9,000 and 10,000.

DR. COHEN: Untreated.

MEMBER REDFIELD: Untreated.

DR. COHEN: So if you took an untreated

African population, the average would probably be between 100,000 and 200,000 copies at the same CD4 count. I'm only telling you the facts, Joe. I'm not going to explain them.

MEMBER SWEENEY: So many people go in and out of treatment with antiretrovirals. Given what you've just shown us, if someone is not going to be able to be on sustained therapy then, it seems that they reach their set point and it would be better to just leave them at the set point without treating them instead of having --

DR. COHEN: Let's leave the treatment issue for a second except to say one thing. We're going to come to treatment in a second, but let me just say, and I appreciate you're still awake, but let me say that the whole issue of treating people earlier, treating them for public health purposes and starting and stopping therapy is very controversial. But certainly we know for sure that starting and stopping therapy based on a study that was just completed is probably a really terrible idea. We know that if you start therapy early, at least from

one or two studies, if we start therapy early and you can sustain the therapy and people are adherent, they do very well with very early therapy if it's sustained, but not if it's started and stopped, not if they leave it.

MEMBER YOGEV: I hope you put into the argument the guidelines now say don't treat if it's 100,000 unless -

DR. COHEN: I don't know. I mean guidelines --

MEMBER YOGEV: From the public point of view for to just showing us -- Would you address that?

DR. COHEN: Yes. I think the guidelines that we've written are we get into an issue Mike -- The MP chair is Mike Saag. He is the guideline guy and the guidelines in general on the treatment of people in general have not paid much attention to their public health obligations and responsibilities. When Tony Fauci got into a whole big interruption, vacation holidays, drug holidays, we called him and said, "Are you crazy? This is exactly the most

destructive thing you could do, render somebody feeling better, stop their drugs so they have a rebound," etc. So we had great trouble with what they called STI, strategic treatment interruption, which we called sexually transmitted infection. So even the language is a problem, but I mean complicated.

STDs, one last point about STDs, if you take a person with gonorrhea, this is from a study that was published in `97, you take a first week of infection. We're looking at semen. You see 150,000 copies in semen and over time you see a very rapid lessening of HIV concentration. So this is what we think is a more realistic picture. Ramp-up viremia, some control, but not that level of control. But then the person with HIV doesn't remain a newly found virgin. They go out and have sex and a substantial number of people who are HIV infected acquire STDs. We know from most studies in the United States it's probably about six percent a year, five percent a year.

So that is a sign that our counseling in

clinics is not optimal because so many people who are HIV infected acquire STDs and when you acquire an STD even on ART, you can break through the ART. So if you're not on ART, you are for sure going to increase your concentration of HIV in your genital secretions. If you are on ART, about ten percent of people break through the ART. When they break through the ART, they have resistant virus breaking through especially protease resistant virus.

So now we're beginning to see how we're going to blow our drugs. We're going to take all the drugs we've made and we're going to see transmission of resistant virus to the next person. Therefore, we're going to be in a constant race to make drugs that are going to be effective for newly infected people.

Now this is not completely played out yet. It's played out at the level of 16 percent, 15 percent. So if you went to Bob's clinic and we did single gene amplification, we would find at least 15 percent of his new patients have resistant virus. How did they get their resistant virus? Either they

were seeing a patient on therapy who got an STD and broke through or who stopped their therapy either transiently or completely and had resistance develop.

Somebody had a question or not? Yes. Isn't it more fun when you interrupt? Isn't this a lot more fun?

MEMBER GREEN: Putting this in the context of prevention, I'm thinking about the multi-site study in Africa that was published in the special issue of, what was it, anyway in 2001, *Journal of AIDS*, I think. When they looked for factors that seemed to be causally associated with higher or lower levels of HIV prevalence as you recall there were biological factors such as presence of GUD especially HSV too and male circumcision were the factors. The only behavioral factor that emerged in the first round of analysis was the pattern of older men having sex with younger girls and I remember thinking and discussing with people at the time one reason for that would be that a young girl when she's recently infected she's lost her virginity. She probably would be susceptible to

having sex with somebody. Older men are thinking if the girl is young, she's probably not infected, but they are more likely to end up with a young girl in the three week period of high viremia. So this pattern is pretty dangerous. Have you thought along those lines besides prevention?

DR. COHEN: Yes. We've thought a lot about it. So the first issue is the older men/younger women thing bears fruit in a variety of ways. The younger woman often has an exuberant cervix, so there's more surface area. The younger woman often has vaginal flora that offers less innate resistance to infection. There is a lot of biological beggars putting a young woman at a disadvantage.

But in addition, the chance of running into an infected person would increase if you did it with an older man and just as you've said. So in South Africa where we're pretty sure that it's not older men infecting younger women, it's not that grazing phenomenon, where it's much more complicated, but in Tanzania you might have an infected person who

believes it's an advantage to his own health to have sex with an uninfected virgin and the more years that man has been sexually active, the higher the probability he is infected. So you're increasing the kind of hits of a molecule just as you've said.

Okay. So this is one other way we've looked this and now I'm just going to end up a little bit on prevention just with a couple of things that I think probably are relevant to your committee. These are all the prevention strategies going on on this planet that I'm aware of and I would welcome Bob who is my kind of gadfly, I want you to look at this slide because you'll always some butterfly.

This ABC, STD interventions and there are still trials ongoing. The most powerful trials that are being done are the HSV-2 interruption trials, trials to try and prevent HSV-2 transmission or HSV-2 acquisition and I can tell you more about those trials if you want. Vaccine trials, there's a bunch ongoing, but I guess it's important -- Well, I'll say something about that in a second. Bacterial vaginosis, there are no trials ongoing.

Microbicides, there are many trials ongoing. A very important diaphragm is ongoing. The male circumcision trials, there are three ongoing. One was stopped. Antiviral therapy trials, there are several ongoing using antiretroviral transmission event. Incentive for safer sex, we're not really doing trials, but there's a lot of thought about how societies might approach this problem.

By way of disclosure, I should say that I'm chair of a Gates Committee which is actually going to have temerity. So this is interesting. So I'll just slow down for a second. Gates realizes as it's invested its money its distorted research. Because every time it decides to do something in research that thing becomes important even if the thing is not important and these decisions are made by single individuals. So one issue is what have been the effects of Gates on the whole research portfolio. Have they done a favor or have they actually damaged the research portfolio? I don't want to say it that harshly but it's an issue.

The second issue is truth in advertising.

What are we really going to do in the next 20 years and who has the courage to tell you the truth about what's really going to happen? And if it does happen, how important is it really going to be? For example, are we going to make a preventive vaccine in the next 20 years? Bob, is there any way on earth?

MEMBER REDFIELD: It's successfully -- distributed --

DR. COHEN: I mean even we don't have the capacity right now. Any vaccine that's being tested is not a vaccine to prevent HIV infection. It's a vaccine to lower set point. That's all we're trying to do right now. But no one wants to tell the public that. It's like kind of an anathema to tell the truth. So instead we just keep doing this stuff and pretend like we're not doing it.

Diaphragm trials. There is a diaphragm trial almost complete. If the diaphragms work to prevent HIV transmission, that's a huge finding with immediate impact because that's just a little piece of plastic over the endocervix. The circumcision trials, those will be done this year. So we're

trying to make a molecular clock. We're trying to say with the Gates Foundation how have you distorted research, what research is going to be done, when is it going to be done and what are the possibilities of the outcomes and how powerful could the outcomes be and I think that will be an interesting committee. That committee is just meeting this year.

Having said that we can't make an HIV vaccine that's preventive, I need to introduce you to an organization that you might not be familiar with that I'm one of the leaders of and that's called the CHAVI, the Center for HIV Vaccine Immunology. So recognizing, the NIH recognizing we weren't really making a preventive vaccine, they made a giant award, $300 million and the purpose of the $300 million for the CHAVI is to try to help us to enable development of a vaccine, to start over essentially and say what do we need to know to make a vaccine, why have we failed, where are we right now and why have we failed, not to make a vaccine, not to test a vaccine, but to do the science necessary to develop a vaccine properly.

So these are the kinds of things we need, subjects with acute infection for longitudinal studies, large numbers of transmission pairs, the infected person and the person who got the infection, HIV exposed and uninfected subjects. Who are HIV exposed and uninfected subjects? Do they really exist on this planet or is this another one of the big lies that we might be subjected to? What about genetics? We only have just tiny scratched the surface.

So the CHAVI has enough money to do the entire genome for very large numbers of people. So there is 30,000 snips in the human genome. We have enough money to do 30,000 snips of a very large number of exposed uninfected subjects and then there's studying mucosal samples in much greater understanding and depth than has been done before. So the CHAVI is worth knowing about, the NIH Center for HIV Vaccine Immunology. The leader is a guy named Bart Haynes. The principal investigator is Bart Haynes.

And lastly antiviral therapy to prevent

transmission. Bob Bollinger and I have been working on this and many of us in this room have worked on this for a very long time. We do know how to make antiviral drugs. This came up already and there are three ways you could use antiviral drugs to prevent transmission. You could do post exposure prophylaxis which we're going to do whether it works or not because we have guidelines. You could do pre exposure prophylaxis with a pill or pills and there are randomized trials ongoing right now to test whether a pill before sex can prevent HIV acquisition.

And lastly the most important question is when the person is HIV infected takes their pills are they rendered less contagious and if so, how long are they less contagious and can we develop drugs for this purpose much as we've tried to do in the tuberculosis field. Over the next 20 years, can we actually focus on not just treatment for the sake of improving the health of the host, but also treatment for the sake of public health.

In summary, we can measure the

concentration of drugs in general secretions and what's important about this is not all the drugs get in the same. So when you make a therapeutic decision, the therapeutic decision might be good for the host, but you might actually be giving the host a drug that actually renders them more likely to develop a resistant virus. So over the next few years, we expect physicians of drug companies to be more sensitive to this. This has to do with -- And Joe, you're giving me that confused look.

This has to do with compartmentization. Protease inhibitors don't get into semen or female genital secretions. They are too highly protein bound. So if you use a protease inhibitor alone you would be giving a subtherapeutic concentration to that compartment. So we always use combinations, but some of these drugs actually concentrate in the genital secretions. This is constant percent greater than blood in genital secretions, here the male genital tract.

There have been 14 studies looking at the effects of --

MEMBER REDFIELD: Could you just go back for one second because if I see that slide just to point out that the most common regime used in the world would then be d4T nevirapine and 3TC.

DR. COHEN: d4T very poor penetration.

MEMBER REDFIELD: Nevirapine.

DR. COHEN: Yeah, very poor penetration.

MEMBER REDFIELD: And 3TC.

DR. COHEN: Excellent.

MEMBER REDFIELD: So you would argue that if we were doing that that this could --

DR. COHEN: It's probably not the best public health. Right.

MEMBER REDFIELD: But this is the regime that's probably used around the world.

DR. COHEN: I understand but this is an unpublished slide. This is an article coming out in the Annuls of Internal Medicine. But again, I'm giving you where we are in research right now today. But your point is well taken and obviously prefer tenofovir, 3TC, FTC that they be used for all regimes for prevention, that they be included in all regimes

especially for post exposure prophylaxis in the emergency room. We're trying to get the CDC right now to go back to their guidelines and say the guidelines ought to focus on some drugs and they ought to focus on some drugs because of drugs that get into the genital secretions.

MEMBER REZNIK: I'd like to say we actually brought that up yesterday as a point when we had a person here from Gilead.

DR. COHEN: Good. Who was here from Gilead? Jim Rooney?

MEMBER REZNIK: Jim --

MEMBER YOGEV: Nevirapine you cannot say is not very poor.

DR. COHEN: No.

MEMBER YOGEV: It has a very good track record.

DR. COHEN: It's comparable in general secretions to blood. It's not poor. He said it. I didn't say it.

MEMBER YOGEV: Okay.

DR. COHEN: He's saying it has 70 percent

there.

MEMBER YOGEV: Yes, and I was wondering where you got your data on the efavirenz because there is some data to suggest that it's as good as nevirapine and it's fascinating. It's the only one which you have a three percent and that it's almost the same molecules. So I'm wondering where that for efavirenz is coming from.

DR. COHEN: You know I would have to break apart. There is a lot of data that goes into this slide. This is a summary slide. So I can send you the raw data. If you send me an email, I can send you the raw data.

MEMBER YOGEV: Please.

DR. COHEN: Angela Kashuba, K-A-S-H-U-B-A.

MEMBER YOGEV: Because efavirenz as you know now is one of the considerations to go into because of liver disease in multiple studies and it would be very important to have it.

DR. COHEN: Of course. I do understand that. Combivir and efavirenz is what we're using for

-- Actually you've raised a good point. So let me just show you. If you take semen and if you go before therapy and after therapy, before therapy you can easily detect HIV in semen. After therapy, you have trouble detecting HIV in semen. You can still detect HIV DNA in semen and as I've said, some of the drugs concentrate in semen and they can also concentrate in female genital secretions.

We're doing a study for seven years called HPTN 052 designed to determine whether if you treat the host you can reduce transmission of the infected partner. These are the study sites for HPTN 052 and the bottom line of HPTN 052 is that the anchor tenant in HPTN 052 is Combivir and efavirenz, sensitive to what you're saying. But the Combivir would be believed to achieve at least the concentration necessary to cause suppression and the efavirenz you need because you need a well-tolerated third drug. But that's the anchor tenant. Other drugs are possible. So we expect equipoise and evolution over the seven years of the study.

So I've said a lot of different stuff and

a lot of this is unpublished and this is exactly where we are right now and these are our belief systems. They are not like -- This is controversial. This is like what Frank was getting at earlier. If I took ten epidemiologists who did among the 26 studies of transmission we would argue about the methods and why they might be right or they still are right. They certainly are --

For example, let me give you the most common error and this is an amazing error. This kind of boggles my mind that most of the studies done for transmission were done with discordant couples. So a person would come to the clinic and they would say I'm infected and I have a partner. So we would say bring your partner. And if the partner was discordant, they would enroll in a trial and they would be followed for two or three years and then you'd measure whether transmission occurred over the two or three years and you would see no transmission events. You come up with the one in 1,000 or one in 2,000, one in 3,000.

But remember you never studied concordant

couples. You took away all the concordant couples that all transmitted instantly. So you were biasing this towards people who already were not going to get HIV and it's very comparable to this. If you were looking at pregnancy, if you looked a young 25-year-old woman who was going to get pregnant and she had sex twice, she'd get pregnant. You would say "Whoa. Look how fertile the species is. They get pregnant so quickly."

But if you looked at breast feeding woman with one child and then you went and studied her to see if she was going to get pregnant, it might take two years for her to pregnant. And you would say "Whoa, how does this species survive" because if you didn't know anything about the effects of breast feeding on hormones you would draw a totally different conclusion. So in the `80s when we were doing all these studies somehow we got incredibly misled. Enough.

So it's not somebody who's trying to do this wrong. It's just that's how it came out and these are other errors. There is a whole series of

errors.

So in summary and then I'll stop and entertain any real dialogue, genital tract viral burden determines HIV transmission. I think we can probably agree on that and there's not a lot of disagreement. STDs and HIVs are likely sequentially transmitted and large numbers of subjects with acute HIV infection will present with STDs especially ulcer disease. So I think we could probably agree on that, that STD are important, although I've already indicated to you it's been hard to demonstrate that you can treat your way out of the epidemic.

Recurrent risk behavior allows subjects with established HIV infection to be detected in STD treatment settings. What do I mean by that? Why do we find all of these people in STD clinics who are HIV infected? It's because the very behavior that allowed them to acquire HIV is just another sexual behavior that allows acquisition of STDs emphasizing the point I made earlier.

HIV transmission is almost certainly amplified early in disease and late in disease and

subjects early and late help to fuel the epidemic. How much they fuel the epidemic is the point you could argue about.

HIV prevention in my opinion will increasingly focus on the most contagious subjects and biological behavior and interventions will be developed to reduce HIV transmission probability. And those interventions I think have to be developed marrying treatment and prevention and getting back to the preceding talk, getting treatment much more involved in the public health of HIV. Because that is most people we see who want to go to training in HIV now have masters degrees in public health and are actually very interested not just in being HIV providers, but also in fully realizing public health opportunities and both domestically and internationally.

That's the last things I'll say. This is a globalization thing. We're so focused right not today on the U.S. and its 600,000 or 800,000 patients. But in fact, this is a global epidemic and I don't think you can separate the global from the

domestic and I understand my colleague from HHS earlier made the point that the epidemic in the U.S. is quite different. The patients are much more difficult to reach sometimes. But still it is a global epidemic. Yes.

MEMBER GREEN: I'm really interested in what you said earlier about the biological disadvantage that Africans may have. It's widely believed among my colleagues in AIDS prevention that Africans start to have sex at an earlier age than in the west and have more partners. So I was interested to hear you say something that I've long held. In my book of a couple years ago, I have a table comparing DHS data on two common measures, one, the proportion of youth 15 to 19 sexually active and secondly, life time members of partners and just as you said there's not that much difference between Africans and Americans.

The one difference that has emerged if you look a little more closely is a pattern in Africa maybe especially in Southern Africa of multiple concurrent partners rather than serious monogamous

partners and maybe that's something that you could do something about.

But getting back to this biological disadvantage --

DR. COHEN: May I -- Before you go on, so we have two pieces of data and we're trying to write this up now. We have Ad Health which is 22,000 U.S. adolescents followed for almost 14 years now and their HIV prevalence was just published last month by Martina Morris in the *American Journal of Public Health*, very low prevalence in the U.S. adolescents.

MEMBER GREEN: Right.

DR. COHEN: But we have an incredibly rich dataset from the U.S. Comparing that directly to the Audrey Pettifor dataset, national, cross sectional for South Africa, what I can tell you is it supports what you've already said. Unless the young women are lying in either country, they are very similar not very different and the age discrepancy is 2.5 years not ten years in South Africa. Rectal intercourse is zero unless they are lying which may be a big factor and concurrency doesn't appear to be

a major factor.

So you either have to say that they are lying or that there are things we don't understand. So those two datasets need to be compared.

MEMBER GREEN: Right. So the biological disadvantage, are you suggesting that some of it might be compromised immune system health from endemic tropical diseases?

DR. COHEN: So March 30, 2000 *New England Journal*, I wrote an editorial about this biological disadvantage. First of all, let me cite an actual editorial. It's an editorial about the biological disadvantages.

MEMBER GREEN: This summarizes what you think.

DR. COHEN: It summarizes some of my thinking five years ago, six years ago. But then I think it's more complicated now. I think that what am I really concerned about. First I'm really concerned about bacterial vaginosis for women. Mos Taha (PH), our collaborate at Hopkins, did a very good study that said that flora that most African

women are sustaining which is rich in anaerobes and poor in lactobacillae offers a threefold odds ratio of acquiring HIV relative to women who don't that flora and there are three studies like that. So this vaginal flora thing is probably a pretty big deal and we're trying to work on that more. There's at least ten studies about vaginal flora and HIV.

MEMBER GREEN: And that's not in your earlier material.

DR. COHEN: It is an earlier thing, but it needs to be better and better refined. I don't know. Bob may have feeling about this, but it was a very good study and it's not the only cite. So there's the vaginal flora issue. There's the clade issue that we talked about.

MEMBER GREEN: Right. You mentioned that.

DR. COHEN: And then there is the genetics.

MEMBER GREEN: Most of my colleagues don't believe in the importance of clades.

MEMBER REZNIK: I hate to interrupt this

conversation but we have time for one more combined question from that side and because we have people waiting for public comment. I hate to have to do this because it's engaging. So whoever is going to grab the mike.

MEMBER BOLLINGER: Mike, can I just ask you to say a little bit more about the relative impact? I mean you've talked about host factors and susceptibility factors and borrow factors and you did a great job. By the way, you do just as well as when you're jet lagged as when you're not jet lagged. I've heard him speak when he's jet lagged and not jet lagged and he sounds great both times.

DR. COHEN: I have a feeling I've said more wrong things per square meter. You have the voracity probably down to about ten percent.

MEMBER BOLLINGER: One of the things that you said --

PARTICIPANT: (Inaudible.)

DR. COHEN: That's what I'm thinking. What did I say?

MEMBER BOLLINGER: One of the really

important things that you talked about was the higher viral loads both in the acute and the chronic infection in the African studies compared to the U.S. and that gets to viral factors which I think is really behind a lot of your emphasis on the 052 study and the actual impact.

DR. COHEN: And CHAVI.

MEMBER BOLLINGER: And CHAVI on treatment and its impact on prevention. So I'm wondering if you could talk a little bit about your thoughts about the relative impact of host susceptibility factors and borrow factors.

DR. COHEN: I think that the CHAVI got $300 million to sort that out. No one and in my opinion it is not known. Most of the stuff done in virology has not been done with single gene amplification. Everything in virology is moving very fast now in a very different way. The genetics, we've not even touched the surface of the genetics. We've done kind of few snips here and there on some HLA. That's not the way to approach the problem. We're going on the world's biggest fishing expedition

and the geneticists they are going to find fish.

MEMBER BOLLINGER: What is the implications on whether treatment of virus --

DR. COHEN: I understand, but I don't know the answer. I'm telling the truth, my first truth.

MEMBER YOGEV: You know it's interesting because the genetic, 60 percent of outpatient is genetic from African and I wonder if we're ever going to look into the new activation of those patients. You know there are studies from Helman for example.

DR. COHEN: Yes. The --

MEMBER YOGEV: TB. Malaria. You have too many people in Africa who (Inaudible.) activated to receive the virus which do we have any data on teenagers and so forth in the U.S.?

DR. COHEN: The Israeli colleague, Veben Benvich (PH), he has a paper that embraces the Helman hypothesis. There have been five studies since including one we did. I don't think the Helman hypothesis is going to bear fruit. The malaria hypothesis bears a lot more fruit. That's already

kind of written in stone and TB probably bears fruit as well. But you said it exactly right. I think Dr. Reznik's going to -- Let me answer Frank's question and then I'll stop or I'll stop.

MEMBER REZNIK: Dr. Redfield and then we'll have to end.

DR. COHEN: You're okay.

MEMBER REZNIK: Short, Dr. Judson.

DR. COHEN: I'll be brief too. I can be brief.

MEMBER JUDSON: Mike, these are always great and I certainly always I think recently agreed with your view of the biologic-viralogic world. And I think where we may disagree although probably not is what you do with this information from a practical standpoint in terms of public health control programs.

One thing I'm sure we'll agree with is as Thomas Perron said many, many years ago "When you're faced with a diabolic enemy, you use every weapon at your control" and wherever there's a reasonable possibility for efficacy we should pursue that.

The next thing that comes to mind in my varying experiences is that in looking at epidemiologic information that would attempt to show causation between co-infections with other STDs and HIV transmissibility, in my view none of these studies has ever been constructed in a way that can prove causation. You don't know even what the order of infection is and in most of them, the majority of the easiest ones to do has been cross sectional and you simply cannot do it. So that accounts for the huge variability and results from study to study, location to location, organism to organism.

Then I take that information and I try to say what do we do with that. The people who believe that other STDs, there are some who believe that HIV doesn't need any help from the other STDs and I probably fall closer to that. But I'm not willing to -- I'm not attempting to exclude in any role at all for them.

But I think the question then is what you do with it and I don't think that as I think most here don't think that it's really possible,

practical, economically feasible to treat our way out of the HIV epidemic. That means either directly or indirectly. I don't think we can do it directly with antivirals without changing fundamentally exposure behavior and I would be even less certain that we could ever do it indirectly by attempting to eliminate other STDs.

For this I go back. Some of the most formative experiences in my career go clear back to gay men. In 1970s, when there were such incredible rates of STDs, all STDs in gay men, but we're owing to bathhouses and multiple concurrent partnerships, the same thing, gonorrhea, syphilis, hepatitis B were 20 to 40 times more common.

We thought we had in Denver practically as good of clinics as you could have, outreach to the bathhouses, to the gay groups, homophobia was not a major issue. We through every resource did everything we could. There was open access. We treated thousands and thousands of cases of gonorrhea in gay men every year and we never got anywhere. By the end of --

DR. COHEN: With HIV. Never got anywhere with HIV.

MEMBER JUDSON: Yes, we never got anywhere before fear of AIDS and fear of AIDS managed to reduce over a three year period looking backwards through sero-archeology (PH) incident rates for HIV probably 70 to 80 percent then, by the end of the decade probably close to 90 percent. Within three to fours, the incidence of gonorrhea, syphilis had dropped by 90 to 95 percent.

This is the power of change in behavior. We couldn't measure it. There were no CDC prevention programs at the time. These were gay men understanding how their sexual behavior probably spread this deadly condition. So I think we're faced now with the same things in the developing world and everywhere. Unless we come to terms with the fundamental driving factor of multiple concurrent partnerships often during the early most acute stage of infection, often before infection has even been detected, our success is going to be limited and to continue to I think debates approaches if we treat

gonorrhea -- I'll ask you. Do you think we can treat our way out of HIV by simply treating gonorrhea or syphilis?

DR. COHEN: I'm going to give an eight word answer. One is no one is going to disagree about embracing all the tools in the toolbox. It's the first five words. Second is I think using the gay sex thing in Colorado is probably a bad idea because the efficiency of rectal course changes everything because of the number of dendrite cells, receptors and trauma. So you can never overwhelm, you can't win against anal intercourse. It's almost impossible.

Not gay. Anal intercourse is a really bad sexual practice for HIV transmission. It changes the equation. The efficiency is probably one in ten or one in eight.

MEMBER REZNIK: Final word goes to Dr. Redfield.

MEMBER REDFIELD: Mike, I just wanted to comment briefly. We had a number of your group here over the last two days and part of it just from the

respect of both HHS and others. Clearly, I think you make a compelling argument. Policy always has to be based on imperfect or incomplete information.

But I think there's a compelling argument now that most people can sense this is moving towards, Mike said it and others, that we're moving towards sort of opt-out policy. You made a compelling argument that we should really also concentrate on STD clinics.

The United States, the kinetics of the epidemic could really be driven and I think you make a pretty good argument for that. The kinetics of the epidemic could be done by the zero negative viremic group, the acute infection period. I mean you make an argument for that at least if you believe inoculum maps and you could also make an argument in the United States that the other part of the inoculum might be is you get more advanced disease. The United States has policies to treat advanced disease. We don't try to identify acute infection as our public health policies.

So it seems to me again with the desire

to blend prevention and treatment we actually really ought to critically reevaluate our policies to be looking a little more aggressively. There are so many times you have to -- And some people have to see a chicken cross a highway before they can see a chicken cross the highway I mean even though they've seen it cross a road or they've seen it cross a street.

It seems to me that trying to go after the ability to diagnose this infection during the acute infection and trying to move treatment early sounds like a sounder public health approach in the United States. It may be in Africa because you've shown that established infections drive in that epidemic.

DR. COHEN: Let me in the interest of time what we have to do, it's a very simply model. It's the same as the blood bank decision. We have to decide how many acute infections we want to find for how much money and if we want to spend that much money to find that number of acute infections with the predicted outcome whether it's curing a person or

treating him earlier or preventing an additional X number of infections, we can do it. At this point, I don't think we have enough -- I mean the policy has to stem from the data we collect. We don't have enough data. But I agree with what you said. It's like we can model and say do we want to spend the money and that's what the blood bankers do.

MEMBER REZNIK: Dr. Cohen, thank you for a very engaging presentation.

(Applause.)

MEMBER REZNIK: And you didn't speak as fast as I do.

DR. COHEN: I can speak faster than you.

MEMBER REZNIK: I don't know. I'll turn it over to Dr. Sullivan.

CO-CHAIR SULLIVAN: Let me add my thanks to you for a very informative and challenging presentation. We've now come to the Public Comment section of our meeting where the members of the public are invited to address the Council. The rules are as follows. Those of you who wish to address the Council if you come to the microphone,

identify yourself and the organization which you represent and proceed with your comment. Each person will have three minutes for comments and we'll ask you to observe that limitation so that we will have ample time to respect everyone who is here. With that, we will proceed. Yes.

MR. WILSON: My name is Mel Wilson. I represent the National Association of Social Workers and what I'm going to do just sort of give you a little background of who we are but then hit some highlights of concerns and issues that we want to talk about. So I'll be reading from my little paper and hopefully we can get some comments back.

The National Association of Social Workers is pleased to submit the comments. We were founded in 1955. NASW seeks to enhance the well-being of individuals, families, communities through its work and advocacy. Social work is suited for addressing complex problems associated with the HIV/AIDS epidemic because of its comprehensive approach and commitment to social justice.

Now a couple of key points we want to hit

on. NASW believes that federal resources must ensure that all person living with HIV and AIDS have access to comprehensive services. Therefore, we support the language addressing treatment and care within committee's publication, *Achieving an HIV Free Generation: Recommendations for a New American HIV Strategy* in which the right to such access is clearly stated and that's something that the NASW supports.

We agree that all persons living with AIDS must have access to a core set of services to facilitate their remaining end care. This include primary medical care, medications, case management, oral health, mental health, substance abuse treatment and support services. But adequate resources must be available to ensure that comprehensive services are available to person both living with HIV/AIDS and those affected by HIV/AIDS.

One of the ways we want to define comprehensive services is a broader definition. We want to include services such as suitable and affordable housing, for us to care for both children and adults, access to accurate information including

comprehensive sexuality education, legal services, transportation and culturally-appropriate and language-accessible care. The little fact that we want to share is that the NASW or social workers are the largest provider of mental health services in the United States and that we feel strongly that mental health services, substance abuse treatment and adherence counseling and case management should be a major goal for ongoing treatment and care of a person living with AIDS. So my little note about shortness of time.

Therefore, we strongly encourage again going back to your document recommendations outlined in achieving an HIV free generation regarding training professionals that would be expanded beyond simply medical professionals. One of the positions that the NASW takes is that often times nonmedical professionals are assumed by ignored and we want to be sure that we are included in any attempt to improve the level of care that we provide.

There are several examples of enhancing the care of this workforce, the social services

workforce, things such as tuition reimbursement for social worker and other professionally trained mental health care providers who choose to provide HIV mental health and behavior health care in under-served communities. In conclusion, we do encourage this committee that it does support the reauthorization of Ryan White and specifically NASW recommends that the Minorities HIV Initiative be fully funded at $610 million in fiscal year 2007. Thank you very much.

CO-CHAIR SULLIVAN: I failed to note also that if you have a written document that the committee invites you to leave that document with us. Yes.

MR. SCHMID: Hi. Good morning. I'm Carl Schmid, Director of Federal Affairs for the AIDS Institute. I've given I think the staff a copy of my written comments and hopefully you'll receive them.

Today we'd like to discuss three issues with you, the authorization levels in the proposed one-time ADAP booster fund and the proposed Ryan White Reauthorization Bill and ADAP funding in FY

`07. While we're generally supportive of the reauthorization legislation currently before the Congress, we're extremely concerned about the unrealistically low funding levels proposed over the next five years. Depending on the title, it's either flat-funded or an increase of 3.7 percent per year. These levels don't even keep up with the medical inflation rate, let alone the growing demand for medications and health care services.

In the years ahead, the number of people who rely on the CARE Act will continue to rise. People are living longer. There are 40,000 new infections every year. More people are being found to be positive through increased testing efforts. There are several new drugs coming on the market and health care costs and drug costs continue to climb.

We're particularly concerned about the propose flat funding of Title IV when there is an increase of more women and younger people affected with AIDS. We're also concerned about the extremely low increases proposed for ADAP when the role of medications continue to grow.

While the Bill has taken steps to help alleviate the ADAP crisis in certain distressed states such as increasing the ADAP supplemental from three to five percent, the overall ADAP authorization is not increased in FY `07. Since more money will be going to the supplemental, less money will therefore be available in FY `07 through the ADAP formula. As a result, many states will actually see less funding next year.

So we would like to see at least an -- Sorry. As a result, many states will see less funding in FY' `07 and an -- increase after that in FY `08. It will translate into only $30 million a year which is a too little amount of money. We ask you to join us in asking the Congress to increase the authorization levels proposed in the Bill.

Also any funding for ADAP has to be more than just one year. There's a proposal to do just a one year booster fund. You know that people have to maintain their medications and we're afraid when those patients or when the state stop receiving that money, they're not going to have the continued funds

for those medications.

And finally, as I said earlier, we're very concerned about no increase for ADAP in FY `07. So we would ask you to encourage the Appropriations Committee to find ADAP an increase in FY `07. Thank you.

EXEC. DIRECTOR GROGAN: Do you have Daren Dosier? Is there anybody else for Public Comment? That's it. Okay.

CO-CHAIR SULLIVAN: All right. That concludes then our Public Comment section. I'm going to suggest because we want to be sure that we finish by 4:00 p.m. because I know some of you have commitments. Yes. So we will work to see that we will finish by 4:00 p.m. Before we break, Joe Grogan has just reminded me of a ritual that we really need to go through. So, Joe, why don't you proceed.

EXEC. DIRECTOR GROGAN: As I said yesterday, we're losing some valuable members of the Council and it's a sad day for me personally and for all of us. I want to take the opportunity before I present those departing members with their service to

read a letter from Secretary Leavitt that was sent today to Dr. Sullivan to his office. But I just wanted to share it with the rest of the Council and with the official record and the public.

"Dear Dr. Sullivan, It is with deep regret that I am unable to thank you in person for your years of service as Co-Chairman of the Presidential Advisory Council on HIV and AIDS. For over four years, you have distinguished yourself through steady envisionary leadership in an area of deep concern to the President of the United States and to all of us here at the Department of Health and Human Services.

Under your leadership, PACHA has provided invaluable advice to President George W. Bush and the team of people working across the Federal Government to fight this disease. Your tenure has seen progress that five years ago would have been unimaginable. During your tenure, the President launched the Emergency Plan for AIDS Relief, the largest international public health effort in history, called for the renewal of the Ryan White CARE Act in two

State of the Union Addresses, delivered emergency medications to those on ADAP waiting lists, unveiled an ambitious HID testing initiative, called for greater funding of prevention and testing resources and brought a renewed focus to the disproportionate impact this dreaded disease is having upon African Americans. Your leadership played a central role in all of these efforts and your legacy will be an unwavering determination to achieve the dawn of generation free of HIV.

Your time on PACHA is but a small part of a public health career marked by self sacrifice and service to public health. Not only as Secretary of this great Department, but as a physician, administrator and public servant, you have contributed immeasurably to the health of all Americans. In your capacity as an advisor and counselor, I have come to rely upon your experience and wisdom.

My sadness at marking the end of your tenure as Co-chair of PACHA is mitigated by the certain knowledge that I can look forward to working

with you in the future on many areas of public health concern. I know that you will continue to be a valuable resource to the President and myself as we work to help Americans live longer, healthier, more productive lives. God bless you and your continued work. Secretary Michael Leavitt."

(Applause.)

CO-CHAIR SULLIVAN: Thank you very much. A quick comment which I will certainly share with Secretary Leavitt. I think all of us are here because we want to serve the public. We want to see that those things that interfere with our ability of our citizens to live healthy, productive lives that we make changes so that their lives will be better and we're also here because I think we receive gratification from service. We are because we do really benefit ourselves I think psychologically and otherwise from seeing the result of our efforts.

And I would like to say to my colleagues that I leave behind I think that the Council will continue to do excellent work. I think this session has been really quite outstanding and I'm sure that

this will continue to improve. So thank you very much. It's really been a pleasure and I'm sure that I will interact with many of you in the coming years in many other capacities, but the bottom line is serving the public and we're very privileged to have that opportunity. Thank you.

(Applause.)

EXEC. DIRECTOR GROGAN: So, Dr. Sullivan, I'm going to give you your plaque here and I have a set of cufflinks. My suspicion is you may have a pair of these already probably, probably a stack of them somewhere but thank you very much.

Dr. Sweeney was the only one to make a demand of me that not only would she get a lapel pin as the women normally get but she demanded cufflinks because she's that type of pushy New York broad she said. So here is your lapel pin and your cufflinks as well.

(Applause.)

MEMBER SWEENEY: I just wanted to say two sentences, David. Dr. Sullivan, you've already received your comments from our Secretary, but

they're not mine. I want to say thank you very much for all of your leadership during these four and a half years that I've been here and how much I've learned from being on the committee and to Joe Grogan and the wonderful staff, Dana, who did so many things to you that I won't even tell you now some of the things she had to do to me and for me and to our staff who is our recorders who sometimes I would think how can they stand us. They ask us one simple thing, just put our microphones on and say our name and we didn't do it and they still were very pleasant. So I thank you, Joan, and the rest of you very much.

And for all of my fellow PACHA members, I'm really deeply sad for two reasons. One is that we continue to need to be here. There's a disconnection between what we know and what the public knows. There was a major research study that showed only 17 percent of Americans think HIV is still a major issue. In an African American press that same week, it showed that over 60 percent think it's a major issue. So there is a major disconnect.

So all of my fellow PACHA members, there is a lot of work left to be done and I'm sure you will.

And my sadness is mitigated by the fact that I hope to continue to work with many of you in a different capacity. I will leave with something the Churchill said that I often use is that "You make a living by what you earn. You make a life by what you give." And for all of you for all that you give, I'm very thankful to have been able to work with you. Thank you.

EXEC. DIRECTOR GROGAN: And Dr. McIlhaney, I have your plaque and your cufflinks for you.

MEMBER McILHANEY: Very briefly, I think that what David Reznik said, I think it was in *Blade*. Was that the magazine where you made your comment about the fact that this group had worked together well? I really thought that was first a very kind thing to say and I think also it reflected what people can do if they have a desire for the good of the public and are willing to sit down and work together and I think that he reflected what this

group has done very well in what he said.

It's been a privilege to be a part of it. I've learned a lot. I've enjoyed working with every one of you and I agree, Dr. Sullivan, that you've done a wonderful job of guiding this group and, Joe, you and Dana and the rest of you, have done just a wonderful job of corralling us and thank you for doing that. It's a privilege to have been a part of this and I'm glad to know you people that are new in the group and to know that you'll continue what's already been begun and I just hope and pray that the number of people infected with this horrible disease just goes down dramatically as a result of the work that you're going to do. So thank you.

CO-CHAIR SULLIVAN: We will take ten minutes for our break, but then we'd like to begin a working lunch at 12:10 p.m.

EXEC. DIRECTOR GROGAN: We're going to go to break and they'll bring us lunch. So we'll go directly to the room.

CO-CHAIR SULLIVAN: All right. Correction. We'll go to our breakout rooms where

we'll have lunch there and the International Committee is at Room 742G and the Treatment, Care and Prevention Committee are 325A. So the lunch will be provided to you there.

EXEC. DIRECTOR GROGAN: Treatment, Care and Prevention are together in 325A.

CO-CHAIR SULLIVAN: We are scheduled for reconvening at 2:15 p.m. Should the committees finish earlier, we will indeed send word to the rooms for reconvening here earlier. But the scheduled time is 2:15 p.m. Off the record.

(Whereupon, at 12:02 p.m., the above-entitled matter recessed to the breakout room for a working lunch to reconvene at 2:06 p.m. the same day.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

2:06 p.m.

CO-CHAIR SULLIVAN: On the record. I think the way we plan to proceed is to receive the committee reports, there will be two reports, from the Prevention and Treatment and Care Committee and with discussion and then from the International

Committee with discussion. So I think we commence.

David, are you ready for your report? Then we will let Dr. Reznik give us a report from the Treatment and Care and Prevention Committee.

(Pause.)

MEMBER REZNIK: Okay. Are we ready for motion time? I actually put up Resolution No. 2 which really does deal with Dr. Saag's presentation that we heard this afternoon. I don't think I need to read it out loud. Actually, reading these out loud is sort of spooky. But if everyone would take the time and let me know when they want me to go a page down and then we'll go through edits.

(Pause.)

MEMBER REZNIK: There's been a request to read the "Be it resolved" part. "Be it resolved that PACHA strongly recommends that the President of the United States and Secretary of Health and Human Services use all means available including expanding existing programs such as the National Health Service Corps for medically under-served specialties to ensure that creative" I didn't fix the sentence,

sorry, "to ensure that creative solutions be found to address the shortage of primary care providers properly trained to manage HIV disease consisting of but not limited to the following:" and there's a problem with the sentence that I have to fix, we forgot about that, "tuition reimbursement for health care workers who choose HIV care in medically under-served areas, recognition of HIV care as a medical specialty, incentives for more nurses, physicians assistants, nurse practitioners and physicians to be certified through their appropriate associations, ensure adequate reimbursement for HIV care and promotional programs to increase the diversity of health professionals trained in HIV care. Be it further resolved, the Secretary of Health and Human Services put a team in place including expertise in health care economics to consider long-term solutions to address the shortage of qualified health care professionals, nurses, physicians assistants, physicians and other key providers of care throughout the United States."

That was in reference to Dr. Sullivan's

comments that we heard earlier. I do need to fix this sentence though.

MEMBER YOGEV: When you say "shortage of health care professionals" specifically for HIV or in general?

MEMBER REZNIK: Our charter is an HIV advice so I would have to leave for interpretation.

MEMBER YOGEV: I would just add it.

MEMBER REZNIK: But there are shortages in medical providers and nurse providers.

MEMBER YOGEV: That's my point.

MEMBER REZNIK: So I think we're limited into what we can advise. I sort of left that a little broad.

MEMBER YOGEV: What I'm saying is just to allude to HIV because there is a shortage all over in nurses for example and you want this specific in HIV.

CO-CHAIR SULLIVAN: I would agree with David's focus that we're making these recommendations as the President's Advisory Council on HIV/AIDS. But I think there's a way we could perhaps address this that is "shortage of health professionals for care of

AIDS patients" which is complicated by the recognition, the increasing general recognition of shortages health professionals, in other words, somehow saying that this is occurring within an environment of shortages, but we are focused on the shortage for HIV care.

MEMBER GREEN: Can I ask a question just because it was raised earlier. If part of the problem in recruitment is a disinclination for whatever reasons to work with gay men, injecting drug users and maybe poor African Americans, what kind of incentives would be needed to over come that whatever that is, disclination?

CO-CHAIR SULLIVAN: Yes. If I could comment on that because what we heard this morning also was a lot more than this. That is the inadequate reimbursement for care that is the environment here that's creating the problem here. So it seems to me that we were to have a sentence such as "better reimbursement for care and again streamlining the bureaucracy" because we also heard about the inordinate amount of time to have

prescriptions filled, etc. So the manpower issue is part of it, inadequate resources to pay for care being another, but then the environment in which these health professionals have to work with all of the bureaucracy being another. So somehow it seems to me that we need to recognize that as part of this resolution.

MEMBER YOGEV: I don't see where is the increasing number of patients with the new policy of opt-out anticipated to increase 25 to 30. I don't see that.

MEMBER REZNIK: I'm sorry. I can't type and listen at the same time.

MEMBER YOGEV: I can't type. You see that's my luck. I don't see the "whereas" and maybe it's hidden there that with the new policy of opt-out the anticipated increase in 25 to 30 percent of HIV infected individuals who are going to increase the burden acutely. Is it there?

MEMBER SWEENEY: It's not there. It's an excellent point and we didn't think of it. Thank you.

MEMBER REZNIK: How would you like me to word this? "The CDC's effort to identify those of unknown status." How would you like it?

MEMBER YOGEV: "Whereas universal HIV testing is expected to increase the number of HIV infected patients known to the system by 25 to 30 percent which increases burden."

MEMBER REZNIK: Did that type right? Yes, I see it. Does that address the concern appropriately?

CO-CHAIR SULLIVAN: If I could make another editorial suggestion.

MEMBER REZNIK: Yes sir.

CO-CHAIR SULLIVAN: The next line where you say "HIV medicine is not a lucrative profession" I would prefer it something perhaps as not a "well-paying profession" because by implication this means that the rest of medicine is lucrative. But some would argue with there, but there could be other ways of saying that.

MEMBER REZNIK: Does that work if I delete? If I can find the delete button and maybe I

can't.

MEMBER BOLLINGER: David, scroll down just a little bit. I have a very quick question about.

MEMBER REZNIK: Okay. Think on this one.

MEMBER BOLLINGER: It's right there. "Be it resolved that creative solutions be found to address the shortage of primary care providers." Do we want to restrict that term of primary care providers? It just seems to me that's --

MEMBER REZNIK: Health care providers.

MEMBER BOLLINGER: I think we're talking about people who care for HIV patients. It's not just primary care providers. It's specialists in HIV care. It's a broader issue.

MEMBER REZNIK: I agree. There's the dental thing I left out for a change. For those of you wanting to know this is dental plaque under a microscope which I did have to get my dental thing out.

MEMBER SWEENEY: David, dental is primary care.

MEMBER REZNIK: I know. Who are you telling that to? Don't type that. Okay. Dr. Sullivan, did we address your concern because there is something on -

CO-CHAIR SULLIVAN: Well, it's simply a phrase.

MEMBER REZNIK: And you want?

CO-CHAIR SULLIVAN: Near the bottom you say "ensure adequate reimbursement for HIV care." It's there but I guess for my view it doesn't have sufficient emphasis because what we heard this morning I thought was an environment in which the reimbursements are so poor that it's affecting the whole system. So it's a question of emphasis here. Is that adequate?

MEMBER REDFIELD: Just to follow up on that, I think that is the driver.

MEMBER REZNIK: So it should be at the head of the list.

MEMBER REDFIELD: I mean the fact that HIV care and treatment right now doesn't provide the economic return to the system such that it's in most

centers it's a lead loser. So I think you want to emphasize that that is the driver. If we can correct the reimbursement issues related to care and treatment that other things will follow.

MEMBER REZNIK: Okay. So I moved it but that doesn't mean we've fixed the language yet. So we only have "adequate reimbursement." "Appropriate reimbursement" or how would we like to? I'm open for suggestions.

MEMBER YOGEV: Incentivize.

MEMBER REZNIK: Incentivize reimbursement.

CO-CHAIR SULLIVAN: What about something like "sufficient reimbursement to cover costs of care" because I think --

MEMBER HOLMER: (Inaudible.) This is Alan Holmer. Including "first and foremost" if everybody agrees it's the most important item.

CO-CHAIR SULLIVAN: Yes, I could agree with that because for those are in the system now, that if we can get some relief, that certainly would be it, whereas the manpower issue is going to take

time to address. So it seems to me the first thing is to try and keep the system that we have now from falling apart by adequate reimbursement, but also streamlining the system of the bureaucracy because it means we are wasting precious manhours of time on bureaucratic things as we heard. So we could use the people we have in the system now more effectively if we somehow got rid of it and they didn't have spend all the time waiting for approval of prescriptions on the telephone etc.

MEMBER HOLMER: So how about "ensuring sufficient and streamlined reimbursement"?

MEMBER REZNIK: Well, I have it down here.

MEMBER YOGEV: You have the same language.

MEMBER REZNIK: This is a lot of pressure.

MEMBER HOLMER: You're up to it.

MEMBER REZNIK: You're seeing my computer skills or lack thereof. "To access medications" because part of the bureaucracy is the reporting

requirements included in the CARE Act just so you know. That's part of the paperwork that needs to be filled out on a daily basis for each and every patient. Do you not find that the case?

MEMBER REDFIELD: No, it's substantial. It's substantial.

MEMBER REZNIK: So that's why if we just leave this "bureaucratic requirements" but Michael was talking about was accessing ADAP or patient assistance programs.

MEMBER REDFIELD: Yes, what drives most of us that are in this business and have been in it like Michael is that -- And I agree with Michael. There's no patient at the University of Maryland that's never got access to a medicine that they need. But it's because people spend literally hours to make sure that we are the thing of last resort and what you're hearing from him is a frustration and I was going to get at it and when you say "whereas medicine is not well-paid medical specialty" the real frustration that's starting to crack for all of us is that the allocation of resources meaning people,

nurses, administrative people that people in and out of the clinic, the system is cutting them back and back and back because we're not profitable.

So now the one group that's not getting cut is the doctor because he's responsible for his own salary. But what's happening now is you're getting less and less support people. So even the good support people are burning out and now choosing to quit because we're just inadequately staffed and why are we inadequately staffed because ambulatory HIV care and treatment and I mean ambulatory is basically you cannot collect the resources required to run the business, bottom line, even with substantial Ryan White support. Most of our clinics are operating if you did a business pro forma on any of our ambulatory clinics I think in this country, many of them are non profitable.

Just to editorialize while he's finishing, to give an example, this year I literally had a 40 percent increase in clinic visits and for that, the institution cut me 1.5 nurses. Okay. So a 40 percent increase in workload and I lost 1.5

nurses.

MEMBER REZNIK: I added that.

MEMBER REDFIELD: I just started my 16-year-old daughter. She is working there as a volunteer and you think I'm kidding. She's there right now as we speak.

MEMBER YOGEV: David.

MEMBER REZNIK: I actually just added something to maybe make it read a little bit better which is --

MEMBER YOGEV: You want to address the financial and bureaucratic pressure.

MEMBER REZNIK: Right. So "ensure creative solutions we found to address the financial pressures placed on ambulatory HIV care and the shortage of health care providers properly trained to manage."

MEMBER YOGEV: But it's not only the financial pressure. It's also the bureaucratic pressures. That's what I'm saying. Put "financial and bureaucratic pressures placed on..."

CO-CHAIR SULLIVAN: What about "financial

pressure and bureaucratic obstacles"?

MEMBER SWEENEY: That I get.

MEMBER JUDSON: We were just reflecting that there's probably an inverse relationship between the length of a resolution and the likelihood that it will have any impact and I don't know how simply you can get. One might be that there is an emerging critical shortage of qualified health care providers for HIV treatment and we would simply urge the Secretary of Health and Human Services to address the problem and solve it, fix it.

CO-CHAIR SULLIVAN: I think you could make a good argument for that because the details of what are the mechanisms certainly the Secretary and his staff are fully aware of what those mechanisms are. So I don't think we necessarily have to spell those out. So I think that could streamline it and keep the focus.

MEMBER REZNIK: And they actually are spelled out already in our publication. That's where they came from, the blue book on page 38. It wasn't something that we just thought up. So I literally

can take that out if there is agreement. Okay. Not agreement?

CO-CHAIR SULLIVAN: As long as you're consistent.

MEMBER REZNIK: Let's let Dr. Sweeney.

MEMBER SWEENEY: Just having all of the information in sort of one place as long as we can keep it one sheet of paper, I think their attention span might -- I mean I think they might have enough time to read one sheet if it doesn't go over one sheet. But I think having the facts there as we see them contributing to this problem and some of our recommendations as long as we can get it on one sheet of paper, I think it might be good to leave some of it in.

MEMBER YOGEV: I agree because if you just put general it just would take a long time to get to what you're suggesting. It would be very difficult to say no you cannot use that. So I agree we should leave it.

MEMBER McILHANEY: I just wonder if we couldn't do a simple resolution and then have this an

addendum to it because we gained a lot of information today. Put a lot of that down in facts and it would be information the Secretary probably wouldn't really have or his staff.

MEMBER REZNIK: Well, my argument against that concept just to give the other side of the argument with Monica is (1) at least 80 to 90 percent of what we have in here was discussed in previous iterations. The diversity in the workforce was something that Dr. Primm had been championing and that's they made it into our treatment and care portion of our paper.

The other thing is there is something in here that Dr. Sweeney suggested that's not in our paper that is quite unique and it is "expanding existing programs such as the National Health Service Corps for medically under-served specialities" because for instance the city of Atlanta is not designated health shortage area but when it comes to providing HIV care, we are. So -

MEMBER REDFIELD: One of the things -- I'm sorry.

MEMBER REZNIK: No.

MEMBER REDFIELD: One of the things I just want to throw out because the ultimate issue here is impact in terms of -- and I know all of us that's what we're committed about and we're talking about whether someone's going to get through this, one of the things we discussed in the International Committee because we were trying to look at some of the areas that were important and we'll talk about that when we get our chance.

But actually Dr. Sullivan proposed and the committee really thought it was an important thing to do is that the out-going chairs, themselves and Anita Smith, would meet with the Secretary and articulate several high priority issues. From my point of view of Secretary Sullivan went to meet Secretary Leavitt and eyeball to eyeball articulated this concern with the request that this committee had for him to address it that would carry a lot. In my view that would probably carry a lot more impact and it's something to think about because we were going to ask him to do that on a couple of the

international issues and I know he was going to do that also on these domestic issues. So I don't know if he wants to comment or other people would like to comment.

CO-CHAIR SULLIVAN: Well, I guess my comment would be this that I think a lot of the details of this such as tuition reimbursement and expanding the National Health Service Corps are things that really could be part of a discussion because one of the things we want to be sure is that we don't have our resolution hijacked by other people. So in other words, I think on any number of these which are very meritorious we could find the press somehow focuses on the Council recommends expansion of the National Health Service Corps. Well, that will create its own dynamic.

So my thought is what we want to do is to be helpful in getting some solutions. So that why my thinking was we could point what the issue is in a general way in the resolution but then in the discussion, assuming we have this meeting, we would then get into those kinds of discussions as a

somewhat private conversation with the Secretary. These are the things that we think could be helpful as you look at this, etc.

MEMBER REZNIK: Okay. So any opposition to me hitting the delete button? Well if there is opposition, I'll hear about it.

MEMBER REDFIELD: One of the things you could say then is "Be it resolved that the President's Committee," I don't know if you said it earlier. Maybe you said it at the very beginning "recognizes a current and growing," you said that, maybe, "recognizes a current and growing loss of health care professionals..." and then you tell the Secretary basically to solve it.

MEMBER REZNIK: And maybe we should move this particular bullet up a little higher or do you like it where it is?

MEMBER YOGEV: That should be the second bullet. The first one is exactly what I thought Dr. Redfield is suggesting, instead of a developing crisis already in taking care of those patients and whereas 25 is going to be added and then everything

else. But there is no sentence that there is a developing crisis, an emerging crisis already.

MEMBER BOLLINGER: I don't know. Again, we want to keep it short. Dr. Sullivan raised the issue about the administrative, the bureaucratic hassles. I mean do you want to have a whereas there that basically lays that out as an issue or is that something that gets discussion privately?

MEMBER REZNIK: I could put "already overburden system of care" but that's going to raise flags or two.

PARTICIPANT: Bureaucratic barriers --

MEMBER REZNIK: That's in there. I think we have that.

PARTICIPANT: (Inaudible.)

MEMBER REZNIK: It might not be a whereas but it's definitely in the "be it resolved."

CO-CHAIR SULLIVAN: I think it might be helpful to have a whereas related to that because this is one of the fundamental issues here and you also say that if the Council agrees with this strategy, I would like to be sure that all of these

details I would be given those. So I don't want to have the meeting with the Secretary and then walking out his office and remember the four things that we forgot about. So I think the help of this Council in really being sure we have those issues.

MEMBER REZNIK: Any thoughts?

MEMBER BOLLINGER: I would suggest using the term like "cost effectiveness" or "bureaucratic obstacles reduce the cost effectiveness of the current investment in HIV care."

MEMBER REZNIK: Okay. "Reduce the cost effectiveness of..." Is that right, Bob?

MEMBER BOLLINGER: That's fine.

MEMBER REZNIK: That's fine.

MEMBER YOGEV: Will you have the "it's a developing crisis already, emerging crisis"? Just use the "Whereas, there is a complicated disease. Whereas already the HIV care system is an emerging crisis."

MEMBER REZNIK: I mean it could be worded into this sentence if there is a desire to add that. I think the universal text is we could put "into an

already overburden system."

MEMBER YOGEV: But put it by itself. This is the message we got today that there is a crisis.

MEMBER REZNIK: We have a message from one clinic. Is that --

MEMBER YOGEV: No. Everybody agreed. I mean the clinic here we agreed.

MEMBER REZNIK: I mean if we say that there is a crisis and in the next motion we have left out a funding issue, then I'm finding a conflict in what we're saying. Is there a consensus that there is an emerging crisis in the management or are we in a crisis already or are we expecting a crisis? I mean I know we're overburdened. There is no question about that.

CO-CHAIR SULLIVAN: I think it's a question of definition. I think it's fair to say that in some areas of the country we do have a crisis.

MEMBER REZNIK: Okay. And somebody is going to have to help with this one.

MEMBER YOGEV: Put it before the 25 percent.

MEMBER REZNIK: Ram, I'm going to have you come up here and do this any second.

MEMBER YOGEV: Then you will sit here until 10:00 p.m. because my skills are even less than yours.

MEMBER REZNIK: "Whereas..."

MEMBER YOGEV: What it is already.

MEMBER REZNIK: No, I need help with the writing. Don't think you're going nowhere here.

MEMBER YOGEV: Sorry. Because can we raise toward the end an issue I discussed with a couple members of the Council about response to our resolution. We produced the resolutions. They are going somewhere. Some of them are not reflected and there is no accountability from what we recommend why they were not accepted, what was the reason. It might be political. It might be no reason. Is there any mechanism that we can develop to hear back what resolution we worked so hard to develop?

EXEC. DIRECTOR GROGAN: It's a legitimate

concern but there is a couple things with that. If say for this resolution, there's a mechanism in place to get a response. Guaranteed the first response is going to be form letter because so many of these things take so much time. So the first mechanistic bureaucratic response would be we received the resolution and we're considering it and then what does that get you? So many of these things either have to take place over a number of months or six months or nine months and it's my personal opinion that the best way to deal with the resolutions and your feedback is to have the people who are responsible those decisions come back and report to the Council when they're ready to do it and then you have the Executive Director follow up personally.

The resolutions do go the Secretary, but frequently more importantly they go to the Secretary's staff responsible for putting the policy in place. So you're absolutely right to expect that people take these seriously and that they should come back and report, but if we set up a process by which we demand a response, it doesn't necessarily do

anything for us and frequently can hurt our efforts more than not because the first response will be we sent a letter. Let's not deal with this issue. When what should happen is we keep pressing until we get an action on the resolution, somebody reporting back to us in a subcommittee or in full committee about why this is taking place or not taking place.

MEMBER YOGEV: I'm 100 percent in agreement with you, but we don't have this mechanism and we should say okay this is the resolution and we come to you on this one. We expect a response from the staff or check on it in six months. So our agenda will start "Welcome to..." and part of our agenda will be resolutions X, Y and Z are now here, there and there or not moving.

EXEC. DIRECTOR GROGAN: I can do that. I mean if you want me to report back at a certain --

MEMBER YOGEV: Not a letter.

EXEC. DIRECTOR GROGAN: No, I know. If we want me to make sure that you get a response at a certain time, maybe for some resolutions it's important that you get a response back in one month,

other ones three months, other ones six months. I'll be happy to follow up on any one of those. But if you want to set up a defined mechanism, I would think that that's a bad decision.

MEMBER YOGEV: No, exactly what you just said. That's a mechanism. You come back in a month for example. You work very hard on this universal testing of newborn whose mother's -- and specifically to talk to CDC or whatever. They will start out for a political reason which I totally understand. Nothing happened as far as we know. Maybe it did. So this is one for example that it will be within a month or three months and you need to announce it because it's coming out. This one may be a little bit longer and I leave it to you to make the decision. But to come back to the Council, let them know great, not so great, failed so we know where we are.

EXEC. DIRECTOR GROGAN: I'm happy to report back to you on any resolution passed by the Council on any subject matter and the full committee. I'm happy to do it and follow up with anything you

want me to do.

CO-CHAIR SULLIVAN: Joe, let me comment on this and really get your reaction. Certainly, there is a mechanism in place and that includes your responsibility. The idea that we talked about in the International Committee was to really have a mechanism to alert the Secretary that these are some of the real concerns of the committee here in really a friendly way, not in an accusatory way and to not interfere with the process. But when we talked for example on the Ryan White funding as I mentioned to the group, from what we heard I'm not sure that Congress is going to really finish that this year.

So whether having a discussion with the Secretary to express to him in a way that we would not want to in a resolution which is a public document, some mechanism of bringing this to his attention and by extension bringing this to the attention of all of those people who would be reacting and responding to the resolution, we saw that as a way, hopefully a positive way of saying we have some real issues here that we think that

deserves some significant attention and these are they and we want you as Secretary and if Mark Dybul should be a part of that meeting and you to be aware of this, at least the Council has these concerns we wanted to share with you in a way that we would not want to do in a resolution. So that's really I think the thinking is.

EXEC. DIRECTOR GROGAN: Yes. I think that's a great approach and I spoke with Dr. Redfield about that briefly that it would be a good idea for you and Anita and maybe the incoming chairs, all four, to go and meet with the Secretary and Mark Dybul and whoever else is appropriate on the domestic front to discuss what the major concerns of the Council are and have a little bit of a discussion back and forth and I can work with you to make that happen.

MEMBER REZNIK: That gives continuity actually as well. I think --

CO-CHAIR SULLIVAN: David, could I make one other quick suggestion?

MEMBER REZNIK: Yes sir.

CO-CHAIR SULLIVAN: And that is universal testing. I would suggest we use the word "expanded testing" or something like that simply again because we put universal in. That's going to set off some other reactions here which we don't want to get into that fight.

MEMBER REZNIK: Okay. What about the title because I think that's a little on the red flaggish too? Well, I had to change the title because we basically changed the motion. "Pending Ambulatory." "Impending." "Emerging."

CO-CHAIR SULLIVAN: I think "emerging" would be appropriate because it is a crisis already in some areas and others it's not. So nationwide, this kind of covers the waterfront. Sure.

MEMBER REZNIK: Okay. Let's everyone take a look at the order, what's in there, as we're soon going to vote on this one and put it to bed or on its way to the Secretary.

MEMBER SWEENEY: This is the one I think I was talking about when we were in our subcommittee. It's in the, I think, fifth "whereas" last two

words, three words, "improving the quality of an access to effective HIV medical care" and that's the one I was talking about.

MEMBER REZNIK: Where are you? I'm sorry. Third okay.

MEMBER McILHANEY: Whether or not we wanted to say "medical care" or "health care."

MEMBER REZNIK: Okay.

MEMBER SWEENEY: Because we want nursing, nutrition, social workers, everybody.

MEMBER REZNIK: Health care.

MEMBER SWEENEY: Yes.

MEMBER REZNIK: I think we decided to use health care throughout.

MEMBER SWEENEY: Yes. Okay.

MEMBER REZNIK: I just missed that one.

MEMBER SWEENEY: Thank you.

MEMBER REZNIK: Big eyes, but they need magnification these days and we did shorten the "Be it resolved" when you were out of the room. You might want to look up, Monica. We shortened the "Be it resolved" while you were out of the room.

MEMBER SWEENEY: Yes.

MEMBER REZNIK: Okay.

MEMBER SWEENEY: I don't know if we're voting exactly or not but I think we've wordsmithed this an awful lot and if we keep on, we'll never finish so maybe we should call the question.

MEMBER REZNIK: I call the question. All in favor? Raise your hand or say aye or whatever.

(Chorus of ayes.)

MEMBER REZNIK: Anyone opposed? If you are --

(No response.)

MEMBER REZNIK: Great. We can save this one. It has the wrong title. Shoot. This is one, isn't it?

PARTICIPANT: Two.

MEMBER REZNIK: Two. Okay.

PARTICIPANT: (Inaudible.)

MEMBER REZNIK: No, I probably did. We want to thank Troy for use of his -- This is a short one. I need to make it bigger so you all can read it. I got it.

PARTICIPANT: It's a little hard to read.

MEMBER REZNIK: Not anymore. Do you need the dark to read it or is it showing up? I can't see.

PARTICIPANT: (Inaudible.)

MEMBER REZNIK: The need to this resolution is that we're trying to get it done this session because we all heard Marty's words that if it's not done this session the bicameral/bipartisan administration process collapses.

(Discussion off microphone.)

MEMBER BOLLINGER: Could I ask? What were the concerns, David, about -- Obviously, we don't want to say anything specific about the funding but there is no mention whether the funding is adequate, inadequate?

MEMBER SWEENEY: Tell him --

MEMBER REZNIK: You tell him what you did. I've had the fun of getting things in there.

MEMBER SWEENEY: We had a big discussion in our subcommittee meeting that if we started dealing with what was flat funded, what was 3.7 and

how the funding was to be changed or what we'd like to see changed that it would muddy the waters and we would possibly delay the chance of us getting it out of authorization this session. So we decided to take it out.

MEMBER BOLLINGER: So what you decided to take out was specific recommendations, but what about a general comment about the level of funding in light of what we just heard about the change in, I mean, just the overall level? Bob, you should really be the one to comment since you know more about the practicalities of this.

MEMBER REDFIELD: I guess there are two issues I should of agree with. With Monica obviously from a starting over point of view, I would like to see a lot of changes. The reality I think is if we suggest any changes that we're going to guarantee that this bill doesn't get passed. So I think even though it's hard, that's why I kind of read it and don't fully support the bill, but it doesn't say that I fully support the bill. It said I fully support the authorization during this Congressional session

and I think if we start to suggest that they're not close to the goal line those people who want to block it and I gave you my perspective on where I think that's going will just use it.

MEMBER REZNIK: And we actually heard that there are certain things that are being negotiated at the last minute that the Appropriations increases are not and if it were earlier in the process, I might have fought harder, but we're at the end game. We're trying to get the ball over the goal line for you football fans from the south here. Go Gators. Any suggestions?

MEMBER BENAVIDEZ: David, the reference to the House and Energy Commerce Committee I think limits the time frame that this resolution is effective. I mean if it's not acted upon soon or there's a change of committee assignments. I mean to me it seems very limiting by putting that reference in there.

MEMBER REZNIK: So?

MEMBER BENAVIDEZ: I would just remove the whole "Whereas, Energy and Commerce Committees"

and it may be said "Whereas the Congress is currently considering it." Leave it more broad.

MEMBER REZNIK: So you would like me to take this out. Let's see if we have agreement on this. Some info in here I don't think would hurt because many of the -- We didn't get everything we wanted or everything that we talked about but a lot of what we did talk about as a Council is included. I think that we should incorporate some of that. But the key is we want this to be done with. Yes sir.

CO-CHAIR SULLIVAN: I just have one suggestion. I would -- That next to the last -- Well, the last "whereas" the last line, I would delete everything after PACHA because you're already said this is consistent with the recommendations made by the Advisory Council and the President has mentioned that because then I think that takes a little out of the potential for being seen as a political document.

MEMBER REZNIK: Okay. Questions? Concerns? Monica.

MEMBER SWEENEY: Maybe we can find out

which Congressional session we're in. Is it 112th?

CO-CHAIR SULLIVAN: It's my understanding from Mosa yesterday that if this doesn't pass this time it will start all over.

MEMBER SWEENEY: I know but I just wanted the number in there.

(Several speaking at once.)

MEMBER SWEENEY: This blank, blank specifically put a number in there.

MEMBER REZNIK: During the 201st or whatever.

MEMBER SWEENEY: Something. Yes.

CO-CHAIR SULLIVAN: Well, I don't know.

MEMBER REZNIK: It's not summer session. I think Congress --

PARTICIPANT: Whatever session.

DR. WASSEF: Whatever session. Whatever number it is.

CO-CHAIR SULLIVAN: Why don't you just say "conversation in 2006."

MEMBER REZNIK: I like putting in the number.

MEMBER SWEENEY: Joe said he would fill it in if we would like.

MEMBER REZNIK: During the XXX and it would then be Congress. Right? Wouldn't it? The 231st Congress. Isn't that how it should be worded or is it session?

MEMBER YOGEV: Put it during the "current XXX Congressional session."

MEMBER REZNIK: Well, the current -- Okay.

MEMBER HOLMER: We're in "The second session of the XXX Congress" whatever it is.

MEMBER REZNIK: "During the Second of the XXX Congress."

CO-CHAIR SULLIVAN: I suggest we get out of the bureaucratic mode and let our staff fill it in.

MEMBER REZNIK: Not a problem. I'm just getting the outline for them. Is that good? We have the intent. Are we all in agreement? I called the question. All in favor say aye and raise your hands.

(Chorus of ayes.)

MEMBER REZNIK: All opposed?

(No response.)

MEMBER REZNIK: That ends the Treatment, Care and Prevention section motions.

(Applause.)

MEMBER YOGEV: (Inaudible.)

MEMBER REZNIK: I run a very large website.

CO-CHAIR SULLIVAN: Why don't you go ahead?

MEMBER REDFIELD: Thanks. Just an update on the International subcommittee. We really addressed and discussed several issues, but really focused down on two and as I mentioned before, the question was really how to proceed. I think the group as a group didn't feel at this stage any particular resolution would necessarily be required but rather what we proposed is really first focused on in a fairly focused way in the International committee the importance of the current PEPFAR program and in particular, the importance as we can see from our domestic Ryan White situation with the

reauthorization on the PEPFAR reauthorization.

So in that context in the discussion, Dr. Sullivan suggested and the committee concurred that as the outgoing chairs, himself and Anita Smith would meet with the Secretary and in the context of that underscore PACHA's view of the importance particularly of the PEPFAR program from the point of view in particular the reauthorization process and that the committee would, PACHA would, be happy to provide assistance particularly if the Secretary would find it helpful to do a strategic review of some of the critical issues related to the PEPFAR as would pertain to the potential reauthorization process particularly focusing on structural issues, impact assessment issues and balance of funding issues. So really that was the discussion. It's the plan of the International Committee to begin to try to address some of these issues as we move forward and it's the anticipation that the Secretary's office will find the input something that would be helpful and therefore request it. I don't know. Dr. Sullivan, do you want to comment any further on that?

CO-CHAIR SULLIVAN: No, only that it seems to me that if we were to have this discussion it really would be with the purpose of saying to the Secretary these are issues which we are very concerned about. We want to bring them to your attention. We would like to offer our assistance to you if this would be helpful, to really to offer to try and help get out in front of some of these things and as I was saying earlier, we could really have some of the detailed issues here and of course, we will have these resolutions here to form the basis for our conversation.

So I can't speak for the Secretary but I would think that he would find this kind of discussion helpful because we're dealing with a lot of difficult issues. He's dealing with the tug of war between what the President wants to do and what the Congress is willing to do and other issues like. But the purpose of this would be really to say to the Secretary we are concerned about these. We want to be helpful to you if you see that the Council can be in trying to address issues in an effective way.

So that's really the spirit of the discussion that we had.

MEMBER REDFIELD: And then the intent would be really to take the lead from what the committee had done in the past from the document that was prepared. It was suggested that we would go forward and hope by the first quarter of 2007 to have an Executive white paper that PACHA could prepare with really addressing some of these key issues and proposed analysis or input from them that could then be used as a helpful document to move forward with this reauthorization process.

I think the clock is ticking. My own assessment would be that this has to be locked out about 18 months before the program is over. So 18 months from the time the program is over is about the summer of 2007. So the reauthorization process really needs to be moving forward pretty aggressively in the spring, summer and fall of 2007. So that was really the first action item that we thought we'd pursue and again pending feedback that Dr. Sullivan and Anita Smith gets from the meeting.

The second issue that was raised and there was some discussion about whether we had a resolution or whether we got more information and tried to move this forward potentially with the opportunity for a resolution or inclusion in this white paper is the concern that continues to be recognized of the persistent limitation of the availability of antiretroviral therapeutics particularly for children that require alternative formulations from the adult formulation. And again the Committee was encouraged by the First Lady's recent announcement and facilitating the gathering of really a number of the pharmaceutical companies in our country as well as the generic companies to meet together to begin to try to create innovative ways to address this requirement.

So at this stage rather than have a distinct resolution, there was some discussion. The commitment was to work together, Joe, to try to get sort of an update. I know the original meeting of the group was in late April and there was a follow-up meeting trying to get a sense of where that is and

then determine if there's a way that we can help just reinforce that process to sort of continue to highlight the need to move forward with given access to these medicines and the pediatric formulations. So those really were the two areas of discussions and summary in the manner in which the group as a group decided to proceed. I don't know if there is anybody else from the committee who would like to make a comment.

MEMBER YOGEV: Just that we agreed I presume to discuss a decision, identify an expert and discuss the issue at the next meeting.

MEMBER REDFIELD: Yes, Ram bought a third area that we did bring just in general just for the topics for discussion coming up at the next public meeting was there was significant discussion as there was in our previous conference about the whole issue of circumcision and what its role is as a prevention strategy and the recognition that it would be extremely useful like at this meeting where we had some different issues raised to try to look and identify many several individuals that may come

different points of view to come present these issues before the committee.

CO-CHAIR SULLIVAN: Thank you very much. Any questions or comments? Discussion? Is everyone comfortable with the proposal? Then we'll proceed according. I'd like to go back to the Prevention and Treatment Committee to raise a question to David. Two of the issues we talked about yesterday was the problem we heard about in our prisons and did you decide to defer that? Now that was one and then the whole issue was the college --

MEMBER REZNIK: The colleges we decided to defer. These motions were written pretty quickly as I think everyone could tell and the college issue is a very sensitive issue and we wanted to make sure that that one is managed appropriately. I think we have probably enough knowledge to write it, but we also want to make sure that it's handled in a fashion that won't cause a greater problem I think is the most appropriate way to word that.

And the prisoner issue actually does need to be addressed as well. We're talking about an

issue that's addressed that's seriously impacting an important community especially in the south. So considering that we had an one and a half to write the motions, I think that it was very difficult for us to come up with something quite that quickly.

With that being said, I think we can be more prepared after hearing the testimony and having our books. I think that we can write during off period and have something ready to go, but it's a very sensitive issue. When it was first brought up, I remember there were some who were very concerned that it would be only associated with HBCUs and it really wasn't. There were other schools that were involved but we do know that it's impacting African American youth and we do know it has to be addressed.

CO-CHAIR SULLIVAN: Okay. Thank you very much. Any other issue to come before the Council? If not, then I think that concludes our business and as I said earlier, it's been a pleasure to work with all of you and also thank my fellow outgoing members of the Council, Monica, Anita and Joe. It's been a pleasure to work with all of you. I certainly have

learned a lot during this process and thank you for helping educate me on this process and, Joe, thank you for great support and your staff and we'll certainly see if we could be helpful by hoping for a meeting with the Secretary. The meeting is adjourned. Thank you.

(Whereupon, the above-entitled matter was concluded at 3:10 p.m.)