PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

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THIRTIETH MEETING

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MONDAY,
JUNE 19, 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
HERBERT H. LUSK, M.Div., 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:

MARK DYBUL, Acting U.S. Global AIDS Coordinator, Office of the U.S. Global AIDS

MIGUEL GOMEZ, Director, The Leadership Campaign on AIDS, Office of HIV/AIDS Policy

ANDREW KAPLAN, M.D., Professor of Medicine and Microbiology & Immunology UNC School of Medicine

PETER A. LEONE, M.D., Medical Director, HIV/STD Prevention & Care Branch, Associate Professor of Infectious Diseases, UNC-Chapel Hill School of Medicine

JOHN C. MARTIN, Gilead Sciences

MARTY McGEEIN, Deputy Assistant Secretary for Disability, Aging and Long Term Care Policy, Office of the Assistant Secretary of Planning and Evaluation

JAMES D. SHELTON, M.D., Acting Deputy Director, Office of Population, United States Agency for International Development (USAID)

DAVID ALAIN WOHL, M.D., Clinical Associate Professor of Medicine, AIDS Clinical Research and Treatment Unit, UNC-Chapel Hill

C-O-N-T-E-N-T-S

P-R-O-C-E-E-D-I-N-G-S

(2:09 p.m.)

DR. SULLIVAN: Good morning, everyone. Welcome to the 30th meeting of the Presidential Advisory Council on HIV/AIDS.

And let me thank all of you for coming. As noted on the covers of your books, this is the 25th year that we have been aware of HIV and AIDS, and over that 25 years a lot of things have happened.

Among them, when I came to Washington in 1989, we as a nation were almost having an AIDS panic. There were demonstrations on the campus of NIH by advocates saying that we were not spending sufficient dollars or giving enough attention to this. There were discussions on the Congress.

And that year in October of 1989 I was pleased to approved reimbursement of AZT as a treatment, the first treatment shown to be effective against this virus.

Which you contrast that to today where we have more than two dozen medications. We also have another contrast: people with the diagnosis of HIV

often look forward to perhaps 12 to 18 months survival; now today they're looking at 12 to 18 years with their families raising children, earning wages.

So we've made a lot of progress. One of the predictions at that time was that within four years we would have a vaccine against this virus. Of course that is something that has proved to be very elusive.

We've made a lot of progress in our understanding and treatment of this disease, but what's clear to all of us is, we don't yet have a cure. This continues to be a major epidemic around the world.

In the United States where we have been more fortunate in our efforts, we still see an increase in the number of people who are carrying the virus. A few years ago it was 800,000. Now the data are a million to 1.1 million.

So all of us are challenged to support our scientists our legislative leaders, and others, as we work to try to find better ways to control this virus.

I think today's meeting and tomorrow's

gives us an opportunity to not only review where we've been but also see some of the challenges that still confront us, and where we need to go, areas not only in terms of research, but funding, policies, et cetera.

So I'm looking forward to the discussions today and tomorrow, and again, thank all of you for your contribution to these efforts.

With that I will turn to our executive director Joe Grogan for his comments.

MR. GROGAN: Thank you, Dr. Sullivan.

Just a few quick points. I guess first and foremost this is a sad day for me, personally, and for PACHA, because we're losing some members who I've grown very close to, I know we all have, including Dr. Sullivan and Anita Smith as co-chairs. Tomorrow will be their last day serving as co-chairs.

I got a nice note from Anita. She's actually in Africa, and she couldn't make it back. She had meetings all last week, and meetings starting tomorrow or the day after, I think, so it would have been a little bit crushing for her to make it all the

way back and turn right around.

But she wanted to express her regrets in not making it today, and also, the gratitude she's felt from all of you in serving on PACHA for over four years.

Secretary Leavitt, also, he wanted to be here today, and he called Dr. Sullivan. He had something on the schedule for about nine months that he couldn't get out of, but he did want to express his gratitude to Dr. Sullivan and to Anita, and to all of you here, and especially those who will be leaving.

And I know Monica who chaired the prevention subcommittee will be leaving as well.

So I want to thank you now. We'll have a little bit more tomorrow, but I wanted to just thank you now before we get started.

And then I guess our first speaker is going to be Miguel Gomez to talk about testing day.

DR. SULLIVAN: I might say, if Dr. Sweeney is our prevention chair, as a comment, as we lead into the discussion.

PREVENTION

DR. SWEENEY: Thank you.

I'm very happy to have Miguel Gomez here again, because he does come and speak to us often, and leading up to next Tuesday I think it's really very appropriate that he's here, and we're happy that you're here to address us again about HIV testing.

Thank you.

HIV TESTING DAY

MR. GOMEZ: Good morning. Thank you.

And Joe, as you are saying all these goodbyes, I know these individuals are going to continue to be warriors in the fight against HIV/AIDS.

So what's important is that many times I actually, because of my role and responsibility for coordinating on behalf of the department, HIV observance day, I just want to give a quite update on what's happening with observance days as a whole; talk about national HIV testing days; and really just pose a question for PACHA itself.

And actually the only reason I'm using a PowerPoint presentation today is to show you, look, there are now eight HIV observance days now, our

newest is Native American HIV/AIDS Awareness Day, which is actually going to commence next year on March 21st.

In March we had National Women and Girls AIDS Awareness Day which went out of the gate with gangbusters with over, in its first year, 160 events across the United States.

What's important to know again is, why are we so invested in these awareness days? Sometimes this is a statement of the obvious, but it's important to reinforce that it's important for the department and I know for national groups and local groups to use their resources and use the day to really get our messages out by supporting observance days, or raising that awareness.

But one thing that is also just core and important to the department it really does allow us to promote our policies, resources and programs.

And look at all those observance days, and I keep getting calls for more. Those working with our elderly want an awareness day. Those just on June 8th in the Caribbean there was Caribbean AIDS Awareness

Day which was not recognized nationally but was first time held in the Carribean so we are looking and meeting with those groups to see what is happening with that event, and will continue into the future.

One of the things that has been so important to us in the department is, we will continue to provide technical assistance, but one thing we have found is that building new partnerships with our faith communities, and community-based organizations who haven't been involved in HIV messaging but are willing to do events around observance days.

And we will continue to work with the lead organization around national HIV testing day, which is the national association of people with AIDS.

And this year we did something different which is, we linked June 5th, the 25th observance, and national HIV testing day, to try to do a one-two punch.

And one thing here in the department which some of you have heard that we do before, which is really important to repeat, is, we try and role model that we should make HIV testing routine.

So if you saw when you were coming up in the elevators today there were signs, we offer HIV testing for our employees around observance days.

It's real important to destigmify, and also make it seem in our health unit just like we offer flu shots, we offer an HIV test.

What's real important is that we also have web page for our HHS employees and the public which is actually housed at the office of minority health.

And this web page which is on the screen is the home page, which if you click on one of the icons, you can learn about events that are happening on those observance days throughout the country.

What's interesting, which is the most popular piece, is, this is the one for national HIV testing day. It's a little bit hard to see, perhaps, but you see that there is a poster. What we place on the web page that's real important is a poster that any community group can manipulate and use so that they have something that is colorful but can list their local event. They can turn that into letterhead, or they can print it out as posters, and

list their local organization.

What's interesting on this web page, the most downloaded product throughout the entire country is a basic one-page fact sheet still on the basic facts on HIV/AIDS. The poster is the second most downloaded thing from our web page. And the third most visited is the listing of all the community events around the country.

Again, national HIV testing day is what's in front of us. Again, it is that opportunity as we already know for folks to learn their status. But it's also important for us, we have to take a step back in our local communities to respond to the terrible myths that still respond in our communities. I'm sure most of you saw the Kaiser study that came out about a month and a half ago showing that perhaps up to 37 percent of Americans think that you can get HIV from kissing; 16 to 20 percent think that you might be able to get it from a toilet seat still today. So we really need to remember that these observance days not only for testing day to get information that we want people to know their status,

but we still need to get some of the basic facts out on HIV/AIDS.

The lead organization, many of you already may know, is the National Association of People with AIDS, and they have a contract with the Centers for Disease Control.

What's real important about working with the National Association of People with AIDS is the fact that their messaging often will focus on having it come from a person living with HIV/AIDS. And all the focus groups, there's been about 27 in the last two years around the country, has taught us again, our testing messages, real important to come from people living with HIV/AIDS.

And throughout the local community, the National Association of People with AIDS, it is highly trusted, and they also have a new executive director with the organization, just as a sidebar.

One of the things that is a step back, and one of the things, what we are doing with all grants, or many grants that we provide any agency when it comes to observance days is to really look to make

sure that we've having evaluation components. And we can say for last year's national HIV testing day that not only did we have 165 events throughout the country but that we actually saw an increase of folks going to HIV test dot org. And I'm sure all of you know what hivtest.org is. It's actually a federal web page, but folks, what they do is, they simply go to this web page, put their zip code in, and they can be linked immediately to a place to get an HIV test in the community in which they live.

It's very easy to use, and it also contains a list of all community events for National HIV Testing Day.

What we found, which is very interesting, is when folks wanted to learn about where to get a test, they did not want it to be hivtest.gov.

For this year's national HIV testing day there are some leading entertainers who are going to be involved. You may not necessarily in this room know who they are, but a group of younger folks will know, especially some of the stars, the first gentleman, he's a rapper and has his own show. Judy

is an absolutely outrageous comedian. Christina folks know, talk show host in the Latino community. Dennis folks know from the show 24. Selma Hayek is a big star within the Latino community.

But again this just shows you that in partnership that we're making sure that we're getting out the press kits, radio and TV interviews are being set up both with local, state and national folks; community papers are happening. And what's really interesting to us is that we this year decided to actually send out less of the kits to help communities do work because we weren't sure if they were actually being used, and there's been almost 4,000 of those kits already requested this year, and double the number of phone calls to the national association of people with AIDS to get information on national HIV testing day.

And already that we know of there are about 135 planned local events.

I already sort of told you quickly about hivtest.org, which is very important, both the White House and HHS promotes individuals going to this

website so they can get information on their HIV testing.

It's also important to know that we link with other national organizations to link to their databases to make sure this is accurate and up to date.

One thing before going to closing what I'd like to really share is that national HIV testing day is the second most visible day. It gets, in the 33 largest media markets, it's the second largest number of hits after World AIDS Day.

And however in the last two years we've seen a 40 percent decrease in the number of news coverage for national HIV testing day, and that's a concern of ours. And so we're of course pushing for more activity.

But one of the things that we found sort of startling is that the First Lady actually spoke on testing issues on June 2nd, which we thought would be very powerful. It got almost no news coverage.

She also called for something called International HIV Testing Day, and we don't know when

that day is going to occur; it hasn't been determined yet. But when you have powerful tools like the First Lady speaking out, supporting national HIV testing day, supporting testing, we really as a community and as PACHA ask you, how do we step back and look at how do we promote these awareness days, because they do work on the local level; they do work within specific community; but there is a lot of work we need to do.

And I've really actually even posed that to the organizations that are sitting behind you. Because again we've pumped a lot of money into observance days. But at the same time what are we doing at the national level? One of the things I liked Joe Grogan on World AIDS Day and other observance days, we'll send you an email asking you to send it out to your colleagues asking them to acknowledge the observance day.

But is there something that we should be doing in advance? Is there something our offices should be helping you do? Because again, we see the lower press coverage, more local events, but the overall goals of getting more people to know their

status, we still are challenged to make our efforts more effective.

I want to thank you again, and if you have any questions, I'll take them.

DR. SWEENEY: Are there any questions?

We have the opportunity now to get all our answers to national observance days.

DR. SULLIVAN: May I? Thank you very much for that presentation.

I really have two questions. One is, what is the process by which an organization gets designated for an AIDS day?

And because you mentioned that there'll be the Native American day, and so suggested that there is some process that really occurs.

And my second question is also with the comment that there are eight AIDS awareness days throughout the year.

And I guess my question here is whether or not having that number may really be confusing, and whether that may be a factor contributing to the disappointing press coverage if we have frequent days.

So I guess my question pertaining to that is, have you thought of the idea of -

MR. GOMEZ: Less is more?

DR. SULLIVAN: So I'm sure that you've had some discussions, but I wonder what the rationale is for having all these days spread out as opposed to having fewer perhaps with a larger effort.

MR. GOMEZ: Sure.

Your first question about how a day gets designated, it's a mixed bag, sir. For example Caribbean AIDS Awareness Day, there was a congressional resolution from a member from California who named June 8th Caribbean AIDS Awareness Day.

Usually what happens is, community organizations in partnership with national organizations, come together at some meeting and declare that they would like X day to be an observance day for the community they reach and serve.

Here at HHS our standard operating procedure is we recognize that call to action, we wait one year to see if actually the events do get pulled off; and if there is a network of nationally

recognized and local organizations who will plan events, HHS to date will recognize that awareness day.

Again, we do have to step back, and I actually love your feedback, are there too many? Given my history what I have found is that at the local level the community organizations are not challenged by this, and the best example is, because I was very concerned when we added yet another one in March called National Women and Girls HIV/AIDS Awareness Day, but was astounded in the first year, again, there were over 160 events immediately around the community.

It increased testing from our evaluation within those communities; it brought new people to the table, so we were very optimistic.

But it's a question I can't answer, do we have too many at this time?

DR. SWEENEY: Yes, David.

DR. REZNIK: Hi Miguel, thank you for your presentation.

My question is, when it comes to HIV testing day, is there buy in in activity from the

medical associations, the American AMA, the Hispanic medical association and the national medical associations? Because the CDC guidelines are calling for routine testing, and it would be interesting to see if the medical associations are sending out fact sheets via email communication, or are they involved in these events, et cetera.

MR. GOMEZ: Sure. The Hispanic Medical Association and the National Medical Association have been requested and have committed to actually placing information on their web pages and doing newsletter articles. The other medical association to my knowledge have been approached, but I can't document if there has been any action.

DR. SWEENEY: Dr. Redfield. Oh, I'm sorry, yes.

DR. BOLLINGER: Thank you, that was a great presentation.

I have a quick question. Reflected in my question might be a suggestion about marketing this issue a bit.

What percentage of the HHS employees have

been tested and are aware of their HIV status? And how much has this national testing day contributed to that awareness within your own organization? Could you use that as a marketing tool?

MR. GOMEZ: We do, actually. One thing that is really important for the last several years, both on World AIDS Day and national HIV testing day, we have about 67,000 employees. What we do is, we send most every observance day, those observance days, an email to our 67,000 employees letting them know that it is X observance day and that we encourage them to know their status, and we also highlight the fact that at least in the DC area we offer our employees HIV testing and then we direct them - we encourage them to learn more about HIV testing, and to go to hivtest.org.

And that model has helped us work with four different faith denominations and about five corporate entities. What we do is, we challenge them to do the same things for their employees.

And so we're very excited that actually this World AIDS Day all the Catholic parishes in the

United States will actually get a message to the individual parish encouraging them to have an HIV testing message very much like we do here at HHS. And there's about five national organizations that will be sending out emails to their employees and networks saying, we're basically challenging them, we can do it here at HHS, you can do it for your entity.

DR. BOLLINGER: But how effective is it? You talked about how important evaluations are?

MR. GOMEZ: Oh, I'm sorry. Actually, what we have found with our evaluations of the individuals who do get tested that we - actually, I can't quite - I remember I was pleased with the results. I can't remember the exact data. People were pleased it was offered at the workplace, and I don't want to guess what the other information is; to be honest I just don't quite remember.

What was real important to us because we also do it in partnership with our local health department here in D.C. is that their testers felt satisfied that they were willing to keep coming back, and with their limited resources I found that

pleasing, but I can't answer your question at this time.

DR. REDFIELD: Thank you, Miguel.

I wanted to follow up too on this sort of evaluation, because obviously the purpose of these days, and I think Dr. Sullivan's point of view probably deserves some reflection, you can dilute this out, but the purpose is that ultimately we become much more routine, not that day, but 365 days a year, in trying to get early diagnosis of HIV to be the prototype so that at least ignorant transmission of HIV can be confronted.

And my own view is, our nation hasn't optimized that historically, and we're 25 years into the epidemic, and we're still trying to see if we can actively totally engage the health community.

But what I would suggest is that people look at ways to be really very aggressive in getting evidence-based data to evaluate whether our policies are doing that.

For example one simple way which again in Bob's and my state, which is a little discouraging in

Maryland, if you look at the mead CDC four-cell count at the time of initial diagnosis, it's under 300. And that suggests to me that whatever we're doing isn't kind of getting there.

So it would be interesting to know across states what is the mean CD-4 cell count at the time of initial diagnosis, and then the following year is it getting better? Are we actually proactively engaging?

There may be ways from a policy point of view to - I'm not a punitive kind of person. I'm more the incentive kind of person. So incentivize states to bring that up, that those states that show that they are doing well, maybe they get greater support.

There is a tendency to support those individuals who do worse. I think that doesn't necessarily create the right environment.

So it'd be very useful for someone to really get a handle on it. If the issue is early diagnosis, one of the ways is mean CD-4 cell count at the time of diagnosis.

There's another way that would be interesting to me to get a handle on, how many of us

know that I wasn't infected two years ago but I'm infected now, in other words, as opposed to what we see too frequently in our clinics, we found out someone is infected and we ask, well, when is the last time you've been evaluated, and they say, well, I never had an HIV test before.

So people who are at risk for HIV infection, if they are proactively engaged, if the medical community is engaged, they should be able to say, well, I know I wasn't infected two years ago, because I was HIV negative two years ago.

So I think there has to be a much more objective criteria for this evaluation of the effectiveness of our policies in gaining early diagnosis as a standard.

MR. GOMEZ: I agree with you.

I mean it's great to know that last year we saw a bump of 35 percent in the number of people being tested, and X number of communities; but more data would be helpful.

DR. SWEENEY: I've just been told that we're just about out of time. But I'm just going to

ask about the poster.

People over 50 are increased incidence in people over 50, and of course with the health disparity, African-Americans. And yet on the poster as I can see it here, there isn't anyone that is representative of an older person.

And it's disproportionate in the number of - I'm looking on the observance day website - in the number of people who are representative of where the epidemic is now, which is primarily over 50 percent black.

I just wanted you to comment on that.

MR. GOMEZ: Sure. Actually I believe we do have a mature individual who is in the bottom corner. I can actually show you a copy.

And I do take note about needing to make sure that we are representative of the disproportionate impact on the African-American community.

DR. SWEENEY: Thank you.

DR. SULLIVAN: Madame Chair, let me ask one final question if I might.

On the poster describing HHS efforts, you say you provide free anonymous testing to federal government employees.

I guess that raises a question: Does that mean that someone who is not a federal employee who comes to one of these observances may -

MR. GOMEZ: No, that was just for our building here, sir; that was an example.

DR. SULLIVAN: I see.

MR. GOMEZ: And again in closing I want to thank you, but also actually to step back, because one of the things that we have found that has been - still we're very excited about what's happening locally, and I want to reinforce that.

But also what we haven't seen as much of our national players, like bodies like PACHA, actually speaking out at events or participating, and we really want to encourage that, and we're real excited that about 15 mayors around the country will be involved in HIV testing day events, and the next time I see you I think we'll be talking about perhaps World AIDS Day, and I wanted you all to know that departments in the

United States World AIDS Day event will take place in Memphis this December 1st bringing faith, civil and public health leaders together.

Thank you very much.

(Applause)

DR. SULLIVAN: Thank you, Miguel, for that update.

We'll now move to our Treatment and Care Committee under the leadership of Dr. Reznik.

So David.

TREATMENT AND CARE

DR. REZNIK: Thank you, Dr. Sullivan.

We're going to have quite a challenging year in treatment and care because of the new prevention initiatives, the testing days that you've heard about, getting people identified earlier into care.

We're going to have to look at how we provide that care. And one of the key aspects of that is Ryan White which we're still waiting for reauthorization on.

There will be other issues that we'll face

as well. But to start off our presentation today, I have to read this lady's title: deputy assistant secretary for disability, aging, and long-term care policy in the office of the assistant secretary of planning and evaluation.

So in this job Ms. McGeein, who is a nurse, has responsibilities related to active aging, innovative ways to finance long-term care, improving the quality of life for disabled persons, HIV/AIDS, medical malpractice, regulatory reform initiatives, and patient safety.

And when you look at all those different things that Ms. McGeein has had to deal with, there has been an extraordinary amount of time spent on getting the Ryan-White Care Act reauthorized.

I believe that our voices were heard over the last two years, as we've discussed this with Marty. And I'm very grateful for what is basically a thankless job. Because people don't realize the amount of time and effort and meetings with community and legislative folks that go into something as complicated as the care act is. I don't know if

people realize how complicated this piece of legislation is, and how small changes can have large impacts.

So it's with a great deal of thanks and respect that I introduce Ms. Marty McGeein.

(Applause)

RYAN-WHITE REAUTHORIZATION

MS. McGEEIN: Thank you, David. As always, I am delighted to be here. And I think I'm a decent multitasker. It's how things get done. But this doesn't explain why I haven't returned any of your phone calls in the last few months.

I see lots of new faces at the table. Some of you have no idea who I am. Others know that I come here routinely and tell you either good or bad news.

The news today is mixed. We're going to talk about the reauthorization, and it is a work in process.

I'm going to divide my presentation into three pieces: principles, process and product. And of the three, although the product is what most

interests you, the process is the one that we really should be focusing on today.

As you know the president is intensely interested in this issue, and he laid down some principles that the Ryan-White reauthorzation was to follow: life-saving care to those most in need; establish a core set of medical services; establish a severity of need index; do away with some of this jockeying around the formulas; routine voluntary testing in public facilities; redistribute the unobligated balance; and unless you are a cost accountant, the unobligated balances things goes right over your head. Let me just explain the bottom line, money the grantees do not use that we the department are unable to recoup and put into better or more product uses goes back to the Treasury.

Out top, bottom, side was, no intent to destabilize the system. Absolutely the guiding principle: do not destabilize the system.

The process that we're involved with, Secretary Leavitt announced the administration principles last summer. And I think some part of

PACHA was there.

As soon as the announcement we started a series of educational briefings for Hill staff. These briefings included HRSA, they included CDC, they included ASPE, my shop; they included ASL which is our legislative shop. They included anyone who needed to bring in to instruct a very large group of legislative assistants who were going to be active in this issue.

That series of briefings went on for six months. The congressional leadership of the two authorizing committees, Senate Health and House Energy and Commerce, committed to a bipartisan and bicameral approach to writing this legislation.

The goal was to have one bill that everyone had agreed to prior to the bill going to any of the committees for markup or vote, so that we have one bill, that once it was settled, it could be passed and signed into law.

This group became known as the Four Corners Plus One. The Four Corners were the Republican-Democrat Senate-House leadership; the

Energy and Commerce Democratic and Republican leadership and HHS.

So it was Four Corners Plus One which some of the people in the back seats have heard about, oh the Four Corners are meeting.

This bipartisan bicameral group has met over the past five or six months a lot. There have been some days when there have been meetings everyday, and some meetings that last three or four hours.

And now I understand why people hate meetings so very much, as if I needed it really impressed on me.

But we've gotten a lot of work done. In May the Senate Health Committee passed the Ryan-White HIV Treatment Modernization Act of 2006 with one dissenting vote.

There are basic elements of the bill - and this is where I need to warn you, warn the PACHA people, the people in the back - we are not through. The bill changes - as data becomes apparent, the bill changes; as someone makes a case that we have

made, a tactical flaw, an error, or a policy flaw.

We are open and listening to suggestions. And I see Bill McCall back there.

What I'm telling you is, there are some basic tenets. There are some things that will not change. But I am not going to tell you in deep deep detail what's in the bill, because of what I find is a moving target.

The basic elements in the bill: the title structure remains the same, so there'll be a Title I, Title II, Title III, Title IV.

Elements of the current act that are working effectively will remain.

Funds that were distributed by formula today will be distributed by formula under the new act.

The HIV reporting requirement which was in the 2000 reauth will absolutely remain in this and the department will enforce it.

All grantees will be held to a 10 percent cap on admin cost. All grantees who treat beneficiaries - because not everyone treats or has

their hands on clients - will be held to the 75-25 percent division. And when the president talked about core medical services, he believed that any penny not spent on these life-saving services was perhaps not best used.

So our negotiated position was that 75 percent of the finances that you received to treat a beneficiary must be spent on the core medical services.

The 25 percent, remaining 25 percent, may be used for support services as long as they achieve a medical outcome.

All formulas where appropriate will be based on living AIDS cases. There's a big change for some areas. All grantees will submit an audit, submit to, and submit the audit every other year.

All grantees must demonstrate in their application how the proposal fits within their state plan.

And HRSA is going to be fairly stringent on this requirement.

In Title I at the moment it's proposed to

create three tiers. As you know Title I is the EMAs. Eligibility would be based on living AIDS cases over the past five years. And EMA would cease to be if it fails to meet the eligibility criteria for three consecutive years.

The division of the funding in Title I would change from 50-50, which is sort of in my language 50 percent base, 50 percent for supplement, to a 66 two-thirds 33 one-third change. The 33-1/2 would be the supplemental.

There would be a three-year phaseout of the hold harmless provisions.

In Title II, the base and ADAP remain. There are two new supplementals, one in Title II base, and another in ADAP.

The three percent set aside in ADAP is increased to five percent.

Each state that receives ADAP funds, which is everybody, must create a drug list that reflects the public health service HIV/AIDS treatment guideline, to provide for consistency across the nation.

In Title III stays very much the same. All grantees providing services must adhere to the 75-25 split. Rural health clinics and certain Indian health centers are eligible for Title III funding. This is a major change.

And the Indian health service is excluded from payer of last resort provisions.

In Title IV - David is going to do the hi-fi this time - much stays the same. There will be an increased focus on family-centered care. All grantees must submit audits to the state agency, which is the same as the other titles.

And GAO will be asked to conduct an evaluation of Title IV funding for program effectiveness - actually the language is better than that - but it's something that has never been done.

Title V, coordination of HIV programs must include the minority AIDS initiative. We have inserted public health emergency language.

Katrina taught this department, the government, and the United States, a lot of lessons. But what it taught the department vis-a-vis Ryan-

White was that we were unprepared to do anything for the grantee that needed help during this emergency.

Once our emergency authority expired, we were helpless. So we were trying to do some fix, but it's not going to be in this act for Louisiana. But it did, it all of a sudden made people realize, my goodness, we really need to be prepared for this in the future.

In Title V, GAO will submit a report to Congress every two years on barriers to program integration. What we are trying to achieve, although it doesn't sound like it from all these pieces, is, there is one profile for treating a patient within a state, so your Title Is, your Title IIs, if you've got Title III money, if you've got Title IV money, that they are working together to improve the health of the particular client who is receiving services.

Spends money - this is a basic change. The spends will be used to develop a standardized electronic planning commission data system to improve grantee reporting of client level data to the secretary.

We struggled with this. This secretary and the president and I think all of us in the room understand that health IT, health information technology, is really where the world both needs to go for quality, but it also is the better way to maintain records. It ameliorates medication errors, overtreatment, undertreatment. There are things that health IT can do that a paper record can't do.

And there are some major institutions, the VA for one, Hopkins for another, that have already instituted health IT and are understanding its value.

We struggled with how to introduce it into Ryan-White understanding full well that every penny of a grantee's money is so precious, it is so necessary for care. So we feel that SPINS was an appropriate place to take that up.

And that pretty much concludes what we are planning to do.

Joe had asked that I allow some time for questions, so have at it.

Oh, good, I'm done.

DR. REZNIK: Ram?

DR. YOGEV: You mentioned that at least two of the titles are going according to living AIDS cases.

MS. McGEEIN: Correct.

DR. YOGEV: This is markedly in contrast to what we are trying to do. We stop the AIDS. I have now my own state, Illinois, children who have AIDS by definition, because they don't have active AIDS, they reach 18, they don't have where to go.

Why are we not going through the HIV? It's also contradictory to me to go and identify HIV patient, because the HIV is not a major burden of my system, and yet I'm giving only by AIDS or reduced by number, whether they died or because of treatment.

So the premise to go by AIDS doesn't make sense to me.

MS. McGEEIN: Thank you. Actually I'm glad you brought that up. The statement will be HIV/AIDS, so your clients will be picked up.

DR. YOGEV: So we are going to go by HIV.

MS. McGEEIN: Yes.

DR. YOGEV: And that's why we'll go to annual reporting and so forth? Thank you.

MS. McGEEIN: Soon as you started I realized, but I didn't say it. You guys are doing a good job. You're keeping clients from progressing to AIDS.

DR. REZNIK: Dr. Redfield.

DR. REDFIELD: I just would be interested if you could give me some sense of the debate or the thought process that decided to keep all the titles separate.

As a recipient I think I have about 40 separate Ryan-White grants which I try to patch together to provide care for 3-4,000 people, and some times I get funding for all the pieces that I need, and sometimes I don't get funding for all the pieces I need. And we don't have Title III money unfortunately, which I have seen to be a more effective way of integrating comprehensive care and treatment.

So I'd just be interested from your perspective about how that debate goes of trying to

integrate this rather than having all these separate titles and separate perspectives and separate requirements.

If the purpose is now to try to see that this is integrated care from a medical point of view, which I'm an advocate of, the 75-25 split, so the support of care supports primary care.

So I'd just like your view on that, or how those discussions happened in this six months of interaction that you had.

MS. McGEEIN: Well, it was endless. There were both political reasons and policy reasons.

The political reasons were obvious. The Title I to EMAs said, we can't do this. Please don't do it.

The groups that advocate for the Title I grantees said basically the same thing, that they could not rely - they did not believe that they could rely upon the state to adequately address the needs within what is now their EMA, and they felt that they made better use of the money by coming straight to them.

That has some validity. If California had to consistently go to the governor to find out, or to the state AIDS director, this is what we need in San Francisco, there probably would be a loss of efficiency.

And one of my goals, and people who have been talking to me for a period of time know that I want this act to be efficient, we feared a lost of efficiency.

From the policy side, as a policy person, I don't disagree with you. I believe that one fund however we allocated it out to states and territories, have the potential for being more efficient.

But that would be the equivalent of a demonstration project that I am not willing to undertake with a $2.2 billion program that people's lives are dependent upon.

So I hear you, I understand you. We're not that far apart, but it presents lots of problems.

DR. REDFIELD: But again I guess the door

would be open then for considering in the future what you said, for some areas to try something like that as a demonstration project to see if and how that could be accomplished.

MS. McGEEIN: If somebody wants to step forward with a proposal we would love to look at it. What state are you from?

DR. REDFIELD: Maryland. Do you have HIV name reporting yet?

(Off-mike remark)

DR. REZNIK: I have a question, Marty? And I don't know how to ask this without asking a specific, so it might take me a second.

I guess the best way to ask the question is, will we have reauthorization before the recess? I'm not talking about the July 4th recess; I'm talking about before people go home for elections. It's been two years, two state of the unions, incredible effort on your part, and of the Four Corners, and we seem to be held up again.

So your take: will we get reauthorization this year?

MS. McGEEIN: Oh, gosh, are you going to hold me to this.

All of us are desperately wanting reauthorization. We believe that the changes that are being proposed sets the - lays the predicate for a different type of Ryan-White system.

The hold up on the House side - and I actually admire the person who held it up a little bit - he - the belief was the data, the modeling data that we had presented, didn't exactly capture all of the changes and so basically to use my kid's language it got kicked to the curb.

We ASPE are about to start a new modeling - a new modeling run to see if we can get data sufficient. That is the only thing that's holding it up on the House side. As you know it was scheduled to be marked up last week. A good look at the data said, time out, we're going to do something different.

It is scheduled - I was actually going to look before I came - it is scheduled in the House this week or possibly next week. There is on all

sides, the Four Corners Plus One, the advocacy groups, the people at this table, the grantees, they want this over; the president wants this over. But we also want an effective bill. We also want something that is actually going to work. So we are willing to spend the time.

But I understand the election year pressures, and the need to get out of here. The House is supposed to go out the 5th of August, and it's going to stay out until the 5th of September. That means either a really really busy July or a really really busy September.

But I'm not giving you a yes or no answer, because in my heart of hearts I so want this to be enacted.

DR. REDFIELD: Well, on your data run that's coming out of your department, will you have that prepared?

MS. McGEEIN: We don't even have the data yet. So once we get - these are not hard runs. These are not complicated multivariant runs. We're waiting for one set of data. As soon as we get that

data we'll start loading codes and it's good to go. And computers are nanoseconds.

But because we are making changes, the data that we are looking for has to be changed along with it. So we are asking agencies and operatives to do things that they do not routinely do. I understand the reluctance; I also understand the difficulty.

MR. HOLMER: Are there outstanding funding issues?

MS. McGEEIN: Not really. Do you have one in mind?

MR. HOLMER: No.

MS. McGEEIN: I'm just trying to think. No.

DR. REZNIK: I think there's been some community push-back on the level of increase that some of the titles within the Care Act are getting, and some are actually being flat funded. I think that might be.

MS. McGEEIN: Is that your - okay. As you know the president is putting in $95 million into the

Care Act, that currently is targeted to go, $70 million of it, is targeted to go part of it into the base Title II and the remaining into ADAP. It's very specific months to clear the waiting list. The $25 million would go into Title III, it's scheduled to go into Title III.

But as I've said before to this group, my famous Lyndon Johnson quote, the president proposes, the Congress disposes, the appropriators are meeting as we speak, and we will see if we get the increase.

Easy group.

DR. REZNIK: Dr. Yogev.

DR. YOGEV: My understanding now is that some of the title will be open to cities with 500 HIV/AIDS cases; is that correct?

MS. McGEEIN: That is not - that much - in the current act there is something called the emerging communities. I think it's a city within the metropolitan statistical area, and they have 500 up to 999 cases that is not all - this is basically the same thing. The proposal is to move that grouping, that type, into Title I. It may get moved back into

Title II. That is one of those - it flips on alternate days.

DR. YOGEV: If you do it it will increase the number of cities that are going to pick up on the same amount of funding. Obviously it will affect the biggest -

MS. McGEEIN: If it's a five year count. So they would have to demonstrate that that had that number of cases for five years.

DR. YOGEV: Yes, but still, 500 is a much smaller number, which is appropriate; I have no problem with that.

The point is there will be many more competing on the same amount of money. Is that taken any way into consideration.

MS. McGEEIN: We're the authorizers. The Four Corners are the authorizers; they're not the appropriators. Whether the appropriators make the choice to put more money into Title I or Title II, we can suggest but we cannot make them do it.

DR. YOGEV: I'm a little bit worried about the efficiency, because with all the documentation

audit now you are requesting which are appropriate, it's going to increase that administrative part, which are not going to be paid by the same funds that are not going to be disbursed to a much bigger number of cities.

MS. McGEEIN: I'm going to have to ask you to remember that all of these cities are located within states. The states will get money, and if there is a city, or a grantee within a city that seems to be bearing an unequal burden, then it's there obligation to let the city know that. That's number one.

Number two, the Title III grants are designed to look at sort of overall. If you've got a city that has had a serious decline in their financial resources from Ryan-White because of this new category, they can certainly apply for one of the supplementals.

So there are two or three branches, avenues, revenue streams, that are in the act that a city as you describe certainly could look at and go, hm, I think that might work.

DR. REZNIK: I'm back, and then Dr. Redfield, Marty.

There's two questions I have. One concerns ADAP, because you just mentioned that part of what the president wanted was funding to address the waiting lists.

And I've read the legislation. Actually, I've never read legislation so many times that my eyes started crossing. Is there a mechanism in this bill that would allow - we have that president's AIDS initiative last year that was $20 million, and there wasn't a mechanism through the Care Act to actually get the money where it needed to go.

Will there be a mechanism in the reauthorized bill that will allow that to happen.

MS. McGEEIN: These are all really good questions, thank you.

Yes, the second set aside in ADAP is called - Dr. Sullivan and any other medical person - a potential space. For this time, for this cycle, it is anticipated that $40 million of the president's money will go into that second set aside, the second

supplemental. There's a set aside, and then there's a supplemental. And the criterion for the supplemental is specifically that there is an AIDS waiting list that needs to be cleared, or that as Michelle very graciously identified, you have found new cases through testing initiatives and cannot provide care for them; that that's where $40 million of that money is to go.

DR. REZNIK: So it could be states in the south. It could be New York; it could be California, depending on their case minding.

MS. McGEEIN: Correct. But since one of your criteria would be a waiting list, one can presume it will be states in the south.

DR. REZNIK: And then my follow up was, you just sort of mentioned that tier three is sort of bouncing back between Title I and II depending on the conversation.

Is there any similar conversation that you're willing to scare - she scares me sometime - willing to share on core services? Is that discussion - are the core services sort of set now?

Is that set by the Four Corners Plus One and over with?

MS. McGEEIN: That's done.

DR. REZNIK: That's done.

DR. REDFIELD: I just wanted to take an opportunity to learn a little more on the waiting list, and you didn't mention the south as disproportionately probably in that category in terms of patients that have waiting lists for medication.

In the state of Maryland we've been able to avoid waiting lists. How much does the state contribute to this process? How much is federal versus state? I mean are we again rewarding people that don't contribute? Or is it the fact that southern states, like say North Carolina, has a waiting list because they are not getting adequate federal funding, or is it they're not using some of their own state funding?

I'd like to understand this a little better, because I'm perplexed by it.

MS. McGEEIN: All the above and next. First of all under the current formula where we are

counting AIDS cases, and it's a 120-month count, so basically it's a 10-year count, in those cities and states where the epidemic is fairly new, or that are doing a phenomenal job of keeping people from progressing to AIDS, they do not get picked up in the formula either for Title I or for Title II.

So in the south where for some period of time the epidemic was either hidden or it had just migrated to there, they are getting very little through the current formula.

So part of it is, certainly in Alabama, Georgia, Louisiana, North Carolina, South Carolina, part of that is, there is aa federal - they're getting less federal funds than the northern tier who have had the older epidemic. That's number one.

How much the state puts in, I don't have that data; I don't even know if that data exists. I'm looking at Joe. David is telling me yes, it does.

But it's a blend. The thing that we can fix is the federal formula. The formula issue does affect those states that have a younger epidemic or

are doing a really good job keeping people from moving to AIDS.

There are some states who have their own financial problems who are unable to put much money in. We have some states with less than perfect Medicaid programs.

The fine line that we tried very carefully to walk is, we did not want to create any perverse incentives to those states that have readily good Medicaid programs who are willingly treating HIV patients or the AIDS patients that take the burden off Ryan-White.

So it is a mix, it is a stew of reasons, that we could thread our way through, but the only thing we've got our hands on is the federal funding.

DR. REZNIK: Dr. Sullivan, and then one more from over here.

DR. SULLIVAN: Marty, thank you for keeping us informed about the latest study process.

I guess my question is related to I think some of the feeling I sensed with members of the council, and that is, there aren't many legislative

days before Congress adjourns, and this really has been a long slow and tedious process.

I guess my question is, would it be helpful for this council to urge the Congress to really complete this bill before it adjourns before the year; then coupled with that is another question to be sure if I'm on cycle, if they don't complete the bill this year, do they start all over again? Or is this carried over?

Because it's taken a long time to get here, and what I hear you saying is, we're very close, but somehow I get the sense - and this may be my own misinterpretation - but I get the sense that this could run out of gas, and we might end up without this.

So my question is, how can this council be helpful in trying to be sure we get this really across the goal line so we'll really have this bill and this funding.

MS. McGEEIN: This is when I speak very directly and I make everybody in the room nervous, so of OGC is here, you might want to step out.

I don't know what PACHA's charter is. I don't know if it is within your purview to send a message to Congress urging them to get this across the goal line. I don't know that; I would bow to your more considered opinion. I can't tell you that.

We are acutely aware of how few legislative days are left. You were secretary here, sir, you know how much we live by the legislation calendar.

There is among the Four Corners Plus One, we want to get this done for all sorts of reasons.

There are people, there are groups, single people, groups of people, that do not want us to get it done. And there's a movement to try to stop it.

So we are working mightily to get it done. We believe that we have the power to get it done. But you do need to know that there are people who do better under the current act than they will under the new act. So there are people who would just as soon see this fail.

If this fails, if this effort fails,

regardless of what happens in the November elections, we will not see a bipartisan bicameral group start over again in January.

The president is still president. We will put our proposal forward; the Democrats will put theirs forward; the Republicans will put theirs forward; and then we'll duke it out.

But the reason I spent some time on process is, this is a very unusual process, and the goal was to make sure that everyone was heard - I spent a year or more, Joe was at many of the meetings, more than a year - listening, thinking through, analyzing, collating information, from your group, from the CHAC, from the advocacy groups, from individuals, we read everything. We analyzed everything. We came to the table prepared we thought with positions such that they represented not everybody's personal opinion but the collation of those.

I want this to happen. I want this to occur. I want a new Ryan-White act as predicate laid down. It is important for the clients who receive

the services.

DR. REZNIK: Marty, first, the amount of effort as I mentioned earlier -

MS. McGEEIN: How many questions are you allowed?

DR. REZNIK: I'm chair of this section.

MS. McGEEIN: Fine.

DR. REZNIK: Until they boot me here. It's been an incredible effort by all members that have been involved in this.

I have one question that's sort of a little bit different. It ties in the testing initiative that really emanates from HHS through HRSA, it's the bureau of primary care. Is the bureau of primary care actually working towards routine testing in the community health centers which is a concern?

And two, since I think that eventually has to happen, my final concern, I guess my final statement, because as I said I've seen the latest, my latest version of the bill, I'm sure not what you've seen, I am concerned about the percentage increases

that are in the titles.

I know that it's not an authorized decision on appropriations, but I do know that when the appropriators look at a bill, and it suggests that 3.7 percent for titles one through four, maybe - or three - and then that four in part are flat funded, I think that we're going to - if we're successful we are identifying more people; we will identify them earlier in the disease.

But as someone who works in a very large program in Atlanta, we are slammed. I mean honestly slammed. We are already a core service model in that community. We have been for several years.

And if we see another huge influx of patients with a percent increase that is much less than the cost of providing medical care, I'm afraid - and then Dr. Saag will talk to this tomorrow - and we're not seeing a great swarm of new young providers coming to deal with this, I'm afraid that our own infrastructure, our own ability to care for this patient population could dwindle with that number.

So I guess it's a two-pronged question.

One, is the bureau doing what it needs to do to get people tested?

And the 3.7 percent, I mean if that is what it's going to take to get something passed then I'm going to support it, but I think there is an issue there, and I think there is an issue for ADAP. I think there are issues for the care providers in one, two and three and other parts of the act. I think that's important.

And I guess I ought to finally say before I let you speak is that we will come up with a motion, whether or not it's within our jurisdiction; Joe can determine that. But we will say something very strongly, because I've been acutely aware of the effort and the dedication and the compassion that's gone in from all parties involved in this process, and it needs to be completed.

MS. McGEEIN: Thank you.

On the Bureau of Primary Health Care and community health centers, they are as committed to testing as probably anybody in the department, and they are - and NIA is an interagency transfer of

money - they operate for this purpose with IAE from CDC. So they are receiving funds outside of their appropriated base on a transfer level to make sure that testing is occurring in the community health centers and other centers where they are active.

But the big difference, and you probably picked up on it, but the big difference in the law is that we are now seeing the rural health centers, before were excluded from any service or any treatment money, are now an eligible grantee, so that expands that base where we keep hearing a lot of the problem is, but there are not the providers per se to take care of it. So by including the rural health centers, and by including the Indian health service both as a grantee, but also excluding from the payer of last resort provision, we hope, we believe, we're expanding that network of providers more broadly.

On the 3.7 percent increase there is this wonderful language called notwithstanding. The appropriators tend to do what the appropriators want to do. As I say they're doing it right now in Congress.

As I remember over the last three years or so that this issue has been on my desk, I do believe that ADAP has consistently received additional funds while the other titles have not.

David, I agree that there should be more money in this act. I also know that there are multiple demands. Talk to Dr. Sullivan sometime in an offhand moment. There are multiple demands on the federal budget right now; this might be the best we're going to do. And it is an increase. Everyone keeps saying it's level funding. Only in Washington is a 3.7 percent increase level funding.

So I hear you. I understand you. This is probably the best that we're going to be able to do. Plus we're getting $95 million extra.

DR. REZNIK: Jackie, and you'll be the last question.

MS. CLEMENTS: Okay, thank you.

Dr. Redfield, I guess in defense of North Carolina, I have to say we put an enormous amount of money into our ADAP program. We are in the southern states that are seeing a huge emergence of this

infection, new infections.

So you ran through, Ms. McGeein, a whole list of things that are part of this legislation.

Can you tell me - and it really sort of blows my mind sometimes - but do you see that this new act is going to help the southern states? And the president did say, and we said, that we want the money to follow the disease, and it is in the south, so we're in need of help in that area. A lot of southern states are.

And so do you see that that is going to happen?

MS. McGEEIN: If we did nothing else other than shift the formula to HIV/AIDS, if we did nothing else and walked away, your state would do better, because you're a named space reporting state.

So if that alone, that changes the dynamic. It changes the way the funds will be distributed; that should make a significant change.

Is it going to be enough to make up whatever shortfall exists in your states? I can't tell you. But I do know that just that alone will

make a difference.

The federal government theoretically cannot legislation for states. But the thing that we heard consistently over the year of information gathering was that the epidemic is in the Southeast. The new burgeoning epidemic disease zone.

So without creating a Ryan-White program for the Southeast, which you probably would like, what we needed to do was to make the program that we've got more rational. And counting AIDS cases doesn't cut it.

So the biggest piece that you're going to get is going to be the HIV counts. DR. REZNIK: Thank you, Marty, for a wonderful presentation, for putting up with all our questions.

And again, please thank those Four Corner people plus yourself for the tremendous effort that's gone into updating and modernizing.

Thank you.

MS. McGEEIN: A pleasure. As always, it's fun.

(Applause)

DR. REZNIK: Dr. Sullivan.

DR. SULLIVAN: Well, thank you very much.

We'll take a break until 10:25, and we will make up the 15 minutes we are behind by having 45 minutes for lunch. So we'll try to keep the rest of the schedule going. So 10:25, thank you.

(Whereupon 10:15 a.m. the proceeding in the above-entitled matter went off the record to return on the record at 10:31 a.m.)

DR. SULLIVAN: Our next part of our deliberations will be under the leadership of the prevention committee, who is chaired by Dr. Sweeney. So Monica we'll have you take the chair.

PREVENTION

DR. SWEENEY: Thank you.

At this time I am going to introduce Dr. Leone, who is going to talk about HIV sexual networks in college campuses.

I will just read what is written in our agenda and hope that you will read his impressive bio.

Dr. Peter Leone, medical director, HIV/STD prevention and care branch, associate professor of infectious diseases at UNC Chapel Hill School of Medicine.

And it's really a pleasure to have Dr. Leone here. I have read some of his things, and know that this is going to be very informative for us as we go forward.

Dr. Leone, welcome.

HIV, SEXUAL NETWORKS AND COLLEGES CAMPUSES

DR. LEONE: Thank you. I appreciate the opportunity to present. And I want to thank Joseph in particular who arranged for me to come here.

And we'll hopefully get into some lively discussion. I wish I could tell you I had great answers for what I consider to be an ongoing epidemic on our college campuses. I don't.

But I think one of the things that I'm concerned about is that there was a lot of attention brought to this matter maybe two years ago when Lisa Hightow and I first reported on what we saw as a burgeoning college outbreak among black college

students in North Carolina.

Unfortunately, that epidemic seems to continue, and we have data that actually runs through 2004. So what I want to do is give you a brief overview on how that came to sort of our understanding of the outbreak; what it means I think in terms of how this thing ties together. And I'm sure we'll get into some discussions about whether or not this is unique to college campuses in North Carolina; whether or not it's a broader issue that needs to be addressed; and whether or nor these cases are somehow different than the underlying issues that black MSM face in the south.

So with that I'm going to go ahead and get started and actually present a real case, a 21-year-old African-American male college student who presented at student health at UNC, the urgent care clinic there; had five days of sweats, heartburn, sore throat and fatigue, and on examination was febrile but had a yeast infection in his mouth, had what we call pharyngitis, and some tender cervical adenopathies, the swollen lymph nodes in his neck.

And again if you look at his labs pretty nonspecific findings, low white blood cell count, mild elevation of his liver enzymes, all which would suggest that he had some diffuse inflammation, viral illness.

He had an HIV antibody test done, which is a standard way of doing testing, and was negative, but he actually saw one of the infectious disease physicians at UNC who thought about acute HIV, and this is indeed what he had.

And the HIV viral load had over 6 million copies per mil, was p24 antigen positive as well, which is one of the proteins that we see expressed on HIV, and was HIV-DNA positive.

So what this college student had was acute HIV, the very earliest stage of HIV, and who Mike Cohen who is going to be here tomorrow - it's like UNC day I think between today and tomorrow, so I'll have to give Mike a little bit of grief, the fact that his staff actually made it here before he did. He's coming in from England tonight.

But the importance of this was that we had just set up a program in North Carolina at around

the time that we started seeing college cases, picking up this very early stage of acute HIV. And I think this is important when we look back at how this epidemic took off, what drove I think the early stage of this epidemic was the fact that we had a lot of new cases with very high viral loads. Six million copies per mil means that you're looking at very high potential for transmission. Short phase of high infectivity during acute HIV only about eight weeks to 12 weeks, but important in terms of the fact that a lot of these kids are missed, given a diagnosis of a nonspecific viral illness.

Now to put things in a broader context before I come back to what we see among college students in North Carolina, this slide is looking at modes of transmission in North Carolina in terms of risk factors. And what you can see in this slide is that starting around 2001 - 2002 we started seeing an increase in the number of MSM that were being diagnosed with HIV, which has continued actually through 2005.

This parallels what you're going to see

in terms of the takeoff of college cases in North Carolina.

In November of 2002 North Carolina established acute HIV tracing and screening program call STAT Program. It's a program designed really to look at doing screening on folks who are HIV antibody negative, and rolling those tests over to pooled assays which we can do HIV/RNA screening. It's robotic pooling. It allows us to pick up this very early phase like the case that I just talked about among the college students in North Carolina.

First three months of the program we had five acute HIV cases. Two of them were among college students; same town; they weren't connected through direct sexual partners.

Now that may not seem like a lot, but for us that seems pretty unusual that we would have two cases in the same town, and really raised a lot of questions about, is this a bigger issue? What was the sexual transmission network like? And so we would be looking further.

To be honest we made a few phone calls to

a couple of clinics in the area, and we found out that some of the clinicians in these HIV clinics reported seeing college students newly referred to them, so that actually started us looking back and doing a retrospective review of all the states' surveillance records, and men between the ages of 18 and 30, starting January 2000; now we have data through April 30th, 2005, and in the summer we're going to be doing another sweep to complete 2005 and the first part of 2006.

We reviewed all 100 North Carolina counties. Now the reason we were able to review records in North Carolina is that North Carolina has had HIV reporting for years, name reporting of cases, all newly diagnosed cases of HIV in North Carolina are interviewed. That information is entered into the CDC STD MIS system. It's an information system that is kept confidentially at the state.

When we saw this we were able to go back, review those records, and actually abstract data that would allow us to look at this age group and look for risk factors.

So we looked at all the counseling and testing site data, and reviewed all of the DIS interview records that were available for newly diagnosed young men between the ages of 18 and 30.

In doing that with Lisa Hightow we actually found about 1,400 cases of new HIV diagnosis in men in that age group during that time period, about a five-year time period.

About 1,200 of these cases were available for reviewing; that's about 85 of the cases. And it turned out that 13 percent of these were among college students.

Now let me be very clear about what I mean by college students here. That means when they were diagnosed they were enrolled in a school. So we asked them when they were being interviewed, what's typically asked is, where do you live? Where do you meet partners? Our DIS routinely do that as a part of interviewing and review.

And in this case what they heard was that they were enrolled in a school. So this college student listing is a pretty narrow definition. They

had to be enrolled in a college at the time they were diagnosed.

Does that mean they got infected in school? Not necessarily, but given the age of these folks it's hard to believe that they got infected at 15 or 16, and what we are seeing when we start looking at this a little bit more is that I do believe that many of these students got infected while they were in school.

Now the bulk are still non-college students; 87 percent or so are not in school. But it's the trend that is concerning here.

If you look at 2000, and look at the number of cases on the left hand part of the slide, and the Y-axis here is by year, you can see an increase in the number of college students, which is the light blue column in terms of number of cases. The number of newly diagnosed cases has also gone up during that time period.

Now it looks like there was a drop in 2005 but part of the reason for that is, this is only the first quarter, and even though we have reporting

of cases that is mandated within seven days, there is always a lag in terms of getting reports into the state where we can review. So we're actually not going to have 2005 data until the end of the summer. So I'd be happy to come back at some point and tell you whether or not our programs that we've instituted in North Carolina have made a difference in the last year or so. If anything the cases may have gone up because we're doing more work on campuses.

So let's just look at the college cases, and what you see here are about five cases in 2000. By 2004 we're up to nearly 50 cases.

Now that may be because we're seeing a slight increase in MSM, but if you look at the percentage of total cases of young men between the ages of 18 and 30, and how many of these were in college students, you can see that it's not just a matter of increase in sheer number of total new cases diagnosed. We went from around five percent in 2000 to around 15 percent in 2004.

So what we think is an alarming increase, and one that from an epicurve standpoint would

suggest that the numbers have gone up.

Now this doesn't explain why. It just says that we're seeing and increase, and an increase in the number of cases in college students.

Now 14 or 15 percent may not seem like a lot, but just stop and think about that number for a second. That means that about one in seven newly diagnosed cases are in college students. That's pretty alarming.

In addition what it means is that we're probably underestimating the number of cases that we're seeing here because again, the way we collect this information is what's reported to us. It doesn't mean that there aren't other folks that are infected.

And when we break this down a little bit more and look at the number of college cases based on classified them as rather AIDS cases, whether they were chronically infected or recently infected, and by recent infection we mean that they either were acute HIV where they did not have antibodies but were RNA positive, the first eight to 12 weeks of HIV

infection, or they had a documented negative test within six months of being diagnosed with HIV.

And remember I said that early phase of HIV is very infectious. Lots of virus in the blood and in general secretions, and again, may be a driving force for transmission.

Now this is a retrospective look. So we don't believe, at least starting in 2003 when we looked backwards that we biased the information.

There were no new interventions on college campuses to increase screening. And yet you can see here that when this thing took off, what we can see is that about 30 plus percent, almost a third of these cases, were recently infected college students.

Again, probably an underestimation of the total number that are recently infected. Now we think that's important, because that's a driving force we believe in terms of transmission, and I would like to think that that's a contributing factor for why this thing took off when it did in 2001-2002.

Now if we look at the cases, 85 percent

of these are among African-American males. So the bulk of these are young black men. In `79 about 60 percent report only having male sex partners, but about a third report having both male and female sex partners, and about four or five percent only female partners.

So almost 40 percent of these men report having female partners. Now unfortunately Oprah got hold of this information, and invited an individual who has written a book on the "down low," focused on this information. He actually posted this article on his website, or at least the initial reports. And I think what's happened is we've had a lot of diversionary talk around men who are on the quote unquote "down low," men who identify as being heterosexual but have male partners on the side.

And really what we're seeing here is more bisexuality, not men who are not identifying as having sex with men; and I think that information has further stigmatized MSM of color, further marginalized the group that we're trying to reach, and has really sort of I think removed attention from

what is an ongoing issue here which is about how do we address an issue of transmission that is affecting the broader aspects of the community, both men and potentially women.

And we'll come back to this MSM-W, men who have sex with men and women issue here in a second.

Now if we look at the college students, and we do a comparison of the college cases, meaning the young men who are in college, and compare those to the newly diagnosed men who are not in college, we find that the college students were about three times more likely to be African-American; about three times more likely to be diagnosed with a recent infection; three times more likely to have both male and female sex partners; and note where they meet their partners - the Internet about sixfold greater than the non-college students, and on college campuses.

Not surprising they would meet students to have sex with on college campuses - about 16, 17 fold greater risk. There are 30,000 African-American male students who attend colleges in North Carolinian

any given year. If we assume that five percent of those are MSM, men who have sex with men, that only leaves about 1,500 MSM black male college students. So if these students are more likely to meet other students to have sex with, and our data would suggest that they are much more likely if they're college students, it's a pretty small sexual network pool.

If you have HIV that enters into that network, then you're going to see much more transmission occur, especially during these early stages.

So what we have here, I think, are small networks and isolated groups of individuals who connect up with acute HIV driving the epidemic.

The question has been, well, how do we make that connection, given that we have all these scattered cases, we're looking at the whole state.

What ties them together? Well, the two - three things are going to be the bars, the Internet and the college campuses.

The college students were less likely to meet someone who was diagnosed with AIDS. They were

less likely to know or have a partner with known HIV or AIDS, which would suggest that we're going to have to do a lot more testing and education on campus.

We published an article with the CDC, the MMWR article where they did interviews, college cases, and they also looked for quote unquote controls, meaning non-HIV infected MSM who are college students, and those who were young men who were not.

We found no differences in behavior, but a common thread in all this was that none of them thought that they were at risk of acquiring HIV. In fact about 70 to 80 percent of the young men who were diagnosed with HIV, when they came in for the test that led to their diagnosis thought that they were unlikely or very unlikely to contract HIV; yet 40 percent of those men engaged in unprotected receptive anal intercourse with a partner that they did not know their HIV status.

Are they dumb? No. They know how HIV is transmitted. But as human beings they underestimate their risk.

Lots of reasons for that. They don't consider themselves quote unquote gay. When they hear messages that are talking about HIV, they view it as something that's out there in other communities, not theirs.

Number two, there is no discussion in North Carolina leading up to this around ways that MSM can protect themselves. What they hear in their schools is about abstinence, and abstinence until marriage.

I'm all for abstinence, but these men don't perceive risk, and when they engage in sex, whether it's anal intercourse or oral sex, they don't understand that they're putting themselves at risk for acquiring HIV, even though it seems obvious, because they don't believe their partners are at risk, because they are young healthy men.

When asked why they didn't think they were at risk, what we're hearing is, well, they didn't look like someone who would have HIV. They were in school; they were healthy; they were good looking; they drove nice cars; they dressed well.

Has nothing to do with HIV, yet that's what they're holding onto.

They're afraid, frequently when we talk to them, about getting HIV tested, because they're worried about being further marginalized or stigmatized on their own campuses.

So what's happened because of a lot of the homophobia that still exists within communities, these guys meet folks, have anonymous sex, and because there is no discussion about ways that they can protect themselves, no open discussions about the risk for them, they put themselves at risk.

Now you've got a lot of maps. I'm going to run through these pretty quickly, because I really do want us to have time to talk.

We wanted to understand what the extent of this was, and this is a map that looks at the number of cases by colleges, and where they connect.

And what you can see here is that we can connect many of the schools into a network, the yellow dots the size of the yellow dots represent the number of cases. And you can see, our metropolitan

areas tend to have the higher number of cases, and these cases connect across the state.

But note here, we've got cases that connect into Alabama, Louisiana, South Carolina. We know for a fact we have cases that connect up into D.C. and Virginia.

Yet there is very little reporting about what is going on amongst college students in other parts of the south. I don't believe based on our data that this is unique to North Carolina, nor is it unique to our college students. It's a much broader issue in the south that is going to have to be addressed; otherwise we're going to have a generation of young men who are going to be dying in the next five to 10 years, or coming in sick, because they don't perceive themselves at risk or infected with HIV.

To understand this a little bit better, we did a network analysis, and this is done for other diseases. But we wanted to actually look at HIV in a slightly different way, and that is to treat the individuals and the schools as well as the clubs as

individual sites, and see if we could connect things up to explain this.

Now this is a network diagram of the college cases who are connected by partners. And what you can see here is there's been a lot of scattered partnerships.

Individuals here that don't seem to connect, and these closed loop networks, mean that these are all sexual partners, but nothing that ties all these cases together.

So the question here is, how do we explain this big epidemic if we've got these small little clusters? Well, the way to do that is to not - is to realize that we're maybe not getting all the information on partners. And indeed a lot of these partners are anonymous sex partners, so there is no name, no contact, no information.

But we do know the schools, and we were able to get information from these students about where they meet their partners in terms of what other schools. So we treat the schools like partners here to draw networks.

So the circles represent the different schools. You can see the greens are out of state schools, but note here we have University of North Carolina system, community and technical college, and private schools such as Wake Forest, Duke University.

These connect up, so this is one school. The triangles represent students. The solid line means that this student with HIV attends this school; the dotted line means that this student meets partners at this school.

And you can see that we can connect much of the individual cases if we start looking at the schools as a place of connection, not just individuals.

If we did what we call an egocentric network where we look at the schools as the component first, and then look at where we branch off, you can see that the S here represents schools, the Cs represent college cases, and you can see a rather large network in red that connects many of these cases together. All the reds are all one network.

So the explanation for why this took off

I think again is that they're meeting students at other college campuses, which is why we desperately need more activities on our college campuses to say HIV is real, it's not just real out in the community; it's not just real in developing countries. It's real and it's being transmitted on the college campuses which you attend.

Now I said that we've looked at multiple factors that connect. We only have several MSM bars for minorities in the state, and they tend to be in the major metropolitan areas, and again, these are major connecting points.

Here we look at one of them. It's a bar. And we look at the cases. And you can see how many of the college cases connect to one bar.

It acts as sort of an accelerant, a way to bring these students into one place where they can meet across geographic areas. Jackie knows that students drive to Greensboro from Charlotte to Raleigh. There is a big night in Raleigh, North Carolina where students actually come down from Washington, D.C., to see a DJ, which brings students

in from across North Carolina and other states.

Charlotte is a hub that brings people in from South Carolina, Atlanta, we've got a mixing of populations here, students meeting other students.

And then there is the Internet. This is one website where the students that we interviewed said they met partners. And you can see how the Internet also ties this together.

Now why is this important? It's important, because when you look at acute and recent cases, you can see how they tie up very well with this network. So the red dots here represent acute cases of HIV, and you can see we've got websites in here and bars and colleges that connect up with all of these students.

So these students are connected through many different ways, and when we start looking at only named partners, it falls apart.

So if we are going to do interventions, we need to actually plan on doing more over the Internet, which allows a safe haven for folks to meet individuals, especially in rural North Carolina. We

need to do things in bars. The CDC based on the early reports funded an initiative called a popular opinion leader model for young black men in our bars in North Carolina. We got funding for one year. It's over; no continuation funding.

And we actually had a very good campaign that started to do education outreach to young men in the bars where they did not design their own outreach information, their own distribution. And the whole goal, to be blunt, was to reduce the amount of unprotected receptive anal intercourse.

The data over the course of a year suggested that we had statistically significant reduction in risk behavior with students reaching students; yet that funding has stopped.

In some ways you can't keep going back after the populations we're trying to reach, tell them we're going to start initiatives, do it for awhile, and then pull the plug on the end of it and expect that they're going to be able to do this either on their own, and that it says that we have good faith to continue the activities.

So one of the things I'd like to see happen is a reinvestment in some of the initiatives that have started, not just in North Carolina, but other parts of the country, to reach minority students.

Now again looking at these cases, you can see how complex all of this is, and I just throw these up here, mostly so you have an idea of the complexity of the components.

Now let's go back and look at the MSM-W. Remember I said that I thought that I thought that talking about the "down low" has been somewhat distracting dealing with the overlying issues around transmission.

Taking a quote out of the New York Times that did an article now three years ago on the "down low," it says in a letter written to them on their article, I think a lot of these young men only have wives or girlfriends to cover up their homosexuality. In the meantime they are denying who they are.

And my question is: Are they? And I don't think that they are. And the reason for that

is based on these three things.

We get them confused when we have discussions, and unfortunately when we're doing outreach I think it also gets confusing. Sexual orientation refers to whom you are attracted; that could be men, women or both.

Sexual identity is how you describe yourselves to others, and it's contextual.

Sexual behavior, though, is with whom you are having sex. Our outreach activities need to be based on sexual behavior.

So I'm going to use a very brief example because people say, well, how can this possibly be? Either you're gay or you're not, you're straight or you're not.

My question is, how many times do you have sex with a man to be gay? Is it once? Twice? Three times? In our country we tend to think of things in very divisive attitudes. We do that with race and skin color; we do that with sexuality.

I'm going to use my ethnicity as a stepping off point. I'm an Italian-American. My

grandparents were from Italy. They moved to - or took a boat - to New York. My parents were born and raised in New York. So was I. We moved when I was a kid to Ohio. And about 21 years ago I moved to North Carolina.

When I lived in New York as a kid, people asked me what I was, I said Italian.

When I went to Italy to visit my relatives, they looked at me like I was crazy if I said I was Italian. I was American. In New York I was an Italian-American. In Ohio I was a Yankee, and when I moved to North Carolina, there was another expletive in front of that.

The point is, I'm all of those things, but it really depends on where I am and who's asking the question. Yet around sexual identity and behavior, we like to lock people into blocks.

So let's go back to this issue of MSM-Ws. I mentioned that about a third of the college students reported having sex with men and women in the previous 12 months to their being diagnosed.

The overwhelming majority of those were

African-American. In fact the college MSM-Ws were more likely than the non-college to frequent bars or clubs, to meet sex partners, and one-third of the college students who identified themselves this way reported the names of only male partners.

So we have a problem reaching a lot of the women. I think that that's something again we need to redouble our efforts here to do more outreach and encourage testing among young women who are at risk.

Now looking at the gender of the sex partners, you can see the comparison here of the 18 to 30 year old men, the first 103 cases. Thirty-six percent of the black college students reported both male and female sex partners, compared to seven percent, or only one out of 14 of the white students.

And in a multivariable analysis when we compared this, we found that MSM-W were twice as more likely to look at all those 18 to 30 year old men to be college students.

And note this last bullet. In terms of reporting 10 or more sex partners in the past year,

about three times more likely.

So the MSM-W is an important bridging group we believe, not in terms of the heterosexual community, but there may be some difference here about really connected across networks.

So barring an article, some data from an article we published with Lisa Hightow, looking at these networks, you can see looking again at the college networks, we have six separate networks, seventeen schools, 58 students. If we add any MSM-Ws here, we have one giant network, 95 students, 26 schools.

So the MSM-W we believe is a critical group to do outreach if they don't identify necessarily as being gay or heterosexual. So we have to come up with the right target message, the right way of really doing outreach.

So prevention for bisexual men. Some bisexual men may be in transition to homosexual identity; I don't think we really know. Other bisexual men will never identify as being gay, and may not even identify themselves as being bisexual.

Again, more research around this is really needed.

And all of this again comes back to being more creative and dealing with the Internet. So again if we look at the percent of students meeting folks over the Internet, we can see that this has really taken off to now more than 60 percent of the new cases report meeting their partners over the Internet. And by doing that you don't have to identify yourself, you don't have to identify your sexual identity, necessarily. You can meet people, but the problem is you know nothing about them. So even if you ask about sero status, it's only helpful if you are positive and your partner is positive.

If you are negative and the person says they're negative, you're still taking a chance. So I think again we're going to have to be very clear on our messages. And I'll skip over these for the sake of time.

Then we can see how complicated these networks are.

Now it's not just black college students. In the last year we've seen a change now where we're

seeing crystal meth in the mix, and again the Internet that plays into this.

So this is a rather complicated sexual network looking at primarily white college students. You can see the reds are the acute, and not how this one acute case in the center connects up over the Internet to many other cases, and crystal meth is in the mix.

So I think if we're going to do activities on college campuses, we need to address issues around a growing at-risk population.

So what do we learn about this outbreak? We recognize it because we've had real time surveillance methods that have been linked to partner counseling referral methods, and traditional outbreak investigation, which is what we did.

We did a network approach which allowed us to find things that we didn't seem to see connected before, and what we demonstrated is that this was an ongoing network transmission for African-American MSM and MSM-W attending school.

And more importantly, bars and the

Internet really do I think act as accellerants for transmission. So if we're going to begin doing interventions, and if we're going to try to intervene, we have to address not only the college campuses, but really be more creative in our efforts in bars, and in particular over the Internet.

And finally college students represent an at-risk population for an ongoing HIV prevention interventions. Now again, you may say well, this is a small percentage of all the transmission that we're seeing, but it's an important percentage, because it is a rising middle class population in the south. Future leaders for African-Americans in the rural south in particular. They are going to be dying with HIV if we don't intervene now; we are going to see further transmission if we don't intervene now.

So we really need to step it up in a way that doesn't further marginalize a group that we so desperately need to reach.

I'm hoping again we'll have a chance to talk. I think it's 11:00 o'clock, and I assume we have a few minutes for questions.

So I'm going to stop talking about PowerPoint slides, and maybe move from behind the mike.

DR. SWEENEY: Thank you very much for that, and we are going to take a few questions. And I know there are a lot of questions, but we'll give Jackie privilege this time being a North Carolinian.

MS. CLEMENTS: Oh, thank you, thank you. So very southern of you.

Peter, I want to thank you for your presentation. I've seen you do a part of this before.

And I think I want to say something that sort of reinforces something you said earlier. We've been talking a lot about routine testing, and I think it's important to have routine testing to reduce the barrier for an opportunity for a person to get tested.

However with the routine testing comes the removal of the educational or counseling piece, and one fo the things that you mentioned, and that I have talked about, though a lot of folks know the

basics of how you become infected with HIV, what they don't do, like you said, is internalize that and use it to protect themselves from infection.

So when we're talking about getting rid of counseling, we're talking about getting rid of providing that educational piece, routine testing will reduce the barrier; just that. It will reduce the barrier. However, most of the folks that we test are probably going to be negative, and when they hear that they won't get the education, and so they're going to go back out and do what they've been doing because they keep coming back getting that negative result, so they don't get that information to say what you're doing is putting you at risk for infection.

And that is my big concern for - I work down the street from HBCU. I test a lot of those college students that come through there. And that is an issue they don't understand how the risk factors are actually - what they're doing, what their behaviors are.

DR. LEONE: You know I actually agree with

the CDC initiative to try to expand testing and make it routine from the sense that, one, we've got about a third, 25 percent of known HIV infected individuals who don't know that they're infected.

However if you look at minority communities, especially black MSM, it's much higher. Some of their data would suggest that it might be 50 - 60 percent of these men don't know that they're infected. So expanding testing is critical, and yet I don't think you can do it to make it routine and have all the counseling pieces in place.

But I do worry about cutting out counseling altogether, and addressing the needs that are there for high risk individuals.

Now on the heterosexual, married, and we're in a mutually monogamous relationship. Do I need HIV counseling? I don't.

So I think we have to recognize that there may be different needs in different situations, and we're going to have to figure out ways of delivering that.

My big concern is that, and I've seen it,

a negative test doesn't mean that it's okay to have unprotected sex. Yet this group, I think, will take their negative test as a get out of jail free card. And I've seen it happen.

We had a case of five transmissions that happened because a case of acute HIV was missed, a college student thought he was HIV negative, and had unprotected sex, and we saw transmission down the road.

So the problem we get into is, I think we're going to have to also counsel folks that a negative test on your partner doesn't mean that you don't use condoms, that you don't engage in risk reduction if you're going to engage in sex.

And somehow that has to get out, and I think we still need to provide counseling around that, but it may be in a different setting outside of the medical setting. I think you can't necessarily do all of this at once.

DR. SWEENEY: I'm going to follow David Reznik's model - remember he asked about 10 questions because he was chair; I'm only going to ask one.

Based on the 21-year-old actual case that you presented, I'm wondering whether you think when you're testing for HIV that the HIV/RNA antigen test should be the standard instead of using antibody tests?

DR. LEONE: Well, you ask the million dollar question. I think my boss, Mike Cohen, will hopefully address it, because we exchanged slides, so I promised him I wouldn't talk too much about it.

I think we're going to need to change our strategy. The antibody test works really well. The problem is, you miss this window.

Now should RNA or antigen testing be done everywhere. The problem with RNA is that it's expensive and there's a time delay. But the technology is certainly there to do really sensitive p24 antigen testing.

And so I think what we're looking at is probably coming up with a combined assay that would do a rapid antibody and antigen test, and then you can roll those folks over. That's where we need to drive, I think, development.

What would be even better yet, and I was just in New York at NYU talking about this last Monday, what we need is a point of care test that can be rapid for p24 antiget. And it can be cheap now.

There is a company that actually is marketing, not in U.S. yet, an antibody p24 combo assay that would be relatively cheap compared to the RNA assays.

So what we're doing in North Carolina is to step over, I think, until we get to something like that.

It doesn't have to be everywhere, but I think in high risk settings like STD clinics we do need something else besides the antibodies.

DR. SWEENEY: Thank you.

I think Dr. Bollinger, and then Ted.

DR. BOLLINGER: I just had a very quick follow up question. Thanks again for a great talk.

As you move toward more routine availability of some rapid testing that you're describing, particularly for acute infection, it gets back to a question that was raised a few minutes ago

about the need for counseling.

One of your premises is that the acutely infected people are significantly driving the new subsequent infections in these networks, and so without - if you have that kind of rapid test available, and you are not linking counseling to them, you've got a particular challenge.

So I think it's important as we have more and more technology for more rapid testing, particularly for identifying acutely highly infectious people, the counseling is critically important to link to that testing.

DR. LEONE: We need more I think understanding about what's the appropriate counseling message. And the nice thing about this, and actually Andy's wife, Carol Golin, and I have been talking about this, is with acute HIV a small change in behavior for a short period of time can actually have dramatic downstream benefits in terms of reducing transmission.

So if you can get people to just change their behavior for 8 to 12 weeks you can maybe have a

significant impact in transmission networks.

DR. SWEENEY: Dr. Green.

DR. GREEN: Thanks for an interesting talk.

It sounds like a very basic problem was that these men didn't feel at risk for HIV infection. So I was thinking about the first two countries in Africa, the first two AIDS success stories, Senegal and Uganda. Both countries were successful in making men and women feel personally at risk for HIV infection. In fact of all the countries in Africa by about 2,000, women in Senegal felt more at risk than women from any other country in Africa, and yet Senegal has the lowest HIV prevalence of any continental sub-Saharan African country.

Anyway the formula seemed to be fear arousal, even though we don't like that term, and then self efficacy, showing people clearly what to do to not become infected.

So it sounds like with the population you're dealing with of MSM/W because they were college students and drove the right cars, men didn't

feel at risk, so here in these countries in Africa men and women were made to feel at risk, and then people were told clearly what to do.

In the case of Uganda in particular, the main message was, stick to one partner; it wasn't abstinence. It was partner reduction. Or be faithful to one partner.

So you mentioned you had a program in bars. I`m wondering if you use either education to make men feel at risk, when they don't - when you know that that is a basic problem. And then if the prevention message was, stick to one partner for something, you mentioned distribution and protected sex, so that sounds like condoms.

I wonder what your prevention message was.

DR. LEONE: Well, the prevention message was something that they developed about HIV is here, they knew about the data, they needed to take steps to protect themselves, so it was a self efficacy model that was used. And I think it really had tremendous impact, because the messenger was one of

their peers.

I think the challenge here, especially for young black men, is, they don't relate frequently to what they view as gay white male message, and frequently because of the homophobia that exists in many of the communities, they don't want to be identified that way, and I think what happens is, while they're trying to explore this, many of our young men come from rural counties, rural towns. They come to a college campus. They're not sure what they're interested in, or who they are attracted to. So they experiment, or they do activities that put them at risk.

The hard part has been delivering that message in a way that's viewed as being safe, because a lot of them don't want to hear it in a large group setting. So I think you are right, we need to deliver a broader message to men, because we don't know if a person is straight, gay or bi, and the truth is, in some of our minority communities in particular, if you are sexually active you are at risk, period. That's really all that really matters.

Which is why I think we want to focus on behavior.

How we deliver that in a way that doesn't just create fear is the real challenge, and I don't know, we need more I think behavioral research to figure out what is the best message or how do we deliver it.

DR. SWEENEY: Dr. McIlhaney.

DR. McILHANEY: I think that what you presented, your studies were brilliant, just really, really good.

I'm going to ask a couple of questions, three questions. And I'm not challenging your comments, but just to know what you have to say about this.

First, you said 18 to 31 -

DR. LEONE: 18 to 30.

DR. McILHANEY: Do you have a distribution. Were most of these real young college kids?

DR. LEONE: Yeah, so most of them were under 25. I think the median age was somewhere around 23, thereabouts.

DR. McILHANEY: So they were mostly pretty young people?

DR. LEONE: Yep.

DR. McILHANEY: Second, if your behavior change message primarily is the usage of condoms, our group, our science group, looked at the effectiveness of condoms with alternative sexual behavior, oral sex, anal sex, particularly. And as I remember, there wasn't one good study about the effectiveness of condoms with anal sexual behavior.

Are you familiar with one that -

DR. LEONE: No, I think part of the problem is to be honest getting funding to do those kinds of studies and how you do them. And I think - so it's hard to do them.

But also what I want to be very clear about, I believe in telling a lot of these students that they should wait. No one is advocating that they should go out and engage in high risk activity. Nor do I want anyone to get the opinion or the feeling that by talking about condoms we're saying it's okay to engage in these behaviors.

But the truth is for many of these students they have no other venues to talk about their sexuality, or to explore it. So the least we can do is make sure they can protect themselves with condoms. Yet there is not much information out there, both pro or con, about anal transmission.

DR. McILHANEY: Don't get me wrong, I think every one of these kids should use condoms if they are - I think they should be set down in front of somebody eye to eye and told you must use your condoms.

But my question is, when we say protective, if we don't have studies that show what the level of protection is, we need to be straightforward with what we know.

DR. LEONE: We have good studies looking at transmission of HIV in condoms. What I'm not aware is condom use specifically for anal intercourse.

DR. McILHANEY: That's what I'm talking about.

DR. LEONE: So I think we can look at

discordant couples. We can look at population based levels. And there at least the suggestion would be that condoms really are very effective.

DR. McILHANEY: And intuition wise I would say that they are probably somewhat effective with anal intercourse. But we know they break a lot.

Anyway, I just had that question. I think we need to be careful about what we know and what we do tell people.

The other is that you made a comment that you certain thing abstinence and faithfulness important, and that's a message all these kids have heard.

Do you have data on that, that these kids, the primary message they've heard has been about abstinence?

DR. LEONE: Well, I do, because North Carolina is an abstinence only state, and it's been that way for awhile. We have four school districts - I think it's down to three now - that have a comprehensive curriculum.

So virtually all these students, when

they were coming through school, because that started in the mid-1990s, heard abstinence only.

And the abstinence curriculum I reviewed in North Carolina - I was booted off of reviewing the subsequent thing - does not talk about anything other than vaginal intercourse and abstaining, period.

So the dilemma, and I'll be really blunt about this, if you are told to abstain until you are married, and you only hear about vaginal intercourse and you can't get married, then you are sort of told if you are someone who is attracted to men, your options are never to have sex.

DR. McILHANEY: Sure, I understand that.

DR. LEONE: So that's the dilemma for a lot of these kids coming up to be really blunt about it, and I think that that is unconscionably bad public health.

DR. McILHANEY: The real question is, what do these kids, by the time they get in college, even understand or retain what they've heard.

DR. LEONE: They have an hour or two hours of HIV education in high school, and that's it. And

Jackie can tell you, and I've looked at the curriculums. It's really pretty basic.

So we really need to - I think the problem is that it's the highest risk folks that we're really missing what we need to deliver. The messages that are out there for lower risk heterosexuals probably may be sufficient; may be not, because they get other STDs, that's a whole other story.

But around HIV we're going to need to do more to target, I think, MSM, especially young MSM.

DR. McILHANEY: Okay, thank you.

DR. SWEENEY: You're on, Sandra.

MS. McDONALD: It is always a pleasure to hear you present. I really appreciate your hard work, particularly looking at college students.

Have you had any contact or any information on any other college campuses that might be experiencing young males or females who are positive? Do you have any information about any other college setting?

DR. LEONE: Outside of North Carolina?

MS. McDONALD: Yes.

DR. LEONE: Well, I know there was some work down in Atlanta that was being done, and that as far as I know involved a series of meetings and one town hall meeting that was conducted there. And then that, so far as I know, didn't continue after that.

I've talked to Dot Brown who is at an HBCU outside of Baltimore who has done some work up at her school. That's been about it.

So there's been a real lack, even though we've met with the college health association around doing more, we need more funding to do more on the campuses, and particularly, the HBCUs.

MS. McDONALD: Unfortunately, stigma is a great barrier.

DR. LEONE: We talked about that, and my big concern is how do you do outreach on HBCU campuses who are very dependent on not so much research grants but on students attending the schools to survive, without their being labeled as being the HIV school.

So when I've gone out to talk, I've

actually had students, or schools, asking, well, how many cases came from this school or that, which I never do.

And the concern is that whoever steps up to the plate first is going to be labeled as a school that has lots of HIV and people aren't going to want to send their kids there.

So we really need a grassroots I think across-the-board effort to address this and embrace it that has to happen at a much higher level in the system.

DR. SWEENEY: Joe Grogan, and then Rev. Lusk.

MR. GROGAN: Thanks, just quickly I have two questions.

One is, have you been speaking on college campuses at all? Is there any interest among college presidents in having this message brought to students?

And then the second question is, you mentioned a couple of times about the students getting missed, and getting diagnosed with maybe

indeterminate viral infections. I'm wondering is that because maybe nurses and doctors don't perceive the students are at risk, and they're not doing these tests? Maybe you could comment on that.

DR. LEONE: So the first question, yes, Lisa Hightow, Justin Smith and I are working on college campuses. We have a grant though the Department of Health and Human Services, project style, to do outreach on campuses in the area and Raleigh.

It's been very successful at Central. North Carolina Central has stepped up to the plate big time to be involved. But even they have sort of a little bit of resistance of doing even more activities.

North Carolina A&T has also been really open to activities on campus. But the problem is, a lot of the college university presidents don't want to be identified with HIV, and that's true in the majority of universities, too. I can't get the chancellor at UNC to ever address this in a broad way.

So I don't think it's unique to HBCUs. We've only had a couple of schools.

Benny Primm came to speak in North Carolina. We had a meeting, great attended meeting at North Carolina A&T, and then the plan is, over the next year, we're going to have a little college tour of HIV testing days with this project style on each one of the state campuses in North Carolina, so we aren't just targeting HBCUs but the HBCUs in North Carolina, some of them have stepped up to the plate.

Now getting back to the second question, the problem has always been around acute HIV, as it's a relatively rare event, and clinicians don't think about it, and if they do they order the wrong test. So we really need to do more awareness around the signs and symptoms and get clinicians to start thinking about it in terms of their differential diagnosis.

The second thing is, we know who's at risk, so I think there should be an awareness campaign for MSM around the signs and symptoms of acute HIV so that they go in and get care.

Looking at the five cases that I didn't talk about of the acute HIV that we had last summer among college students, all of them went to be seen. None of them were diagnosed the first time they went in for HIV.

It's a real problem, and I think we have to do more education around that.

DR. SWEENEY: Reverend Lusk.

REV. LUSK: Great presentation; thank you so much.

I was just wondering, could you give me just a little more information, detail, on what you felt the confusing or the conflicting message was on the Oprah show regarding the "down low" message, and how it conflicts. And also these numbers are really kind of frightening, particularly just hearing you say that many college presidents are not even open to discussing the situation.

Some type of rejection if it's not dealt with, if there is no intervention, how bad could it be in your estimation?

Those are the two questions I have.

DR. LEONE: Pretty bad. I don't think we know the extent of it. And the problem is I see continued transmission that is happening on the campuses. And again because these networks are small, I really think that we are sitting on the precipice of the significant problem on our campuses.

We're now up to 153 cases, and I anticipate by the end of the year when we do our sweep for the last year we'll be probably close to 180 to 200 cases, somewhere in that ballpark, since the beginning of this. So that is significant.

I think that I worry about it actually moving more into the middle class, because this is an ever-revolving population. Students are in for a couple of years and then leave, and they go back to their hometowns or communities, many of them undiagnosed. So we don't know how many students we've missed.

The confusion I think with the Oprah show was the fact that black men in this country have been marginalized, pushed to the side, stripped I think of a lot of dignity that's been there. To have a show

which focused on sort of raising the suspicion that black men are again transmitting a disease, not only to other black men but to women, in my estimation, can further marginalize the group that we are trying to reach.

And the truth is that, in looking at the college students, virtually none of them were quote unquote on the down low. The majority of them identified as being bisexual. They weren't open about necessarily talking about wanting to fit into one slot or the other with a definition. But they didn't have this sort of I'm heterosexual and I actually have sex with men on the side mindset.

So although I think it's probably real, my concern is that it's sensationalism; it doesn't really get down to dealing with the core issues here about behavior and understanding how to deliver message.

And I think as long as we talk about trying to identify who it is who can give me quote unquote HIV we never get down to the basic issue, which is, you have to be responsible for yourself,

and if you are someone who is dealing with your own sexuality, you need to find out what your own status is and protect yourself as well.

And that's what I worry about. Actually Oprah asked me to come down to the show, and I said no, because I didn't like where the show was going to go. Initially it was going to be talking about college students, and then the next thing it was going to be about the book. So I stayed at home. One of our college students actually went and was interviewed. And J.L. King has made a lot of money off this.

DR. SWEENEY: We have time, and the two hands were David Reznik and Dr. Redfield.

David, you get to ask one question.

DR. REZNIK: The abuse I take.

My question is, any training going on for the clinicians at these colleges to recognize acute HIV syndrome, and if you knew how many of them present with candidiasis, just out of curiosity.

DR. LEONE: Yeah, it's a small number that present with candidiasis. I've looked at the

presenting symptoms, and it's small. It' somewhere less than 10 percent. I think it's actually down around three to five percent. So we've seen it, but it's relatively rare.

We've done some education. We haven't done enough. We've met with the colleges. We've talked about this. We talk about acute HIV. We're actually trying to do a series of interventions across the state now to sort of take it on the road, but again, I think we need a lot more help. There's only a handful of us going out there doing this, so we've met with some of the student healths early on with this thing, and they've been on board.

I still get pages and phone calls from in particular some of the student healths in the area, but I still think we're missing it. Because the students unfortunately don't necessarily go to student health. When we went to North Carolina A&T what I was impressed, things haven't changed much from when I was a college student. Students are afraid that they get diseases from going to student health, rather than student health helping.

So we had a big meeting at A&T and I swear they went on for 15 minutes how people were coming back with urinary tract infections from going to student health and being seen. And so like whoa, let's get back to the issue here.

Unfortunately, they go back to their primary care providers quite often in North Carolina because they have insurance, or because they don't want to talk about their sexuality, and they get missed.

So I think we've worked on student campuses, we've worked with the coalition of college student health, but we need to do more.

DR. REZNIK: Just to follow up there is a very good AIDS education and training center, Southeast AIDS education and training center, which is based out of Emery, that has a presence in North Carolina. And maybe they should focus on training the clinicians to recognize acute HIV.

DR. LEONE: Well, I've met with Robin Swift who is at Duke, and we've talked about this. We actually have posters now that we're distributing

and little cards, so we're going to be sending those out.

The problem is, we tried to set up some meetings, and we didn't get any hits from the clinicians on wanting to give talks. We had three of us that had agreed to give talks through that training center in North Carolina.

So again, I think we're going to have to push the agenda on this, because I think many clinicians just don't think it's important.

DR. SWEENEY: Before Dr. Redfield, are condoms easily available in North Carolina without waiting to ask the clerk or go behind the - you know, they're put behind the desk so you have to ask - behind the counter so you have to ask for them? And are there free condoms available on campuses?

DR. LEONE: There are free condoms, and Jackie can comment on -

MS. CLEMENTS: There - well, on campus, I'm not sure how available they are.

DR. LEONE: I'll tell you a story which is still a little disturbing. Go ahead, Jackie.

MS. CLEMENTS: But they can go to any health department, they can come to where I work and get free condoms. But they are not just sitting out, and you do have to ask for them.

And also with response to David's question, students don't like to go to student health to get tested. They don't like to be tested at student health because of their concern that the information may get out. Students work in student health, and so they don't usually go there for testing.

DR. LEONE: So condoms are available through all our publicly funded clinics for free, but you usually have to come up and ask for them, which is a barrier.

In terms of college campuses, it really varies. Some of the schools that are more religious based, we've worked with, are now at least beginning to approach having condoms, but many of them didn't like the idea of having condoms.

But even on our status campuses, UNC in particular, they have free condoms that are

available, but the students aren't actually allowed to physically hand them to someone. They have to be in a bowl or a bag or out, and the reason is that one of the former chancellors didn't like the idea that they were handing out condoms and said that you can't do that.

So there is no written rule about it, but a sort of unspoken rule on campus. So my suspicion is that if that is true at UNC which is viewed as one of the more liberal campuses in North Carolina, you can think about the barriers that exist on some of the other campuses.

DR. SWEENEY: And Dr. Redfield, you'll have the last.

DR. REDFIELD: I'll shift gears for a second.

Peter, again, I think people know, again, really to congratulate you and your team over the - I think it's been almost three or four years now I've been following the idea of trying to diagnose HIV infection using viral detection methods by pooled, and you've obviously demonstrated it and its

effectiveness.

I'd be interested from your perspective, because I again, having been in this now for 25 years, I know when we got the antibody test, the public health service fairly rapidly applied that, for its prevention consequences.

I think you can make a very compelling argument that sero-negative HIV infection, particularly among young people that are sexually active and STD clinics in particular, a lot of the epidemic is driven by that population; a lot of work has shown that. So what's it going to take to try to take these evidence based data that your state has provided and you have done to try to more effectively integrate that into a public health approach?

DR. LEONE: I think it's going to take more data than just North Carolina. And we talked about this. I've been out to Colorado and Denver. Frank knows. Literally we've been going from state to state to try to push this.

Now I'll give my little beef here. I shouldn't in North Carolina be the person going out

there having to push the agenda countrywide. I don't mind doing it; it's fun; I like working with my colleagues.

But there really should be a more bigger buy in at the federal level around this. Instead what we got is a demonstration project which is great, but it's been saddled with too many questions, and it's going to take another five or 10 years before this gets rolled out.

And I don't think you need more data. At some point you respond to what you know in HIV, because by the time you wait for more data you're five or 10 years down the road.

So we can do this; we can do it cheaply. We know where we need to target this. And I think STD clinics is a great place to start. We should be doing it, but we need more help and support.

Upstate New York is doing this, but they're doing it on their on. Colorado and Denver is going to be doing this, but they're doing it on their own.

This is the story across the country.

DR. REDFIELD: I'd just like to echo that point of view. It's sort of frustrating to see commonsense and public health and then to have evidence based data show this with the perseverance that your group has done to take it through the different steps to make this practical, and then demonstrate its practicality.

And I think this is an area where the public health service in particular, on the federal level, needs to be much more aggressive in trying to see this implemented.

DR. SWEENEY: I `d like to thank you again. You wanted discussion. You knew you could count on us for a very lively discussion, and I hate to cut it short.

I hope you'll be here -

DR. LEONE: I'll be here.

DR. SWEENEY: -- you'll be here so that we can get you at lunchtime, because there are other people who have questions.

Thank you again very much.

DR. LEONE: Well, thank you for the

privilege of being here. Thank you very much.

(Applause)

DR. YOGEV: Can we discuss a new committee that PACHA recommend to revive p24 antigen? p24 antigen was killed. The two companies that did it and are still doing it, because it doesn't detect less than 10,000 as effectively. But acute infection, what's unique about it is, if you notice, six million. That's exactly what happened in the pediatric, and we cannot get p24 antigen.

P24 antigen is so cheap if you do it enough, and maybe PACHA should push to encourage companies to produce it and people to use it, and here you have one of the indications, it would be very important to push it forward. It would be cheaper than the ELISA. It was cheaper than the ELISA.

(Off-mike voice)

DR. SWEENEY: Joe is taking notes on things we need to follow up on, and that will be on the list of things that we need to address, and thank you.

At this time we are going to move the program to our next speaker, Dr. Andrew Kaplan, professor of medicine and microbiology at UNC School of Medicine. And he's one of the founders of the UNC Prison Work Group, and he will be speaking to us, I have on my paper, HIV and Incarceration, but on the slide, we have Collateral Damage Incarceration: HIV in Vulnerable Communities.

But he's before us to speak on incarceration and HIV.

Thank you very much.

HIV AND INCARCERATION

DR. KAPLAN: Yes, thank you very much.

I think before I begin it's at least worth acknowledging that following Dr. Redfield's comments about North Carolina, there have been three consecutive speakers from North Carolina. So I'd like to express my condolences.

In any event we're going to talk today about the impact of incarceration on the treatment of people living with HIV, as well as the spread of the epidemic through vulnerable communities.

I feel that this title is a particular apt one, because we have come to understand, and we hope to convince you, that incarceration is an important barrier to the effective treatment of HIV infected people, and it also plays an important role in encouraging the spread of the epidemic through vulnerable communities.

So I'm going to talk a little about the setting of incarceration and the overall impact of incarceration; the spread of HIV within prison; medical treatment in prison; HIV testing in prison; and then the special case of county jails.

Following my talk Dr. David Wall is going to talk with you about the transition from incarceration to freedom for HIV-infected patients.

Before I begin, though, I need to acknowledge our collaborators. As we heard we're members of the UNC prison working group. And here are the people that are part of that group and have done a lot of work that I'm going to speak with you about.

And we've heard a lot today about

funding, and I also need to acknowledge the people that have provided the money for the work that I'm going to tell you about. Pretty much all the data that I'm going to show you has been funded by grants from the National Institutes of Health, specifically the National Institutes of Mental Health and the National Institutes of Drug Abuse, and at NMH it's Chris Gordon, Andrew Forsyth, David Stott and Dianne Rausch; and NIDA it's Elizabeth Lambert.

And these people in addition to providing the funding have provided a lot of the intellectual support as well as the guidance, and we're thankful to them.

So it really is no exaggeration to say that minorities in general, and African-Americans in particular, reside at the intersection of two powerful overlapping and ultimately reinforcing epidemics. Those epidemics are the epidemic of HIV infection, and the epidemic of incarceration.

Black Americans are as you know black Americans are at risk of acquiring HIV at rates that are severalfold higher than white Americans. Sixty

percent of the prison population are racial or ethnic minorities. As you can see about 12.6 percent of all black men between those two ages are in prison or jail.

And then finally the prevalence among inmates is about eight to tenfold higher than in the general population.

As I said I'm going to talk about the setting and impact of incarceration, and I'd like to think about it in different levels starting with society.

First of all incarceration reflects a tremendous diversion of resources from other things we could be doing with them. For example North Carolina, the budget of the department of corrections is about a billion dollars a year, which is just about the same as the budget for the division of social services and the same as the budget for the division of mental health and substance abuse.

There is one example you can use. About three million children have a parent in prison. That's about five percent of the children in the

country have at least one or both parents in prison, and as you might imagine children with parents in prison are at risk for a number of bad outcomes, including about a fivefold risk of becoming incarcerated themselves.

And then finally I think it's worth noting the sort of what I think is the morally corrosive effect of having all these prisons, keeping all these people under incarceration, and spending all this money on this one thing.

It's interesting, those of you who are familiar with the work of the early abolitionists, they talk a lot about the moral depredations of slavery, particularly the obviously the effect on slaves. But they also spend a lot of time talking about the morally corrosive effect of slavery on the slaveholders, and I think that's something that affects all of us, and that we need to consider when we talk about this debate.

In terms of the national level at any one time about two million people are incarcerated in the United States, and this is a 300 percent increase in

the last 25 years.

As far as the state prison systems are concerned, about 600,000 people are released every year, and we'll hear more about the impact of that from Dr. Wall later, but it's important to note that not only do you have two million people in prison, but there is a tremendous churning of people going in and out of prison which causes disruption of social networks as well as lost economic opportunity.

The county jails, ten million people pass through that system every year. One out of every five of the HIV infected people in the U.S. will pass through the correctional system every year, making the point that there is a tremendous overlap between HIV and incarceration.

And then finally it's been estimated that if current trends continue, about one out of 20 of us can expect to spend a night in jail sometime during their lifetime.

I'd just like to do sort of a little prison 101 just to kind of get you up to speed in terms of the system of incarceration. There are -

virtually all of the people that are incarcerated in the United States are kept at one of three levels of incarceration. There is the federal penitentiary system. These tend to be older inmates. They're in for longer periods of time. And the medical system in the federal penitentiaries tend to be in house systems in which all the doctors are employed by the federal government and they have prison hospitals et cetera.

At the next level, and what I'm going to talk mostly about, is the state prison system. Each state has an integrated system of state facilities. Usually quite a few; in North Carolina it's about 87. These are different levels, maximum, medium and minimum level security.

The inmates are a little younger. They're usually in their early 30s. The average length of sentence is three to five years. In terms of medical care there is usually a hybrid of prison docs that are employed by the state, as well as usually some contract people.

And in fact that's what we do; we provide

the HIV care for the North Carolina Department of Corrections.

Finally, there is a different entity, and these are the county jails. And these are very different from the other two. Usually these are run as independent entities by each country, generally run by the county sheriff. They have a very high turnover. The average length of incarceration is on the order of 48 hours. Police bring people to the county jail straight off the street, so there are a reasonable percentage of people who are either drunk or high or actively psychotic.

Because they are each run by the individual counties, although there is - there are rules in terms of how they need to be managed, and how the medical care needs to be delivered, as you might imagine, this is the level of incarceration at which there is the most amount of variability, and I'll talk a little about that at the end of my talk.

The impact of incarceration at the community level, in the United States there is about one white man for every white woman. In terms of the

African-American community, there are about nine black men for every 10 black women, so the ratio is somewhat skewed.

That's in part due to the fact that the African-American men die at greater rates than white men, but it's also due to the fact that so many African-American men are in prison. AS you can see about one-third of black men between the ages of 20 and 29 are under correctional supervision, either in prison or on parole.

And then finally as far as the community is concerned, you know prisons are dangerous places. There are a lot of people who are there for drug crimes. And I think when you have so many people go in and out of prisons, what eventual you'll see, certainly you're at risk of seeing, is a normalization of incarceration itself, as well as a change in the normative community values in terms of what's okay in terms of sex, violence and drug use, what's acceptable.

Here's a study that was conducted by a colleague of ours, a member of our group named Dr.

Ada Adimora. She looked at about 250 black men and women with and without HIV infection in North Carolina.

So comparing the HIV-infected men with negative men, she found that the infected men were sixfold more likely to have had a sex partner who had been incarcerated; the HIV-positive women were fourfold more likely to have an incarcerated partner; about 81 percent of the HIV-infected women reported that at least one of their last three sexual partners had been incarcerated; so four out of every five women knew that one of their last three sexual partners were incarcerated.

And then finally, about a quarter of the HIV-infected women, and about two-thirds of the HIV-infected men, had themselves been incarcerated during the past 10 years.

And obviously their individual impacts of incarceration affects, obviously affects your employment prospects, benefit eligibility. For example in North Carolina if you've been convicted of a drug crime you're ineligible for food stamps for

six months following you release from prison.

Once again, you'll hear more from the next speaker about all the challenges associated with reintegrating into society, so now we're saying that in addition to those we're not going to help you find food for six months if you're convicted of a drug crime.

They're disruptive of social and family networks. Prison itself can be a brutalizing experience, as we'll hear in a minute. And then finally I'll talk a little bit about HIV transmission itself within prison.

So before we begin to talk about the inmates themselves, it's probably important to think about who is getting incarcerated. What's the population that's getting incarcerated?

And due to limitations of time, I'll just focus on one thing, which is the experience of violence for the people who are incarcerated, and talk specifically about women.

There are a number of studies that have been conducted, but in general, they report that

between 10 and 90 percent of women have been the subject of violence.

In a study that was conducted by another member of our group, Kathy Fogel who is a professor at the UNC School of Nursing, she - we're conducting a randomized control trial of an intervention to limit HIV risk behaviors of HIV-negative female inmates upon release.

And one of the things we did is, we collected data about their experiences with violence, and the results are shown here. What you see is 81 percent of them report that they have ever experienced violence or abuse. About half of them have said that they have ever been forced to have sex. About half of them also said that they were hit, kicked, slapped, physically hurt in the last year. Three quarters say that they were physically or emotionally abused. Ironically only 10 percent say they are afraid of a partner or someone else. And about two-thirds said that they ever felt unsafe.

To look at those numbers a little more, of the women who said they were physically hurt, hit,

slapped or kicked in the last year, they reported that this happened an average of 32 times in the last year, so about once a week or so these women were physically abused.

As far as who is conducting it, once again to give you a sense of what their lives are like, almost all of this violence is intimate partner violence; it's almost all people they know, either a partner or an ex, in terms of who's hitting them, who's abusing them, and who is making them feel unsafe.

Now to move to HIV transmission within prison, it clearly occurs, although there is not a lot of data saying how much.

Here is an example of a syphilis epidemic in the Alabama Department of Corrections that was evaluated by the CDC, and you can see the number of cases increasing.

Just in case you thought that there wasn't sex going on in prison, here is another example of the social networks that Peter so eloquently described.

Here is someone that is infected with syphilis, and these lines indicate sexual contact between this person and this person. This guy had sex with nine people, and this person had contact with six people in prison. So this is something that occurs, and certainly presents a risk for HIV infection.

Now a more thorough study was recently reported by the CDC and the MMWR in April. And what they did is, they looked at HIV transmission in the Georgia state prison system. So in 1998 Georgia implemented a policy in which everyone entering prison was tested for HIV. And then people were tested again later on a voluntary basis. So inmates were tested at the beginning, all of them, and some of them, for whatever reason, decided to get tested, or if there was a medical indication that they should get tested, they were tested.

And what they found during a seven-year period is, 88 male inmates were negative when they came in but turned positive sometime during their incarceration, which indicates they were infected

while in prison.

Remember this is a lower estimate of the number of people, because although they tested everyone when they came in, they didn't test everybody again, so we're certainly missing some people.

The Georgia Department of Corrections has about 45,000 inmates. The median age is 34 years, and about two-thirds are blacks. This is a reasonable approximation of all the state prison systems in the Southeastern United States.

About two percent were known to be HIV infected, and among those the overwhelming majority were African-American.

To look for a minute at the people who were infected in prison, 54 inmates reported have male-male sex while in prison. About three-quarters of those reported no male-male sex during the six months before incarceration, and this gets to another idea of sexual identity and sexual behavior. These are people who at least six months before prison had no male-male sexual contact, but while in prison had

that, so there is some suggestion that there might be more male-male risk behavior when you're incarcerated for a long period of time with just other men.

Among these, about three-quarters reported consensual sex, and 89 reported sex only with other inmates.

Of the 43 inmates who reported consensual sex, 30 percent reported using condoms or other improvised barrier methods - things like rubber gloves or Saran wrap.

Of the 14 inmates who had sex in return for something else, about 3 reported using improvised barrier methods but not condoms, and no barrier methods were used during rape.

I think it's important to step back and consider this for a moment, what this means. So these are people that were convicted of a crime, that we've put in prison. They're incarcerated; they're under our supervision. We can't protect them from getting raped. We can't protect these men under our supervision from getting raped.

In addition, in almost every jurisdiction

in the United States, it's not permitted to have condoms in prison. So these are guys who are using Saran wrap. They understand they're at risk. They try to protect themselves; but we deny them the means to protect themselves.

Here are the people that are most at risk in that study in terms of a multiple variable analysis. If you had male sex in prison, if you received a tattoo in prison, or if you are African-American, you are more likely to be infected.

Perhaps more troubling is this information that if you body mass index is under 25 at entry you're at greater risk of infection.

The body mass index, or the BMI, is an overall measure of your size. It takes into account your weight and your height. So in other words, just to give you a frame of reference, my BMI is about 23.

So smaller people, smaller men, were at greater risk of infection. And whether that's because they were more likely to have sex, or were less able to defend themselves against sex, is not

clear; but it's certainly troubling.

It's interesting, medical treatment in prison, there is a fair amount of data, although there is a lot of variability, you've all heard the horror stories, there is a fair amount of data that medical treatment in prison is actually better than comparable people get on the outside or the same people get on the outside.

And here's a review of studies of pregnancy. These are women who gave birth in prison. And what you can see from that top panel there is that women who give birth in prison are shown up here, and these are compared to themselves to the same women who gave birth out of prison, or compared with these controls. And what you can see here is the risk of having a low birth weight infant.

Women who give birth in prison are about half as likely to have a low birth weight infant as women who give birth - when the same women give birth on the outside. And I think that is a measure of what it means to take people out of a chaotic environment and provide them social service and free

medical care.

And it's also telling that as horrible an environment as prison is, it's better for these people medically than when they're out of prison.

Here's some data that was published by one of our colleagues, Becky Stevenson White, and what you see here in the gold bars are the viral loads of people who stayed in prison, and the red bars, you see the viral loads of people who were released and then reincarcerated. So the gold bars are much lower indicating that the viral loads are better controlled than after people are released.

I only have one slide for HIV testing in prison, because almost nothing is known about HIV testing in prison. Nineteen states have mandatory testing; 31 states that incarcerate about 70 percent of the state prison population, prison testing is voluntary.

We have recently submitted a proposal to do HIV testing anonymously in all of the inmates entering the North Carolina Department of Corrections, to look at what encourages testing, and

to look at the risks associated with getting diagnosed in prison in terms of abuse or violence.

There is a fair amount of data to suggest that the people who decline voluntary testing when they get to prison are the people most at risk of in fact being HIV infected.

And then finally to end with the special circumstances in talking about jails, remember I told you that jail is a fairly chaotic environment with high turnover. This is a study that was done by one of our students, someone named David Rosen. And he surveyed all the county jails in North Carolina. He found that only a quarter tested more than one person for HIV per month. In three-quarters of the jails the health screening form was administered in a common area, typically to a group of inmates.

So essentially what you're saying is that in the last 12 hours all the inmates that are incarcerated get into a room like this, and a prison guard will ask, who wants to be tested for HIV, raise your hand? Obviously it's not an optimal setting.

Corrections officers then administer the

screening form in virtually all the jails and dispense medication in four out of five of the jails. And as you might imagine these are not people that are trained as pharmacists; they are not people trained to do health screening. And it's an inherently coercive environment. So this is obviously not the best way to get sensitive health information from a newly incarcerated person.

And in terms of confidentiality, all the medical staff and all the offices agreed with the statement that if an inmate is taking medications in jail, other inmates will know about it.

So I'll stop there and let my colleague, David Wohl, take it from here.

DR. WOHL: I want to thank the board for the invitation to present to this group, and I'll just jump in so we don't lose any time.

As Andy mentioned we are providing HIV care in North Carolina to the state of North Carolina Department of Corrections, and also are doing the work that we've talked about here.

So I'm going to just capitalize on the

background that Andy gave you and try to make several points.

One is that incarceration fuels the HIV epidemic through the modes that Dr. Kaplan has gone over, and I'm going to capitalize again on some of the themes, indicating that we felt HIV is fostered by incarceration, by the disruption of the existing relationships, personal relationships that people have before they're in prison and after they get out.

And that there may be prompting of risk behaviors in and out of prison. I'll go over some of those data.

As Dr. Kaplan mentioned, HIV care in most prisons and some jails is good, but I think the benefits that are accrued during incarceration are usually lost after release as we saw with the increasing viral loads of people after they get out of prison.

And I think in the absence of a reduction in the absolute number of people we incarcerate, who are at risk for HIV infection, the transition from prison or even jail to the community is probably the

best opportunity we have to reduce the contribution of imprisonment to the spread of the virus.

Some points that are worth thinking about again and emphasizing is that, again, one out of every five persons living with HIV infection passes through a correctional facility, so there are opportunities that we can leverage in order to impact the effect of incarceration on HIV, and also, HIV on communities that people return to.

And I think it's also important to recognize that the vast majority of persons who are incarcerated do not stay in prison for a very, very long period of time, especially HIV infected persons. For men the mean duration is about two years, and for women, it's probably half of that. Women get incarcerated for other types of offenses, and usually petty crimes that carry shorter sentences. So people are cycling in and out of prisons and into the community at an astounding rate.

So we've gone over some of the disadvantages, and I'll point these out again, of incarceration as far as HIV is concerned, and

incarcerating large numbers of persons, especially persons of color, can have deleterious effects, socially disruptive, just as we've talked about, a removing a significant number of men from a community can contribute to some of the behaviors that we're trying to avoid as far as HIV transmission, and that gender imbalance that Dr. Kaplan mentioned.

In prison HIV transmission does occur, and the Georgia data are very insightful there. But again in the context of how many people are infected in Georgia in the Department of Corrections, it seems that just a small percentage of those who are incarcerated with HIV in that system acquired their infection in prison, and a great majority came into prison with their HIV.

I'll show you data that indicate that there are probably increase risk behaviors by people after they're released from prison, and that there may be increased risk behavior by the partner who remains in the community.

So there are all sorts of effects that are going on both within prison and outside of

prison.

There are advantages of course to incarceration, and this has been pointed out as well. It's a point of opportunity for HIV testing. Many states do a better job of that than others. Transmission risk reduction interventions can also be applied. You have a captive audience, and effective evidence-based interventions can be applied and can be effective.

In prison HIV treatment improves the health and potential productivity of the individual inmate, but possibly even has benefits after the person gets out, and reduces infectiousness, as you'll hear more about I'm sure in the next day or two. HIV therapy can reduce the amount of virus that is in the blood plasma, and by extension, in different compartments within the general tract, and reduce infectiousness, so there could be a public health benefit that should be realized as well.

And effective discharge planning if done correctly can link people to community resources that they may not have accessed prior to their

incarceration.

So who are the people who are getting out of prison? Well, our research and others indicate and paint a picture of a very complicated setting, where most people have no home to go to. The majority of people in our system don't have a stable setting in which they will return. Our work also demonstrates that more than 50 percent of the people require ongoing mental health care either for depression, other mood disorders, or psychoses. Almost all need substance abuse counseling, especially HIV-infected individuals who have largely incarcerated for drug-related crimes; job training; parenting classes; go without saying.

And then ongoing HIV transmission risk reduction is becoming an important feature, we think, in people who are HIV infected. Certainly everyone who is HIV infected needs HIV care.

So I'm going to capitalize a little bit more and expand upon the last two points that are being made here. We've done some work looking at the effective release of people who are HIV infected on

behavior and access to care. So this is a prospective observational study of over 170 HIV-positive persons; 74 percent were African-American reflecting the population in North Carolina Department of Corrections, and almost 60 percent were women. Again, more women are incarcerated for shorter periods of time, so there are more women who are released relative to men, even though their numbers are smaller in the prison system.

So there are two groups we were studying. In blue is the group that we interviewed before they got out of prison, and then an average of around 36 days after they got out of prison.

So the blue will code for people who were interviewed in those two time points. We also took advantage of people who were coming back into prison after a delay, so these were people who were released and then came back into the prison, and we interview them when they came back into prison. These two groups are mutually exclusive; these are not the same people. So we have the two cohorts that I'll go over.

So for people who are released, when we interviewed them about a month after they were released, 100 percent had received HIV medications at release, and that's pretty standard at most department of corrections. You'll get a 30-day supply or basically what's left over in your pill bin and given to you when you get out the door along with prescriptions and maybe some appointments.

The mean number of days of the supply was about 32 days, which is about right. And then since release, though, 17 percent have gone without medicines of a lapse of at least two days. And most of these when we asked them more about it is, they run out or they lost it. And as far as accessing care, 41 percent had not seen a health care provider since they've gone out. This is any type of health providers, emergency room or routine appointment. And 46 percent felt that their health was better than when in prison. The other proportion obviously felt the opposite.

When we at recidivists, people who had been incarcerated and then were freed for a period of

time, and the mean duration of freedom was a little over a year, you see a greater opportunity to have more trouble. Thirty four percent, or a third, who were on medicine run out of medicine while they were free. And the mean time from release to running out of medicine is about 159 days, and the length of time offered therapy of course is over 200 days.

They did not receive care while free, a third of them; hospitalized, almost a third as well. And most people agree, you could read this yourself, but they had trouble accessing and using care while they were out.

Again homelessness being in a halfway house or shelter was common as was substance abuse, relapse.

Importantly we asked these people about their sexual behaviors, and for the people when we interviewed them prior to their release, almost 80 percent had indicated they had unprotected sex during the year that they were - the year before they were incarcerated, and then when we followed up with them a month after they were out, already 26 percent had

had unprotected sex. And I should tell you, there is quite a bit of counseling that does go on in the North Carolina Department of Corrections regarding safer sex.

When you looked at recidivists who epidemiologically were no different from the cohort listed in blue, but had more opportunity to practice unsafe sex, again, we're seeing numbers approaching 70 to 80 percent of people who indicated they had unprotected sex while they were outside of prison. All these people knew that they were HIV infected.

Rates of unprotected sex were fairly high, especially among their main partners as opposed to casual partners; and they believed - most of them believed that about half their partners were HIV uninfected. And a third of each group felt it was somewhat or very likely they would infect one of their partners.

So Dr. Kaplan went over this, and this has implications. If we see that there is increased risk behavior when people leave prison, and this slide shows you - these are couplets, so each of

these colors are one person. So the yellow represents the viral load in the blood fo someone getting out of prison, before they get out of prison, and the red is what their viral load is when they got reincarcerated. And about 42 percent of people in North Carolina get reincarcerated who are released. So you can see the people who stay low are yellow and red are at the same level. You can see the majority of the slide is red, and that people that started out with a very low viral load or undetectable, and then came back in prison with a very high viral load.

So you can see this is a perfect storm of increased risk behavior, and high levels of virus, probably also in general secretions.

And that's important, because other data, I won't get into it, that the amount of virus you have in your blood predicts whether or not you're going to infect your uninfected partner.

So what can we do to make transmission more successful? I don't really have any very good answers, because we don't have a very broad collection of data to guide us.

Education certainly is something we could center our thoughts on. And there are different types fo educational interventions, motivational and skill building, educational counseling has been found to be effective for risk reduction, both for HIV infected and for HIV uninfected persons. This can be done in jail, and in prisons. The challenge is doing it also after people get out.

We could spend a lot of time and money educating people and counseling people while they're incarcerated while they have limited access to some of the things we're asking them not to do, as opposed to when they get out of prison where it's a free for all and the intervention stops.

So things that can bridge that period of time from incarceration to community release might be more effective, although again we don't have a lot of data yet.

I think community partnership is a big part of this, and this is kind of a commonsense move. We'd need buy-in from communities, from AIDS service organizations, work out ways to get them inside of

correctional settings so they could work with people before they get out.

It's going to take some buy ins from leadership. Faith-based programs may be particularly effective, and there are pilot programs that are going on, but I'm not aware of any results to date.

Again, I want to center our discussion on HIV therapy, because we know that it's effective for the individual, but also has a public health role in reducing infectiousness. For many of our people who get out of prison, they have limited access to HIV medicines. In our state when people get incarcerated they lose access to the AIDS drug assistance program, and if our AIDS drug assistance program is no longer taking new applicants, they cannot get medication through that program.

And also lastly, I'm going to talk a little bit about new approaches to traditional case management, and end on that point.

As most of you appreciate, case management is a comprehensive approach to providing services and coordinating services and mental health

and other services that are used. It's considered a glue that holds together a bunch of different needs that people may have, and the setting of HIV case management, it's been shown to be effective in creating benefits advocacy, supportive services, home health, and it's been also shown to decrease recidivism, reincarceration, both in Rhode Island and in Massachusetts in studies that have looked at it.

So there are a number of improved health outcomes that can come from quality case management. Currently, we're doing an NIH-NIDA sponsored randomized controlled trial of a novel case management program that begins before people are released from prison, and continues with that same case manager after release for six months.

This is different than traditional case management, in that it's a very motivational strengths model, case management that's very motivated and tries to let the client lead where the case management is going within limits.

And this is a randomized study, so people not randomized to the bridge in case management

receive standard discharge e planning, which I described as, here's your medicines, here's your prescriptions, here's your ADAP forms, don't forget to send them in.

And we are following people for a year after they get out, the bridging case management program will exist for three months before they get out, and then six months after release.

So to date we have 102 participants enrolled. They're all HIV infected. Again, 76 percent are men, 81 percent African-American, fairly consistent for all our work. Seventy five participants have been released to date, and the median time out is about 130 days. And I'll show you some preliminary data that we put together for the purposes of this meeting.

Re-incarceration in prison so far in the standard of care arm, the standard of practice, five people have been re-incarcerated today, and only one bridging case management participant has been re-incarcerated in prison so far. Utilization of emergency room care, which is one of our outcomes,

standard of care has used ER at least once 44 percent of the time in the three months after release, versus 28 percent of the bridging case management.

And our primary outcome that we're interested in, although the case managers are not privy to that necessarily, is access to HIV care. And again, this is just an early look, but in red, or pink, is the standard of care, and in blue is the bridging case management.

We're seeing some separation here where time to access the care is favoring people in bridging case management, and by week 12, 21 percent of people in bridging case management have not seen an HIV provider as opposed to 43 percent of people in the standard of care who have not seen an HIV provider for any reason.

So I think we're seeing some overlapping converging data that indicate that probably this kind of intensive case management intervention for example can be effective. And Dr. Redfield has experience with sort of kitchen sink approaches as well, and has very nice data showing that we can impact recidivism

and other health outcomes if we package services and make it available.

So I'm going to end on just a few quick notes, and this will take about 15 seconds.

As was talked about, there is a lot going on with people who are incarcerated. There's a lot going on with HIV-infected people who are incarcerated. We have an obligation to them and to the community to try to reduce their having trouble after they get out, whether that be trouble accessing meds, trouble getting training, trouble staying out of prison.

I also want to talk a little bit about their communities of origin, because I think we ignore what happens with the people who get left behind. And we know again with that altered perturbed ratio of men to women that that leads to all sorts of things that are not good when you think about HIV prevention including partnerships that may be concurrent; that means a partner - someone having a partner, and having another partner at the same time. That mathematically has been modeled to show

to spread the HIV virus much more efficiency than other modes.

Many of the men who are available who are not incarcerated at that moment may be underemployed or financially unstable, and they are sexually mixing wearing women who normally would not be hooking up with these men are hooking up with these men because there are less men available in that community.

And work that has been done again by our colleague, Dr. Adimora, indicates that a substantial portion of African-American women who are HIV positive have relatively few risk factors for HIV infection, and posits that that is a clear sign of how endemic HIV infection is in communities of color.

So schematically one thing that we're very interested in exploring is whether or not in a partnership where the man gets incarcerated, not focusing so much on him for the moment but on her, and if he's gone out of the picture for awhile, are there pressures that lead her - whether they're community pressures or personal pressures - to hook up with another individual, thus placing her at risk

for acquisition of an STD, HIV included, and then of course her partner comes back out, she hooks back up with him and may have other partnerships in addition to that.

So we think that this sort of cycling could theoretically lead to her being exposed disproportionately to HIV infection, especially of her relationship now breaks up because of the stress of incarceration. And in a community where there is a lot of HIV and there is a lot of incarceration, I think this could multiply, and we might see spreading of HIV amongst the women, and I think that may reflect what we're seeing.

So I'm going to end there, and open it up for both of us to take your questions. And I appreciate it.

DR. SWEENEY: We're going to take questions, but I've been given strict instructions about lunch and breaking and getting started this afternoon. So I'm going to start in order of people that didn't get to go last time, if there are any people who want to ask questions, and we hope that

Dr. Kaplan and Dr. Wohl will stay through lunch so that we can have additional questions answered if we don't have time now.

Dr. Sullivan.

DR. SULLIVAN: Really a question to Dr. Leone. Is he here?

You mentioned the survey that you did I guess educating men who I believe if I remember correctly frequenting bars; during the course of one year there was a significant drop in the rate of infection.

Why was that study not continued?

DR. LEONE: So the study I referred to was called the Popular Opinion Leader Model. And it was funded through CDC post our outbreak investigation. And we were told that that was all the funding they had available on that, period.

To be blunt, it took a lot of pushing. I think the folks at the CDC were very supportive; certainly the epi branch agreed with our data on the college outbreak. And I don't know where the problem was about continuing it or coming up with more

funding, but it took literally a battle in the press in order to get that funding to begin with.

So there is more than a little bit of frustration on my part that we have a program that's been successful and the plug has been pulled on it after a year.

DR. SULLIVAN: We can discuss this tomorrow. But it seems to me that really is an issue that concerns me, and I think we need to discuss it further.

MR. BENAVIDEZ: Thank you, Dr. Wohl. I appreciate that. I found it very interesting.

A quick comment. I think you mentioned the mental health problems of people leaving prison were significant, over 50 percent I believe. So obviously that will have an impact on compliance, seeing a physician, having access to the medication.

How do you incorporate I guess that mental health component in your studies and how you're looking at these patients?

DR. WOHL: At this point, up until very recently we were observing this, and were quite

surprised to see how much mental health needs our patients had.

With the case management intervention that we've applied, the case managers are well equipped to refer people to the available resources that exist in the community.

The problem is if there aren't resources available in the community, and then it takes a lot of creativity. So I think what you're getting at is a really important point of the lack of what I call good, clean, well-lit places where you can get mental health care, and that is certainly a problem.

Our case managers many times will tell us they physically drove someone, sat with them at a mental health center, and tried to get them care just to ensure that it happens.

DR. SWEENEY: I just wanted to ask a question about contact tracing and partner notification.

Is it done? Are people who are incarcerated, and who know their partners, do they get notified that they may have been exposed and

offered testing?

DR. WOHL: Yes, so when people are diagnosed with HIV in the North Carolina Department of Corrections, contact tracing follows just as it would in the community. And Peter, I don't think you have any indication that there is any difficulty with contact tracing of prisoners.

I know that there is - we're talking about contact tracing of people who are diagnosed with HIV in prison, and I think that system seems to work very well, and I don't know if you've heard of any problems with it.

DR. LEONE: I think it works well. The problem that I've seen from my perspective, and Andy and Dave can comment on it, is, actually empowerment for a lot of these in particular women about negotiating either not having sex or using condoms.

So second paper that was published a year ago on black AIDS awareness day, MNWR looked at women in North Carolina and HIV as an outgrowth of the college outbreak.

And what we found was, again, very little

empowerment for these women, either around poverty or being able to negotiate with their men condom use.

So even though they're notified, it frequently doesn't seem to change in the results of protection in that couple. So it's an ongoing issue. But to be clear, North Carolina law requires partner notification. So everyone who is newly diagnosed will be interviewed. If they give us the names of partners, we will locate them and notify them. But we've seen it, and maybe Dave and Andy can comment, where women know that their male partners are infected, and they continue to have unprotected sex.

DR. KAPLAN: But I think you're talking about within prison.

DR. LEONE: Within prison.

DR. SWEENEY: I was talking about within prison, while the partner is within prison.

DR. LEONE: Yes, absolutely. I think that one works much easier than the community link, because they know who they are. So they will easily call someone over - the prison has complete control. So if someone mentions another person that they had

sex with when they were diagnosed, they will find that person and then offer them HIV testing.

DR. WOHL: The only problem I see, if you are talking about in prison, their partners, is that you may not get information about who they had sex with.

So the bottom line in all of this is, you're stuck with someone giving you a name or letting you know what happened.

And I would think - I don't know, because there is no data - that in prison there is a lot of pressure not to talk about what actually transpired.

DR. KAPLAN: Well, it's illegal to have sex in prison. That will extend your time in prison.

DR. SWEENEY: No, I wasn't talking about tracing the partners in prison. I was talking about tracing their partners who are in the community, and notifying their partners in the community.

DR. WOHL: That happens. But Peter's point is well taken, and our data show that men who come out of - men and women who come out of prison and go back to their main partner, frequently don't

use condoms even though their partners are HIV uninfected. But say they've disclosed their HIV status to those partners, as opposed to their more casual partners.

And most of our people when they get out have on average about seven to eight partners. And when we ask them about this, they say that their main partner si the one that they are least likely to be safe with. Their casual partners who they are, A, less likely to disclose to, they are more likely to use condoms with.

And these are data that we thought were very odd. There is another research group that is similar to ours in San Francisco that has found very similar results in San Francisco.

DR. SWEENEY: Thank you.

I see Ram, David. Before we have any other questions, Joe Grogan has to make an announcement.

MR. GROGAN: It's a new wrinkle for us here. We've got a little extra time for questions, because the catering van bringing the food got

stolen.

(Laughter)

So the members do have a guarantee that the sandwiches will be super fresh this time, because they are working as quickly as they can.

(Simultaneous voices)

DR. YOGEV: I was just wondering with the new recommendation of the CDC for universal testing, do you think it's about time for the committee to consider recommending mandatory testing of incarceration, not only when you come in but also when you come out, with partner notification? Because it's not. You got a refreshing, but I'm coming from a state you can't even talk about it.

DR. KAPLAN: I think we're in agreement on this.

DR. WOHL: I think we're in agreement on this. I don't know if our group is unanimous on this, and it's a divisive issue about testing inside of correctional settings, especially prisons.

And I think that - and Andy can speak up - I think testing in prison has a lot of value, and

as I mentioned provides a lot of opportunities.

I think one thing has to be very clear, though, is if you are going to test in a correctional setting, how, A, those data are going to be handled. Can it be done confidentiality and not coercively as much as possible.

And B, what are you going to do with the data as far as treatment? If you don't have treatment available as is the case in many jails, why are you testing? And can you apply therapeutic and prevention interventions? If you can't, then I don't understand why you are testing?

Part of the problem is, we don't have uniform quality of HIV care in prisons, and especially in jails.

DR. YOGEV: I'm raising exactly that issue because of what you just said. It's interesting that I belong to the International Subcommittee, and we're committing HIV testing to treatment in Africa, and it's about time we do it here in the United States. And that should be part of the resolution is, what's fascinating to me is, one out of five who have HIV is

going through the system that can help us to identify and connect to treatment, you are also correct.

And the only way to do it is incentive, and maybe connect to Ryan-White or whatever, just the issue of mandatory is so controversial, and that's why I was raising it.

DR. WOHL: We see both sides. Certainly if we have mandatory testing we see that there are more people that will be identified. But we also know that before you mandate, before you do HIV testing against someone's will, you betting think long and hard about it and make sure the benefits are there.

It's very interesting about the Georgia outbreak, they had a voluntary system for two years during that long period of time where people were offered annually HIV testing. Half of those 88 cases were detected , seroconversion in prison, were detected during those two years, out of 25 years of this program going on where they test people.

So clearly we know that we can raise the level of people that we can identify with very good

voluntary testing programs.

I think mandatory testing is something that's not off the table in prison, but we haven't even explored expanding voluntary testing in a way that I think -- to its full potential.

DR. KAPLAN: Yes, I think we could do a lot without that testing. We can do a lot without forcing people to get tested before we decide to go that route.

The other thing you need to keep in mind is that when someone is diagnosed with a treatable illness, the Department of Corrections is obligated to provide treatment for them free of charge, so it's very, very expensive, and I'm sure there is a tremendous financial disincentive. They are only going to be there for three years, so this idea of preventive care is really not on the table.

There is a tremendous disincentive to identify people that will then require expensive care.

As just sort of an anecdote, the medical director of the North Carolina Department of

Corrections has to go before the state board - I'm sorry, the state legislature, every year and rationalize her budget. And I guess one of the legislators asked her, said, look, the food service's budget decreased by 15 percent last year, but your budget went up 20 percent, why is that? So maybe they're related, but it is the kind of pressure that they face. So this is one way of not having to pay for it.

DR. SWEENEY: Sandra, did you have your hand up?

MS. McDONALD: Thank you for your presentation.

Our agency in Atlanta has been doing a lot of work in corrections. In fact we had a program in county jail where people got released to our program. My hands are off to you. It is tedious work.

Did you link in the services for substance abuse and housing? We almost babysat. We had very good outcomes, but one of the persons in that program told me that he was better off

incarcerated than being with us, because we really do hands-on stuff to get the results.

DR. WOHL: That's exactly right. And again this is a plug. Everyone has their own agenda. This case management and intervention that we are piloting we've received funding which was wonderful from NIDA. Unfortunately our funding is running out, so we're going to end this program very soon. And we were hoping to implement it, and not just be something that someone could look up in a dusty issue of a journal. We want this to become a reality, so we're really looking hard to make this happen in real life, and not just in an academic setting.

And your example is very good. When I go to the literature, I go to these boards and I try to prove to people that this works. They say, show us the proof. We don't have studies, rigorously controlled studies, that show that this kind of intervention and others that are like it work, because a lot of people have put the effort into it.

So I think we're really trying to make this happen and have a breakthrough. We could say,

this is the model we should be following. We should be having a link.

Right now there is this huge gap between incarceration and the community, and no one is bridging it; we're just doing it piecemeal, and we need a more comprehensive system to make sure that people can stay, keep their weight on, keep their viral loads low and their CD4 cell counts high, and remember to use condoms; that's what we're trying to implement.

DR. KAPLAN: And Ryan-White funds can't be used for people who are incarcerated, so that's another problem for us.

DR. SWEENEY: David.

DR. REZNIK: Actually, I think you have the data to support at least the linkage.

If I heard some of your materials correctly, the people who were able to obtain care in your program, there was this long period of time where they were no longer able to access medications, which to me means that we're creating resistance. We're also increasing viral load, increasing

transmission, and therefore increasing resistant transmission.

The Ryan White dollars can be used - the reasons they said, at least in the study, that they couldn't access care, but Ryan White would cover them once they're no longer incarcerated.

So there needs to be - so there seems to be, and this is Dr. Primm's point, and he's not here, and it's hard for me to speak for Bennie, but there seems to be an issue with linkage from when they get out of the corrections into Ryan White, and that has to be a priority for the community itself, when you're talking about such a high percentage of males that are incarcerated in the minority community, where not only are we fostering an epidemic among those less fortunate, but we're creating a more complex epidemic because of resistance issues, and attached with mental health and substance abuse.

So I think that there needs to be a priority put, maybe not exactly, or in your case, maybe in the model that you created, the six-month model. But at least some kind of model that links

people upon release into the Ryan White system of care, because the qualifications in any state they would fit that. That's got to happen.

DR. KAPLAN: We're both trying very hard to raise money to continue this project.

DR. WOHL: You'd be surprised how hard - this is like the obvious point. We're going to private foundations. We're applying to different grant sources. This sort of obvious case that we need linkages.

And you could count on your hand how many systems of formalized linkages that start before people get out, and continue after they leave, and we're being told, it sounds like a good idea, but we're not so sure about it.

DR. REZNIK: It sounds like medical case management, which is a core service under the hopefully soon to be reauthorized, correct.

DR. SWEENEY: Dr. Sullivan.

DR. SULLIVAN: I have a more fundamental question. I'm sure that this is something that you talk about, but here you have a system as I

understand it of individuals going into prison, really being exposed and being infected with HIV, and of course it fosters the epidemic.

What is done in prison to try and prevent that spread? Because it seems to me that it's a head-in-the-sand philosophy that years ago we quarantined people with tuberculosis to prevent the spread of the infection.

So I know this must be an issue, but what is being done, or what can be done, to really stop the spread of the infection in prisons?

DR. KAPLAN: Well, there is aggressive counseling of people that are infected. But in terms of unprotected sex, it's an infraction. But there isn't a lot of supervision.

I think one story - David and I went to a medium security prison not far from where we live, and we were on the yard with the captain of the guards, and we just sort of were walking across the yard, and there were maybe 2-300 men just sort of very buff kind of men walking around. It was David and I and this guard. And I said, well, what happens

if they decide to grab us? And he said, well, there's a guard in the tower with a rifle, but other than that, the numbers aren't good.

(Laughter)

Which is very comforting you can imagine, but there isn't a lot of supervision. I mean these guys have a lot of time on their hands.

DR. WOHL: I think when you look at state prison systems, it's federalism at work. What we see is every system takes their own approach. So some systems have said, the way that we're going to curb this problem is, we're going to mandatorily test everyone who comes into prison. Those who are HIV infected we're going to have centers of excellence, segregated units, where there will be care, social work, whatever, and that way, they can have sex with each other if they want, but there is no HIV transmission going on, and we'll sort of cull from the general population before they check in.

That system has been very hard to implement in many places, and you have to have a lot of safeguards in there. Are we segregating? Are we

taking away privileges? Are we taking away opportunities? It could be done very well. It can be done very, very poorly as well, and there are states that have had a lot of trouble providing services to people who are congregated in a situation where everyone has the same infectious disease.

There are public health aspects of that, too.

So I think testing, letting people know that they're HIV infected, is a major part of that. The majority of people who are HIV infected don't want to give their HIV to anyone else. I think there is a lot of data on that. There's exceptions.

The majority of people who come into prison, the majority of people with HIV in prison come into prison with their HIV, so I think we have to do more about identifying who's HIV positive, counseling them, and allowing them to have the opportunity to be in prison, and I think personally I think allowing people to have access to condoms, the intervention that we know works very well outside of prison should be applied in prison as well,

especially given the circumstances that are existing.

Will it obviate transmission that occurs during rape? No, just like in the general community. But I think there's more that we could do to try to do that.

Increased security is not going to be an issue. You can't keep it secure enough to prevent these episodes from happening.

DR. SWEENEY: We have two, Dr. Judson and then Dr. McIlheney.

DR. JUDSON: Well, I think we appreciate even more the challenges of turning prisons into HIV prevention and treatment centers, of the highest order.

But it still seems, using the PP analogy, and maybe the sexual predator/sexual assault analogy, where people who are known to be HIV positive when they're released, a condition of their parole or continuing parole would be that they not have anyone who is HIV positive not have sex or contact with anyone without their prior knowledge and consent.

And we would follow somebody with active

TB, and it wouldn't be their choice as to whether they go back and infect others in the community, or in their homesite.

So where has there been any progress on that?

DR. WOHL: It's already state statute that you can't knowingly spread your HIV to anyone else. So everyone signs a form that says they recognize it. When they leave prison, every single one of our known HIV positive inmates signs a form that says, I'm aware of North Carolina law that says if I do this I'm breaking the law.

The other thing that we have to realize, a lot of people get out not on parole or probation. They're out, scott free. In fact our HIV positive inmates prefer to complete their entire sentence rather than get caught in the trap of parole violations.

So we have very, very limited contact or control of people who get released in many, many circumstances.

MS. CLEMENTS: Can I speak a little

further to that? The control measures, North Carolina control measures, not only say you must use a condom, but you must also inform your partner that you have HIV even though you do use a condom.

DR. KAPLAN: And you can incarcerate them for violating those.

DR. WOHL: And that happens. It's not very often, but we do have people incarcerated now. Usually it's for sex work.

DR. JUDSON: But that's been the law?

DR. WOHL: Yes.

DR. McILHANEY: Have you - if you said this I didn't hear it - have you tried to calculate how much of the HIV burden, the new HIV infections of the 40,000 a year in this country might be attributed to the whole penal system and what you've been talking about today?

DR. WOHL: It's a real - like Peter said, it's the million dollar question. The reason that we formed this working group is because a group of us at the university who were working in separate areas started to realize we were all finding the same

thing. Whether you look microscopically or microscopically, from a behavior approach or from a medical model approach, all arrows started pointing towards incarceration.

Dr. Adimora's work that showed that HIV positive people were more likely to have had a partner who was incarcerated really lit the flame and we started to see incarceration is playing a major role in what is going on in these people's lives.

When we do qualitative interview it comes up every time. If you get a group of African-American women living in the South together, and you start talking about STDs and HIV, invariably, the shortage of men, the type of men that are available, and incarceration will emerge during the discussion.

We think we're on to something big here. We don't think this is the pie, and we're a little small dot. We think this is a big deal, and really fueling HIV epidemic, especially in the South.

DR. KAPLAN: I think if you believe that the context in which someone lives influences their spread of - whether or not they're going to spread

HIV or STDs, and then this plays a tremendous effect on minority communities; tremendous.

DR. McILHANEY: Do you think you could draw lines to as much as 25 percent of new HIV infections, or are you just not there yet?

DR. WOHL: Well, in certain communities, I think it's rampant. I think it's a major role.

Now these might be small communities. We've done some work in small urban areas in North Carolina, Jackie knows what I mean, there are these small mega-centers like High Point and Greensboro where we go and we interview people, and half the people just going to a nightclub and interviewing them, have been incarcerated themselves.

So incarceration has become sort of a rite of passage or a natural thing that happens, usurping other natural things like joining the military or graduating from college or getting married; it's become a normal life event.

And we think there is some interplay here between risk behavior and that event. So I think you're right. I think we're talking clearly double

digit percentage of maybe people who wouldn't be HIV infected were it not for incarceration.

DR. SWEENEY: My question is, Canada has made condoms available in prison for years, as has a couple of states and a few municipalities in the United States. And I wonder if you have any data from any of them about the effectiveness of their making condoms available, particularly Canada who has done it for a very long time.

DR. WOHL: There are no data that have been reported. If anyone in the room has something more up to date, but I belong to a group of people who write a newsletter about prison issues, and we ask this question of our board just a few weeks ago, and there were no data that anyone had access to.

Canada reports on their success of implementing it. Vermont has a program as well where they implement it. Even Riker's Island, condoms were available for a short period of time. So we know that these things exist.

But again in corrections we see the same thing over and over and over. People do something,

they report about it, but they don't study it. And so we're seeing a real acute shortage of the kind of data that would be wonderful to see.

The good news is, horrible things haven't happened. People haven't used them as weapons. We're not hearing reports of people smuggling contraband using condoms and swallowing.

These are the things that, rightly so, security officers, correctional officers, were very concerned about. We haven't seen that.

DR. SWEENEY: We're going to have to stop now, even without lunch Joe says we have to stop. And he's going to tell us what to do.

And thank you both and Dr. Kaplan very, very much.

(Applause)

REV. LUSK: Can I say one thing please? I'm listening to this, the previous study and this study, what's going on now. It's obvious to me and to all of us that the African-American community is being affected disproportionately.

And it just seems to me when you have

these kind of numbers that some special intervention ought to take place. You know, even the Ryan Act where you can't use money for this, you can't use money for that, I think we really have to think seriously about recommending some kind of intervention that's different than what we've been doing.

Obviously if we don't, many African-Americans and children are going to go by the wayside, and I just wanted to go on record saying that.

DR. SULLIVAN: If I might second that, I want to thank our colleagues from North Carolina for coming.

I agree. It seems we have a major issue here, and we can't be asleep at the wheel, and act as if this doesn't exist. I think we have to really work with our colleagues in the medical community to really address this. Otherwise, why are we here?

So thank you very much.

(Applause)

MR. GROGAN: It doesn't look like they're

going to get the food here unfortunately.

So what I'm going to recommend that we do is just walk over to the cafeteria and we'll reimburse you for your lunch.

But try and be back on time, because Mark Dybul is on at 1:10, and I know he's got a meeting at the State Department, so we got to nail that; we've got to start at 1:10.

So thanks.

(Whereupon at 12:38 the proceeding in the above-entitled matter went off the record, to return on the record at 1:17 p.m.)

INTERNATIONAL

DR. REDFIELD: I think if we can get started now, if I can get everybody to gather around the table, that'd be great.

I want to thank Mark Dybul for taking time to come. I think everybody knows Mark. He's now the acting U.S. global AIDS coordinator, NOGAC, and Mark is going to talk about the U.S. response to global HIV infection, particularly some challenges and opportunities.

Mark, thanks for taking time to be with us today.

U.S. RESPONSE TO GLOBAL HIV/AIDS: CHALLENGES AND OPPORTUNITIES

MR. DYBUL: Thanks a lot, Bob, and it's very good to be here. Thank you for letting me spend a few minutes with you.

Joe asked me to go over a couple of hot topics. And I guess the most recent hot topic is the annual meeting PEPFAR had last week in Durbin, South Africa. About 1,200 people from around the world came. Fifty countries were represented. And President Bush opened the meeting with a video. As I think many of you know, he doesn't particularly like doing such videos; the fact that he was willing to do it really highlights his commitment to PEPFAR and the administration's commitment.

The president outlined the results so far, through March 30th of this year. The U.S. government, the American people, are supporting treatment for 560,000 people in sub-Saharan Africa. 552,000 of those 560- are in sub-Saharan Africa.

560- covers 15 countries, the 15 focus countries. We are certainly supporting more in other countries, but our reporting beyond the 15 countries is only on a yearly basis, not an mid-term basis.

We are supporting care for 3 million individuals, including 1.2 million orphans. We supported PMTCT services for 4 million women which resulted in the counseling and testing and services to those women resulted in 350,000 receiving short-course preventive therapy, which probably averted in the neighborhood of 65,000 infections.

We're spreading behavior change messages throughout the world. We're supporting now counseling and testing for 13.6 million individuals.

This is all in two years. So this is what the president outlined in his talk, but mostly thanked people for being here, particularly the people from the countries, the 50 countries that were represented, particularly the people from the focus countries.

The meeting was heavily African, because the epidemic is heavily African, and a lot of our

response was there. About 80 percent of the individuals were from Africa.

And importantly many of the presentations were from Africans themselves or other in country folks, which demonstrates the capacity that is being built. For those of you who have been to other international meetings, this is not the norm. And so we are very excited to see more and more people from the countries presenting their work, and the capacity that is being built to do that to understand what they're doing in order to aggregate information and present it.

But we can do better on that. We still have too many international organizations presenting in my opinion, so we're going to focus them in the coming year on technical assistance to help grantees, particularly the local folks, feel more comfortable with their data, feel more comfortable writing abstracts and presenting them, so that they're not only comfortable for our meeting, but international meetings, to put together their work and present their work, and we are going to do a little more

capacity building there.

There was a lot of good emphasis on the meeting on what's been accomplished, but also looking at questions. On what has been accomplished, it was the first international meeting I've been to where the ABCs were fully represented in all three components, including two plenary talks which presented both an overview from an African on the effectiveness of ABCs and what she's seeing, particularly in Kenya the country where she's from, where we have seen dramatic results over a five-year period; and then a member of USAID actually presented the evidence base, and I think it actually provided a lot of people with a view of what the evidence for ABC are, and I think it had a significant impact, including among our European colleagues who came up to me and said, I didn't realize that there was that much data behind this.

So we're making some progress here, and some good press reports came from it.

There was also some very good coverage on utilizing community health workers, and nontechnical

experts to do counseling and testing, to do things that people can do.

One of our biggest challenges is utilizing the resources that are available, the human resources that are available, because there just aren't enough human resources for a Western-based approach in a place like Mozambique where there are 600 doctors total for 19 million people, you can't have something like Washington, where you have six university medical centers within spitting range.

So you have to use the resources that are there. And there were a lot of good data presented on this topic.

I was recently in Ethiopia, and in many of the clinics I visited, 20 percent of the nursing workforce in every clinic was being utilized to do counseling and testing.

Anyone in this room can do counseling and testing, and can do a finger stick to show HIV positivity with some training.

So you could tomorrow have 20 percent of your nursing workforce doing more clinically based

work if we could change some of these policies. And there was a lot of discussion about effective utilization of community health workers, or nontechnical folks for things that they can do. A lot of data on the challenges to that, but the need for policy changes. So that was a very impressive highlight.

Another important highlight is the success some countries are having integrating HIV and TB. Rwanda now is testing in the neighborhood of 70 percent of TB patients for HIV, and that's doubled since - in a year.

A number of countries, Kenya, Tanzania and others, have instituted what's called routine counseling and testing, or diagnostic counseling and testing. So most people entering TB clinics are almost routinely offered counseling and testing.

Namibia introduced such a policy, and these data were presented in a nationally for PMTCT, and they doubled the uptake of counseling and testing by the women by having that policy.

So some of these things are happening and

changing in terms of better utilization of policies, and it seems to be working quite a bit.

The two big surprises, I think, from the meeting, and those of us who spend a lot of time with international meetings, I won't say if that's a good utilization of time, but nonetheless, we have to spend a lot of time at international meetings, there is this attempt to link poverty with HIV/AIDS, and to say, rather than addressing direct prevention care and treatment, let's just solve poverty.

Well, there were some very impressive data from very careful analyses from two sites that showed that if you looked at people who were relatively poor in the country, they actually had a lower prevalence of HIV infection.

Now as people gain access to resources and other things, they engage in activities or become urbanized in a way that actually increased the prevalence rate.

Now it is true that the people in those countries that are relatively well off are still poor by U.S. standards. But we're not going to get

countries in Africa to U.S. standards economically for 25 - 30 years, rather than spend - if we're lucky - so we need to concentrate on saving the lives there. And that was a message that challenged a lot of people, but it was very important to hear.

To be honest this isn't rocket science. South Africa and Botswana, two countries with very high prevalence rates, are two of the wealthiest countries - and Namibia - are three of the wealthiest countries in sub-Saharan Africa. Yes, they're not as wealthy as we'd like them to do, but it's a demonstration that this attempt to say, let's just solve poverty, isn't going to save HIV/AIDS lives in the near term.

The other very surprising thing is, there's been lots of efforts to link nutrition to clinical benefit in HIV/AIDS, particularly in treatment. There is no question nutrition in the early stages may - well, I wouldn't say there is no question, but there are some data that nutrition in the early stages may delay when you need to start antiretroviral therapy.

But from Malawi they're actually doing a

randomized control trial introducing food with antiretroviral therapy, some food supplementation in the same populations, and not introducing food, just giving antiretroviral therapy. And the preliminary data showed no benefit clinically to adding the food supplementation.

That doesn't mean food isn't important, and people aren't hungry. There is no question; everywhere we deal people are hungry. The question is, how should HIV/AIDS resources be utilized. So we'll be following this closely. This is not a definitive word, but I think the two challenging things to most people in terms of their perceptions were the link between poverty and prevalence and the link between nutrition and clinical outcome when added to antiretroviral therapy, not to care.

But overall I think it was - and unfortunately to a lot of people it was challenging, was the database for ABC. But we're making progress on all of these things, and I think it was overall a very good meeting.

The reason I wanted to go through the

meeting because I think that summarizes to a large degree where we are in terms of gains that have been made, but also some of the significant challenges that remain.

And this meeting really brought those out. John Donnelly even did a piece surprised that we would have people question what's going on.

Of course you need to always question what you're doing, and self analyze what we're doing, because we're not going to reach as many people and save as many lives if we don't. And I think this meeting was a good demonstration of that.

We began the meeting in fact by pointing out that PEPFAR and the successes of PEPFAR have become the base for the role model for the president's malaria initiative, for what is now happening with the director of foreign assistance, by pointing out that if you look at a business model, the first company out of the box in most fields doesn't do so well in the long run. And they reason they don't, they kind of get bogged down in their ways of doing things, and don't innovate, don't

constantly innovate.

So what we're trying to do is ensure that in PEPFAR we constantly7 innovate, that we are constantly out ahead of the curve, that we are challenging and looking at what we are doing, so we are a successful startup, and we don't get overtaken by others.

And we spend a lot of time talking with them. So I think ti was a very good meeting, that highlighted both the successes and the challenges.

The successes I don't want to lose sight of, are extraordinary, are absolutely - they're breathtaking, they are extraordinary. But we have a long way to go. We need to almost quadruple the number of people seeking therapy to meet the president's goals; almost triple the number of people receiving care; and expand our prevention program.

So lots of great work has been done; extraordinary hope. But we still have a lot - a long way to go.

One of the issues Joe asked me to address specifically is the GAO report on our prevention

strategy. There was, as many of you know, a report at the request of Congress, but then turned into a Comptroller directed report rather than response to the congressional inquiries regarding our prevention policies and what it's doing in the field. And there was a lot of activity around that, probably more than was in the report. In fact the person who headed the report, David Gutnik, had a meeting at CSIS, and most people who walked out of there were wondering so much noise was made about this report.

There were a couple of important things in the report that pretty much dropped when the press was covering it. I think the most important thing is, in three or four places, the report stated that there was a consensus among U.S. government employees that ABC is the most effective prevention strategy in generalized epidemics.

That would never have been the case three years go. So the evidence base is getting out there.

There was not a single statement in the report, and I have no doubt they looked pretty hard

for it, from a U.S. government professional who said that they wished they could do less AB, or that the AB programs weren't working. It wasn't anywhere in the report.

So I think from that we can conclude that ABC does work well; the field believes it works well. But there are resource constraints, and this is what the report focused on, the need to balance resources in the country when you don't have unlimited resources.

And while President Bush's emergency plan is an extraordinary initiative, the largest international health initiative in history, $15 billion over five years, we are currently as a people providing about as much resources as all other international partner governments combined, so that the resources are huge, but it's not going to solve all the problems of the world, so there are resource constraints.

One of the issues that was pointed out in the report was PMTCT, and whether or not our sexual transmission activities were squeezing out some PMTCT

activities, prevention of mother to child transmission, and had some comments, as well as data from a number of countries of relatively level resources for PMTCT.

I think there are a couple of important points on that. First, we've had a massive increase in PMTCT resources under PEPFAR, and actually to go back to the president's first initiative, which was the prevention of mother and child initiative.

Second, a lot of resources for PMTCT are not counted in PMTCT for bureaucratic reasons. PMTCT - prevention of mother to child transmission, as it implies - is counted in prevention. But there are aspects of PMTCT that were shifting rapidly out of that direct prevention, which is single dose therapy for HIV/AIDS.

First of all, much of the counseling and testing that is accounted for in PMTCT is now accounted for in what we call care, because all of our counseling and testing is counted in care.

Secondly, we're trying to move as rapidly as possible, from single dose therapy to combination

therapy for pregnant women, because it probably has a much better effect in terms of preventing infection.

There are clear data that just adding one drug significantly reduces prevention, or significantly reduces transmission. But if you can get to three drugs in full therapy to the women who need them, you will probably reduce transmission further.

All of that type of therapy is counted in treatment, not in PMTCT. So there are significantly more resources for PMTCT than are counted for in the budget line for PMTCT, which is bureaucratic in many ways, but it's important programmatically because it means there are a lot more resources than were accounted for.

But overall, we would agree with the report. There are resource constraints, and you have to balance them. And to be honest, had the president received his full request for the focus countries, none of this would have been an issue.

Congress has over the last couple of years reduced the amount - although the top line

number, the total number the president has requested has remained the same or been slightly increased, the total dollar amount for the focus countries has actually not met the president's request as they have been redirected towards other priorities.

It's one of the reasons we're advocating so strongly this year to maintain the president's full request for the focus countries so that we don't have as much need to balance resources.

But I think importantly again, nowhere in the report did it say, anyone thought we should spend less on the AB component or it wasn't working. There was just concern that we didn't have enough resources to do everything we need to do.

And I'd be happy to answer any questions on that.

So actually I'd like to save most of the time for questions and answers, because I know you just had lunch, and most people don't want to hear people talk anyway. And your questions are more important; they'll probably bring out some key issues that you are concerned with.

But I would have to say, the state of PEPFAR is very strong. The president's vision is holding up, and his bold and decision action are having a tremendous impact on the field.

I'd like to end by saying that the impact we're seeing is not limited to numbers. What we're really doing is building local capacity, and country ownership, to fight the epidemic. And that's having spillover effect.

The numbers are but a reflection of a higher goal, which is to save as many lives as rapidly as possible, and to serve our global brothers and sisters in a compassionate and humble way.

Those are our goals. The numbers are a numeric reflection of that, and the president stated that goal beautifully in his state of the union address.

We are achieving the higher goal, and by achieving the numbers. And the change in the ground is night and day, the hope that has been created doesn't come reflected in the numbers.

And it is the hope that's being created

that is transforming Africa in particular.

So Secretary Rice's vision of transformational diplomacy, transformational development, is happening. What we're seeing is local people who now have resources to fight their epidemic, take control of their community, take control of their epidemic.

It's creating a culture of accountability that you can't describe unless you are there, and we have trouble describing it numerically, which is why you don't get a sense of it. It's creating a culture of accountability which is leading local folks to question their government and hold them accountable.

To wonder why don't we have the same accountability for water programs and food programs and malaria programs. It's leading to an account of people holding governments accountable.

In a word, as a young Namibian told me, it's creating democracy. And so there is a fall out effect that you don't capture in the numbers, which is inspiring and breathtaking, and those who have had time to be there would see it.

So things are strong. We have a lot of obstacles. But things are well on track to achieve the president's goals. And we appreciate your insights and comments you have, questions you have, on PEPFAR.

So with that, Joe, Bob, however you'd like to handle this.

DR. REDFIELD: Are there some people who would like to ask questions?

So we'll start here, and then Frank.

DR. SWEENEY: Thank you very much. That was a very nice overview.

I was very struck by the statistic that you did that people who live in poverty are not as effective as people who are I guess middle class, or whatever the class you call them. And I was wondering if that indicated a lack of incidence, or a barrier, to being found in terms of the testing and so forth.

Because I went to visit David's program in Georgia, and it was very much like the people that I often seen in New York City, that the people who

are most affected are from the lower socioeconomic groups, and I just wonder if you'd comment on that.

Ninety percent of his patients are at 100 percent or more below poverty; is that right, 92?

MR. DYBUL: I'm speaking about Africa. You can't apply the poverty situation, and compare people in poverty in Africa to the United States, or people in the middle class in Africa to the United States.

In Africa it's not a difficult in finding them. They actually - and these are effectively randomized controlled looks, looking at the same number of poor people and relatively wealthier people.

Now by a U.S. standard those relatively wealthy people are still poor. So it's really within Africa, and Africa is a much different place, and you cannot apply what I said to the United States. And I don't know the data in the United States, because I don't work here. I work predominantly in Africa.

Now why that would be the case in Africa is probably remarkably different than here. The

poorer people tend to be in more rural communities, for example, and in the rural communities the family structure is stronger, and there is a system of support that is much stronger than you would find in many sections of the United States, particularly in the inner cities here.

As people start to get more money in Africa, they tend to migrate to the cities, where some of that rooting and family and support disappears. There is a four season phenomena where young girls will have transactional relationships with older men to gain goods, clothing, cell phones, cars, things like that that you don't see so much in the rural communities.

So it's a much different situation; it's a much different situation. And the - and I'm talking internationally here, not domestically. Internationally there has been this push to say, let's not focus on HIV/AIDS. It's not a unique thing, because of poverty, that people are becoming infected. So let's just put all our resources toward poverty reduction, and then HIV will go away.

Well, these data are kind of a wakeup call to people who are arguing for that, saying, until we get to wealth levels such as the United States we are unlikely to have a significant impact on the HIV infection, so over the next 20 or 30 years, which is what it would take under the best of circumstances to get most of these countries to level like the United States, tens of millions of people will die, so we need to focus on the HIV piece, that it is exceptional right now, and we can't have a huge impact if we fight the epidemic directly.

But I would not take anything that I said as applicable to the United States.

DR. JUDSON: I'd just give a commentary on my own personal experience, just to underscore what Mark was saying.

Many years ago I wanted to start a program to do HIV care and treatment in rural Malawi. We estimated based on prevalence rates that the infection rate was going to be between 20 and 30 percent based on the urban community.

Our initial first year prevalence rates

an hour from the capital city came back 3.7 percent; I didn't believe them. Seven years later our average prevalence rate is between 3-1/2 and 4 percent.

We are going to get a little into this with the next speaker as we kind of follow up on the Washington Post articles, et cetera, about did we overestimate the epidemic. I think what Mark is trying to underscore is that there has been a bias that this is something we can't just focus on, and that is, confronting AIDS, because we've got to confront all these other problems.

And that bias can keep us from confronting AIDS, and I think, just being open, I mean I know in my own personal experience, I was shocked, because trying to find the resources to treat this village, the 60 villages which I calculated had 75,000 HIV positive people in rural Malawi could have been overwhelming. It turns out in reality it's only 7,500.

So that is overwhelming, and I think I would have stopped if I thought I had to do 75,000 people.

DR. GREEN: Thanks, Mark, that was really exciting.

We're three years along now?

MR. DYBUL: We're three years from the president's announcement, but two years from the first funding.

DR. GREEN: A comment and then a question.

As far as the poverty wealth issue goes, for some of us that was laid to rest a long time ago just from very obvious correlations. In developed countries white gay men have the highest disposable per capita income of any other, most other identifiable groups, and in Africa, early on, I think 12, 13 years or so, they did just a crude correlation of per capita income, and HIV rates, and there was no association or perhaps a negative association to poverty, and then more recently, the studies that have come to the deeper or obvious conclusion that wealth gives you mobility, choices, options, and time to pursue sexual exposure possibilities.

The question is, is - are there a set of

cutoff values for when a country would be viewed as potentially not achieving the goals? And what are they? When would you decide this isn't working here, we knew it was going to be tough, we are going to have to divert resources elsewhere.

MR. DYBUL: Thank you, those are excellent questions.

And on your commentary I really appreciate it. Unfortunately, there is a lack of willingness to face things you don't want to face. And having been accused many times of ignoring evidence, the propensity of many people to just ignore evidence on many different topics, because they want something to be a certain way is rather mind boggling to me. But nonetheless it's there, so we fight this on many different fronts, because we want to be based on the evidence; we want to base our activities on what the data show.

In terms of your second one, it's actually an ongoing process. And I think an important part of this is, we never anticipated that every country would be on the same trajectory.

So in Uganda because they have a national strategy, not because they have resources - the number of people around the world who think Uganda is wealthy because of their success in prevention, treatment and care is rather amusing to me sometimes. But it was because they had a national plan and a national commitment that predated availability of resources, so they had resources to go.

Namibia moved rapidly because the government coalesced rapidly with the partners, including faith-based and community-based organizations, to set a plan, so they're taking off.

South Africa, now that they've gotten going, is taking off, probably because of infrastructure.

Rwanda looks a little bit more like Namibia, the government and the civil society is coming together to move rapidly.

So those are countries we kind of put in what we expected to be a first rapid upswing. So we expect different swings. One is a very rapid upswing to get to where we intended it to be, and then a

leveling off.

Other countries were not quite in the same situation, such as Ethiopia, or Nigeria, where infrastructure was very weak and there wasn't much leadership . And there you would expect exactly what we're seeing, a slow upswing, but we're starting to see the uptake after two years of concentrating on building the infrastructure, and building the support that is necessary to expand programs.

And then you have countries in between like Tanzania and others that have some, a little bit of the Ugandas, Botswanas, Namibias, South Africas, but still weren't quite there. And there we're seeing a faster initial uptick, but also a much faster upswing now.

So we expected all of that. So what we do is ask each of the countries to predict on an annual basis the progress made toward the five-year goal. And when we look at that, many of the countries are exactly on the trajectory we expected.

Our resources are based on that trajectory, so our annual appropriations to the

countries, our annual allocation to the countries, is based on that initial trajectory, but also where they are.

So if they for example have big pipelines, a lot of money that has been allocated to them but not used, or if they are not reaching their goals, as we put together the next year's allocation, there - we actually reduce the dollar amount that we give them for that year as they're building the infrastructure that's necessary to utilize the resources.

That's built into everything we do. It does cause us some problems, for example with Congress. We have to put it in what's called the congressional budget justification, start that process almost 18 months before we actually allocate resources for that year.

So we put provisional numbers, but based on the results that come in and our evaluations of where the countries are, we radically modify the dollar amounts that will go to that country that year.

So we do this on an annual basis. We look at the results, and where people are, and then allocate money for the coming year based on that.

So far most of the countries are achieving the projections or the direction that we anticipated. Some of them are moving a little bit more slowly. Ethiopia and Nigeria were moving a little more slowly initially, but now they're taking off; they're starting that upswing. So we increase resources as we see that happening.

But it's an annual effort using both the March report - that's one of the reasons we ask for the half year way number in terms of where they are on the way to their goals, but also the annual report, so we have both those sets of data to help us in those determinations.

DR. JUDSON: Thanks, Mark. Exciting news coming out of the most recent PEPFAR conference.

This will be sort of a rhetorical question, because you know my answer to this question. But in light of the accumulating empirical basis for ABC, why is it we still have leading AIDS

experts who say that fidelity and abstinence, sure, we're all for it, but such behaviors have little relevance in the actual lives of women today in Africa.

What do you say when you hear that?

MR. DYBUL: Well, as to motivation toward why people have these views, we actually try not to attribute motives to people. We try to hope that everyone is trying to do their best with the information available and come up with a good decision.

Unfortunately most people don't accord us the same respect, but our view is that everyone is working to try to do the best thing they can.

So why people are in that situation, I don't know. I think some of it has to do with the early epidemiology. You know the early epidemics and the early control were in concentrated epidemics, and there is this effort to apply lessons learned from concentrated epidemics to generalized epidemics, and you can't do that.

I understand the propensity to do it, but

it makes no epidemiological or medical or clinical or scientific sense, but if you grew up with a certain mindset it's going to be hard to change when the underlying situation changes.

So I do think there is an attempt to bring lessons from a concentrated epidemic to a generalized epidemic, and you just can't do that.

I've heard the head of the AIDS program in Brazil say if South Africa had just done what they did they wouldn't have a prevalence rate. Well, there is no evidence that Africa ever had an epidemic that looks anything like Brazil's. So you have to apply lessons to a situation and use the evidence base. And I think there is just a lag in that.

There may be other motives, but we'll hope that that is the major reason.

There is no question that gender plays a role in HIV/AIDS, just as there is no question that, writ large, the basic situation of joblessness - there are many things that play a role. But that doesn't mean you don't use concentrated approaches where you've seen the data.

So on the small issue of how does gender interact, and gender is not relevant to ABC - well, to some degree it's not, but we know if we can focus on men's behavior toward ABC, that will take care of that to a large degree.

So you have to target the men, and we have a lot of programs that target the men for responsible behavior, because if the men aren't abusing the women and following those approaches, you get a much different response.

But there is no question we need to work on the underlying culture and gender issues, too. And we do do some of that.

I think one of the best recent examples is, there was a church in Zimbabwe that had throughout its history taught polygamy, and because of the links between partners and multiple partners and the spread of HIV our folks in country and some others worked intensively with the church to show them the relationship between HIV and multiple partnerships and the spread, and this year, because of HIV/AIDS, they revoked their policy on polygamy,

and said that you should not be polygamous because of HIV/AIDS.

So you do have to deal with some of these underlying issues, if you are going to overcome and get to the best results you can get to, which is what we're trying to do, not just to get a good result, but the best possible results.

So we are also dealing with some of the underlying gender issues, whether it's targeting men. One of the other things we're working on, there is one place stigma is good, and that's stigmatizing older men who prey on younger girls. And we actually have some programs designed to try to stigmatize transgenerational sex.

So we do have to deal with some of these underlying social issues while we're putting forward the best possible programs that we can in a focused way as well.

So it's balancing and mixing, which gets again to why we need the president's full request for the focus countries.

DR. YOGEV: The question I have is, I was

a bit surprised to hear that you move money from mother to child transmission, they are focusing on the treatment. And when you are also correct, when you give three drugs you prevent 90 percent plus. When you give one drug, you prevent 70 percent. But if you do the simple mathematics with the enormity of the program it doesn't make much sense to give one drug for 4 million women versus two drugs to 1 million women, you are going to save more kids and insist on moving into the treatment to help to really get the number that the president was hoping to get.

MR. DYBUL: That's a very good question, and it gets to resources. Maybe you can't do the best thing; you can only do what gets you the furthest along.

And I think it's a very important and good question.

First of all, money is an accounting issue in a lot of ways - where do you count, where do you put the money, not is it really PMTCT.

Most countries are moving towards full care and treatment for the mother as well as the

child, because the goal is to have a healthy and happy child to prevent transmission, and one of the best ways to do it is to keep the mother alive, and to keep the family alive.

One of the pieces of data that we're presented at this last meeting which really shocked me is that in households where the child lost a parent, even if that child were HIV negative, there was a threefold increase in death in the first five years, because there is no one to care for the kid.

And then of course what will happen to these orphans over time without a family structure, without someone to take care of them, we're seeing more and more orphan-run households.

So the purpose of preventing transmission is not just to prevent transmission. In some ways it's to have a broader picture.

So even under the president's initial initiative, the goal was to utilize resources where possible, to save as many lives as possible now, because you can get single dose therapy out there much more rapidly. But to move towards, as rapidly

as possible, where resources and infrastructure allow, towards that full care and treatment. And that's what we're trying to move towards.

But even in the short course therapy, we now know that for not much more money you can have one drug, and for a longer period of time that will cut that transmission rate down further.

I was in a meeting in South Africa at a meeting in McCord Hospital that has gone in this direction, and they went from a 50 percent transmission rate to an 85 percent transmission rate, to a 90 percent transmission rate, to zero over the last six months. And that's what we're trying to get to, not only for transmission, but also to keep the parents alive so that the children will have healthy and happy lives.

But it's a very difficult balance, and we leave it to the countries to sort that out.

DR. BOLLINGER: Thanks, Mark.

I have a comment and a question. Comment is about the association between poverty and HIV. My experience obviously is not in Africa; it's in India.

So I'm not sure how relevant this experience is.

But certainly as you've described in Africa, there has been a long not only an association with the lower HIV prevalence in poor rural communities than in more economically higher level urban communities.

And yet I've never interpreted that to mean poverty isn't important in India in the HIV epidemic, because in fact it's the poverty in the rural areas in India that forces women into the cities; that forces men to seek economic opportunities in the urban areas, where the risk increases.

Because again, I agree, they leave the traditional relationships that are present in those rural communities that provide support for lower risk behavior, but are also in situations where the poverty is so severe that it drives them into the city seeking other economic opportunities.

And certainly in the case of women, opportunities where they are not empowered to protect themselves.

So while I agree there is lower HIV prevalence in poorer communities, and particularly rural communities in India and maybe in Africa, I'm not yet convinced that necessarily means that poverty is not an important driver in the HIV epidemic.

I'm not suggesting PEPFAR needs to fix that. But I think we have to be careful about suggesting that poverty is not an important driving force in the epidemic, even in Africa and Asia.

My question is about some of the really encouraging things you said about the ownership that some of your in-country partners are beginning to demonstrate for the programs, some of the additional benefits of the program.

And one of the issues that we're thinking about as a group is sort of the transition period, the longer term sustainability of this great initial effort. And that's going to require us more buy in, more ownership from your local partners.

I'm interested in your thoughts. My question is about your preliminary thoughts about how that can be done effectively, so that not only is

there greater ownership emotionally and spiritually to these programs, but also financially, and whether there are incentives in place to help assure the sustainability of what you've initiated in some places, beyond simply the hearts and minds issue if you will.

MR. DYBUL: Thanks, Bob.

On the first point, I actually agree with you. There are many underlying issues. There is almost no underlying issue in Africa or India that doesn't have some relationship to AIDS. I think what these data show over and over again is that we're not going to solve the AIDS epidemic in the next short term by focusing the resources on poverty, and there is an effort to do that, to say this is not an exceptional epidemic, that it should just be poverty reduction, and that's true, you do need that, and we're very pleased that the president has supported the Millennium Challenge Corporation so heavily, and other economic drivers within USAID to build those economic bases so that over time we can advance not only against HIV/AIDS but the basic condition in

these countries.

I think it's more important - what we draw from that is not that poverty is irrelevant, because it's not, but that the almost panacea that's being proposed is that if we just move people up a little bit up out of poverty that HIV will disappear is not accurate either. And so we need to work on all these things simultaneously, using the incredible programs the president and Congress has supported to build some of that economic aid. So I don't think anyone is disagreeing with your first comment.

In terms of the sustainability, there are two pieces of sustainability in our view, and we've actually just issued some guidance on this. In development terms, sustainability means basically freedom financially and in every other way.

In our terms, at least for the near term, in most places, sustainability is going to be local ownership completely where our need is more resources and a little bit of technical exchange. But we need to get to the point where the country and the local folks fully own the program.

To do that we've done a number of things. One is the new partners initiative which the president announced on World AIDS Day to bring more and more leadership up.

The other is to push heavily for sub-partners who have moved towards competency to be full partner status, to get them out from subpartnership into individual partnership, so that it's a local group that is fully managing it.

The other is to emphasize on local umbrella organizations, because you don't want a lot of small groups that are doing great to have to build a bureaucracy over and over again to manage grants, so we're creating new umbrella grants that will cover those for kind of budgetary accounting purposes, but let the smaller local groups do the work, so that gets more ownership there.

We've instituted a policy that Ambassador Tobias instituted initially, and that no more than 10 percent of any country's total budget could go to a single organization; we've dropped it to eight, to try and spread the money out so it's not all held in

large international organizations.

We're putting contractual language in after two years of fighting with lawyers and contracts officers, which has been just the funnest part of my job and most time consuming I would have to say. But you actually have benchmarks within contracts, within grants now, so that you not only have to report on your success in achieving your numbers; you have to report on what you're doing to turn over what you're doing to local organizations, whether it be government, faith-based, community-based, or whatever organization.

So we're doing all these mechanistic, bureaucratic steps to get to that local ownership.

Now in terms of sustainability beyond that in the development sense of financial sustainability where you work in India that is probably possible. In China that is probably possible. In Russia that is probably possible, and in a number of other places, mostly in Asia and a few other places.

In Africa, South Africa can probably get

there. Botswana can probably get there. Namibia can do a lot more. There are some countries that can do a lot more.

But the fact of the matter is, going back to the first issue on poverty, we have to build an economic infrastructure that can support massive costs.

You know this year in many of these countries PEPFAR will be supplying $200 million sometimes more than that; Kenya is $300 million; South Africa - the countries will not get to the economic development to support those types fo dollars for a long time.

You can do things underneath that to support the local infrastructure, which is to try to get government to spend more money on their own programs.

So we've been working very carefully with Namibia in this way, to say basically it should be a third global fund, a third PEPFAR, and a third government. We need the government to pick up, and they're starting to.

We're doing some fascinating work within the, for example, government structures, where we will support on a contract basis employees in the government.

For example in Namibia we're supporting pretty much everyone doing counseling and testing in the public sector, and about 80 percent of the people doing care and treatment in the public sector.

And we're working on agreements -- and we're doing this in Botswana too - we're working on agreements so that over time the civil service absorbs those people into their civil service structure.

So we pay for them on a contract basis, and they have a process in place over time they're absorbed into the civil service.

So there are a lot of these things we are doing to lead towards that, but outside of a few countries, we're going to have to foot the bill for quite awhile.

DR. REDFIELD: Maybe before Joe I just wanted to follow up with a question that leads into

it.

Mark, could you sort of tell us, this morning we had a long discussion about the reauthorization of Ryan White. Where are we with beginning to get the reauthorization for it?

I understand that the PEPFAR was a five-year authorization, so maybe you could comment on that, because that plays into this, and then Joe, and then Reverend.

MR. DYBUL: Well, we've begun the process internally. The fact that Ambassador Tobias left has put us back a little bit, because I think we really need not an acting but a full coordinator to push that forward. It will be our office's responsibility to present the president with options, but ultimately it's going to be the president's decision to lay out his vision for the next five years, even though he won't be in office. He began this, and he will I would imagine want to lay out a vision of where he would see this going, and of course working with Congress.

Timeframes, we're still okay, probably.

You know just on - no one is going to want to get into this in 2008. As you all know there's lots of other stuff happening in 2008.

So we're probably going to want to begin the process, so a vision is presented sometime in 2007, and then start working through the process.

We have not gotten in full swing in that, yet, but that would be the normal process, unlike the first time, of course, there is no secret that there is going to be a next phase. So there will be more public discussion.

DR. REDFIELD: Joe.

DR. McILHANEY: Thanks, Mark. Work is so important.

I understand that in Uganda years and years ago a very very popular singer developed HIV/AIDS and died, but was very influential because he went public.

That led me to think, as you were talking, about another popular singer, Bono, and his emphasis on forgiving debt, and also HIV.

In your opinion do you think he's a

distraction or an asset on all of this? Or do you want to comment?

MR. DYBUL: Thanks a lot.

(Laughter)

Anyone who highlights global HIV/AIDS who has access to us is an advantage. There is still a great deal of lack of understanding of the scope of the epidemic and urgency of need to respond.

And I think it's probably less so in the United States. I mean the fact that the United States is now providing as much as the rest of the world combined, we don't say out of pride, we say out of almost astonishment that after the 2001 UN special session the president is the only one in the world who stepped up to say, you're right, there is a massive problem and we need to respond.

And so the American people are doing that. We need the rest of the world to respond in a similar way. And anyone who can get the rest of the world to do that I think is important to have everyone step up who can do it.

You know we don't always agree with

everything they advocate for. I don't know that we agree with anyone all the time on what they advocate for. But they do play an important role in pushing some of these initiatives forward.

And sometime attribution of successes might be an issue for some people, but it's not for us. As many people as want to take credit for what happens, it's great with us, because then they feel more ownership, and will push forward even more, so I think that's great.

The fact of the matter is that this administration was interested in debt relief for a long time and worked hard on it, worked hard on many of these issues, the malaria initiative, and many other things too.

So I think what he brings to this is very important in terms of getting the word out, spreading the message, and trying to get others to respond.

And we work very closely with their organization, they have great people.

REV. LUSK: One of my questions you just answered. I was just curious, I thought I heard you

say that the president's initiative has given more money than perhaps all the developed countries together; is that what I heard?

MR. DYBUL: Yes, as a matter of fact that is true. As the accounting goes, if you add up what everyone else in the world - I'm talking about developed countries, countries that are considered donors normally. We don't like using that term, because that is not the true relationship; it's not donor-recipient; it's partner.

But if you look at other donors the United States is giving about as much as all the rest of them combined.

REV. LUSK: Just wanted to just commend the president and the work that he's doing as it relates to the resources that he's allocating. I think that's commendable, being an African- American and knowing that some of those monies are being directed to Africa. And in that way it's encouraging.

I'd also just say, I have two questions. One question is, we have an organization, Stand for

Africa. We're in Malawi, South Africa, Mozambique, and we're going to Swaziland and Tanzania and do some work there as well.

One of the things that we've noticed is how resilient the people in Africa are, and the indigenous people there actually can do a whole lot of things that I think a lot of people perhaps think they can't do. I mean this whole idea of having missionaries coming from America to do some of the work that needs to happen over there, we've found that the people in Africa, the indigenous people, can do things like some testing; they can do some things that would cost us an awful lot of money if we tried to do them another way.

Could you comment a bit about that? And also, that would involve faith based initiatives, some churches and faith-based organizations in Africa that we're working with, we found them to be extremely helpful.

The last question is, the new partners initiative, just wanted you to talk a little bit about that, and when the RFP is going to come out.

MR. DYBUL: Thank you, pastor.

I think you put your finger on a very important thing, and why we emphasize the importance of having everyone respond to the global epidemic, including community and faith-based organizations. Because they are in the communities. They have credibility in communities. And they can frequently do things at a much lower cost, and get a reach that you cannot get otherwise.

And that's why we've encouraged so much the inclusion of faith-based and community-based organizations. Because we won't achieve the president's goals, you cannot get to national scale up without it.

The countries that are doing rather well, their national plans, in Namibia and in Ghana, and in South Africa, the scale up of mission hospitals, Kenya, the scale up of mission clinics and other centers and the use of mission centers and faith organizations to expand prevention, care and treatment, is part of the national plan.

They incorporate the mission hospitals

into their rollout schemes, and that's one of the reasons that we're moving so rapidly.

So we agree completely, and so we're very pleased to continue to see an increase in the faith-based percentage of partners, and also the dollars; there's actually been a doubling in resources for faith based organizations in the past year. And we think that's important, because we're not going to achieve results, we're not going to save as many lives as possible unless they're included.

In terms of the new partner initiative, the first request for applications is actually out and due - responses are due July 16th I believe, although I could be wrong about that.

There've been a number - there have been four preliminary bidders' conferences around the country to let people know about it, and this is just since the president announced it on World's AIDS Day.

There have been two or three more intensive three-day sessions to provide information on how to apply for U.S. government money. One of the problems is, many organizations out there doing

good work, to them the United States paperwork is like a massive wall that's inpenetratable. So what we're trying to do is provide information for people to learn how to jump over that wall and break through to explain grants; how to apply for a grant; what is necessary for a grant.

We're using a system for the NPI which decreases the burden required for concept papers and things, so you don't have to do 70-page intensive concept papers to get the ball rolling.

And then we'll have post-award technical assistance to help build the capacity within the organizations to help maintain that process.

This is not new. The U.S. government has been doing this for quite awhile. Some of the large international partners started exactly the same way 20 years ago. They're often the groups now who say you shouldn't be doing this, when that's how they got their start.

So it's a way to effectively level the playing field. So that everyone has equal access to dollars, everyone has equal competition.

And we think it's essential just like for the faith based groups, we think it's essential to bring in all these partners to achieve the goal. We need everyone engaged.

And I hate to get too far off the track, but in 2001 there was an historic document in development. It basically said what we've been doing in development hasn't been working. We need four things to get where we need to go.

And everyone in the world agreed, but it's kind of falling away as everyone wants to talk about harmonization and alignment, as if that is going to solve our problems.

The four principles were country ownership, good governance, all sectors and all people responding; private sector, public sector, faith based, community based, everyone, because we are not going to overcome these massive problems unless everyone gets engaged; and results based.

And that summarizes what we're trying to do with everything, and it is one of the reasons we're pushing forward with the new partners

initiative and these other approaches to build local capacity, because you are not going to get country ownership, good governance, all sectors involved, or the results you need, unless you do.

DR. REDFIELD: One last question or comment, Mark, and then we're going to move on. And we want to thank you for the time.

You mentioned several times the importance of trying to get the full funding for the president's request for this. You know, again, some of us just sort of hear whether there is money that is going to be moved from the president's initial to the global fund, or the global fund. Obviously both avenues are very important. Is there still tension there? Is there any question about whether the president is going to get full funding on PEPFAR program? Anything this committee could do to help in that regard?

MR. DYBUL: Well, the House has already passed their bill. And our budget, at least from the State Department piece - we have multiple buckets of money, but the State Department piece, which is the

biggest piece, which comes in foreign operations or foreign affairs, that falls within something called the 150 account which covers all development assistance.

And that 150 account in both the House and the Senate is down considerably from what the president's request is, a couple of billion dollars.

Now and that means some money has got to go somewhere. So the House bill is fairly close to the president's request, with a decrease for the focus countries of a couple of hundred - a little over $200 million.

But we're in a process now where the Senate will pass a bill, and then there will be a conference. And we work extremely well with our colleagues on the Hill. There is a bipartisan dedication to HIV/AIDS which is extraordinary. I mean when President Bush took office, the American people were committing $840 million for HIV/AIDS globally. In 2001, only five years ago, $840 million.

The president's first request for PEPFAR

was $2.4 billion, around 2.4. Congress actually exceeded a little bit the president's request. The second was $2.8 billion, then $3.2 billion, and now the president is asking for $4 billion; more than a quadrupling of where we were when President Bush took office.

You don't get that without bipartisan congressional support, without incredibly good working relationships, without good advocacy by folks like Bono and others.

So the money has been there. The money has been coming, but we always have to work within the top line budget to try to get what we can.

But both pieces are important. I mean the global fund is part of our strategy. It's part of the president's vision and part of our strategy.

But given our bilateral strength, we believe our proper contribution is more heavily towards bilateral and global fund. Getting to the question of where the rest of the world is, most of the rest of the world doesn't have that bilateral strength, so if they are going to give, they should

probably give to the global fund.

DR. REDFIELD: Well, I know I speak for everyone, Mark, we want to thank you for your commitment, and your continued leadership.

(Applause)

I think our next speaker, James Shelton, is an acting deputy director for the Office of Population in USAID, and Jim is going to talk to us about directions and level of the global HIV epidemic. I think we've all seen some publications recently in some of the major media trying to suggest whether we overestimated or underestimated the epidemic, so - James, he wants me to give you five minutes to get everybody awake, to go to the restroom, and then we're going to come back. We're going to start in five minutes.

(Whereupon at 2:14 p.m. the above-entitled proceeding went off the record to return on the record at 2:25 p.m.)

DR. REDFIELD: Again, I want to thanks James Shelton for coming. Again, as I introduced

him, he's the acting deputy director for the Office of Population at USAID. He's going to talk about directions and levels of the global epidemic.

Thanks, James.

DR. SHELTON: Okay, so let me start off by saying that these are my views. They are not the views of the U.S. government or the Agency for International Development.

I happen to think they're pretty insightful, but they are just sort of my take on things.

I'm an epidemiologist public health person by profession. And my passion is actually prevention, so that's the lens that I'm focused through. I mean I love all the rest of the work, but I'm really interested in that core of HIV transmission, especially in what I call the hyper-epidemics.

So I was asked to talk a little about the trends, I suppose in the aftermath of this Washington Post article that came out in April sometime. I didn't actually go back and look at that. I remember

reading it, and I thought, yeah, there's some truth here, but it's kind of exaggerated.

In a way, I was actually surprised, there was a very vigorous response from UN AIDS, and I actually have a statement that I'm going to quote from on that.

So I'm going to talk a little bit about the numbers and how you arrive at them, but also what it means programmatically, because I'm just going to take this opportunity to kind of make a pitch for what I think is the most important approach to prevention.

So if you will bear with me, I think one of the key points, which is like epidemiology 101, but it's funny, myself I didn't pay enough attention to it. But in HIV the relationship of incidence, which is the rate of new infections per population, and prevalence, turns out to be pretty profound.

And this is the example of Kenya. And here's incidence of new cases. Now this is modeled. This is part of the problem. We can measure prevalence reasonably well. Incidence is basically

either modeled using computer modeling, but there is a lot of consistency in the data. Or sometimes infections in young people is used.

But I'll show you, there's actually two major groups of modelers in the world that are kind of interrelated, one at the Bureau of the Census, and one at UN AIDS, and they kind of work together, but they also work somewhat separately. They have separate estimates.

But anyway for the sake of illustration, here is Kenya which probably peaked in `93, `94 in incidence. So notice that at the same time incidence - I've lost my arrow - was actually declining. Prevalence continued to increase, so obviously - for some time - and it wasn't until about 2003 that actually people kind of woke up and said, hey, prevalence has been declining in Kenya for years. I mean I never heard anybody saying that before that, and I'll try to explain that a little bit as we go on.

So obviously prevalence is important to understand the burden of the disease, potentially to

some extent estimating treatment; but if you are interested in prevention, you've really got to focus on incidence.

And if you are looking up here at prevalence, you are literally behind the curve, if you will.

Now these are - this is actually UN AIDS modeling. I got this sort of unofficially. They are not really officially available. But these are basically all the countries in Africa. This is one that we know well, which is Uganda, and then the subject of - can you see that? -- subject, it's kind of got its own nice little early peak.

One of the things I wanted to point out though, this is incidence. It's modeled. It could be off slightly, but I don't think it's off a lot. But notice that incidence always peaks, and everyone of these African countries. Now it may be a gentle low peak, or it may be a peak that ends in sort of a kind of tail off, but incidents always peak, which of course is true of all infectious diseases at some point.

Now just to kind of get away from some of that kind of spaghetti in a way, here's - I'm back to Census modeling. I picked these out because they are not - are you having trouble seeing the screen?

This is just kind of illustrative. Again, here is I think Uganda. If you want to evaluate prevention efforts, too, you can't just look at the peak. What is really working, since it always peaks, the real question is how fast does it come down?

So notice that Kenya comes down, but also Uganda comes down. But some of these other hyper-epidemic countries - notably here is Botswana, Lesotho, and South Africa, which is sort of a later one, these sort of had a peak, but they never came down. They're still like - here is Botswana. Maybe the modeling is off. But it's got incidence of something like four percent of the adult population per year. That's horrendous. So what's happening in HIV/AIDS is that some countries are getting a lot better, especially in East Africa. Some countries never really took off in West Africa. And the real

epicenter is in southern Africa, most notably, South Africa.

So the question is, why is HIV so high in southern and eastern Africa, but especially now southern Africa, and why were there these peaks in incidence?

So part of the explanation, and this relates a little bit to what Mark was saying, is that there's come a realization that concurrent - this is a belief; this is - it's justified by the modeling and a lot of data; I would say it's still something of a theory in a certain way, but it explains a heck of a lot, which is the concurrent partnerships. And Mark was absolutely right. The knowledge about concentrated epidemics and intervening with sex workers and so forth which was absolutely and still is pivotal to a lot of prevention efforts, notably in India, as well as Cambodia and Thailand and so forth, that model is not what was really going on in southern Africa. It's more an issue of concurrent partnerships and the relationship with poverty is sort of interesting.

And one of the things that in all likelihood that feeds that is the fact that when people are newly infected, they are much much more infectious than at other times.

So this is only part of the explanation, and I don't pretend to understand all the modeling. But the part of the problem with concurrent partnerships is that when people are newly infective, and if they have regular partnerships, then you can basically have new infections spawning new infection over and over again, and causing much higher rates.

And just to give you a feel for that, there may be also an issue at the tail end when viral load goes up again.

Now this is from Malawi, and it's only illustrative, and if I don't purport to make it say that it's totally representative of Africa at all, but this is just to give you a sense. These are actual data. This is a sexual network in Malawi, a study, a published study of seven villages in Malawi. It's actually rural Malawi, and this is actually the two-thirds of the population in these seven villages

are actually linked together in kind of one big ball of yarn of concurrent partnerships.

Now, I don't want to exaggerate this. It's not as if you just sort of light a match and all of a sudden the whole thing takes off. It doesn't work like that at all.

But it really is the risk of concurrent partnerships that I believe is sort of one of the major factors in southern Africa.

So what you have in effect is something of a perfect storm in southern Africa of factors, first of all lack of circumcision, which is very common in West Africa, sort of intermediate to some extent in eastern Africa, not that common anymore in southern Africa, networks of multiple concurrent partnerships of men and women.

Let me just go back to that one. This is men and women. It's not as though one person has 20 partners, or something like that. It's more like many people have two, three partners, that sort of thing. It's not a youth thing. It's not all that the youth are hypersexual or something like that.

It's a societal thing, or phenomenon.

And it plays out in different ways.

In addition to those two factors I've already mentioned it's possible that the presence of other STIs and also potentially a different clade, for example, the C clade is I guess thought to be more infectious in southern Africa. I don't happen to think that that is probably all that important.

So what is the reason for those peaks in incidence that I pointed out? Well, the most important one is probably simply the epidemic natural history, which is that at some point the people that are most susceptible get infected, and they are no longer able to get infected. And it's compounded in my view by this role of acute infection. Because once acute infection sort of passes, for most people, no longer can acutely infected people infect other people.

So the main thing is simply the epidemic natural history.

The second most likely thing in my opinion is really just self adopted behavior change,

which is essentially fear based. And I know Ted has made the case for fear-based behavior change, and I think he's right. I don't think it has to be all fear based, but I do think fear plays an important role, and we've kind of done a misservice by the sort of dogma in public health school 101 you don't do fear-based behavior change. Well in fact that's wrong, and that's not what the evidence shows. I think you can overdo it, but I think basically what's motivated this behavior change is, people think that they could die if they don't change their behavior.

Then I do think, then there is a small effect of programmatic effects. And I don't think we've been nearly as focused as we could have been. I think we've kind of been sort of not being as knowledgeable or as focused or as action-oriented as we could have been or as precise in this.

But I think there have been some program effects.

So as I was saying incidence will always peak. The effectiveness of prevention is actually reflected more in the rate and the decline, the depth

of decline. So again my thinking of this has evolved. At one time we were trying to explain what happened in Uganda. So the big question was, well, why was there this peak around 1998, 1999. And I now think well it's not really so much about the peak in `98 or `99, but rather the decline that occurred thereafter and continued on.

I still think part of the reduction was the main thing that contributed to that, but it is a slight change in thinking.

Okay, now I'm going to shift a little bit to the numbers, because that's actually what Joe wanted me to talk about. And if you are following along in you8r books, this will sort of spoil the suspense. But these are all estimates for the year 2003, it just happens that actually about every six months, UN AIDS, WHO, puts out their estimates, and they have estimates for various years.

In 2000 year itself the estimate of new infections was 5 million. The following year, again talking about 2003, they downshifted to 4.8 million. And then in 2005 downshifted again to 4.6 million,

and then into 2006 report 3.9 million.

So that's all for the same unit. That's quite a downshift for the same year. So something is definitely going on here in terms of global estimates.

Let me also point out that parenthetically the 2005 estimate and the 2006 report was 4.1 million. So if you compare that to the 2.9 million that they were saying for 2003, what happens every year is that you still see this rising curve. It just sort of gets ratcheted down.

So every year the headline is, HIV is increasing, even though the headline in a way could also be, HIV is decreasing. Depends on how you look at it.

So to understand how you get to this, it is important to understand the way that these data are collected. And there are really three different ways. I'm going to talk about two ways. There's antenatal care, antenatal settings; there is population based. And then there's also testing among folks at highest risk, which we're not going to

talk about.

But the two main ways, traditionally the main way was antenatal sites to estimate prevalence, and I think over time the methodology has gotten a lot better with that.

It's not easy trying to do these estimates. My hat is off to these people trying to do them. It's difficult to sort of look at the data and try to come up with good numbers.

More recently in the last five years or so, we've been using more population based, representative surveys, especially the demographic and health surveys, which have a long history in my own field, family planning, going back well over 20 years. And we basically have added child survivor and now HIV/AIDS in the last five years.

Notice that - I guess I'll go ahead and bring out the antenatal care. The advantage of antenatal care is you can do it more often. That's the major advantage. And there are not many refusals.

But you have a very select population.

You have women, not men. You have pregnant women. You have pregnant women who happened to go to antenatal care sites.

So there is a lot of bias if you will about who goes for antenatal care and where the sites are.

And it turns out that even, sort of getting to this previous discussion abo8ut poverty, and I very much agree with the point, I actually published on this about a year ago, that actually wealth is more of a risk factor than poverty per se, but there is a very important economic/financial/poverty dynamic that I'm convinced still induces HIV infection. But the fact is that sites that are more urban, and where antenatal sites are, they tend to be district hospitals, so they tend to be places where there are more people. There are more people that are commercially and socially interactive and so forth, and potentially of higher socioeconomic status.

The main thing, though, is gender, sex. It turns out that many of these places, the sort of

conversion factors if you will that people use to extrapolate from women to the general population had to be readjusted in a major way.

The classic example is Kenya which in 2003, and when the DHS survey came out in 2003 for Kenya, the estimate for HIV prevalence dropped from 13 to 7, and a lot of that was just because men in Kenya have one-half the HIV prevalence as women.

So a lot of what's been happening in these changing numbers is simply that the methodology is getting better, the methodology of the population based surveys is a lot better, and causes a ratcheting down of the estimates. Now that's not the only explanation, but that's a lot of it.

So I've already talked about this with the - you have this problem that the antenatal care sites are more urban, they're around areas of social - of higher social interaction and so forth.

I also think that there has been a tendency, and I've done it myself, there's been a tendency to look at prevalence, and not look at incidence. And that's partly because incidence data

hasn't been available.

But if you are kind of worried about HIV, and you see that the rates have been going up, and now it looks like they might be turning down, and you've got a methodology with antenatal test sites that are - is a bit iffy anyway, you are not going to want to say right away or that quickly, it looks like things are getting better. And to some extent rightly so. I mean I do think you don't want to send the message that everything is a lot better all of a sudden.

Another sort of similar thing is that I think there's been actually a major misconception that HIV was going to sort of take off in India and China and other parts of the world in the way it did in Africa. And I think that's just really not the case. And the evidence, I'll show you a little bit of the evidence. But also, they're different sexual patterns, especially for women the number of partners.

Then I think - this is kind of a euphemism in a way - I think there is still

processing going on in the minds of people that do these numbers. One of them is that for example China which I'll talk about briefly I guess in 2003 they had an estimate from the government that it was about 800,000 total cases, and they didn't have a lot of basis for that. So they sent in a special team in 2005, this is UN AIDS, you know, very painstaking hard work, and they decided 650,000 was a better estimate, just based upon - I don't actually know what methodology they did, but I respect their methodology. So when that happens, again, people are afraid, I don't want to give the message that HIV is going down. Because I don't know that that's true.

But I also think, I have a little bit of evidence I'll show you, I think we haven't quite caught up yet in terms of the estimates. And I'll show you a little bit on that.

So in response to the Washington Post article, this was a statement that they put out, and you'll notice that all the data that I show that came from UN AIDS and from the Bureau of the Census really showed, if you believe the modeling, that incidence

did peak around 2004 or a little bit before in southern Africa. So in fact they're agreeing with that. They're saying that incidence in southern Africa peaked - I went to the website; I couldn't find this document, but I saved it, so if anybody wants it I can share it with you.

But then notice it says for the last three years there have been 1.1 million new infections per year. So I don't - I think there's probably been some decline in the last year. Now granted there's another subtlety in a way. Numbers of new infections is not quite the same as incidence, because incidence has population as the denominator, and population is growing a little bit. But that is kind of a refinement.

But remember I said that their estimate for 2005 was an increase in global new cases by about 200,000 I guess. I don't know how you get to that. If HIV new cases is stable in southern Africa, and I think it's at least stable in India; there are estimates in India that - sub-Saharan Africa is five-eighths of the number of HIV infected; India is

another eighth; that's three-quarters of the world. Their estimates for new cases in India did not go up, and we'll talk about China. I don't know actually know how they're getting to those higher numbers, and they don't give you the breakdown by country systematically.

Okay now, this is - I was talking to Bob before the meeting about this. This was published in Lancet I guess in early April online, and this is antenatal care data from India. And Bob's concern that there may be a dilution by this here, in that - that's my term - that as you add more antenatal test sites, and they are in lower prevalence areas, you may actually kind of dilute your numbers down.

Notice also that these numbers are really - this is 1.1 percent, and for northern India it's point three percent; that's three per thousand. Think about the precision of that estimate. It's not real good, if you are testing 1,000 women in order to find three cases. It's obviously susceptible to a lot of small numbers.

Nonetheless, at face value, if you look

at - these are infections in younger women. In southern India, which is four states in southern India, including a couple where we have pretty active programs, in Tamil Nadu for example, HIV prevalence among younger people which is taken as an indicator of incidence is actually falling fairly substantially.

And don't forget that the way the sort of epidemic evolves, even if it's stable, if it reached a point of stability, you'd probably come to a point of declining incidence already.

So I don't think we really know entirely what's going on in India, and I still worry about it, but to me it's much more of a concentrated epidemic phenomenon.

And China the estimate as I was saying is 650,000 HIV positive, and 70,000 new infections. So if you just sort of divide 70,000 into 650- you get something like nine. That ought to tell you that this is a relatively stable, based on the numbers, a relatively stable epidemic, and it's primarily intravenous drug users.

So my view is, incidence has peaked, although it's not this sharp of a peak.

Okay, now I'm going to shift a little bit to the programmatic, if you'll bear with me. I heard ABC mentioned a bunch of times in this meeting. I will probably not use it too much, and I'll tell you why.

The reason is from where I see, mostly what I see is kind of a battle between the forces of A and the forces of C. And it's unfortunate, and it's - the problem is with that is, first of all it's a lot of wasted energy, but secondly, with some merit, actually, it's always good to have some diversity of views, the real tragedy to me is that actually what is the most important component, which is the B, the partner reduction, which is far and away the most important part of this, has actually been neglected quite a bit, both in terms of the sort of global discourse, but also programmatically.

And one of the reasons why I worry about saying ABC, ABC, is because I think people hear A. They hear the A, they don't hear the rest of it.

That's been my observation.

And then I don't know how many op-ed pieces I've read where people talk about ABC and then they say abstinence, and they sort of make that jump, which is unfortunate, which is not to say that A and C don't have important roles; they do. I think they have extremely important roles. I just think they are more like supportive roles.

And again as Mark was saying, I don't know if any of you got a copy of it. I've got a little piece called "Confessions of a Condom Lover." I have spent almost 30 years promoting condoms, and I feel like I have good condom credentials.

And I feel like condom promotion in sex workers has maybe been the most important intervention in the entire global pandemic. I mean it has helped containing what could have been very, very bad epidemics primarily in southeast Asia but also India and other places.

However, I don't think that translates necessarily to the epicenter of the epidemic, and I'm going to talk about South Africa a little more. Here

is a place that is literally flooded with condoms. And believe me, I spend a good deal of my life trying to help flood these places with condoms, and I think it's actually been a useful thing.

But here, with a population of 48 million, 346 million condoms provided by the public sector alone - now this is from the national survey. And in the survey, also, among single youth aged 15 to 24, 69 percent said that they used condoms in their last sex act. But still the epidemic is raging on, notwithstanding.

So here are some of the limitations of condoms. They are 90 percent effective, but they have to be used correctly and consistently - I'm probably telling you stuff you know. And this is a virus that is not all that infectious to begin with. So in the right situation that can do a lot of good.

But they are often not used consistently. More often they are not used consistently, or correctly. There is some data to support that.

Also quite importantly, they tend not to be used in these longer term relationships, so that

if you believe the concurrent partnership model for southern Africa, if people are not using these in their established multiple relationships but only in sort of sporadic ones, then you are not getting a lot of benefit.

And then the last kicker is that I truly believe that as with basically any other prevention modality, they are subject to risk compensation, to disinhibition, such that people will use condoms, and there again there is enough evidence for this that's in this little essay, that rather than limiting partners, people will use condoms. And then it becomes kind of a tradeoff to some extent.

Now, lest I spare abstinence either, the problems I see with abstinence are, of course we already talked about young women. Women may be subject to coercion. My main issue with primary abstinence is it's actually a very narrow effect that you can have on the epidemic directly. Because the average time period between sort of setting aside whether or not you can change that behavior, which I think you can to some extent, the actual time between

the initiation of sex and marriage for example is actually a fairly narrow range, specifically for women. In some other countries, it's a bit broader than that.

But also, people have the belief that adolescents are sort of the engine of these epidemics. Somehow I think people generally - well, it's an STI, and it must be young people having a lot of partners or something like that.

And indeed that is quite important. But in fact these are generalized epidemics, and it's a sexual behavior not just of youth but of basically a lot of people that are at issue.

So just to show you now a little bit of data, this is condom use. Now for Kenya. So we now have - I should have said this - in addition to Uganda, we now have two major successes in sub-Saharan Africa: Zimbabwe, which is not as clear as Kenya; and Kenya.

And it turns out though that for Kenya, that serendipitously, or maybe not that serendipitously, but for `93, `98 and 2003, there are

these DHS surveys which are right smack in the middle of this decline in HIV incidence, and are somewhat instructive.

This is sort of evidence based judgment we're talking about here; still a judgmental thing. One problem is the methodology change, but you can see that between `93 and `98 actually there probably was a fairly substantial increase in condoms. So you can give condoms some at least in terms of correlation some credit for the effect.

Between `98 and 2003 however there really isn't much increase in condom use among men - as reported by men, I should say. Again the denominator changes slightly. If you were to adjust for that, it would actually increase that second bar probably a little bit, because what's missing is the cohabiting nonspouse who tend to have lower condom use. So there is not really much difference.

My judgment of this is this sort of correlates with some benefit, but is probably not enough in and of itself to have that much impact.

Now here's primary abstinence. And I

actually did this two ways. It turns out primary abstinence is kind of tricky to measure, because it's a cohort phenomenon, and if you want to sort of measure it over time, sort of what time does the initiation start. So it's kind of - and you can't look back at people when they're age 40, and sort of look back and see - you can to some extent, but it becomes difficult.

There's not a - I won't spend that much more time - there's not that much change in primary abstinence during this time period, either if you look at it sort of survey by survey, or actually if you look back sort of in time, by people older cohorts if you will.

Now in contradistinction to that, this is maybe one of the most important sites I have to show, this is in those three surveys, changes in the number of people, men, reporting multiple partners. And if you remember that sort of slide of all the different partnerships, basically of all age groups, the number of partners that men say they're having - in the first instance, it's the first six months; and then

it's the next 12 months - these are really quite profound changes in my opinion. It's judgment. You can form your own judgment if you like. But to me this is fairly profound. It's actually the number of partners that has a major impact on the epidemic.

And of course the example of Uganda was much, much cleaner, because there really wasn't that much condom use or change in abstinence.

Now in contradistinction, and these are not DHS surveys, this is actually South Africa, and there is a different research group that does these surveys, and I have a little trouble making the numbers add up, but at face value, these are between 2002 and 2005, these are from these two surveys, what percent of men and women having more than one partner. You can see there is a little bit of a decline in women, but if anything there is an increase in men.

So you are free to draw your own conclusion. My conclusion is that South Africa has had sort of a situation within inundation by condoms, and not much partner reduction. And the reasons why

that might be. And that hasn't been enough to turn the epidemic around.

Whereas I think if you have a platform of partner reduction, and you add condoms, and you add abstinence, and you add a lot of counseling and testing, and you can - and I'll have a slide on that - you can have a major impact. That's the ideal way we should be doing these epidemics.

So that's what I'm calling the overall B strategy. And the question is, how do you get to that? How do you support the behavior that people are largely in my opinion doing on their own?

I'll skip down here. I think we ought to be using behavior change best practices to reinforce that behavior, and by and large we're not doing that. By and large our prevention efforts are not really focused on job A, if you will, job one. I don't see that happening in the field nearly as much as I would like to see that happen, and to me this was the most important thing we could be doing for HIV globally that could have an impact on the pandemic is trying to reinforce partner reduction and other supportive

kinds of activities, and it's beginning to happen a little bit, and some of it is happening on its own, but we're not doing nearly as much as we should.

Part of the reason for that is, I think, many people that are working at HIV, if you say, well, we want to change the general social norm to reduce partners, don't really have a programmatic sense about how you go about doing that. You know a lot of people have medical training and they know you have some feel for counseling, so how do you change a societal norm?

Now there's a way to do that. There's actually a fairly straightforward way to do that, the behavior science people can tell you. It begins with an open environment by the government about HIV; that people are dying of HIV. And it's clear messages about concurrent partners and numbers of partners and condom use and abstinence, and so forth.

But we really ought to be doing it, and I think we're starting to get there.

Let me just digress a second, because I think there are sort of three main strategic thrusts

about trying to affect these epidemics. One is the one you've already heard about, which is, if you reduce poverty, you'll take care of it. And I think we know that will probably not really solve the problem.

The second is that if we only test everyone - and I'm exaggerating this a little bit - if we just do voluntary counseling and testing, then everybody - there was an article in Science this past week for China, sort of just talking about testing. I think testing is very important, but I think unfortunately the way it's carried out, we don't get the counseling we need to get the behavior change that we really need.

And part of the problem, I mean these research studies show you can do it, but in real life it mostly doesn't happen that much. So it's not just enough to do the testing.

But the third major thrust is changing the overall behavior, which is daunting to many people. But part of the solution is that you do mass media, but you also use every fiber of social

capital, which means the faith based groups, the schools, the military, I've listed some of these people, and try to get that consistent message of reducing partners, which is to some extent what happened in Uganda.

So I think we ought to be leading with B, and I do think that - the idea is that condoms then have this residual high risk sort of role. And even though I've talked a lot about concurrent partners and so forth and the evolution of these epidemics, it's important to not fight the last battle, because to some extent that's - even though it's still happening - a lot has happened, and we're going to see more mature epidemics where there'll be less in my opinion new transmission, and more people that are HIV infected either with treatment and so forth.

So this point about discordant couples ends up being quite an important point. And part of the testimony to the fact that it's not as infectious as we think, this virus, is there are a lot of discordant couples that are having a lot of sex, and they're still discordant.

Okay, so an abstinence programming helps set the stage, forced in and of itself, for responsible initiation of sexual debut. Secondary abstinence, which I should have mentioned, actually is on the increase in a lot of places in Africa, but also sets the general social norm of sort of responsible sexual behavior, and when you do start having sex, have one partner.

I'm getting a lot of head nods from Ted over here.

And then counseling and testing has got to support the message, and then - oops - sorry. Male circumcision which is right around the corner, it's got to have a strong B component. If the men who get circumcised are then subject to risk compensation such that they then start having more partners or not using condoms or something like that, you've got to have that platform.

I happen to think male circumcision, regret that we are not doing a lot more than we are already, because I'm convinced it's quite effective. But vaccines, same point. It's not going to be 100

percent effect. Microbicides, same point. You've got to have that sort of prudent partner platform if you will.

So where does the global epidemic stand? Mature generalized epidemics in eastern and southern Africa. Actually a fair number of bright spots. In addition to Zimbabwe and Kenya, and Rwanda, Haiti and probably in Ethiopia there have been some significant declines as well.

But it's still raging on in the southern African countries. West Africa is stable. In the Muslim world, I think because circumcision is so prevalent, I find it hard to believe that there will be a whole lot of HIV in really any Muslim country, and that also includes other countries like Madagascar and Philippines where circumcision is close to universal.

But in the rest of the world I think what we're facing, and this is a pretty key point, is a lot of pernicious intransigent low level sort of concentrated type of epidemics, that are not going to go away, and we ought to sort of get away from this

idea that AIDS is going to explode or the former Soviet Union is going to explode a la Africa, but rather we're going to have this burrowing difficult kind of epidemic to kind of deal with.

And my last message is just simply to lead with the B.

(Laughter)

DR. REDFIELD: Thank you, James.

(Applause)

Okay, Dr. Green.

DR. GREEN: Yes, I was nodding a lot. Fantastic presentation, Jim. After hearing you and Mark Dybul, one after the other, I feel like I can retire.

And I agree with everything you've said. I think it's supported by the evidence, except there is only one comment that I would maybe raise a question about, and I'm sure you know which one it is, and that is that in your estimation the single most important intervention so far, and keep that slide, because it will keep the minds open that need to hear what you're saying.

But just for the record, and I'm sure we're thinking of countries like Thailand and Cambodia, from what you yourself said about the nature of the epidemic in Asia, women tend not to have multiple concurrent partners, I think that the reproductive number is always going to be less than one. Yes, sometimes a man will infect his wife from going to a sex worker, but she is not going to infect someone else. So I think the prevalence would have fallen because of the natural dynamics in Thailand and Cambodia.

DR. SHELTON: You could well be right.

DR. GREEN: Also in both countries at the same time we had very high condom use in commercial sex, we had a significant decline in the proportion of men reporting going to sex workers, and even reporting casual sex. So we don't know how much of that decline was due to high levels of condom use, and how much to other more fundamental types of behavior change.

DR. SHELTON: No, I've made that latter point myself, and it's in the little essay, that in

fact what we've got - and this testifies to the ability to influence behavior - people were promoting condoms and yet we also saw - with sex workers - but we also got a behavior change where men went less to sex - even though there wasn't - there was a little bit of promotion of that, but not a lot.

So there's a lot of quote unquote agency. There's a lot of ability to influence this kind of behavior. My own view is that people actually get it. Even if there is all this vague stuff out there about protect yourself, which really doesn't tell you anything or what have you, to some extent people get that this is sexually transmitted. And I better be a bit careful.

I just wish we were reinforcing that message, and telling people specifically this issue of concurrent partners in sub-Saharan Africa. Because I don't think people know that at all.

DR. GREEN: I totally agree. I hope these slides will be made available? Can we get them in electronic form?

DR. SHELTON: Sure, or I can send them to

you, Ted. I've got your email address.

DR. REDFIELD: Dr. Sullivan?

DR. SULLIVAN: Thank you very much for a very informative presentation.

You went by rather rapidly the comment that you don't expect the epidemic or the pattern of the spread in India or China to be like Africa. So I wonder if you would comment a little bit more, because I would have to plead guilty to being one of those individuals whose been saying, if we don't do things we're going to see that. And so it'd be very helpful to understand that.

DR. SHELTON: I think the heterosexual - as Ted was just saying - the heterosexual patterns are not like this. My counter to Ted's point was, I think there was sort of a culture in Thailand and Cambodia where men went a lot to sex workers, and I think you can get a fairly high level I think just by that.

But the extreme example was China. I mean those women, to some extent they are kind of - here's a situation where social isolation protects

you. That women just do not have that many partners. Not that many women have more partners in China; it just doesn't happen. I mean that's what I'm told.

So to get this kind of explosion it might only take five or 10 percent or women or something that are having multiple partners. But if you're down in the half or one percent of women, it's a heterosexual epidemic; you've got to have men-women, men-women. And you know men may be the same everywhere, but if women are different or made to be different - sorry, I'm on thin ice here - if they are made to be different by the social situation, then it's not - you have men having sex with men, and you have all these other things. But you are not going to get to a heterosexual epidemic at this level.

DR. REDFIELD: David.

DR. REZNIK: Just a follow up. I understand the concepts that you're saying about China. And although I've never been to India like my colleague, Dr. Bollinger has, from what I've read there has been a pretty substantial increase in an epidemic that started in the IDU population and it's

now moved to heterosexual means as its number one way of passing. And although it's 5.7 million cases out of 1.1 billion people, that's a lot of cases. And I think that epidemic to me is somewhat worrisome.

DR. SHELTON: Oh, I'm worried about it. I think my very last slide said I'm still worried about India, by the way; or the one before that. But to me it's not a generalized heterosexual epidemic. You don't see that level; that's why the antenatal care levels are still so low. You'll see it spike up in IVUs and then having sex with men and so forth.

It takes more to have it spill over, not to mention all the Muslims, which is something like a fifth of India or something like that, they are all circumcised, so that's going to help keep it down.

DR. REDFIELD: Joe and then Robert.

DR. McILHANEY: Jim, great presentation, thank you.

What's your reflection on the U.S. epidemic and why - of what you've said?

DR. SHELTON: No, I'm sorry, no. Well, it never went generalized. It's interesting. Fifteen

years ago you heard the same, it's increasing in women. And it does. But it starts from such a small base that it - and circumcision is about 50 percent in the U.S. or so. We're just really lucky it's not that transmissible I guess, and it hasn't evolved to be more transmissible.

Yes.

DR. BOLLINGER: Just a comment about India, where I've been working since 1992. Like Dr. Sullivan, when I started there, the first case of AIDS was reported in `86, `87, and in the early `90s we saw just tremendous increases in prevalence rates among sentinel high risk groups of sex workers, STD patients. And I was one of the people expecting to see a similar pattern to what was seen and beginning to be seen in southern Africa at the time.

But I was finally convinced a couple of years ago to actually write an editorial in Lancet questioning my own presumptions from that time. And I think it's exactly for the reasons that we've just heard.

You look at large behavior studies, I

mean again, it's not a major problem. They're number one and number two in the world as far as their burden of infection, but the epidemic is very different, because there is not the bridging group of heterosexual women other than sex workers.

You look at large behavioral studies in India that were done a few years ago and they're now being repeated, about 11 percent of men, or married men, in India report extramarital sex, and less than two percent of women. Now compare that to the United States or some other populations, and I think you'll see that particularly for the women they're not a bridging population. Their only risk factors if they're married is their husbands.

And that's one of the reasons why you're seeing for instance the antenatal clinic preference in Bombay and Mumbai in 1992, when we started, was the same as Durbin, South Africa; it was one percent. It's not 1 or 2 percent in Mumbai in most places. So it's been a flat prevalence in antenatal clinics.

Obviously Durbin has gone straight up. So it's a very different dynamic. It's not that it's

not an important public health priority. It should continue to be a public priority. But it's a very different epidemic.

DR. SHELTON: When you have serial monogamy, in other words you have multiple partners, but they are spaced if you will, then presumably there's considerably less risk from that.

DR. McILHANEY: Could I just throw a word in right here? Actually the best studies we've seen about sex outside of marriage in this country show that it's really rare for people in this country when the marriage is intact to have sex with anybody except their marital partner. So that could be one of the factors in this country that has kept it from becoming such a problem.

DR. SHELTON: But our lifetime number of sex partners actually is pretty similar to some of these countries as it turns out, because people have serial monogamy.

DR. REDFIELD: Monica.

DR. SWEENEY: I was very interested in your statistic about the prevalence of HIV in women

being double that in men, and I don't remember where you used -

DR. SHELTON: This was Kenya.

DR. SWEENEY: Kenya. And then you talked about changing social norms to change behavior. Were you also talking about Kenya or Uganda or both.

DR. SHELTON: Both.

DR. SWEENEY: In this country we have used changing societal norms to change the way we think about and accept smoking.

DR. SHELTON: It's a good example.

DR. SWEENEY: Do you think we could ever do that with HIV and still not be accused - in smoking no one accused you of being homophobic or whatever the other negative terms they say when you're trying to talk about changing behaviors both in heterosexuals who have multiple partners and men who have sex with men.

Can you see any relationship of how we could maybe change societal norms using the smoking model here to try and impact HIV?

DR. SHELTON: I think there is a similar

phenomenon such that if it becomes socially declasse to indulge in risky sex or - I can see where there can be a social norm where - I don't want to exaggerate it, but in certain contexts it's not done, it's not socially done. It's not cool. It's just no one would think about doing that.

And obviously it's sort of a continuum of behavior, but in fact when people talk about social norm, they're not just talking about all the individuals and their behavior. To some extent they're talking about how the group kind of looks on that behavior, and thereby influence the behavior.

So yeah, that's part of the objective, and if you push all the buttons, I believe, if you - I really think you can do that.

But it's - you got it.

DR. REDFIELD: Frank.

DR. JUDSON: We previously I think discussed the parallels between tobacco prevention and HIV prevention, and there are really many from the biochemical addictive nature of sex, and nicotine, both play out in dopamine reward pleasure

pathways to some extent, so they are hard to give up. They are pleasurable; they're addictive.

For tobacco, I think what we have learned over the years is that there have only been two major factors in a developed country that have really caused us to have the success that we have had. One is the cost of tobacco which has been taken care of somewhat by taxes, somewhat by litigation, which is sort of an indirect tax.

The other has been the nonsmoker's rights and laws to back environmental tobacco smoke and indirect tobacco smoke regulations, which really have turned this thing around from smoking was normal, desirable, supportable, to the point where smoking is viewed as socially undesirable and unacceptable; there aren't many places you can do it; your peers don't think it's cool any more.

And that same thing hopefully could apply in Africa. When you look at the motivators for people changing sexual behavior, one of them is, far and away the biggest one is understanding AIDS and being afraid of getting it yourself, and believing

that you can change behavior to reduce your risk.

Another part, though, would be from just as your looked on poorly if you light up and expose somebody to tobacco smoke, the same thing can be turned around where somebody who is exposing someone to HIV against their behavior, or claiming large numbers of partners, unprotected, that becomes just really a source fo stigma, of positive stigma; you're an outcast if you are out there spreading HIV or getting HIV. And I think we've moved closer to that.

DR. SHELTON: And I can see it for example in the behavior of younger women and older men. This is a reciprocal exploitation going on. It's very complicated. But to some extent, young people have strong social group norms, and if the group norm is that that's dumb, or what have you, then I think that that is possible to happen.

The nice thing about this is, you know, nobody is saying you can't have sex. People are saying you just need to have one partner, or one - you know one - that's what most of us I think do most of our lives. I don't think it's totally that

unreasonable to try to promote that as a social norm.

DR. REDFIELD: Ram, and then I think this will be the last question.

DR. YOGEV: Very quick, would you kind of speculate on the economic boom which now is going in China, some places in India. This is a B but in the wrong direction.

DR. SHELTON: Yes, I think that would be expected to increase risk for STIs. I mean it's already known for I think for STIs.

DR. YOGEV: But just one question, in Shanghai for example there is an increase, and I just wonder how that works against the norm that you traced.

DR. SHELTON: I do think in concentrated epidemics you still try to promote this norm. And it relates to sex workers, it relates to condom use and so forth, but yes. In China, even though that is happening, the vast majority of people are still rural. The vast majority of women are still sort of in this sort of situation. I don't think it's going to -

MR. HOLMER: Not so much a question I guess but a follow up to Monica and the discussion we had earlier.

This is an international discussion because it relates to the United States, and your emphasis on being faithful and engaging in responsible sexual activity and the group norm.

Some of us are old enough to remember when the group norm was engaging in promiscuous sex with multiple partners was something very much to be frowned on. And sadly, that's not as much the case today as it was 30 or 40 years ago.

But those norms could change again.

DR. SHELTON: I would argue that the norm in the `60s was much more permissive than it is now. So that pendulum has swung back to some extent. And it's a social norm to some extent. I mean I think we've seen it to some extent in this country, to some extent.

DR. JUDSON: In Sex in America -

DR. SHELTON: Yeah, I read that. I did read that book.

DR. JUDSON: The most recent edition their survey had, and this has been surprising to most people to see America is a totally permissive, maybe promiscuous place: 95 percent of adult men and women in the United States have one or zero partners a year. That is an enormous barrier to the spread of this infection to general population spread.

Same thing I think is from living in India for a period of time. When I thought back to what I learned about the culture of India, it is fairly conservative at a family level.

The same thing in China, despite communism, it's actually maybe more puritanical than we are.

So I think there is an enormous barrier for heterosexual spread I would guess in most of Indian society, Chinese society, U.S. society. We shun that.

DR. REDFIELD: Well, Jim, I want to thank you for your time and your comments. Thank you very much.

(Applause)

DR. REDFIELD: I think since we had a break between we're going to go through, right?

So I'd like to ask John Martin, who is the CEO for Gilead Sciences, to come up. I think people know I've expressed my own point of view that as a practicing physician the early patients I took care with AIDS in 1981, `82, `83 had about a 10-month survival. Now many patients can live in that for a lifetime.

Largely that is because of the pharmaceutical industry. And I think John Martin and his company has been a very important part of it.

When we asked Mark Dybul about the issue of sustainability, I've also expressed to a number of people on this committee, one of my concerns is, the long term sustainability of keeping the pharmaceutical industry engaged in the effort, as it becomes more and more an epidemic in resource limited areas.

And the challenge is to keep that pharmaceutical industry fully engaged so that the best weapons for HIV therapeutics are available to

our government's programs I think are fundamental, and I think the opportunity to have a dialogue with the pharmaceutical industry to see how to keep them engaged, the same way we do the defense industry, and our defense technology, I think is fundamental.

So John, I want to welcome you.

MR. MARTIN: Okay, thanks, Bob. Am I ready to begin?

So thanks for inviting me today. I don't know, maybe I shouldn't use the mike?

(Audio difficulty)

So I am pleased to have the opportunity to be here today. Thanks for inviting me.

I was assigned the topic, the future of HIV treatment. But of course I'm presenting to the group that has come up with these recommendations, and I congratulate you on these. I think they are very good, and in some cases somewhat controversial, that you are making points that will work in fact toward achieving an AIDS-free generation.

My title, I believe, refers more to the fact that at Gilead we're working with Bristol-Myers

and Merck to come out with a pill that'll be all three drugs taken once a day in a single regimen that will be available probably well before the end of this year.

So to begin with, I think a lot of stuff I'll review in the context of this talk are things that have been discussed by others here, and I even heard them today.

We have a number of challenges. New therapies are necessary to simplify treatment, decrease long-term toxicities and resistance, and increase tolerability.

And that's what we've been working toward at our company. There's also an awareness now that late diagnosis and lack of awareness increases transmission rates and/or mortality and morbidity. New infections are more prevalent among low income populations.

And then some of the challenge we face in emerging work means that there are additional challenges there.

So the single tablet regimen is our two

drugs, tenofovir and Entriva, combined with efavirenz, which is provided around the world by Bristol Myers and Merck.

And the story begins of the development of this regimen begins at the time we filed for Truvada in the United States and Europe in March of 2004, so just over two years ago.

Truvada, I believe most of you know, is a combination of tenofovir and Entriva, both once daily medications that have long duration of action, so they combine very nicely together.

The filing and approval of Truvada has led to a very successful product. Tenofovir in its forms, in Truvada and Viread, is now the number one molecule in the United States. Last month in May it surpassed lamivudine in sales. So that's lamivudine as lamivudine, Combivir, Epzicom and Trizivir.

So this regimen of having a combination product with very well tolerated drugs is in fact been well adopted by practitioners in the U.S.

At the time we filed on Truvada we were already talking with Bristol Myers and Merck about

putting together a combination product that would be the first single triple given once a day. And what we realized, it would take some time to negotiate the agreement, because of all the commercial and regulatory complexities.

So Gilead we requested from Bristol Myers and got a very substantial supply of efavirenz, and started that spring working on that triple combination product, because we wanted to stay on the critical path of getting this product approved.

Also at this time, Truvada by FDA regulations was under a 10-month standard PDUFA review.

The two individual products already being on the market meant by regulation there wasn't an unmet medical need for a combination product. And of course everyone recognizes, including government scientists, that this combination product would make a real difference to patients, to improve adherence and make sure that we minimize development of resistance.

So the FDA hosted a meeting with us, and

Bristol Myers, and Merck, to talk about ways to expedite the review of combination products. And in fact DHHS announced guidelines for that expedited review in May, and at the same time we with Merck and BMS announced our plans to develop the triple combination product.

Subsequent to that, Truvada was approved after only a 4-1/2 month review, so that really was a very impressive effort by DHHS to change the regulations and to work with the FDA, and the FDA to expedite a review, where the product was approved very quickly and on less stability data than would normally be required, but you extrapolate it - accelerate stability to estimate what the shelf life would be.

I said working on an agreement was tough. We actually didn't finalize our joint venture for the U.S. until December of 2004, but we did not lose any time in the work of the product, but it did take awhile to establish bioequivalence. That was done in January of 2006, and I think maybe many of you know the story of how this bioequivalence turned out to be

very difficult.

Most people think that making a bioequivalent combination, or making a combination product, you just mix them together and press a tablet and ship it off somewhere, and that is certainly not the case. It took us five tries to come up with a pill that was bioequivalent to the individual components. And FDA has a very strict definition that bioequivalence has to be in a narrow range.

And that's really important when you think about it, because if you have suboptimal ability, a broader range of exposure, that's what's going to give rise to resistance.

So the FDA is right to have a very high standard of bioequivalence so when you're given a combination product, you know you're getting the same amount of drug as if you're taking the individual ones.

It turns out efavirenz, the third drug in the regimen, is quite insoluble, and it needs to be specially formulated with excipients. And what we

tried to do was use tenofovir and Entriva excipients to minimize the size of the pill, and that simply didn't work at all. The bioavailability is very low.

So what we went to for the final three tries was to have a bilayer tablet with efavirenz on one side; our two drugs, Truvada, were on the other side.

The third pill we did was actually pretty close but it was a little bit low, just out of the range of what the FDA would approve.

The fourth pill was off, and the fifth pill actually was very good within the range, and that's what we filed for approval in April when we garnered sufficient stability studies for the FDA to be able to review.

And now discussions with for the ex-U.S. markets are still ongoing with Bristol Myers and Merck.

I would like to say there is another aspect of this that the FDA was very creative on. Earlier, with Viread, to make Viread or Tenofovir, the brand name is Viread, to make it available in

Africa for instance in PEPFAR countries.

We were concerned about importation back into our major markets. Viread is a blue pill. The FDA approved another Viread pill that's white for export only, and this is the first product that the FDA did that for, and they really did it within weeks or our request of doing that. It was very much an expedited review, and it comes with a label saying for export only; it's not for use in the United States.

That was an example. In the pharmaceutical industry we talk about innovation all the time, and how important innovation is. But other aspects of the U.S. government, throughout their efforts on global AIDS, has been incredibly innovative. And that's one of the ways that the FDA has been innovative.

And in fact the day we got Truvada approved, we had a different colored pill approved for export only on the very day. It's part of the same package that was approved in 4-1/2 months. And with the triple we also expect to have approved by

the FDA a different colored pill for export, so the day the product is approved for use in the United States, there will be a product approved for export only.

So the partnership that we have with Bristol Myers and Merck, as I indicated, the formulation work was led by Gilead. We just, rather than have a delay, we went ahead and made the entire investment with Gilead resources to make sure we had this product out there as quickly as possible.

BMS though has worked very closely with us on the technical aspects, and of course the regulatory filings. The manufacturing is also being led by Gilead, and once the product is commercialized, we will work together with our commercial efforts, medical efforts, to provide immediate access. We'll work together to educate physicians on the product profile, and partly securing formulary approvals as quickly as you can do that. That allows for patients to get access.

And finally we have what we believe to be the best in class patient assistance program to make

the product available free of charge for individuals who cannot get reimbursement. This program we put together working with people who deal with this on a day-to-day at medical institutions around the country, including Dr. Redfield's at the University of Maryland.

So what we call the single tablet regimen addresses treatment challenges. It greatly simplifies treatment. And that type of simplification has been published to increase compliance by up to 30 percent.

Also recently published was a survey, a patient survey, indicating that in one week an average of 17 percent of patients missed one dose; another 17 percent missed two or more doses of more complex regimens.

We by doing this these products can decrease long-term toxicity and improve the resistance profile. And it's important to come up with products that have increased tolerability, and I want to show you a little data on that.

We compared, and this was published in

the New England Journal earlier this year, tenofovir versus Truvada essentially, so AZT lamivudine, versus tenofovir Entriva, both in combination with efavirenz. And you can see the efficacy at one year is 84 percent versus 73 percent. That's a highly statistically significant result.

And so - and that's a real difference in terms of the number of patients that are benefitting, and that is entirely driven by the adverse events profiled. There are fewer adverse events on tenofovir, and that's why the efficacy is higher at that one year time point.

Another study, and this is quite an old study - as you can see the number of weeks goes out to 240 now - we compared d4T to tenofovir in combination with lamivudine in this case, and efavirenz, and looked at limb fat. Unfortunately when we started this study, less was known about the issue of lipoatrophy, and we do not have any slide numbers. But you can see at 96, 144, 192, and 240 weeks the difference in limb fat is approximately three kilos. That's more than six pounds. That's a

pretty dramatic difference.

And what - we do have weight gain at the earlier part of the study, and what you see in the course of one year is both arms gain weight as you expect for AIDS patients, followed by a decline in weight on the d4T arm, and it continued to increase on the tenofovir arm.

And this data versus d4T has really helped to highlight some of the concerns about d4T.

Okay, well, we've heard a lot about this, education and early diagnosis are necessary to reduce transmission. Many patients are diagnosed late. The Kaiser Family Foundation showed that 39 percent of those diagnosed received an AIDS diagnosis within a year of testing positive for HIV. You heard from the health commissioner of New York City recently than 25 percent of AIDS patients - or HIV cases are diagnosed with a concurrent AIDS, and those are serious problems, and these patients have mean survival of only four months.

So there is, again, the theme of many presentations here, a need to support a diverse

portfolio of prevention strategies. And we and others are involved with routine testing initiatives to help with early diagnosis.

Early and continuous treatment is the most - with the most effective and tolerable treatments will successfully suppress HIV, and the lifespan as Bob mentioned in his introduction, with drugs, has really been improved with the advent of antiretroviral therapy.

Many of the things that are thought to be complications of drugs are really complications of HIV, and it's important to have uninterrupted therapy.

However, less than half the patients in the United States that are infected are actually being treated.

I want to sort of digress here and talk about something else about Viread. The study of AIDS drugs, because so many are on the market, start out in the most advanced patients. Our first two studies that led to approval of this product in the United States and Europe were done in patients with an

average of 4-1/2 years of prior therapy.

Then we were able to study the product in naive patients, subsequent to that we were able to go into children, and also studies have started in HIV negative individuals, studying the potential of tenofovir for prophylaxis.

And this is all based on data that I'll share with you that dates back more than a decade ago indicating that this product can completely prevent infection in monkey models.

Clinical studies with Viread, as I said, began with advanced patients in `96. The product was approved by the U.S. FDA at the end of 2001. Subsequent to that a variety of organizations - you've heard from the CDC I think several meetings ago about the use of tenofovir in some of their studies. The NIH, UCSF, Family Health International, and Gates Foundation have all supported these types of studies.

There have been - these studies have, to say the least, been controversial, especially for some individuals concerned about how the patient

populations are being affected.

But they are important studies. Just this year the CDC has also announced data indicating that Truvada, as you might expect, is even more potent than Viread in preventing infections or preventing disease in animal models. And we expect the first human clinical data to become available this year.

The concern of course is that by the reduction in the number of experiments and the scope of the experiments through a variety of different types of protests that we may not have enough - the number may not be enough to be definitive.

So this is data generated by Che-Chung Tsai at the University of Washington, published in Science in 1995, showing that by a variety of measures, antibody virus and PCR, monkeys that are infected with SIV develop AIDS, or monkey AIDS, and of course die. These are very high lethal does. And yet patients that are given tenofovir, and in this case tenofovir is given 48 hours prior to inoculation, but it even works if it's given 24 hours

after, were completely protected by all these measures.

And that of course was very exciting data at the time, and it's continued to move forward in studies that are sponsored by major organizations.

Well, so government programs are critical for success, moving back to the main theme. More than half of diagnosis were in African-Americans by CDC in 2005, and many patients rely on government assistance.

The ADAP program or Ryan White, and I believe Marty talked about that today, provides medications now in this country to 96,000 patients, and eligibility to these programs are administered state by state and municipality by municipality and the eligibility range is from 100 to 500 percent of the federal poverty level, but in point of fact, 62 percent are people of color, and 80 percent have incomes below the 200 percent FPL.

And the majority are uninsured. So our program provides a link to treatment. It provides same day access and reimbursement counseling.

The approximately 860 U.S. patients are now receiving drug through our access program, and as of February, 2006, the patients who had been on the program who transitioned out of it, 80 percent went to ADAP and 13 percent went to Medicaid. And that's out of - since we launched Viread in the year 2001, late 2001, we've had 7,000 patients move through this access program.

And importantly, more than half of our access patients reside in the nine states with ADAP wait lists. And the point I'd like to make here is that although we've worked to make this access program as user-friendly as possible, lack of normal types of reimbursement is an impediment to getting on drugs.

Many patients are not in a situation where they can get access through an access program. The health care providers don't have the resources or the know how. We spend quite a bit of time training people on that, but as much as possible, I'd really like to encourage the members of PACHA to work to make sure that Ryan White is appropriately funded,

and also importantly that states do their part to make sure we minimize these wait lists that really are a barrier to access in the United States.

And that's important if we're going to be bringing more people in to care.

So challenges for the emerging markets as we see them, and I think others do, is the - again it's impacting lower income populations, and the financial resources to treat patients are limited.

We also have issues around access in emerging markets. This is challenging, middle tier companies that can afford a middle tier contribution or price. And one example is, we recently announced a partnership with the Brazilian government where we continue to ensure access to tenofovir, that we have lowered the price based on Brazil's economic development level to allow for more of their patients to be on tenofovir.

Brazil has had a very successful free program that has about 170,000 citizens on AIDS treatment with another 20,000 expected to enter this year. And this has been a successful program for

sometime. So as you might imagine, many individuals fail in the regimens they're on, and there is a great need for tenofovir.

The prevalence rate is similar to the U.S., and the benefit - a recent NEJM article has indicated that savings to Brazil has been $2.2 billion in reduced hospitalizations.

It's easy to make the pharmacoeconomic benefit of the treatment with antiretroviral agents. It's very cost effective.

China just came up. Again, the conservative number for China is 650,000 people living with HIV. However only 20,000 patients are currently receiving treatment, and some of those are - need another regimen.

We've been in discussions with the Chinese government to make both Viread and Truvada available through government programs in China, and are optimistic we can work through the issues to do that.

And other emerging markets, also, like Brazil has done, can make a lot of progress by

prioritizing HIV/AIDS.

There's tens of millions of people, 30 million infected in the developing world, and that's 70 percent of all cases. The number is growing, quite a bit, of patients on treatment, to 1.3 million, as you know. Yet many of these patients will eventually fail therapy and develop resistance.

I enjoyed hearing Mark Dybul's comments today. I think he and others are doing a tremendous with PEPFAR that - providing direct assistance, and importantly, assuring that the products are FDA approved, whether they're branded products or generic products.

It is important, and having worked in a pharmaceutical for a number of years, I feel it's really critical that the products that are given to people do have th potency they are what they expect to be, and that the manufacturer who makes it not only has demonstrated bioequivalence, but has demonstrated good manufacturing capabilities, so batch after batch is produced at that same high level of quality.

And the FDA is a very good gatekeeper for that.

We provide our product now to 98 least developed countries at no profit, and we now have about 45,000 patients receiving our drug through the program. About 80 percent of that is through PEPFAR, and more of that is Truvada that Viread. We actually are disappointed in that number. We thought it would be a higher number at that time, and have built up a more, we've actually had to do a writeoff on some inventory that I would have liked to see the product get to the patients.

And we are as a result considering other models for access, and we'd appreciate any feedback you have on this topic.

What we're started doing is talking with Indian generic manufacturers about voluntary licensing for our API in tablet. And a concept is that the not-for-profit aspect of our program may not quite incentivize people to get the largest number of patients on drug, and with multiple manufacturers that do do business in these countries, they could

ensure competitive prices in the broadest access as possible.

So what we're prepared to do is do technology transfer to enable production and improve the quality and get the product out there faster, but we're working with the Indian government to make sure that we do that in a way that protects our IP, and that is a critical aspect of this for us.

So my final slide, for the future HIV treatment, is the simplified regimens that we and others have been working on definitely will provide - has been providing better outcomes for patients. We've shown that in clinical studies. And is working to help address access issues in the U.S. and around the world.

The U.S. treatment market has grown about three percent year after year for a number of years in terms of patients coming into treatment. Last year I don't think it's a coincidence with the better tolerated drugs and combination regimens, the number of patients on treatment actually increased by eight percent in the United States last year after those

multiple years of three percent.

So with that I can close, and I believe we'll have time for questions and comments.

Thank you.

(Applause)

DR. REDFIELD: John, I want to thank you, and we'll open this up for some questions right now.

If you feel more comfortable sitting up here at the table, you can.

Alan.

MR. HOLMER: Under Robert's leadership our international committee has had some discussions about what he has termed the importance of a pharmaceutical industry strategy, that is, to make sure that we are able to discover the vaccine.

And the question there is, how do you ensure that companies continue to invest in HIV/AIDS. I think it would be particularly useful for me, and I think members of the council, just to hear the thoughts of a CEO of a company like yours. As you're making decisions, you don't even have to apply it go Gilead, what your sense is of other CEOs of other

companies. Because they're trying to balance decisions. Do I invest in cancer or diabetes or cystic fibrosis, or do I go with HIV, invest in HIV/AIDS?

But particularly what the impact is if you know that with respect to HIV/AIDS there is a risk that at shareholder meetings you are going to be attacked by critics; that some are going to demand that you give the product away; or that you really don't deserve intellectual property protection for what you've brought to market and what you've discovered.

So how do you approach those constellation of issues, or how do you see your colleagues in the industry approaching those?

MR. MARTIN: I think for Gilead we've built a company that has the capabilities. And we have a lot of people that worked at - you know, ours is a business - people don't realize, you can't possibly realize how complex drug development is unless you've worked in the field for a lot of years. It's extraordinarily difficult.

When we were a smaller company I met with all new employees after they've been on board for six months and talked to them about the complexity of our industry, and how building a jumbo jet for instance is easier, because the design is based on previous designs. You just put the parts in there, and it's actually very complex.

But our industry day-in and day-out, the years it takes to develop a drug, we're making decisions that could go either way on how drug works. And many companies have done less and less in the field of HIV, and we were able to recruit the people who were dedicated to this area to come to Gilead who can make a real difference, and that's how I believe we got to the forefront.

So for us we're comfortable working in this area, but it does take - it is quite a distraction. The vast majority of individuals and organizations greatly respects what Gilead has accomplished, and what our commitments are. We're a very small company, and a small part of the resources that are being employed to combat global HIV, and we

feel like we're doing really a very good job of that, and we're very proud of what we've done, and what we could do in the future.

Yet the plain fact, our last shareholder meeting had demonstrations. There are people, it's just that type of area. I spend a lot of time dealing with access issues, and my senior management team does too, that is an opportunity cost about working in other areas.

So you can sympathize with companies that say that the challenges of this area are just too much. We can deal with that. We really love the contribution we're making, and the response to this.

One thing, an example is of how we're trying to work, it's sort of a trial and error thing to go through the iterations, so we recently came up with this Indian generic strategy, because we think that for-profit competition in Africa for generic drugs will increase access and drive down the price.

It's not a market that we've been able to grow exceptionally with our no-profit product just doing it by ourselves.

We have worked for hard for registrations in all these countries. It's an art. There are reviews. We've had reviews going on in countries for over two years. Several years after Viread has been on the market, after FDA review of only six months.

So I think there are a number of activities that you end up getting involved in as a company when you work in this therapeutic area. You can't begin to imagine when you start, but it just keeps growing as you go along.

So we're continuing to work in HIV. We feel like we can continue to make contributions in this area. And we're not giving up on this.

The way we very simply think of our products is, AIDS is treated with three drugs, A, B and C. Viread is A. Before Viread, d4T and AZT were A.

Entriva is B. And before Entriva lamivudine was B.

We don't have a C, and given the patient experience in the United States with NNRTIs and protease inhibitors, we need new classes.

So we have two products in development for integrase inhibitors now, because patients have been exposed to those.

And one is already in the clinic. It's in phase two, three type study, given once a day because we had phase one data showing it to be very potent.

I don't know, it's sort of a rambling response to your question, but it gives a perspective.

DR. REDFIELD: James.

DR. HU: I'm very happy that you work with the Brazil government to make drugs, and negotiating with China, and also working with the Indian government to make the generic drugs; I think that is a very good approach to help the world.

And I just want you to know that the Chinese government recently organized more than 100 generic pharmaceutical companies, Chinese. Maybe you should also approach the Chinese government how to make generic drugs.

MR. MARTIN: I wasn't clear I guess.

That's in fact that we're doing. We're working directly with the Chinese government.

And we actually have quite a few operations in China, but through Chinese organizations. As you might imagine, Gilead is a company where much of the work we do is done outside the company. Most of our manufacturing we do with other companies, and we manufacture our drug product in Asia, North America, Europe - I mean API, active pharmaceutical ingredient; drug product in similar markets; and we're also doing it in South Africa.

But it's through other companies. We have probably created well over a thousand jobs in China, because we buy and source much of our raw materials for the manufacturing from China, so we have knowledge of China.

We are also able, just as an aside, we're the inventors and developers of Tamiflu for influenza that became a high profile drug because of avian influenza. We worked with Roche to secure additional raw materials out of China to be able to manufacture that.

So we are definitely working with the Chinese government.

The one thing I'd like to emphasize here is, we and others don't believe it's appropriate for the U.S. and Europe, the citizens of these countries, to bear all the costs of the innovation of drug discovery. And so the middle tier markets according to their ability to pay, should actually pay for drugs. And that, the negotiation with Brazil was fairly difficult, but it did end up with a successful outcome that we concluded after about 18 months of negotiation.

DR. REDFIELD: Before I call on Frank, maybe you could just follow up on that comment.

How do you see tiered pricing? So there's a U.S.-European price. There's a no-profit price. Now you're getting into this, well, we'll figure out what your market can bear price.

Particularly with the United States, and I'm going to assume maybe Japan, some of the - Germany, France, England, several of these countries deciding to fund these global health requirements

like PEPFAR, like the global fund, those citizens paying it.

Do you think it's really a long term sustainable strategy where we have multiple prices of drugs for different individual countries? Particularly in light of the way our health care access issues are going in this country as it is?

MR. MARTIN: I think around the world there are concerns about health care, and the prices of various components of health care.

The one thing that - and there is a lot of pharmacoeconomic research on this - is that the HIV products are extremely cost effective. When we launched Viread, we priced it in a range of HIV products that it more reflects sort of what the accepted prices become as opposed to pricing at a premium, because it's a drug that provides a lot more benefit.

And that's not necessarily true in other therapeutic classes where you see an escalation of cost. So I also believe that it's - I know the model is, well, maybe we should have a lower price, and

then have the subsidies from the richer governments go to the drugs. But we don't see a way that that has been workable, so we think a better way is to make it available at the lowest possible price without profit in many of the countries around the world, but then make sure that the intermediary countries do pay a fair share, that I acknowledge is kind of a gray calculation how you do it, it does involve some negotiation.

We've worked very hard to make sure that the price bands for Europe, Canada and the United States are very similar. We did not launch the product in Canada, until we had a price that we thought was similar to the U.S., because we all know that U.S. citizens get pretty unhappy when there is a lower price in Canada, and rightfully so.

DR. REDFIELD: Lower prices everywhere.

When you speak of no profit on your slide here, first of all let me say I'm not trying to corner you or anything. I'm a strong believer that invested capital should have competitive returns, and if we don't - if that isn't provided for we're not

going to have new drugs, new vaccines, anything else.

But there's a very narrow way of saying - of defining no profit. One would be just simply the incremental costs of the incremental production of a drug that you've long realized most of your other costs on. Obviously a much broader definition would include proportionate research and development and marketing and distribution and regulatory and everything else that goes into that.

So are you somewhere in between when you say no profit?

MR. MARTIN: Just cost of goods of manufacturing. And we're using our current cost of manufacturing, but the product we're shipping is from earlier in inventory. It's first-in first-out, that's how they do the accounting. And that means that we're actually selling at a loss on an accounting basis.

DR. REDFIELD: So it's really at a loss by any other definition, right?

MR. MARTIN: Well, it's at a loss by accounting. But it's the price we're basically at in

our manufacturing now.

The one thing we underestimated was all the cost of our regulatory efforts which are huge, and they are not included in that. Maybe they should have been, but they're not.

DR. BOLLINGER: I would like to follow up to Bob's earlier question. One of the issues we've talked about is how to incentivize this process over the longer term, and I guess what I heard you say is that the current model would be - if I can simplify for my own purposes - is that this nonprofit or loss tier is subsidized by other tiers that can absorb and may actually contribute to subsidizing the cost in other countries.

Is that a long-term strategy for subsequent drug development? Are there other - I'm just wondering if that's enough incentive to drive the kind of drug development that I think all of us are interested, particularly for the developing country needs.

What I was thinking about, for instance, is - I know Bob is concerned about this as well, and

it was actually in one of your slides, is the resistance issue.

And while we expect and really look forward to having a single drug, single pill per day, we've got issues in India and elsewhere of the interaction of these drugs with diabetic treatment, with herbal treatment, with nutrition, with bioavailability issues, that are all - and in fact in my clinic at Hopkins if I have a patient or situation where compliance is an issue, I try to avoid the single-dose drugs because of the pharmacokinetic issues and the risk for resistance. So these are complicated issues. We don't know how they're going to fall out. What it really comes down to is, we need a lot of things in the pipeline, so that if we run into problems with one drug we have some second or third salvage regimens.

So we want to incentivize the process, not just for the U.S., but for the PEPFAR program. And maybe that's a long question, but maybe you could tell us whether you think there are enough incentives in the current system, or what else we could be

thinking about.

MR. MARTIN: I think in response to Alan's question, I covered some of that. Probably not very articulately, because it's complicated. We keep going through layers - what we believe to be true today seems to be changing tomorrow, and there are a lot fo forces in the world that talk about not wanting to have IP protection at all for our industry.

Obviously all of you are aware, and most people are aware, that the IP protection is what allows us to have future products.

Yes, I'm very pleased that the administration has very much understood this, and has also stated that we don't want, with our programs, to be giving people regimens that aren't the best regimens that we want to have in the United States. And I think that is a very important concept.

We have had a lot of support from Commerce, USTR. The Commerce Department is involved in a lot of foreign trade issues, and the United States Trade Representative is an office of the U.S.

government that also helps us and advises us on how to make sure our intellectual property is protected abroad.

The U.S. government has in fact been quite helpful in these things, and it's really important to maintain that type of environment. There are so many big issues in the world, but the trade issues and IP issues associated with pharmaceutical products are very critical to the future of the industry; there's absolutely no question about it.

DR. REDFIELD: Ram.

DR. YOGEV: I'm unfortunately or fortunately the only pediatrician on the committee, so you can see the question. It's not Gilead, but all pharma companies somehow, because of multiple issue, production, and profit and so forth, put into pediatrics so much behind. For example you are talking about a triple drug when your own drug is not yet available for the pediatric. And how much was the formulation. Also the pharmaceutical companies as a group almost refusing to go with a group which

is NIH supported to try to get to some liaison to help the pediatric to be at the same place so it doesn't come two years later or not at all.

Is there any thought in that direction of expediting the pediatric and start working with it with other agencies of the government?

MR. MARTIN: So I should have said, and maybe you all know, my background is chemistry, so I'm not a physician, and my knowledge may not be as good as yours on these.

So but I do know about the timeline of our product. Our product, Entriva, has a pediatric formulation. Tenofovir has had more complexities. When we were developing tenofovir, we were really appropriately only allowed to study it in adults, because there is concern about bone toxicity related to our animal safety studies.

The bone toxicity is secondary to very high dose - probably - secondary to very high doses that cause kidney toxicity and then allow for demineralization of bone. But that concern delayed our ability to take it into children until we

garnered very significant human clinical experience. And I alluded to that when I talked about how we first studied the product in very advanced patients; then in naive adults; then in children and HIV-negative individuals for prevention.

So the other aspect, our first pediatric product, we didn't like it. We thought it was okay, but the taste was not good. The limitation, we were not able to achieve the stability we wanted, because it needed to be brought up in water, suspended in water. And it just didn't have quite the stability we needed there, and especially for Africa where it would require refrigeration.

So we've now come up with a product we like quite a bit. It's encapsulated sprinkles that can be spread onto food for instance and taken that way. And we do have ongoing phase three studies to get this product out there, and those studies are in fact being conducted, obviously, outside the United States. There just aren't enough patients. The main sites are in fact in Brazil.

One thing that I wanted to make a

comment, I didn't get to it, is that countries that do support IP tend to get a lot more investment; that's been shown over and over by economists. So for instance in Canada we have a reasonable price for our products. We also do a lot of work in Canada. We own a manufacturing - we just bought a manufacturing facility in Canada. We've manufactured drug and drug product in Canada since 1992. We've carried out a lot of research in Canada on scaling up of manufacturing. We've done a lot of our safety assessments and pharmacokinetic studies in Canada, clinical studies in Canada.

It's also true that we've invested in Brazil, a number of our adult HIV studies have had sites in Brazil, and we're doing the pediatric studies, a large percentage of studies in fact, is in Brazil.

DR. YOGEV: I appreciate what you're saying, but the NIH or NIAID has no system that takes the benefit of knowledge in the United States with sites in different places in Africa, Brazil, for the pediatric.

And there is a tendency of pharmaceutical company not to go there because of the IP -

MR. MARTIN: No, we work with NIH all the time.

DR. YOGEV: I know, but it took us a long time for us to get you to work with us.

MR. MARTIN: Is that right?

DR. YOGEV: And you're not unique, by the way. It's not a personal attack. I'm trying to find out why pharmaceutical companies now, is all their really openness, are now trying to take the best in the United States, bring it to the rest of the world.

But one thing which - it wasn't your company, another company - acknowledging pediatric is not inn the people who are helping, because that is the nature of the beast.

How can that be changed to make it more efficient, both for the company and for the children of the world, because the United States, they're very low, and so it's really mainly for them.

DR. REDFIELD: And maybe one comment to add to that as you talk, because I want to ask you a

question or two about that, but one of the complexities as I understand this right now for a pharmaceutical company to make pediatric formulations of a product, whereas I'm going to suggest is, they really have to look at it, what tier is that product going to be marketed in. I don't think there is going to be a Canadian-Germany-United States tier. They might be able to get Brazil and this middle tier to pay the R&D cost. I don't think that the third tier is going to be able to do it.

It gets at that question, your company has chosen to make some formulations, even though there isn't a pediatric population for you to test it in this country, and there isn't a pediatric market.

My addition is, 10 years from now, 15 years from now, how do we have pediatric formulations of the new products?

MR. MARTIN: I mean clearly, to work in to the pediatric formulations is a personal commitment where you really care about making sure your product is available, because the financial gain, that's clearly been a limitation.

One of the things that is also really important, and I don't know about this specific instance that y0ou're talking about. I do know that we early on engaged in NIH pediatric study that failed to enroll patients. And it just didn't work.

So I'm not aware of the current one. I'm just out of the loop on that particular issue. But we do have often freely worked with the NIH. There periodically becomes concerns that if you accept government money in the development of the products that there should be some sort of control of pricing, but we've never really felt that at our company. We've had a very good collaboration with the NIH, in pretty much all our critical studies.

One thing I will say is that it's our experience, and I'd be happy to talk to you more about it after the meeting, is that the quickest way to get a product to the market is for a company to do those types of phase three studies.

Because companies are geared up to know how to do it. And in the past when we've thought about doing other things, it just hasn't worked out

as well.

So we very much believe that even though NIH would provide the financial resources to do it, the quickest way to get these things out to people is for the company to make that direct investment.

DR. REDFIELD: Maybe just as a clarifier on that, for some of us to think, recognizing that in order for you to get a formulation approved for pediatrics, studies are going to have to be done, recognizing your goals to make it at no cost, so therefore the R&D cost you don't want to roll into the cost, am I to understand if we want to accelerate the ability to have pediatric formulations for not only the current medications that are approved, but the future, we need to figure out a mechanism in which somebody funds that clinical development path.

Because is it realistic to ask the pharmaceutical industry to fund that African clinical development path?

MR. MARTIN: Well, that's the way it works now of course.

DR. REDFIELD: I know that. I'm trying to

go long term. You know, those are really - I don't know the answer to that question. Those are important policy debates.

With a lot of things we do, we find that we with good intentions come up with stuff that has unintended consequences. But I do think that is an important debate to have, the one you're proposing there.

DR. REZNIK: Just a few questions to get some clarification. One, we haven't completely eliminated perinatal transmission. We still have about 300 children a year, and every life in this country is important. So thank you for continuing to work on a formulation fo this that will work.

I have two questions. One, there is 1.3 million people in less developed countries on therapy, but only 43,000 are on a safer less toxic medication. And my question is, are there tariff barriers in place that are causing this? I know there are country-level decisions based on treatment. But when you look at the treatment out there, it's usually AZT/3TC or d4T/3TC. You don't see these

drugs popping up. That's one part of it.

And then the other part would be post-exposure. I know you're working on pre-exposure. On post-exposure prophylaxis, this is also doesn't come up as your first line, and I had an exposure in one of my staff a month or two ago, and I literally had to go through a little bit of a battle with the main hospital to get my staff member on your drug.

MR. MARTIN: That's too bad.

DR. REZNIK: Well maybe you have some marketing issues here.

MR. MARTIN: I do know that shortly after Viread was approved New York City put it as recommended for that for instance. So it varies I think in various places.

DR. REZNIK: Well, it's a CDC guidelines, I think, that needs to be worked on.

MR. MARTIN: Yes, the CDC guidelines, I agree with that. And unfortunately, I think a lot of guidelines around the world follow practice.

The barriers are, there are just endless barriers I think. Probably the number one barrier to

our product being readily accepted in places like Africa is that Viread is still not on the WHO essential medicines list, and probably will not be until the end of 2007. So whatever influence you guys have on the WHO I think that's something that is really important, and something that I'm certainly talking a lot about now, because I think that could help with access.

We are working through regulatory processes country by country, we underestimated how complicated that would be. And so we're really committed to doing that, but that's a barrier.

I don't know, perhaps some of you know more about the economic barriers. Certainly tariffs and taxes and one of your recommendations about not providing drug to countries that do that I think is a reasonable recommendation; or maybe that's some other group's recommendation, but I think that dilutes the economic contribution we make when we pay for those drugs.

DR. REZNIK: My final question is about Medicare Part D. Have you all filed - has Gilead

filed - has Gilead filed for an exception in the OIG's office at HHS to allow patient assistance programs for people who have Medicare Part D who are in the donut hole?

MR. MARTIN: I don't know about that; I just don't know. I haven't been aware that we have any issues there.

DR. REZNIK: Because some companies have been very proactive, I believe, and have done that. Because there are people who are getting stuck with $3,700 that they can't pay, and Americans are not getting access to drugs, you should be aware.

DR. REDFIELD: Joe, last comment.

DR. McILHANEY: John, thanks. We all know that one of the true successes in this whole field has been pharmaceuticals. So thank you. You've used the word, commitment, a lot, and thank you for the commitment.

David, it seems to me that the care and treatment committee ought to consider a resolution something like you know the pharmaceuticals are really important. It cost $100 million to develop a

new one. If resistance develops we're going to be needing new drugs, that we might give him some cover, and other pharmaceuticals, some cover with a resolution like that.

Because it's such a huge and important part of this whole thing.

(Off-mike remark)

DR. REDFIELD: David, you're off mike.

DR. REZNIK: I was trying to be not on the mike for that.

The integrase inhibitors seem to be quite potent with minimal side effects, and can help out even the most multi-drug resistant patients.

DR. McILHANEY: The whole thinking is that particularly with these people that are coming to their meetings and causing trouble, it might be of some help if we did something like this.

DR. REDFIELD: John, I want to ask you one last question and then turn it over to Joe to close.

I want to go back to this issue, probably I'm as frustrated as anybody, about the United States government facilitating access to care that is

profoundly less optimal than the care that we facilitate for our own American population.

And while the most immediate reality is that even in my own PEPFAR program that I'm involved in, probably of the 42,000 people we put on therapy, probably 37,000 went on a regimen that we wouldn't use in the United States.

Better than nothing, but not a regimen that we would use concurrently in the United States. And you mentioned one of the difficulties with getting optimization has been guideline issues, and I think that's true.

I want to take that, and I also want to look forward realizing that five years from now the optimal regimen in the United States may in fact, at least in certain circumstances, be slightly different than what it is today. And there may in fact be optimizations of regimens that are more optimal in certain environments like Africa than would ever be optimal here. There could be a different path.

How do you see the issues that are the most critical to you, as one fo the more successful

pharmaceutical companies in this area of AIDS therapeutics in particular. Because we want you to stay engaged. We don't want to have optimal and less optimal therapy; at least I don't think that is in the American public's long term interest particularly.

How do you see us avoiding that in the future, or how do you see that that doesn't become reality in the future?

MR. MARTIN: When Bob Redfield has that type of distribution of products, I think that there are issues around the system that I don't understand. I'd ask you, what do you need from us.

I think you need things from just work that all the people in this room are doing over time to try to influence how these decisions are being made.

It's obviously a very challenging and complex arena.

DR. REDFIELD: But you see it largely still in sort of the political guideline issue, the WHO guideline, you know many of these countries as

you said, you've applied for - we can't get maybe another strategy because the drug is not registered. It's not registered, because even though it's been two years. So you see it as just a process issue. You don't see it as any fundamental economic hydraulics that need to be corrected?

MR. MARTIN: One thing I mentioned that I'd like feedback from this group on, although some of you are probably going to the airport and thinking about your flight delays at this moment, right? Oh, okay, that's right; you're here tomorrow. No problem.

So I do think that the profit motive allows things to work better, and having the no-profit motive for - and we ask our partners that we work with to deliver profits at a minimal profit does hamper access to some degree. Because people will work harder if there's competition and not opportunity for profit.

So what's why we're approaching the Indian generics, and willing to do technology transfer to them.

I hope that's a good idea. It's kind of one of those ideas I'm sure we're going to second guess, but if we did the alternative, we'd be second guessing too.

And I tend to think of almost everything in our industry as process oriented some. I give a lot of talks or interviews to the media, as I'm sure many of you do, and the media is always looking for that ah-ha moment where you actually know something, and it just doesn't happen. Our business is a process where you go step by step, and sometimes you're up and sometimes you're down, and sometimes you're up. And eventually you get to a certain point.

And I know that people in a variety of parts of the U.S. government are working extremely hard on these issues to make sure that we get the best possible care to these people in other countries, because that will give the best outcomes. That's the best value for the dollar.

DR. REDFIELD: John, I want to thank you very much.

And Joe, I think I'll turn it back over to you.

MR. GROGAN: I just want to thank for coming.

This is pretty much it for the day. The bus will pick up up downstairs. It's supposed to be here at 4:40, so you've got a little bit of time to make phone calls and find your way down there.

So we'll see you tomorrow morning at 9:00 o'clock. Thanks very much.

(Whereupon at 4:23 p.m. the proceeding in the above-entitled matter was adjourned)