PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

34th MEETING

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PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS
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MARTY McGEEIN: Thank you. I would ask that the PACHA members to please take their places. Oh, look at how casually Dr. Yogev is strolling up there.

Okay. As you can probably tell, I'm not Dr. Maxwell, just in case there was any confusion here. Her plane – she got bumped off a flight last night and she should be in the air now coming from Colorado Springs, and so I said, "No problem. I will open up," and then eventually we will turn this over to Carl Schmid to handle the panel, one of the panelists currently here.

So, good morning, and welcome to the 34th meeting of the President's Advisory Council on HIV/AIDS. I am delighted some of – most of you could join us. We've had some members with – that developed conflicts at the last minute and they will be either be joining us later or they will be here tomorrow. And we will lose one member tomorrow.

Before we actually begin the business of the day, I want to tell you that there are some new security rules for the Department of Health and Human Services. You may have noticed it as you came in. You got a little tighter scrutiny than you had in the past, which was tight enough, but the badge that you have on your – on your PACHA badge – this goes for both the members and for the members of the audience – allows you only access to the restrooms, and in this case, to cafeteria. Ordinarily, it would only be the restrooms and the elevator. So you will be asked to show identification. There's security in the hall. You'll be asked to show identification if you do seem to wander off anyplace other than the cafeteria, and I think they're not checking the bathrooms, thank goodness. But I just wanted to let you know. It is part of an ongoing and long-term effort to increase security across the board.

Our meeting today is, as it usually is, divided between domestic, day one and international, day two. We have a very interesting discussion today. It ranges from how insurance companies pay for health insurance or HIV testing, all the way to what's happening in the Caribbean, which is at the special request of Dr. Primm.

I'm going to ask that we go around and introduce ourselves, less for me because I actually know you guys, but more importantly, for our recorder. Again, I am Marty McGeein. I'm the executive director of PACHA and I am the principal deputy assistant secretary at HHS. Dr. Redfield?

DR. ROBERT REDFIELD: Bob Redfield, I'm from the Institute of Human Virology, University of Maryland.

DR. EDWARD GREEN: I'm Ted Green, Edward Green, Harvard School of Public Health.

MR. BOB KABLE: Bob Kable from Washington, DC.

DR. RAM YOGEV: Ram Yogev, Children's Memorial Hospital, Chicago.

BARBARA WISE: Barb Wise, speaker for Wise Choices.

DR. BENY PRIMM: I'm Beny Primm from New York City, of the Addiction Research and Treatment Corporation.

DR. JOSE MONTERO: I'm Jose Montero from the University of South Florida, College of Medicine.

DR. DAVID MALEBRANCHE: David Malebranche, Division of General Medicine at Emory University in Atlanta.

SHENEQUA FLUCAS: Shenequa Flucas, outreach educator for Triangle AIDS Network.

DR. FRIEDA BUSH: Frieda Bush, private practice, OB/GYN in Jackson Mississippi and clinical faculty, University of Mississippi.

JOHN MARTIN: John Martin, Gilead Sciences.

CARL SCHMID: Carl Schmid, the AIDS Institute, Washington, DC.

MS. McGEEIN: And Carl is chair of our domestic subcommittee and Dr. Redfield is chair of our international subcommittee. If you look at your agenda, it appears as though we are loosely scheduled this morning, and then from there on, we just put your little noses to the grindstone and grind away. But we – since we are actually running a little ahead of time, I'm going to check to make sure that Christopher is good to go? Christopher, good to go. Okay.

This is actually an interesting day. It is a special memorial – a special day that Christopher will talk about, as will Miguel Gomez, but today, we are rolling out the National HIV Testing Mobilization Campaign. The legitimate question could be why are we doing this at PACHA, in particular? There are a couple of very relevant points. PACHA asked that we start looking at how we increase testing and the Office of Public Health and Science answered.

For those of you who don't know, Christopher Bates is the acting director of the Office of HIV/AIDS – HIV/AIDS policy – say that fast three times – here at the department and he is located within the Office of Public Health and Science.

In December 2005, PACHA produced a series of recommendations for a new America HIV strategy, several of which are directly relevant to this campaign. You

asked that HIV testing be a routine part of primary care in the United States. You stated that because HIV testing is the gateway to HIV treatment and care, testing should be encouraged wherever possible. And you further stated, with very strong emphasis, that the federal government needs a comprehensive, invigorated campaign, communication campaign, of our domestic HIV/AIDS policy. The National HIV Testing Mobilization Campaign that we are launching here today represent OPHS's, Office of Public Health and Science, part of the administration's efforts to address your recommendations.

And with that, I will turn it over to Christopher. There you are.

CHRISTOPHER BATES: Good morning. Oh, God, you'll have to do better than that. Good morning. Yes, let's get some energy going.

I'm really happy to be here to re – can you hear me, okay, good – to reintroduce, I think, to you the mobilization campaign. I spoke to you about it a year ago as an idea that we had in the Office of HIV/AIDS Policy. Well, now it's a reality and what you see on the screen there are the several fliers that we have adapted for this mobilization campaign, and we're really proud of them. And as you can see, they reflect the subpopulations, as well as the general populations' impact, by this epidemic.

The reason this campaign is important is not simply because of the sense of urgency that you all expressed, but because the CDC has indicated that nearly a quarter of the 1.3 million Americans who are living with HIV do not know their status. They're HIV positive, don't know their status, and should be brought into care and treatment. So this campaign helps facilitate that. It gives us an opportunity to not only bring those folks into care and treatment opportunities, but it gives us an opportunity to further educate the general public and highly impact the population about the importance of HIV testing and the impact that this disease has in our country.

I'm trying to stick to the script, so that I could also keep to the time.

We are basing the root of this campaign on staying healthy, and what we're saying to Americans is that if you are between the ages of 13 and 65, which is identified in the CDC's new HIV testing guidelines, is that you should be tested for HIV. And with the new emphasis placed on the routinization of HIV, we think that this campaign is going to be a very strong element to help further that along in our clinical settings.

I think, without going into further babble about that campaign, because most of you know about it and I think it's very self-explanatory, I'd really like to field your questions. And, Marty, if you want to participate in this with me, you can, but I'll take the heat at this point.

MS. McGEEIN: Ah, good. (Laughter.) Questions from the table?

DR. PRIMM: Let me not allow you to get away without some questions, Christopher. I'm concerned about the CDC's monies and testing. Apparently, there was

$45 million that were funded, were given for the heightened awareness of – to fight HIV among African-American campaign, and only $35 billion now have been allocated to jurisdictions that support that effort. I'd like some answers about that.

In terms of the original proposal that was issued by the CDC called for about 1.5 million African-Americans to learn their HIV status, and now I'm hearing that there's only about one third of that group, or about one million people, that you are targeting. That to me seems to be quite shocking, particularly with the problems in the African-American community as they are. Can you do some explanation about that?

MR. BATES: Sure. First of all, let me – just for a bit of background – all the states received from the CDC HIV testing money, and the states also conduct, as a part of that effort, an assessment of which are the impacted populations. So states really do heed to where they should place an emphasis in terms of their HIV testing activities. And most of the highly impacted states with large portions of racial and ethnic minority folks are, in fact, targeting their efforts towards this – or these populations.

In addition, we are referencing the $45 million that Dr. Gerberding was able to get from the Congress, does, in fact, support additional efforts on top of what's presently being done by the states to, in fact, address HIV as it relates to African-Americans. There will also be a piece of that that will relate to Latinos as well.

So the two most impacted populations will have their HIV prevention activities strengthened and more targeted that has been done in the past. They really are focusing on about, I think, 16 – and we have a colleague here from the CDC in the back, Eva Margolies, who might be able to add to that, but I believe there are 16 cities and states that are being highly targeted, and that right now is making an assessment about where they might want to do additional work, particularly in rural communities. So I think that over the next couple of months, you'll see those remaining dollars probably released.

DR. PRIMM: But what about the extra – the $10 million that's left over, what – would you have somebody answer that question for us sometime today because that's quite a considerable sum of money.

MR. BATES: Eva may know.

EVA MARGOLIES: Thank you. Hi, I'm Eva Margolies. I'm the policy director for the National Center for HIV, STD, and TB Prevention at CDC. Just to clarify slightly, the $45 million was not – Dr. Gerberding found that within CDC's budget. Congress did not give that to us, and we did put out $35 million that went to 23 states in local health departments, and the criteria was based on their percentage of AIDS cases, and that's how we determined who was eligible. Beny, I don't know if we're going to be able to get it to you by today, but the remaining money was used to support testing efforts and going towards some activities, such as social marketing campaigns to get people in to be tested. Some of it's being used internally for contracts, but it's all around testing. I

can get that for the council, but I probably won't be able to get it today. I can send a message back. I just don't have that information with me.

And regarding the number of tests, that was an estimate of what we thought the money could buy, and we really won't know how many tests have been conducted until after the health departments report back to us about the number of tests that were performed. All the money was to be used in high-risk areas, highly focused with the intent of identifying as many HIV positive people who are unaware of their status as possible. So I hope that helps.

DR. PRIMM: Somewhat. I just participated in a meeting in New York last Monday and Tuesday, where over 100 African-American ministers and a number of physicians from the National Medical Association attended that meeting at Time Warner, sponsored by the Black Leadership Commission on AIDS. And I was quite, quite excited about the responses of these African-American ministers from all parts of the country relative to testing and to the acceptance of heightened awareness to be given to their respective congregations repeatedly on Sundays and other times when the church is out. And that was quite, quite impressive.

And I'm wondering, are we going to be targeting those institutions in the church to provide for them ways to be able to better test for people who want to volunteer to step forward to get tested in the African-American community? And I think that would be one of the focuses of the CDC and of any other effort, and to support that effort. You were there, Chris, as you know, and you witnessed the receptivity of that audience, which is quite different than what we have seen in the past. So would you comment on that, please?

MR. BATES: Two things. One is, we have continued to do outreach to African-American churches, as well as other community faith leaders around the country. With the heightened response that the CDC is doing with this campaign, we have every, every intention of partnering with most of those denominations that were represented there and many of the ministers there, and the media activity around public forums and community town hall meetings, where we hope to both, not only advocate for HIV and AIDS, but also work with local health departments and some of the community based organizations that will be providing HIV testing opportunities either on site, at the time that these events take place, or offsite. And we'll make sure that they have the information so people will know where to go and they'll know how to access testing opportunities.

DR. PRIMM: Kevin was there, but he had to leave and I'm wondering whether this message is being carried back to Dr. Gerberding and people at the CDC, so they can move on this pretty fast and furious. I would like for this committee to make recommendations to the president that that happens.

MR. BATES: Okay. If you recall, one of the documents in the binder was, in fact, a form that all of the participating ministers were asked to complete, which would identify a representative in their denomination or from their church that we could start an

ongoing dialogue with, hoping to provide them technical assistance and support as they move forward, trying to create these opportunities for testing at the multiple churches that were represented there at that event.

MS. McGEEIN: Two things and I know I've got two questions here. First of all, there will be a speaker tomorrow morning to give us a recap of what happened at the meeting. And so this – we are not leaving this topic for very long, but could you tell me exactly what the campaign is going to do?

MR. BATES: Okay. The campaign at this – this campaign is situated much different than a lot of the other efforts that we've done. In the past, the department has gone out and tried to create events and at those events, give us opportunities to market our information. Instead, what we're going to do is go through a series of exercises to identify events that are taking place across the country by organizations, groups, and institutions, such as conferences, conventions, and forums. We'll invite ourselves in. We'll have three opportunities of engagement with them.

One is just to pass out information and to have people available to field questions about HIV testing and where to go get tested. Two, we'll be prepared to offer workshops on HIV testing and AIDS 101. And three, we hope, in some instances, to be able to invite federal officials in to be speakers at plenary sessions and major gatherings where they will have large audiences, and we can actually engage with people around the HIV testing message in a different way.

MS. McGEEIN: Do you have a target?

MR. BATES: We hope to touch about three to four million people over the next year.

MS. McGEEIN: Is this on the campaign?

MS. : Yes.

MS. McGEEIN: Because Dr. Redfield is about to explode. Yes.

MR. SCHMID: I guess that was really my question too. What exactly is the campaign, but I guess to take it further, is the White House or the secretary going to issue a press release today on this? Is there going to be a press conference? Are there going to be PSAs on TV? Are these going – these documents, they look great. Are they going to be in doctors' offices around the country? I guess, just to take it a little further.

MR. BATES: Okay, great questions. One is that we do have 10 people out in the regions who will be moving our materials in a whole host of venues and some of that will be to put in the hands of public health departments. Also, we will have all of this information on the – on our webpage and it will be downloadable, and we'll encourage people to do that, to download this information and to make it available that way.

In addition, we will, in fact, have PSAs, both radio and TV, and a part of what we did in New York on last Monday was we had six ministers, both male and female, who sat with us and we were able to create a TV video PSA. And then we had a couple also radio spots done by some of the ministers participating in that meeting. We hope to have that material available probably by the end of November. And we've got a commitment from BET, I should say, on that same day to air it and Creflo Dollar, who also has a TV evangelist program is also going to air our TV PSA. We will be working with a marketing group to do work for radio with our radio spot.

MS. McGEEIN: Mr. Redfield?

DR. REDFIELD: I wanted to follow up on Lenny's point. I think, as you look at how to try to reach this 25 to whatever – 50 percent of Americans that don't know they're infected, and particularly, with the epidemic concentrating in the African-American community, I think more aggressively taking advantage of the structural realities of the church is fundamentally critical.

And – I've sort of – as an old-timer who's been involved in this since the beginning, almost over a quarter of century now, I don't recall of any targeted initiative that the Department of Health and Human Services has had that tried to totally embrace the faith community, the mosque community, the temple community, to become a point of diagnosis. And I think there may be opportunities to expand that.

And we have some small pilots that we've done in Baltimore, but they're very hard to get funded to go into the church community. We, like Lenny, have found that the pastors now are ready. They probably weren't ready before, so I'm not being critical of the fact we hadn't done it before because you can't do something if the people aren't ready to invite you in. But I think they are ready now in many communities.

And so one may want to look much more – re-look at this of how to have an initiative to get diagnosis established, not in emergency rooms only, not in hospitals only, not in clinics only, but the idea of doing it in the structural institution of church, temples, mosques, where people can feel a little safer. And if the church community could get into facilitating diagnosis and then providing that sense of that safety with education support, I think you could probably get a large majority of those individuals who don't know they're infected to have that knowledge much more rapidly than just the program that's targeting medical establishments. So what I'm suggesting is some internal debate to really re-look at, could we do something even more aggressive about trying to engage the church community as a point of diagnosis?

MR. BATES: Okay. If your recall, in the president's FY'07 budget, he, in fact, asked for $25 million to be targeted to African-American faith communities. In this instance, those monies were never realized. But in spite of that, the CDC continues, and so does our office continue, through the minority AIDS initiative, to move forward a dialogue with faith communities, both African-American and Latino, around

opportunities for, not only doing HIV testing, but also educating these communities about the epidemic in ways in which to protect themselves from the transmission of HIV.

So I appreciate this, and hopefully the PACHA will continue to support us in our efforts to try to bring more emphasis on these organized communities and to use the faith community as a strong vehicle for these messages.

DR. REDFIELD: Just a quick follow-up, but, Chris, what do you think right now are the major barriers to diagnosis that we're not addressing as optimally as we could?

MR. BATES: I – two things that I've seen that worked really well recently, and that's when leadership in communities actually take the test in public settings. That has been very, very effective. Jesse Jackson has been doing a lot of that recently. Some of the other pastors who were at this meeting that we just had have been doing that. That's been effective.

It's also been effective when faith leaders and other community leaders actually talk about HIV, actually engage a dialogue around the epidemic and the importance of testing and the importance of people, are really getting to a place of taking charge of their health and being in the control of their lives. I don't think that that has been done at the same levels that health departments have gone out and tried to move their messages through community health workers. I think it's a different dynamic.

And now that we have this movement of leadership around the country, both in African-American organizations national, and also Latino organizations national, we're starting to see a change. But the whole issue of stigma associated with HIV testing is real and every day we're trying to address that.

MS. McGEEIN: Frieda?

DR. BUSH: Yes, Chris, good morning

MR. BATES: Yes, good morning.

DR. BUSH: I wanted to follow up on the question about what's being done in private practice. Being a private practitioner, getting awareness of literature, and even knowing that is downloadable, is something that the person in the everyday nine to five – well, not nine to five, but everyday trying to make a living, may not really be aware of it. We don't necessarily watch BET and PSAs, anything.

And I'm thinking getting the information out to the everyday private practitioner, and perhaps utilizing the organized medicine. I know you referenced AMA a minute ago, but there are other organized medicine areas where African-Americans in particular may also participate, the AMA, the ACOG, the Southern Medical and community health centers. There's a large network of those that are not health departments.

MR. BATES: Okay. Please be sure to understand that the CDC has met with all of the national medical groups, all of the HMOs and the like, and have had extensive conversation about the importance of even downloading their material that's presently available on the webpage. I think this is going to be a slow and probably difficult process to get everybody on board, but local health departments, state health departments are definitely moving the conversation about the importance of integrating into the clinical settings, conversations about HIV prevention, opportunities for HIV testing.

Specifically, we see a lot of movement around testing of pregnant women. And so I think this is going to be an evolving process that's going to happen over a period of time. This has been in play for about two years now, and I think we've moved a long way ahead. I think there's a lot of work to be done, but it's not all going to rest on the shoulders of the federal government. We really have to get our state and our local health departments on board and having them move this conversation along with us.

MS. McGEEIN: Next question, but let me just – to follow up on Frieda's question, are we going to frontload any of the private practitioners, any of the medical associations with this data, with these information sheets?

MR. BATES: We hope to work with CDC to not only move our sheets, but also to move their data sheets as well. And we have not come up with a strategy for doing that at this point, but we are in constant conversations with the CDC. Dr. George Roberts has just been moved to a marketing office, and he's going to be heading up an effort there to do more marketing of not only their materials, but other materials that we find effective in conveying our messages.

MS. McGEEIN: Okay, thank you. Dr. Martin.

MR. MARTIN: I guess I – Chris, thanks. I'd like to ask you a couple of things just to help in my mind for clarification, and I've enjoyed your presentations in the past, I think both here and to the CDC panel, and this is part of a continuum of what you're doing. And I guess what you're announcing today is the new materials, is that correct?

MR. BATES: Exactly, yes.

MR. MARTIN: And is there going to be a press release for that or something from –

MR. BATES: We've really – we've been out piloting this for about six months now. And so it's sort of already out in the community, but these documents have finally gone through a clearance. They've been vetted by everyone who needs to see it and they are together, and we have the materials, and we access them with HIVtest.org and other people can use them.

We're hoping that you can go through our AIDS.gov and then it will lead you to this. We probably are about two weeks away before our webpage is up, but once our

webpage is up, this will be available to the public. And not only can governments at the local and state level, but individual organizations can brand our materials and put their information on it, both name of organization, address, phone numbers, things of that sort. So we're really going to put this in the public domain and make it available to any and everyone who wants it.

MR. MARTIN: I think that's just helpful for all of us to know because we can, through our organizations –

MR. BATES: Well, remember, when I came to you the first time, I said that we had hoped to use some of you to help us convey our messages. That's still on the table.

MR. MARTIN: So when it's up, send an email to all of us to make sure we're – there is an editorial that came out in the *New York Times*, an op-ed from a local doctor in the city – I think many of you have seen it. It was sent around to all of us, about the – that most emergency rooms aren't doing this. They're emergency rooms only because they have outside funding and that – there's just not the money available to broadly do testing.

MR. : You brought up community medical center, that that seems to be the biggest barrier of all and as part – will this campaign help to get at that, or is that something completely different?

MR. BATES: Well, this campaign is not out to have the conversation about money. (Laughter.) That's going to take place in another venue.

MS. McGEEIN: You'll think about that tomorrow, but that is an excellent question to ask our panelists when we bring them because it is how the private side are reimbursing for this testing and how the public side is reimbursing. So it is – it is a very legitimate question.

MR. BATES: But can I give one example of just something I think is phenomenal? Howard University Hospital has completely integrated HIV testing across the entire span of the hospital. So there is no entry point in the hospital where you'd come in for services where you would not be introduced to the idea of an HIV test. And that's being done here in D.C. and we think that other communities will follow Howard's lead.

MS. McGEEIN: Dr. Malebranche.

DR. MALEBRANCHE: Chris, thanks for coming. I was at the meeting too with the black clergy last week, and that was pretty amazing, so I'm looking forward to the conversation tomorrow. My question had more to do about the practical side of implementing the HIV testing initiative. And maybe it's a question for both you, Chris, and for Marty, with regards to what's the status of all the states that have actually passed the laws that have allowed this to happen without the informed consent, because right

now in Georgia, I'm still telling my residents – I'm training my residents by myself to say, "Look, when you're screening for mammography, colonoscopy," I keep reminding them to do the HIV testing, too.

So I'm sending them back individually, but they still have to go back with a special informed consent form. And so as part of this whole initiative, what is being done continually about making sure that those legal barriers are removed, so that these medical facilities can actually incorporate this with – in a quicker fashion?

MR. BATES: I'm not – I don't have the specifics around what CDC is doing so –

DR. MALEBRANCHE: And there was an article that we got about – that was put in our packet about the states. There are a lot of states that I don't think have still passed the law. So what does that mean as far as us, and what can we do as a committee or a council to help expedite that?

MS. McGEEIN: Chris, it's all on you. You take this one; I don't want it, and I feel like this is a preview of attractions to come. At 2:00 PM, Dr. Branson from CDC will be with us to talk about testing initiatives, and once again, as I told Dr. Martin, that's an excellent question for him. But remember that there are some infrastructure issues that we – the states are independent – that we can't deal with, and especially states that only meet every other year, their legislatures only meet every other year, but that's an excellent question for Dr. Branson. And Eva is on her Blackberry right now, tell him, "Heads up, this question's coming."

Dr. Primm, how could I–

DR. PRIMM: Thank you, thank you. I don't mean to monopolize this thing. I was wondering who Bob was talking about when he was talking about supporting Lenny, and I looked around the room – (laughter) – but he was talking about Beny, really, and – (laughter) – so anyway, I want to thank you, Bob, for that. But I'm concerned about something else too. In the American Medical Association news, there is an article about routine testing making slow inroads. And one of the things that's reported here is that the National Alliance of State and Territorial AIDS Directors found the lack of funding was by far the most important reasons for physicians and other health care professionals to resist making testing more common.

And when we spoke about Gerberding funding the $45 million within CDC, it kind of shocks me that $35 million supposedly had been spent and $10 million is still there. What's happening with that money? Is – are there going to be more monies appropriated for testing so they can help physicians and these ministers and other people who want to get involved? That's really important to know if – she just found this money.

What about our own president's emergency plan for AIDS relief? Why don't we have one of those kinds of things here for domestic focus so that we can get these people

tested and get them into treatment, and so forth? We need a pep (ph) for our country. And so I think that just finding some money within CDC, that's nice, but there ought to be more monies appropriated directly for this problem because if this problem was in another community, like it is in the community from which I come, it would be a national, a national emergency and crisis for us to do something about it.

MS. McGEEIN: Really, that comment has no answer, so we would – yes, Dr. Yogev?

DR. YOGEV: Beny, with all due respect, there is a community that's already suffering, although there is the money and Congress was blocking it. It's pregnant women, and mother to child transmission – (unintelligible) – you're right, but it's your population, but I'm sure you're aware that in Ryan White was specific sanction for $30 million to be given to encourage doing testing on women, and it was blocked in the Congress and it's going to be discussed in the Senate. We support, unfortunately for quite many AIDS advocates. So I'm with you. We need to do a national something, but the fact that between ourselves, we're still fighting on this one –

MS. McGEEIN: Frieda? Dr. Bush, I am sorry.

DR. BUSH: That's okay. I just want to say I'm very appreciative of this campaign and the quality of the brochures, the attentiveness you've given to different faces and ages because it affects us all. So I just want to applaud the effort, although you've heard our questions about the mechanism of instituting it, but the effort and the brochures, I'd be proud to have these in my office.

MS. McGEEIN: We'll see if we can get you some. (Laughter.) I would love to. We have a little bit of time left, and if we have exhausted the questions from the table – well, we have one more from Dr. Redfield.

DR. REDFIELD: It's really a comment or a reaction. The – it really does, I think – it's unsettling to all of us, and I know you guys have worked very hard to try to deal with this, the 20 – now what, 22, 23 years since we had the ability to diagnose this disease. We still haven't been able to interrupt what I call unwitting transmission. A significant number of Americans still don't even know if they're infected or not. So they're not even able to make an informed decision.

I think the data has shown, although some questioned it early in the epidemic, that knowledge of infection does have an impact, and I think there's been a number of studies that the government supported to show that. One of the things to consider that I think – just throw out to take back is, rather than have a national AIDS testing day, maybe we should have a national – maybe it should be – 2008 should be the year of diagnosis, not focusing on a day, but let's say – let's escalate this to say, "We need to get this disease at least diagnosed. It's treatable. It's preventable. We want to get it diagnosed and we're going to have a testing year."

It's not just a day thing. It's not just one day a year. It's going – we're going to embrace for the entire year to try to accomplish that, and really go after this unwitting transmission. If this was multi-drug resistant tuberculosis, we would diagnose it, okay? If this was – well, we don't have it now, but just to give the analogy. For example, if this was smallpox, we'd diagnose it. The fact is, this is an illness that has all the consequences of those – and even more so. It's totally treatable and preventable, but the key to that is diagnosis.

So I think – again, I also applaud the efforts you've done over the years and continue to do, but I think maybe we need to escalate it a little now, and maybe just say, "This is it. The year 2008, we're going to get – the United States is going to eliminate ignorant transmission because we're going to let people have the benefit of knowledge because it's treatable and preventive," and really look at what the internal resourcing requirements are that actually try to facilitate the ability of the states and the cities, and the nation.

And I already argued about maybe an expanded initiative in nontraditional medical facilities that may be more comfortable for some people to get diagnosed, like the church, like the temple, like the mosques, because I think it could be no greater testimony to – from the AIDS prevention point of view to this administration. Let's get rid of unwitting transmission. Let's look at 2008 as a – as the year of diagnosis.

MS. McGEEIN: Interesting concept. We have a few minutes. We have a speaker after Christopher, but I wanted to – are there three quick questions from the audience?

Q: I just want to remind everybody that as you're talking about –

MS. McGEEIN: Wait to get to the speaker or to the –

Q: I just – I'm Frances Ashe-Goins, deputy director for the Office on Women's Health. I just wanted to remind everybody, even though you didn't say it, that nurses are a key player in the healthcare institutions, and as you're working with all the medical institutions, be sure to work with the nursing organizations also. They are key.

MR. BATES: Duly noted.

DR. PRIMM: Marty, I don't want you think greed has seized me. It has not, but I really would like some comments on my suggestion that there'd be a domestic pep for – particularly focused on this issue. And I just feel strongly, so strongly, about it and I see a groundswell, both in the Congress and among the theological population in my community, to do something about this.

And I think this administration could gain a great deal if they began to focus on it as Bob Redfield just talked about, and as I've been talking about it. And we've been together here for some 25 years ourselves, both of us. And I just don't feel that we

should just pass it off by – you didn't insult me by saying, "There's no comment," but we have a few minutes left here for Chris from 9:00 to 10:30 and maybe we could comment on that.

MS. McGEEIN: I am not at liberty to comment on the feasibility or lack of feasibility. This is something you've brought to me before at the domestic subcommittee. I understand the passion behind it. I do not – I would have to investigate the enormous amount of lift that would have to be done. I am not – not no commenting – I am not blowing it off. I am simply saying that I don't – I'm not at liberty to comment on it, but I think Dr. Bush had a comment.

DR. BUSH: My comment had to do with the idea of stamping out ignorance. So the year of – I just think that's a – a year of diagnosis would be great and who doesn't want to stamp out ignorance? So I'd even propose that as a title for the campaign. I also would like to say, when I made the comment about the pictures looking like us, all different across the ages, I recognize that some of the pictures, you can say, are more mature people, but it would be neat to have somebody with gray hair – (laughter) – perhaps Bob or – (laughter) – or Beny. (Laughter.)

MR. BATES: Okay, could I comment a little bit towards Beny's question? Dr. Primm, I think we're struggling in the department to work within the boundaries of the resources that we have to address this epidemic. I think that the CDC was quite brave in stepping up to the plate and saying, "Let's do a campaign focusing on African-Americans," in a much different way than they've done this before.

I think going across all of the CDC and looking at all of the resources they have, and how they're using those resource, and realigning those resources so that they can more effectively account for what the dollar is buying, if you will, in terms of the services related to prevention and particularly to HIV testing. I think, given a year with the evaluation piece that they have aligned with this campaign, I think we're going to see some changes.

But I think we're also going to be challenged by the fact that this is still not an easy thing to do. We have, as a major barrier, questions around the comfort level of people talking about sexual behaviors, sexual activity, substance abuse. All these things come into play and we have not always, at the local and state level, been able to force those venues for people to comfortably do this. A lot of this was done in the late '80s and I think we backed away from it and we went to TV and we went to radio and we went to print media.

But this campaign, and this epidemic, really requires a lot of highly sensitive conversations, people in very intimate settings to talk about things that are very difficult to do through the mediums that we most refer to. So I think that CDC is seriously looking at this, and they are repositioning their prevention interventions to address the epidemic, particularly as it relates to African-Americans and Latinos and in a highly different way. And I would just like to acknowledge that on their behalf.

MR. MARTIN: Chris, we all agree with you on that and what you've done, we've been quite impressed with. But there's a sentiment here of maybe – it's difficult. The resources aren't there. Maybe there is a sentiment that we, as PACHA, can help. And just hearing Bob and Beny talking, it would strike me that we should try to craft a simple – and you can't comment yet because you don't know what's going to happen – (laughter) – but to help the process happen –

MS. McGEEIN: I like my job.

MR. MARTIN: – we might as well reach across maybe our two subcommittees and craft a resolution at this meeting that we can – that we keep simple, that has that 2008 theme, and sort of gets back in a way to what we've talked about a lot and have passed resolutions on as a national plan, which we don't have; but maybe just viewing – rather than say, "We want a big national plan," maybe the resolution should be simple enough to focus on this subset of the national plan, Beny, that you and Bob could work on maybe for this meeting.

DR. PRIMM: Thank you, John.

MS. McGEEIN: If there are no further questions or comments from the table –

Q: I'm Jim Friedman. I'm the new executive director of the American Academy of HIV Medicine. I want to talk a little bit about how we are – we represent about 1,500 HIV/AIDS providers and we really are ready to get involved in this in a much more strong way. I have not been involved in the AIDS community over much of my career, but more recently, obviously, as the executive director, I have.

MS. McGEEIN: Excuse me, Jim. Is this a question about the mobilization campaign?

Q: It really is. I think there is an opportunity here to involve organizations like ours in getting that word out and utilizing our membership as a way to reach out to a variety of different groups. And I would encourage CDC and Chris and others to reach out to organizations such as ours, more proactively on this testing campaign.

MS. McGEEIN: Okay, thank you very much. Okay, one more question? Hearing none. Thank you very much, Christopher, for coming in and sharing your time with us. And the next person coming to the podium will be Miguel Gomez.

MIGUEL GOMEZ: Good morning, everyone. I think many of you know I work in the same – for Christopher in the Office of HIV/AIDS Policy and one of my responsibilities in that office is coordinating our HIV/AIDS awareness days. And today is National Latino AIDS Awareness Day. And we have with us the person who is the president of the National Latino Commission on AIDS, which worked with the Hispanic

Federation, faith leaders, civic leaders, all around the country to build a network, to create one of the most effective AIDS awareness days throughout the United States.

And what we're going to do is pretty simple this morning and we're very grateful to be able to take a few minutes of your time, is I'm going to ask Dennis to talk about what is happening with National Latino AIDS Awareness Day across the United States very briefly, and then I have a handout for you to share what we're doing here at the Department of Health and Human Services to promote awareness in the Latino community across the United States.

And Dennis again, is the president of the Latino Commission on AIDS. He has been there since 1986. Shortly after law school at Stamford, he became a – he worked in the legal field, slowly moving from California to New York to become a legal advocate. And we're really proud to have him here. And, Dennis, thank you, and here's the microphone.

DENNIS DELEON: Thank you very much, Miguel. We've enjoyed nothing but support from Miguel and from the CDC and from the Office of Minority Health. We've been doing this now for five years and we've been doing it really because the awareness of testing was just about – was low to below low in the Latino community. And the major purpose of the day really is testing, and I'm going to – you have the packets that we distribute and prepare that go to all the 1,500 participants around the country. And today, there are 240 events taking place in 15 – in 40 states. So it's a pretty widespread effort. Every jurisdiction fashions its own activities if they – and a lot of them rely upon the website.

And what I want to do is spend a couple of minutes just describing to you how we use the web, and how the web can be a key partner in these mass mobilizations because the technology is there. You just have to learn how to use it and both the providers and also the community, and we've been very successful because this year most of our involvement came through the web.

In addition to the web, though, we also have a national advisory committee which meets on a biweekly basis, starting in March, and we have groups that have come together in different areas of the country. Different community based organizations are oftentimes at war with each other over funding because they're forced into such few funds. What National Latino AIDS Awareness Day, NLAAD, has done is to bring these groups together around a common objective. So we now have, for example, in Northern Virginia and Maryland, we have a combined effort with the D.C. Department of Health where they're working together and that's – that to me is a great deal of success. Los Angeles, we have groups that don't talk to each other working together to promote testing on this day and this period of time.

Now, the basic homepage is – it introduces you to the day and if I could leave the mike for a minute – the basic – here outlines testing. It outlines the sample poster, which you can obtain and the way to go from this page to a Spanish language page is to click

the top corner of the page which says "Espanol" and – next slide, you go to a Spanish version of the home page. And there, you see a person can register to become a participant. And additionally, below the red box, you have actual news about National Latino AIDS Awareness Day.

And below that box, you have multimedia resources. And below that box, you have actually multimedia, and then you have testimony, testimonials, people who have lived with the disease, the role of – how testing played a vital role in their becoming healthy. And those testimonials become very important because when media calls and they want comments on the day, or they want to connect to our local group, testimonials like these things are very, very important to have.

The next slide is the planning. If you look over the top – the bars across the top, we have planning. And this is just one of the planning pages, but it tells people how to organize a local coalition around HIV testing for National Latino AIDS Awareness Day. And we walk them through it in Spanish and in English.

This then leads to the next slide, which is a multimedia – which is, I'm sorry, the resources, of which we have them all listed there, and there really are quite a few resources, most of which are available in Spanish. We wish there were more and people have a wide – they can just download it and they can fashion it to their own jurisdiction. Our name, the Latino Commission on AIDS name doesn't appear on anything. Basically, they can make it their own literature.

The next slide shows multimedia. We have a variety of PSAs that they can download, and I'll show you how in a second. The PSAs were made by Cable Positive, by NBC, Universal, Telemundo, and these PSAs can be either forwarded to a friend, tell a friend or they can be downloaded to the purple bar up on top there. And then we have over on the far – your far right, photographs of actual events that took place in the previous year.

Next slide – the purpose of showing pictures of actual NLAAD events is that people have a sense of what can be done because no one – sometimes people call us and they don't know what to do. And through photographs and through technical assistance, we can suggest ideas within their resources in different cities. Los Angeles spent $200,000 on a bus campaign to coincide with this. Miami did a massive campaign throughout the state, about 25 myths related to HIV. So local health departments are buying into this also and encouraging testing, addressing the things that prevent people from getting tested.

Next slide, please. Next slide, please. They key thing – anyway, go back, yes. The key thing is the red box, the event search. If you click search, you're going to – next slide – you're going to get all the events, and this year, we have all the events listed. And you can just click on an event and you actually find out what's happening in Pittsburgh at this one event in – I'm sorry – Pittsburgh, California and Martinez, California. And so – and the group locally, they can basically choose to create a user account. So – next slide,

real quick – "Join NLAAD." There you can register and basically, you can modify your event. Next slide. You can register – next slide – and here you can select and describe your event. You can pick a poster. And then you can conform that poster to your event. And then you can describe the event, and then you can go back to this page and modify this event. Next slide. Next slide. This is also part of organizing events. The key thing here is the – I'm getting somewhere out of whack everything.

MR. GOMEZ: Well, actually, Dennis, I think I can help because one of the things I want to make sure is that people have a chance to ask you some questions.

MR. DELEON: Okay, let me just – can I have more with that? This is an example of one city. This is Contra Costa County in California. This is all the events happening in Contra Costa, California, and they're listed, and you can – the person who has a password can edit, can delete, and can preview the events in that area, and can edit those events. Next slide. And lastly, this is an example of the District of Columbia. They have a variety of events and this is – basically, these events can be registered on the site through these means. Next slide. Events that are registered, these are more examples of events that can be registered.

Next slide. Lastly, NLAAD is a – this website is a vital resource in the effort to mobilize a community because if the local jurisdictions don't have control over what's being said about their event, if they can't modify things at the last minute about a different location for something, then the media cannot connect to it. They cannot connect to it.

For example, we have 33 faith communities in New York City. We're doing testing today at 33 locations of Spanish-speaking faith communities, and we're – and those are all listed on our – on this website. Some things may change and the media may want to cover one of those things, and this is how the media connects to what's happening in the field.

A really well articulated web presence is truly important. We were helped a great deal by the CDC. We were helped a great deal by OMH and by Miguel's office to develop a really vibrant tool, which I think is going to be very important for the campaign that Chris is trying to do because the web part of the campaign is really essential in terms of maintaining a timely resource for that kind of activity.

MR. GOMEZ: Great, and stay just for a second, Dennis, because mine is really short and I really – why I said I wanted to help you, Dennis, is because I've been coordinating HIV/AIDS awareness days for several years now. And one of the things that I realized is what Dennis pointed out, if you do not use your webpage effectively and do an assessment that people can actually use it and do usability assessment, you're not helping the community.

And that's why I stated the Latino Commission on AIDS, along with others, has one of the most successful days. But I'm very proud here at HHS, I'm going to have a

handout for you all, and for those in the audience, it's on the table. It's very simply from Dr. Fauci at NIH to Dr. Graham at OMH; they are all involved in media activities. At the CDC today, we have finished doing a radio media tour. There's a new MMWR and throughout the country, we've been offering technical assistance to help organizations augment their use of Web 2.0 tools. So if you want more information, you go to AIDS.gov. I want to thank you, and if you have any questions, just let us know. Any questions?

MS. McGEEIN: Thanks to both of you. We've got just a few minutes. Okay. Dr. Green.

DR. GREEN: Yes, just a quick question. Hearing about Latino programs in HIV/AIDS, I found myself wondering about just in our hemisphere, we have daily speakers of Portuguese, French, and Dutch and various Creoles. I just wonder what's available in languages other than English and Spanish.

MR. DELEON: We don't have Portuguese. We don't have – we do have English and Spanish. That's kind of the profile in the United States. This is not meant to be an international campaign.

DR. GREEN: Well, there's quite a few Brazilians and Haitians and native speakers of other languages in the United States. That's –

MR. DELEON: Well, everybody does what they're competent at, and we're not competent at reaching the Haitian community and the Brazilian community.

DR. PRIMM: I have a comment, Dennis, and first of all, let me congratulate the Latino Commission on AIDS and all that you all do because it's really tremendous. And I – to piggyback on Bob Redfield's support and his suggestion that instead of this being a one day situation in the country, that that ought to be 365 days a year, with what's happening in your community and my community. We need this focus instead of having it just one day, it should be every day. And I think these rifle shots are great, but we need a sustained thrust at this problem unless we are not going to be successful. And I congratulate you on what you've done so far, but hopefully, you and I can work together to try to help expand it.

MR. DELEON: I hope so and I hope that there's wisdom in the White House about – it's not just – it's a problem also among Latinos. Latinos are also affected and attention is paid to the need for testing Latinos.

DR. PRIMM: As you know, I've been a proponent in this committee for doing something in Puerto Rico and the Caribbean, and you and I have talked about that. I think that, in itself, because of what's happening in Puerto Rico and New York and the relationship is enough to make us refocus on these two areas in a different kind of way.

MS. McGEEIN: Okay, thank you, Mr. DeLeon for joining us today. I appreciate it. We are about to take a break. I understand that the coffee is hot and the food is hot. I think it's – although now Nancy's shaking her head, no. (Laughter.) Please tell me the food is –

MS. : (Off mike.)

MS. McGEEIN: Okay. So let's take probably a 20-minute break and be back. We'll have our panel.

(Break.)

MS. MCGEEIN: Close, but no cigar yet. Tic-tac?

Okay. Our next presentations is a panel discussion on insurance reimbursement policies for HIV testing, and I am going to hand this over – the moderating duties over to Carl Schmid, who is the chair of the domestic subcommittee.

MR. SCHMID: Good morning. We've already touched on this important issue already this morning, and as everyone knows, the CDC last September issued recommendations that – that asked people to be tested between the ages of 13 and 64, routine opt-out testing in healthcare settings. And it's a goal that we're all working towards and we've already discussed this morning some of those barriers to implementing that.

And this afternoon, Dr. Branson's going to give implementation update, but one of the biggest barriers that we've identified is the whole reimbursement issue and who's going to pay for all these tests every time someone goes to a medical – a doctor's office, an emergency room to get tested in that routine way. We – we've heard that there is some money for – in the public healthcare settings that CDC is supplying. There's also some private money that's out there as well to ensure that people get tested. But if we're really going to have routine testing, opt-out testing in healthcare settings, this reimbursement issue is going to have to be tackled.

And so I'm very pleased that we have three gentlemen who are representing some of the – the largest reimbursers in the country, and that is the CMS that handles Medicaid and Medicare, and then we have two representatives of very large private insurance companies. So I'm going to quickly go through their bios and then we'll have each of them present their remarks and then we'll open it up for questions and answers.

But first, from CMS is Joe Razes. He is senior technical advisor for the Centers for Medicare and Medicaid Services. He's responsible for leading the team that is implementing the health-related portions of the Ticket to Work and Work Incentives Improvement Act legislation. He is also one of CMS's point people on HIV/AIDS issues.

Secondly, we have Dr. Andrew Baskin. He has been employed with Aetna since 1998, where his current position is national medical director for medical policy and program support. Some of his current activities include oversight and support for development in the implementation of medical policy, including regarding medical necessity of new technology in specialized services, reimbursement, and coding policies, as well as disease management, wellness programs and medical plan and benefit designs.

And then we have Dr. Robert Thomas with CareFirst BlueCross and BlueShield. Dr. Thomas' responsibilities include the overseeing medical management, utilization management and case management appeals process, quality in credentialing for the Maryland as well as the national capital area plans. In addition, he is an advocate for the network positions within the structure of CareFirst.

So first of all, I'd like to thank all of you for being here today and we look forward to your presentations. And we'll begin with you, Joe.

JOSEPH RAZES: Okay. Thanks very much, Carl. Thank you very much, Carl. Okay, as Carl mentioned, I'm one of the point people at the Center for Medicare and Medicaid Services, the folks that bring you the Medicare and Medicaid programs. I want to – I will talk just briefly about the Medicare and Medicaid and then the issue of routine testing for this, from the federal perspective. Should be a lively discussion here. (Laughter.)

Okay. Medicare, most you folks in the room are aware of our programs. Medicare is the program that provides medical services primarily for individuals over 65. Also, it provides Medicare for individuals who have end-stage renal disease and also individuals who are disabled. There's a two-year waiting period, but if they're disabled according to the social security definitions. So basically, that's the group under Medicare that is covered.

Now, with respect to the payment for testing, it is paid for by Medicare, but it again has to be ordered by the treating physician. In general, Medicare, because of the age characteristic of the populations, there has not been a large incidence of HIV/AIDS-related findings, but that's increasing somewhat, but it's a relatively small proportion in relation to the entire Medicare program.

So moving on to Medicaid, again, Medicaid is a state federal program which provides healthcare for low-income or no income individuals. There are a number of required services that states must provide. Lab services is one of those five services. Under those laboratory services, states have the option and do provide for – the screening for HIV, but again, it's not on a routine basis. It's based on the potential risk and an order by a physician. So it is not part of a general panel tests for the most part – or I'm not sure – I'm not aware of any state that has it as a general panel test.

Reimbursement for – for this service is usually tied to Medicare reimbursement. Most states follow reimbursement for physician, hospital, laboratory services, but they

often will reimburse at a percent of the Medicare. They can – by law, they cannot pay more than what Medicare pays for – that choosing not an issue. States are – because they can't print their own money, they're looking to try to save money. So they usually pay a percentage of the Medicare reimbursement rates and they can go as low as 80 percent of the Medicare rate, which some would argue, is not generous to begin with. So – let's – but again, as I say, this is a state federal partnership. The federal government does not require states or mandate states provide HIV testing as on a routine basis.

So we get into this issue of routine testing and I want to call your attention to a fact sheet – am I working? Am I too – am I too –? There – a victim of technology here. I want to call your attention to a study that's on the table out front there. It's – it's an (APE ?) – it's Study of Majority of States Bar HIV Tests, and it provides a good – yes, okay, folks, have seen – it provides a good overview of this particular issue, but again, on the Medicaid side, there is no requirement for this. There have been discussions. I know the Center for Disease Control has tried to – has been promoting this particular issue. We get in – at CMS, a number of folks on the coverage side, on the policy side, on the reimbursement side were well aware of this initiative, but again, part of the problem comes down to – we've got states that require – that have laws that require informed consent. We've got – some states have laws with respect to counseling, post-testing counseling. We've got issues with patients who are embarrassed by this. They don't want others to know about it. They're in denial. They are concerned about the potential job loss if this gets out or even with their relationships.

So best to sum this up, again, it's a state federal relationship. We do – we – Medicaid requires the states to cover laboratory services, but the states, in essence, have a broad latitude in terms of determining what they will cover: the circumstances, the frequency of those services. So that's a general background for the discussions here today, at least from my perspective, but we'll get into it later, I guess.

MR. SCHMID: Thanks Joe. Dr. Baskin?

ANDREW BASKIN: Thank you. I was asked to make a few remarks and I was kind of given an open slate there. I was just saying that you're representing the private commercial insurance industry and perhaps talk about the reimbursement and – for this type of testing. But as I was thinking about that, I'll be honest with you, I had a couple of thoughts, and one of them really just came yesterday afternoon when I was driving with my two daughters, 19 and 17 years old. Spontaneously, their conversation was discussing about Gardasil and HPV and getting a vaccine, and how their friends were going to get a vaccine. It's a conversation that, when I was in practice, of course, eight or nine years ago, was almost unheard of. This is an open conversation. They had no qualms about discussing it between them and no problems about discussing it with their father. I don't see that same conversation happening with HIV. And yet HIV has been an issue for a lot – well, not a lot longer, but certainly a much more serious issue for a lot longer and involving a lot more people than HPV in terms of mortality. So that was very telling to me.

By the same token, the pharmaceutical industry has been marketing wizards. Let's face it. It's easy to talk about the HPV and erectile dysfunction, another one sexual disease that doctors are afraid to ask their patients about when they're in the office, but it's common conversation at the dinner table. Once again, HIV has not been that. And the reason I say this is because that – that kind of image or that marketing issue goes beyond just the patient community. To be honest with you, it goes to the physician community and it goes to the insurance community and basically all – everybody that's part of healthcare. I would say that even within the insurance community, we're perhaps guilty of not feeling comfortable about this particular problem.

That being said, I also went online last night to the site that was around this organization here and was very surprised to know that today was National Latino AIDS Awareness Day. I had no clue and I'm in the healthcare industry for the last 25 years. I also didn't know that there were monthly days for the last six months, for other AIDS awareness-related issues. So once again, that's not something that's – that's common knowledge even within my own industry necessarily. So that message isn't getting everywhere.

As far as reimbursement issues, as far as coverage for this type of testing, when the CDC made its recommendations, I guess in September of 2006, it was soon thereafter, at least in my company, and I presume most companies easily adopted that as a covered benefit. No problem. It's a preventive testing and it is covered the same way that any other preventive test, as simple as a lipid panel, or a gonorrhea culture, or any such test.

Interesting enough, it's also at least in our company it's been categorized as what we call a preventive test – for those of you who are more familiar with insurance, there are certainly insurance policies that segregate out preventive testing versus general medical testing, and that there may be actually better benefits for people with preventive testing. And this has been listed as a preventive test for our company. It's interesting that most companies, I think, that I hear about when I get out talking to my colleagues elsewhere, do follow the United States Preventive Services Task Force recommendations for all testing. This is one of the few times, to be honest with you, that we went beyond that as soon as the CDC made the recommendation. We did not wait for that general adoption to be made by the United States Preventive Services Task Force, and felt that this was important enough that we would just go ahead and open the policy, immediately consider this a preventive test and therefore fully covered.

As far as I know, in my company and once again with my colleagues, I don't know of any particular payment policies that would put any barrier to anyone getting this test in whatever venue that they – that they get it as long as it's performed in a medical setting. Admittedly, home testing which could potentially be purchased over the counter is not something that's usually insurance-covered, but certainly the usual blood test and the newer oral swab and the finger-stick test are covered equally so.

One of the – one of the things I do want to mention before I pass it on to Robert is that when this CDC recommendation came out last year, I am on the committee that does develop our clinical policies, our medical policies which determine what's covered and what's not and under what circumstances. It was interesting that it was a little bit confusing in that the recommendation is kind of nebulous, kind of a generic recommendation. It's not – it's not like the – pardon me – the American Gastroenterological Association came out and said that you should have a colonoscopy every ten years, a very objective number, something that people can latch on to.

It's very confusing to say that the general recommendation for everyone 13 to 64 years old to get this testing done in a medical setting. The first question that came off: well, how often? You know, every encounter? When you come in for a cold, or when you come in for your annual physical? I mean, it's not tied to anything. Pap test is tied to an annual examination that a woman gets. Vaccinations are tied to – to get in to school at certain ages, or at certain pediatric checkups which are very much timed. This is a very general recommendation, and frankly, while we – while we easily adopted it, it's very hard to get the message out there to anybody to do it because it is – it's not a very concrete recommendation, not very objective. And frankly, what we hear back from the – (unintelligible) – community is they're little unsure as to – as to whether this really meant everybody, every time or something less than that. And that confusion, I think, does make it a little more difficult to get this message across.

Thank you.

ROBERT THOMAS: I'm Robert Thomas of the CareFirst BlueCross – oh, sorry. There it is. Hi, I'm Robert Thomas, CareFirst BlueCross and BlueShield Association. We have absolutely no barrier to HIV preventive testing. It's – it again – Andrew Baskin stole my thunder, but we consider it just like any other test, just hyperlipidemia and diabetes – even level A1C, any type of test. We don't – we follow the CDC guidelines in a parallel fashion. We reprinted them on our website. It's super transparent, really easy to use, the website, and we've also gone into conjunction with the – (unintelligible) – clinic here to just purchase an outreach van and goes to just all parts of the city, and I think outlying counties to just recommend and encourage the oral HIV testings. So – not just for CareFirst BlueCross and BlueShield members, but for all people. And every time I see that van, I get – I'm kind of proud because there's so much negativity about the medical insurance industry, but that is something that CareFirst has gone into.

Let me see what else to say. And – our post-testing, we also just recommend HIV -experienced physicians have just a printed list for just members who test positive and then later just progress with the disease, et cetera.

But that's all I have to say. We have – we want no barrier for HIV preventive testing. Thank you.

MR. SCHMID: Well, that was easy, and thank you for the good news. (Laughter.) I have, I guess, two questions, then we'll open up as well. I guess for the

private insurers, that's excellent news, what if the state covers – requires prevention and counseling, and that's probably an additional code, would you cover that as well?

MR. THOMAS: You're talking on ENM codes, a certain type of coding, complexity of care. When a patient goes to a physician, there are ways to code of the encounter, of somebody coming in for a Pap test or a routine of a blood pressure check, there is a certain code for that. Paying for other physicians – it's not just about paying for gastric bypass surgeries and these expensive surgical procedures, but we want to also encourage physicians that – spend time with your patients and then have complex care patients, such as HIV positive patients, or this HIV encounter to just code appropriately, and we reimburse those codes, so you know, something about coding and then paying for the physician's mental time. I forgot to turn my microphone off. (Laughter.)

MR. BASKIN: I might add – yes, it's the same thing. There are – there are ways to bill for preventive services counseling whether it'd be a separate – a separate service in and of itself along with the testing, or whether it'd be included in some other examination that you're doing and those are fully reimbursable. There isn't a barrier to that.

MR. SCHMID: Okay, Joe. (Laughs.) How can – how can we get Medicaid to cover routine testing? Is it a directive? Is it a congressional law? What are the avenues to make that happen?

MR. RAZES: Good question, Carl. (Laughter.) Well, obviously a law is one way to do it if you could get – get that passed. I do believe that there may be some resistance on the part of the states on that. So it's – while that may be an easy way to go, I think the approach that CDC is taking in terms of coming up with an initiative and trying to push the benefits of it, is certainly another way to go. Some education on the part of the states is something to do – is a good approach as well, probably better from the ground up rather than the top down, but I think it's not just a reimbursement issue, and that's why I think that CDC, the work that they've done is good and this needs to be promoted, adopted, incorporated at the local level because of the ramifications that I mentioned a little bit earlier about – and Dr. Baskin was even talking about, his daughter is talking about.

You know, one thing – but when it comes to AIDS, it's sort of like a double disability or double negative in terms of the thing that we're dealing with, the disease we're dealing with here. And again, people don't want to know, they don't – they are concerned about their jobs, their relationships, and I think for the states, it's a money thing. States are always trying to find ways to reduce cost. If you're taking about reimbursing for the actual (penile ?) test, then you're also talking about the ENM codes because you're going to have to have post-counseling to boot.

I want to bring up – again, with respect to the loaded nature of this, why I would suggest that we do try to push it from – from the ground up, or at least give the states and the public an opportunity to incorporate this. A few years back, my wife had some testing and there was a positive for a sexually transmitted disease. Okay, all right, that

was not good. That came on a Friday and then Joe's got to explain his behavior – (laughter) – the lab – the doctor's office is closed at 5:00. We get home. We looked at this at 6:00. It wasn't the greatest of weekends, but we've had a good relationship and that was good. Monday, you know, right in there calling, and when we explained it, they checked into it: oh, it was a mistake.

Okay, well, it's good – people aren't allowed to carry guns because I would have liked to have shot somebody – (laughter) – but I mean, this is – this is – I mean, can you imagine if somebody would get this that wasn't having the greatest relationship, or there were lot of tensions there, maybe somebody was unemployed and there were lots of other factors? To get this kind of information, or maybe it came to me directly and I left it out, or somebody else, the significant other found this and saw – it's just one of these types of issues, AIDS is one of these issues. It's not strictly a reimbursement issue.

So I guess to answer your question, I would endorse what CDC is doing, try to get some involvement from the ground up to do this. And it looks like there is some success here, but again, when you're dealing with a social issue like this, nothing is going to happen quickly.

MR. SCHMID: Okay. So is the administration in support then of having this covered by Medicaid? It sounds like you're putting the opposition to the state. So does that mean that the administration is supportive of it?

MR. RAZES: Well, the administration's supporting CDC's efforts presumably. I am not – I'm not sure what CMS's – well, CMC's position is – we're leaving up to the states is basically. It's a state federal partnership. We're leaving it so punting, I guess, in some respects. But again, we do respect the states rights in terms of what they cover and the conditions under which they cover it.

DR. GREEN: Yes, if I may – I'll pose a general question. I work in Global AIDS Africa, Asia – (unintelligible) – so I don't know the U.S. data very well. One of the arguments for promoting testing, in addition to getting people the treatment, who need treatment, is to hopefully testing and counseling impact people's sexual behavior. There's a widespread belief in Global AIDS that testing leads to positive changes in sexual behavior, whether people test positive or negative. I'm not sure the evidence supports that, but there's a widespread belief. So my question is – and I don't know if you gentlemen know – but what do we know empirically about any impact on behavior from testing?

DR. MALEBRANCHE: I can actually answer that. There's plenty of literature in the United States that actually speaks to that. Yeah, it's not just a global thing, but in the United States, with several different groups, regardless of income or sexual behavior, so on and so forth, it's found that HIV testing encourages – if someone finds out they're positive, they're more likely to engage in safer sex. So we've been doing that for a while here in the States.

MR. SCHMID: Dr. Redfield?

DR. REDFIELD: I wanted to try to – maybe one of the two of you or maybe yourself, Andrew, first, I want to get down to the specifics because I still feel that this cost reimbursement is an obstacle to the implementation particularly. And when I look at the cost, there is the cost of pretest counseling, for example, in the state of Maryland where we practice, about 4,500 patients in our population with HIV infection, there's a cost of the actual test and there is a cost of posttest counseling. There is a professional cost and being regulated in facilities like we are, there's a facility fee cost. So I – it'd be useful to me – you might not be able to answer it here, but I'd really like to see how Aetna and how Blue Cross, Blue Shield in particular, and if it's also the case for the federal government's Medicaid program in particular. How it – Medicare and Medicaid, how it compensates for those real costs because my – in terms of reimbursement – because my view right now is that the current reimbursement, the actual money that get reimbursed for doing pretest counseling and posttest counseling, the professional cost, the facility fees doesn't pay for the cost, the actual cost of doing it.

So again, I may be misunderstanding this because I can – in our own – in our own marketplace and it does seem to be an enormous disincentive for some of the major hospitals from more widely introducing this. So I'm a great educator. So if you can give me the actual data that it actually does, there's a way to bill for this and it actually – you don't lose money, I'd like to educate the hospital systems in Baltimore that they actually are faults in their claim, that they lose money by providing the service. So I'd like to get a sense, you know, how do you bill to get the pretest counseling, which may be five to ten minutes of professional time, posttest counseling, five to ten minutes of professional time, the test, the facility fee. How do you bill for that? Because what I usually see is the test gets reimbursed, but I don't see – I haven't seen how everyone else is getting the professional time, facility fee reimbursed because – and so if I'm mistaken, I'd like to learn so I can teach people differently so.

MR. BASKIN: A very complex question and the reason it's complex is because these – the tests can be obtained in so many different settings. So it would be a very different answer whether the test is obtained in the doctor's office, whether the test is obtained by the doctor seeing it and sending it to the laboratory, whether the test is obtained in an outpatient department of a hospital or an outpatient laboratory of a hospital, whether it'd be obtained as inpatient, so –

DR. REDFIELD: Maybe for me, if you could just focus down on whether it's done in an outpatient clinic affiliated with a hospital.

MR. BASKIN: And there are permutations and combinations there. Certainly, there are people that are sent to an outpatient department of a hospital, obviously, not the preferable way, by the way. We'd rather people be hooked up through their medical home, which is theoretically a physician's office, which would be the best way to go, and in fact, that's an easy reimbursement answer because there are specific codes to bill for that and that's reimbursed and it's pretty fluid there.

In a hospital outpatient setting, it's a little tricky. Certainly, the test itself, the technical blood test and the result of it is easy. It's a simple code known to the insurance company. The insurance company pays the bill, that's –

DR. REDFIELD: And the lab gets the money, there's no question of that –

MR. BASKIN: The lab or the hospital gets the money. Now, the problem is that in a hospital setting, a lot of it has to do with the type of contract the insurer may have with the hospital, which can take many, many different forms. Some contracts are more all inclusive and some contracts are very piecemeal. In other words, you bill for every bit of a service rather than a global reimbursement.

And the other problem is who at the hospital would be doing the counseling. In other words, are you talking about a physician, a certain – if a physician at a facility did pretest counseling or posttest counseling, the physician can submit that bill, either on their own or as an employee of the hospital, depending on their situation. So that would be probably analogous to being done in your office, to be honest with you.

Now, the question becomes if a non-physician did the pretest counseling, in most – in many situations or many states, a non-physician, not under the tax, the physician can't even bill for the service. So if a bill doesn't come in, it can't get paid, and there's no direct, in many instances contracting with a non-physician at a facility. So I would say that in those instances, those people usually employed by a hospital and in fact, that the reimbursement for the test would be including the services of their employee, which would be the non-physician, whether it'd be a nurse or some other type counselor.

And then the next argument would be, well, what's the relationship with the hospital in terms of how much they're getting paid, does it reimburse them enough for that service or not. Frankly, in my nine years with the insurance industry, it's never been – I've never had that complaint – that the hospital was complaining about being under-reimbursed for and HIV test.

DR. REDFIELD: I'm just going to come back as a user. It's not going to be solved probably. But maybe I can learn more about the codes. I think you pointed it out that the laboratory always gets reimbursed for the cost of the tests, and they've negotiated whether it's, with any three of your groups, what the discounted price is going to be in the test. And I guarantee you it covers costs. Otherwise the laboratory wouldn't be doing the business, okay? And it even gives the pathologist a little chunk of change for signing his name at the bottom of it.

But the reality is there's really no mechanism, particularly for those services like that where someone would come in and again, we run a number of clinics in a variety of different settings in Baltimore. They would come in and want to have an HIV test as part of their evaluation, say, they've a partner or someone who's HIV-infected or something. That again, to get the reimbursement for the facility fee or the nursing time or the

physician is something that's not operationally occurring. I mean, whether those mechanisms – it's just not occurring, and as a consequence – I've got a lot of pride for (Harvard ?) for what they've done, okay? But most hospitals had not taken to integrate the CDC's recommendations in its current form, even if we're restricted by pre- and posttest counseling consent signing, I want to argue, because of the financial realities of it.

At this stage in the game, no one's paying for that 20-minute of that nurse's time, or that ten minutes of that doctor's time, and as a consequence, no one's trying to encourage a broader implementation of this policy. And again, it's not just the uninsured population that this isn't happening for because I think it's not happening – sure, if you go in for a general physical exam and in the context of that, the doctor charges whatever he charges for a general physical exam in the context he does the HIV. That's – that's going to be covered, and I can understand how that's rolled into the benefit. But if we're doing a targeted effort to try to get an enormous number of people to come forward and get diagnosed in the context, and now we're adding a significant engagement, most clinical interactions in many of these practices are not more than ten,15 minutes. That's a clinical interaction. And now you're adding another ten to 15 minutes of a clinical interaction of some healthcare professional. I think this is what the disconnect has been.

We said we want to do something, but we haven't figured out ahead of time that it has enough value that we want to pay for it, either through our insurance mechanisms or through our federal and public support. So I'm still going to take the point of view, and I'd be glad to have information that you can give us some time in the weeks ahead that this is still a major obstacle, that reimbursement isn't a solved issue in terms of the operationalization of HIV testing in the community. It may – you may think it is, but I don't see it. I don't see it from the side that we're functioning.

MR. THOMAS: I've never experienced – you know, this is the first time this has come to my knowledge. Hospital contracting in Maryland is complex, multilayered, aggressive, and hospital outpatient testing – the optimum of scenario is for a patient to go to their primary care physician, and as I said physician and not provider. And so this testing occurring in hospital outpatient facilities and hospitals' problems getting this reimbursed, I have – I've been working with Blue Cross and Blue Shield for about ten years, and this is – I've never been made aware of this, and I've never experienced this. And if you – if you have some type of scenario, some type of hospital situation, e-mail me – at doctor – www.robert.thomas.com, carefirst.com. But I had never seen this before. I'm kind of confused. I don't know if this is about – for nurse counseling that's not being paid for, or some other situation –

DR. REDFIELD: I think it'd be useful for me –

MR. THOMAS: Totally confused me –

DR. REDFIELD: – yeah, I think get the billing codes to see, because again, it's maybe unique to the hospital-based practices that we deal with, but – and again, it has –

maybe you deal with contracts, say, the hospitals that I work with have with Blue Cross, Blue Shield or Aetna and others, that these are not reimbursable events, but the reality is, I haven't seen evidence in our situation that these are compensated events for the professional time required, whether it's nursing time – in general, it is nursing time. And it sort of just rolled in to the cost of doing business.

And I think it's had – it has a disincentive that if institutions, again – if we could align our public health interest with the ability of the institutions to see that it's also not in their negative interest from a financial perspective, this would happen very easily. If you try to roll out policies, and that institutions see – have a negative financial consequence on them, they don't move out as fast. I mean, we've seen the same thing in our PEPBAR programs. Those hospitals that have expanded PEPBAR care to say 100, 200, 500 people and found that it causes their hospital to lose money, don't want to expand. Those hospitals that learn how to take the advantage of the PEPBAR program to provide great care for people and strengthen their system, want to do more. And I think there still is this issue with these isolated testing events that we're trying to expand in all these clinical settings. Like you said, let's add it on to all these clinical settings. But how do we get it on and get reimbursed beyond the cost of the test? And I've seen the cost of the test reimbursed, but I haven't seen beyond the cost of the test reimbursed.

MR. SCHMID: Dr. Yogev?

DR. YOGEV: I just want to follow on Dr. Redfield's point. What unfortunately unique about this test is the counseling. See, when I sit in my office and I do CBC and a lipid and everything, I don't tell patient why I have to do it. This is a standard of care. I do talk to them when an abnormal result arrive. Over here, by law, I have to spend time in a different state, it's shorter or longer, before I even do the test. In some state, we still have to go and sign in on a consent form which takes the time. That's the time which we're talking about and because of that we shy away from it because it's not a law. So it's – this disease is a political entity more than a disease, and you're treating it as a disease and you pay for the test and thank you very much. And that's the issue that needs to be resolved.

But let me ask a couple of questions, because I think you're taking advantage of the – what's going on, and I hope I'm wrong. But let me tell you that when I go to clean my teeth one day before the six months that you imposed on, I have to pay for it because you say it's six months and it was only 179 days. The word that CDC put it out unfortunately is really to initiate the process because that's so many we don't do, but never told us how often can be done. And at least in Illinois, I chat with four of the companies and none of them is saying how often I can repeat the test, and that's an issue because people who are sexually active can get it in the next act, and we need to put it into some kind of cycle.

So I would appreciate your respond to that. And last, because it's almost the same branch, unfortunately the CDC said 13 to 64. I'm 65. I'm still sexually active.

(Laughter.) You're not going to reimburse me for the test because you're going to do just 13 to 64.

MR. : (Off mike, laughter.)

DR. YOGEV: Oh, thank you. I always like – (laughter) – the point is – the point is really, I'm a pediatrician. I want to look from the other side. We have, unfortunately, girls less than 13 years and obviously, boys who are becoming pregnant. And I was wondering if you would expand on sexually active period of life, or you're going to follow strictly all that CDC recommended because you like to do that, and then unfortunately we take a big part of the population that we need to check.

DR. BASKIN: I'll respond to that and if Robert wants to add something, I suspect it's going to be the same answer, and that is that you can order this test, perform this test as frequently as you feel it's medically necessary. There's no barrier in my company to the frequency that you order the test. And secondly, while the CDC made a recommendation, which we have adopted, from age 13 to 64, there's no barrier if you're ordering this test on anyone from birth until – until death. There is no age limits in our system that would stop this test from being paid for when you order it. So – not – a non-issue from my point of view.

MR. THOMAS: Also a non-issue, and we'll reimburse your physician time appropriately for the counseling each and every time you'd order that test, there is no set of a barrier or limitation on the amount of time you can order that test.

DR. YOGEV: I hope there is a hardcopy of this meeting, so I can take it to my state and show it to the people over there.

MR. : (Off mike.)

DR. YOGEV: Yes – (laughter) – because it's – I can tell you that we refused on a 12-year-old. That's why I was raising the issue, but it's good to know. And you don't represent –

MR. : (Off mike.)

DR. YOGEV: That's why I say you don't represent –

MR. THOMAS: That's tacky, and that's –

DR. YOGEV: Thank you.

MR. THOMAS: Guidelines are guidelines, not set in stone, but if a physician would send this – you know, would – that's a very appealable kind of issue, but that is a tacky gesture not to appeal if there was a 12-year-old girl who was sexually active. You order the HIV test and it's denied – it's denied obviously from a computer set point

maybe, but just – that would be a very appealable decision and we would not – I just find that not appropriate.

DR. PRIMM: I have – I'm sorry – David.

DR. BUSH: I have a – I guess a couple of questions which I think you've touched on with that last answer, but part of mine is that Blue Cross, Blue Shield is not universal, that there is different Blue Cross – Blues, as they say, geographically. And my question is do you all have a universal policy because my experience has been locally in Mississippi that they have, like, a Healthy U that is annually that is designated and they will reimburse based on what's designated as part of the Healthy U, and if you order something else outside of that, whether it's based on risk, or just the patient wants it, or you have read the CDC guidelines and think all people should get it, that it's not reimbursed and the patients say, well, I'll have to pay for this out of pocket, therefore, I'll come back and get it. So my question is you sound really great, but is that universal across all Blues, and what can we do especially, like I said, when there is a risk or something that we identify?

MR. THOMAS: I'm not a Blue Cross and Blue Shield associate. I'm – I would work for CareFirst – CareFirst/Blue Cross, Blue Shield. I think there're multiple Blue Cross and Blue Shields in the United States. It's a franchise, not like Mickey D's, but nevertheless we have national guidelines, www.bcbs.com, and as far as I'm aware, those guidelines – we do recommend preventive testing. What happens in Mississippi – I'm just quite surprised at that. I don't know – that's confusing for me, I mean, because our national guidelines – we follow the CDC's obvious recommendation. So if you could – you could – you could send me some information on that, but I didn't know in Mississippi, they're not – not covering HIV testing for sexually active adults.

DR. BUSH: It's not listed on the – you know, like, with the lipid panel and the things like that, so – the other question that I had to do with the actual cost of the test being reimbursed versus what is it that you have identified as your reimbursement, and the – whether you had any idea – so that's one thing, the actual cost of the test being totally, completely reimbursed in the private doctor's office, what we would charge for it. And the other had to do with the sense that you would have for other insurances besides the Blues and Aetnas, as you're sitting here, other private.

MR. THOMAS: What's the question again? And I think Andrew would love to answer it. (Laughter.)

DR. BUSH: Oh, okay. Well, the actual cost in the private doctor's office, similar to what Dr. Redfield was saying, versus what you have determined you will reimburse. And then the second question was if you had a sense of other private insurance carriers beside the Blues and the Aetnas that are sitting here before us?

MR. BASKIN: So – so you're looking for the actual dollars paid to the doctor's office? I mean, are you looking for a dollar amount? I guess – I'm unclear, to me.

DR. REDFIELD: I think it's sort of similar to my question, but I didn't know if you'd answer it here or you'd have to send this stuff, but it's – you all must have determined what the actual cost is, the real true cost, what the cost to do totally, and you also determined what you've agreed to reimburse.

MR. BASKIN: Well, the reimbursement, as we stated, is broken up into pieces. In other words, you bill for the test itself, which is just technologically, the – you know, you take the blood and run it through whatever machine or whatever testing procedure as you go through to do the test, unless it's one of the point of service tests, then presumably it gets sent to a laboratory, in which case, then the laboratory may bill us, or you may bill us as a pass-through billing, but that amount varies from contract to contract. But oftentimes, it's based on – similar to what better care rates are. It just depends on the contracts. You're talking about a test, however, that may cost – that may be reimbursed anywhere from $7 to $10 or – so it's not an expensive test in and of itself.

The counseling services are billed by the physician as a separate item or a separate line item, and that's once again a negotiated rate. So what do you get for an average visit through your insurance company may be, depending on the level of the visit, a minor visit, you may get $30; a major visit, you may get – a medium visit, you may get $50 or $60. This particular code, counseling services code, if it's separately billed, has its own value relative to that.

And I – once again, I can't give you an exact number because that number varies from place to place around the country, but it varies the same way that your normal office visit reimbursements vary. So it's in line in most companies with the relative value units that are placed on those particular services truthfully by CMS, and then many companies follow that relative value. So how's that value relative to another office service that you would provide. Does that answer the question? I'm not certain that I did.

DR. BUSH: I'm not certain that you did either, and one of the things I'll have to do – you mentioned $6 or some inexpensive number. That's not my recollection of the number, but I will verify that on break.

MR. BASKIN: And I don't have the exact number either. I do know that the – that once again, I can speak for myself in nine years, and I am involved in reimbursements and, in fact, in earlier part of my career, I was part of setting fees in the Mid-Atlantic region for our company. I – (inaudible) – the national job for the company. And frankly, I've never had anyone complaining we underpaid for the actual test itself. Now, if that's happening, that – you know, I think I would have heard it since that was part of my job, but it's never been an issue. If it is with a particular provider, by all means, that provider should contact the company.

MR. SCHMID: Also I have a question about other insurance companies?

DR. BUSH: Yes, I was just concerned about – in our office, we probably have ten or different – ten, 12 different insurance providers that come through our office and I'm thinking, like, United and others, if you had a sense for how they were reimbursing as well.

MR. THOMAS: I can answer that. I don't see there will be – I don't think it's in a company's interest to – not to work with – of physicians appropriately concerning HIV. I don't think there is just money being made in the industry from just under contracting with physicians and labs, et cetera, about HIV. I've never experienced the kind of a – appeal or a complaint from a physician concerning this issue. Again, drawing the blood is a piece of this. Sending the – our sending the blood to the laboratory, or the saliva – just counseling for this testing – a physician counseling for this testing pre-imposed. I – it's reimbursed appropriately.

So it may – and it varies by contract, by contract hospital, physician, ambulatory center, but I'm just not experienced, or I have never experienced any particular animosity concerning this issue, or that we're underpaying for this. I experience a lot of complaints about we're underpaying for other things, but not HIV testing. Unless you have a more specific question, I don't know what else to say. I didn't mean to be so aggressive. (Laughter.)

MR. SCHMID: Okay, Beny do you have a question? And I want to get – I can't see people over here, so –

DR. PRIMM: I have a question for both Drs. Baskin and Dr. Thomas. I – just to give you a scenario, I have a patient, for example, a 14-year-old African-American girl who has had reports from our office and has had receptive anal coitus and, of course, vaginal coitus and oral sex. And I want to, instead of giving her the rapid oral test, I'd like very much to – I suspect that she may be infected because she's been moving around the neighborhood. I'd like to do an RNA test. Would you pay for it?

MR. BASKIN: The simple answer is yes.

DR. PRIMM: Thank you.

MR. THOMAS: Same here.

DR. PRIMM: Thank you. I think this is a real important area of concern that we have because people, they may come to the doctor and in most instances, they don't just wake up one morning and say, I'm going to go get an HIV test. They come because they think that something happened that they may need to know about, okay? And those instances, I think one should consider testing for the virus itself and the reason for that is because they are most contagious at that time, right, that they have just been infected. And to find out then and to begin treatment as early as possible, if that's the doctor's choice, it will also help to protect the community from a public health – (unintelligible).

MR. MARTIN: Yes, Beny, you should add that the normal test would not show they're infected yet because at the early stage. That's why he's bringing that up.

MR. THOMAS: I don't think that would be – that testing would be denied or under-reimbursed, but I don't think that's part of the CDC guideline, by the way, but that's your – as an individual physician and your – your clinical experience, I think it's appropriate, so – and I don't think there would be a reimbursement problem with that. There is nothing within our claim check reimbursement – our computer system that would kick that out, especially if you – (unintelligible) – unless the physician, or the billing company would miscode it, I think, or something like that, but – anyway – and for the audience, the RNA test is the HIV titer, I think, you're recommending that would show the amount of HIV (ever present ?) before the – other more traditional tests would turn positive.

DR. PRIMM: I think that would be an excellent recommendation for certain communities.

MR. SCHMID: David, you had a question? Oh, Shenequa? Okay.

MS. FLUCAS: Thank you for your comments. I wondered once the persons find out that they are HIV positive, will you continue to cover that person?

MR. BASKIN: Absolutely. It's not – not even an issue. I mean, it's ethically not an issue and, in fact, I think it's not legal, but it wouldn't even – not even a consideration that the results of those tests don't commingle with insurance-type information in the company at all, any way, shape, or form.

MR. SCHMID: David?

MR. THOMAS: I agree, but just to (reaffirm ?) the question, if a person is – are you saying if a person is, let's say, covered by Aetna and then their HIV test is positive, do you mean could they be terminated from their coverage, or do you mean if someone who's HIV positive, can they obtain health insurance in America 2007?

MS. FLUCAS: Because most insurance companies, before – like if a person goes –

MR. THOMAS: – underwriting.

MS. FLUCAS: – uninsured, you know that they're positive, then they would not be able to receive coverage, or the person who's already receiving the coverage to continue to receive that coverage.

MR. THOMAS: Absolutely.

DR. MALEBRANCHE: Okay. My question, I think it's great to hear about the private insurers and that's great. I love that. But I'm going to bring to it back here because we've kind of let this issue – kind of go to the side. And my concern is particularly because we keep hearing – in my community – I work in Atlanta, Georgia, and I work at Grady Hospital, where practically all of our patients are uninsured. And we all know that HIV is more of a social issue, and particularly in the United States, when you drop HIV in a condition that is underserved with the other kind of social determinants and structural determinants, lack of income, lack of finances, lack of insurance, this is a problem. And this is where the HIV epidemic has taken hold.

So it's great that for private folks they can go and then get it covered, but it's really, really bothering me that in the – in the areas and with the populations that need to have this test covered that are more disproportionately affected by the numbers in the United States, that we're basically throwing our hands up and saying stuff like, well, it's up to the states. Now, there's got to be something we can do. The question I have is we have to able to hold the states accountable and it's not saying that there has to be some federal mandate that runs everything, but the states have to be held up to some kind of standard. And if there can't be one kind of standard, if you're just saying, well, it's up to the states and if there's a ignorant or uninformed politician in one state that's disproportionately affected by HIV among black and Latino communities, then while you throw your hands up, they won't be able to get the coverage for the test. And so that's going to be a problem.

If that's the case, what can we focus on, say, the test or the states that are more disproportionately affected, and maybe say, look, you guys need to step up and take maybe the top ten states and really start to push this and push them to make this legal because as it stands now, it's really becoming a barrier. And it's great with the private insurance, but I can guarantee you that from the numbers in the United States, the numbers of people that are becoming HIV positive are not the ones who are all holding private insurance.

MR. RAZES: Well, I agree with what you're saying. Of course, from the federal perspective, we've got the Medicaid program. You're referring to, I believe, also a population that probably doesn't have insurance, or – and that's – that's a bigger social issue.

The issue about maybe targeting the states that are top ten states or what have you – maybe, I don't know, CDC or somebody that – CDC's in the driver's seat with respect to the initiative, but I think that to get awareness on the states – and I don't want to just say, well, it's just – it's a state's right. I think there are a lot of things that could be done. The benefits of identifying folks – I mean, states are looking at it maybe from the dollar and cents; people are looking at it from a more practical standpoint, life-threatening impact on life. What's it going to cost a state if the person just has the virus versus if they get full-blown sick? I mean, it's going to double, triple, quadruple their cost.

So you could look at it from the standpoint of – it's like that old commercial "you can pay me now, you can pay me later" type of thing too. So I think there are benefits. I think there are ways of identify – the states that have large populations like that, trying to educate them, to get them to move in the direction to cover these individuals. I don't have any answer for the larger issue of folks who aren't covered by Medicaid. And one thing I want to mention –

DR. MALEBRANCHE: Oh, no, no, let me – let me just say the most – the people that are uninsured that come to us do apply for Medicaid and then they end up getting Medicaid. So that's part of the issue as well. And so it's not – I'm not just talking about the people that don't have anything, but, like, the folks who come to us and come to Grady Hospital, they do go through social services and eventually get Medicaid and that ends up being that coverage. So that is a problem if this is going to come up, and I don't want to get in conversations where we're putting a cost on somebody's life before they even test for the – that's a little bit funny to be talking about at the table.

And you have a group of professionals here that will report to the Department of Health and Human Services, eventually to the president of the United States, what can we do to help move this, because this is not the private insurance seems to be on board. The barrier seems to be with Medicaid and Medicare, which is the insurance coverage for most of the people, particularly black and Latino who are living with this disease and who are at risk for this disease. So what do we need to do there?

MR. RAZES: Well, again, I do believe that the educational aspects of it to again promote the interest at the local level up, and I – I certainly don't want to make this as a financial responsibility, looking at it just in terms of dollars and cents, but states are looking, I mean, they've only got a limited amount of money. Dr. Redfield was talking about reimbursement rates. State of Maryland is in the red. A number of states are, and they're not going to be expanding services if they don't have the money to cover it. And the point I was trying to make with the identification of individuals at an early stage, it is – it is cheaper and more effective to provide those services when as early in the process as possible. So that's the point. It makes – it makes good sense from a medical standpoint and from a fiduciary standpoint as well.

MR. SCHMID: A couple of other people have some questions. I have another one. Could you talk about the discussions that CMS has had with CDC regarding this issue?

MR. RAZES: Carl, I'm not sure. I'm not in at the upper levels at this point in terms of what those conversations have been. I mean, you know, my level, yes, lots of – but I cannot at the higher up.

MR. SCHMID: John?

MR. MARTIN: Yes, I have some questions for you on the same topic. First, just for Bob, what percent of your patients that you're talking about, trying to get reimbursement, have private insurance, from your clinics?

DR. REDFIELD: In the non-federal associated clinics probably 35 percent –

MR. MARTIN: And then –

DR. REDFIELD: 30 percent.

MR. MARTIN: And then beyond that it goes much smaller? Yes.

So one of the issues I think is just sort of uniformity. We hear a lot of discussions of uncertainty, and until reimbursement is handled in a uniform way I think it's pretty difficult to make it work because of the complexity of the patients, complexity of the hospitals. And the – and Medicaid here would be a huge step forward and for – Beny made a comment earlier. I don't know if you were here there (sic) but it's his theme, if this was in any other population we wouldn't be waiting around for states. We wouldn't do this bottom up thing. So I think most of us are kind of – we've lost our patience for a bottom up approach any more. We'd like to know how it can be done otherwise. Carl, you mention a congressional mandate. But my question is has CMS mandated testing for any other disease? Does CMS have that authority? The sort of a mechanism that a flip could be – a switch could be flipped tomorrow and that this problem would be solved?

MR. RAZES: I'm not familiar with it. I mean most of the types of tests are – that are say preventative or what have you, are optional, so to speak, but not mandatory. And like on the Medicare side it's – obviously it's got to be a law and it would have to be so on the Medicaid side as well.

MS. MCGEEIN: I don't want to take him off the hook, but changes to Medicare and Medicaid have to be congressionally mandated.

MR. RAZES: I see.

MS. MCGEEIN: We don't have that authority.

MR. THOMAS: Yes. I thought –

(Cross talk.)

MR. BASKIN: The Department is –

(Cross talk.)

MR. BASKIN: – flipped a switch with the –

MR. THOMAS: Nonexistent I think.

MR. BASKIN: Yes.

MS. : You guys are much more flexible than we are.

DR. REDFIELD: Okay. No I wanted to just go back and get a sense from the three of you then. CDC announced their new recommendations. I think they were formally announced in September of last year. Give me a sense of what impact that's had on the change of HIV testing that you've all had to reimburse or the situations in which you've had to reimburse. In other words, if it's all just doctor's office that has – has there been any changes either in the amount of testing that you're doing in any of the three different reimbursement groups you have, or the situation in which the reimbursement is coming. Because CDC clearly recommended to take this beyond the doctor's office. And I'm just interested to see, how has it penetrated CareFirst, Aetna, Medicaid, Medicare in terms of – (inaudible) – changes and reimbursement requests for HIV testing?

MR. THOMAS: I don't have exact numbers at all for that question but – and there's also been no appeals for any disgruntled hospitals or facilities or ambulatory care centers or nurse practitioners – problems with payments. So we'd like to hammer out this issue.

DR. REDFIELD: Yes. My approach is to the flip-side here. I'm not worried about the reimbursement. You've made the case that you all do that.

MR. THOMAS: I mean not (a testing ?)

DR. REDFIELD: I'm just trying to see as an indicator how effective the policy has been implemented. Maybe you would have numbers. It would be useful for this committee to see what the penetrant was, say, 2005-2006, and what the penetrant was 2006-2007. Does it get a sense – is this policy being translated?

MR. BASKIN: Frankly, I'm not aware that those numbers have even been put together. Not that they couldn't easily be from my company, but I don't believe it's been on the radar screen to do so. Interestingly enough, when you're talking about quality measures like that a lot of what we do is driven by (HETIS ?) measures, and it was actually something I was hoping to bring up. That one of the things that drives insurance companies to promote certain practices – and it's one thing to say that we cover this and we'll pay for it, but frankly, I don't know that we do a lot of active promotion of it. Not that we do a lot of active promotion of things like this in general. But certainly we do promote mammography rates and PAP screenings and certain depression measures that come out of (HETIS ?). And in fact one avenue to potentially get this recommendation more broadly taken off is to potentially create a (HETIS ?) measure of to work with NCQA to do such a thing because that would – it would make everybody stop and simply start to measure, and in measuring then have to show that there's an improvement down

the line. But frankly, it hasn't been – it hasn't been the direction we've gone.

MR. RAZES: From a CMS perspective, I was touching base with folks on both sides of the shop, and Medicare it's basically negligible in terms of any sorts of increase. And on the Medicaid side, at least based on the preliminary data that we've gotten, there hasn't been either. But Medicaid is a bit lower in terms of getting our data.

DR. PRIMM: My question, Mr. Razes, is concerning testing in prisons. Would Medicaid pay for testing of people that are in the prison or jail system? And as they get out, when they are not felons, ex-felons and not necessarily eligible for Medicaid or Medicare, would you pay for tests for those individuals who have a pretty high percentage of HIV infection?

MR. RAZES: Medicaid will not pay for testing for individuals who are incarcerated. If they were eligible prior to incarceration or when they get out Medicaid would pay for it, but not while they're in prison. There are programs at the state level to get people on to Medicaid as soon as they are released from prison, but again, no services while they're in prison.

DR. PRIMM: That process is rather slow in my experience of ex-felons. When they come out of prison, there's great deal of a problem that – it's not necessarily so for people who have mental health problems, because their medication, for example, is paid for and generally they are given medication when they leave prison and they right away can get it at the pharmacy. But not HIV-infected people, which is dangerous for us, out here in the community.

MR. RAZES: Yes.

DR. PRIMM: And there ought to be some recognition of that and maybe some changes suggested by you as you go back to talk about that issue, because it's a serious issue in the African-American community.

MR. RAZES: I agree with you, sir. Some states have programs, limited in scope sometimes, pre-released types of programs so that they link people up with the services so that they've got them when they walk out the door with respect to employment, with respect to medical assistance. It's not done – it's not common place, per se. It's not a general practice, but there are bright spots. But that is definitely an issue. And yes, I can take that back.

DR. PRIMM: I appreciate that. Thank you, sir.

MR. SCHMID: Any other questions from the membership?

DR. BUSH: I'm not sure this is much a question as a comment. And first of all I'd like to say I appreciate you coming and – the private practitioners in particular – and enlightening us on what you are doing, because at our previous meeting we are getting

information that reimbursement was a barrier. And so for you to say the private practitioners are on beard is very enlightening. And for us here in PACHA, we now know, although as I've said I'll be checking some things out myself, but the mechanism that you mentioned (HETIS ?) promoting mammograms, how could you all help us in – or how could that be done to get them to say just like mammograms the CDC has recommended X. And so that it would be disseminated to more than just the 12 of us in this room, but to other people where it will be utilized in private practice. So I guess I want to say again thank you for that information. Now how can we get it utilized on the private side?

MR. THOMAS: I think the answer to that is just national – NCQA that's – for it to be incorporated into the way that insurance companies are evaluated as to quality care measures.

MR. SCHMID: Dr. Baskin, I'm glad you brought up the whole promotion and education of HIV testing. And that's another – the recommendations that came out from the CDC said that every person who gets tested will be given information about HIV and what a test is, what is HIV, how it's spread, et cetera. But I don't know if CDC is still implementing these recommendations in the different healthcare settings, but I would like to see what those documents are. And wondering if – you don't want every doctor's office to have different ones. Maybe there'll be standard ones, but it may be good for something that the insurance companies may want to put together and provide in the healthcare settings. And that's a way that you could promote the testing.

MR. BASKIN: Well, as companies, I would venture to say that we all have web content available to our membership as well as to our providers regarding HIV in testing and the like – and the information that you're talking about. I agree, however, that we all have our own information. Now, if we were to read it of course, I doubt there'd be any actual difference in the information other than presented in a different way and with different paragraph –

MR. THOMAS: Different font size. (Laughter.)

MR. BASKIN: Right. And things like that. Certainly, if we all had the exact same information, that would all well and good. We've actually been able to do that on a few things where we've had some cooperation amongst insurance companies. It's a really –

MR. THOMAS: Diabetes for example.

MR. BASKIN: Yes. Diabetes. Exactly. We have some joint guidelines and there are certain states where we've had to get together and do joint guidelines. But in reality there are hundreds of insurers around the country, and despite what people think, we don't meet, we don't conspire, we don't –

MR. THOMAS: Kidnap small children. (Laughter.)

MR. BASKIN: There's really no reasons for us legitimately to get together other than on quality issues, and that's handled in different forms, to be honest with you. It's handled though things like NCQA or AHRQ or any of these other kind of national agencies of which most of us are members.

MR. THOMAS: Thank you. Dr. Redfield.

DR. REDFIELD: I just have one last question. I do want to –

MS. : The microphone.

DR. REDFIELD: I wanted to thank you for your comments. And I do think as David says the discrepancy is probably more between the public sector reimbursement than the private sector. The private sector – you all seem to continue to sort of lead the way in providing not only access to care for people that are HIV infected which you've done and continue to do, but I'm interested, because we've got this policy – this new policy to try to promote new diagnosis that there's an alignment of interests, the public health interest to eliminate ignorant transmission, and I think just from a health company point of view that getting people diagnosed early and get them in care and preventing transmission to more people within – because they're likely, if they're in the context of different businesses, to have other members that they probably could transmit to.

So there's an alignment of interest here. Are there things that could be changed from your perspective from the outside, from the government's perspective, or others that have not – that could help increase your ability to be part of promoting this new policy? I mean, you mentioned one that I wrote down, clearly that the getting into this measurement issue would be a positive one. There are other ones we forgot to ask about that would allow your industry to be more part of moving this policy forward, not – in partnership with the government.

MR. THOMAS: Your question confuses me.

DR. REDFIELD: Well, I'm asking again. We're trying to get more young – more Americans diagnosed. That's a goal. And it's – again, for someone who's been involved for 25 years, it does sadden me that 22 years after the AIDS – or 21 years after the AIDS test was deployed we still have a significant number of Americans not diagnosed. So we need everybody's help on this, including the – the health insurance industry as a component of that. It's not the whole thing; it's component of that.

You all have done as much – a lot of things that you feel to help make sure doctors can order this test and there's no interference, and that's – I think you've convinced – I mean clearly that's what's on the table and that's reality. I think some of us may not know how to code for everything, but we'll go back and learn some of those issues in terms of the dis-linkages. But the public sector, certainly there's a hole. And in the uninsured there's a hole. And Ryan White recently modified it so that at lest now

using Ryan White funds you can try to diagnose somebody with HIV infection, which historically we couldn't use –

MR. THOMAS: Which are being decreased, I think.

DR. REDFIELD: Yes.

MR. THOMAS: Are they not? Ryan White funds? No?

DR. REDFIELD: Oh, I don't think they're being decreased. No.

MR. THOMAS: Decreased, right?

MS. : No.

DR. REDFIELD: No.

MR. THOMAS: No? Oh, I'm sorry.

DR. REDFIELD: Different states, depending on how they've moved, may have different modulations. So the State of Maryland may have some modulations in a negative side because maybe not of being as aggressively engaging U.S. – federal guidance that came down probably five years ago. But what I'm trying to get at, the question was, just like you in my question told me about this – if we've got this measurement that might help. Are there other things that could better engage the insurance industry to be a more effective member of this team of trying to make it so by the year 2010 all Americans with HIV infection know that they have HIV infection? That's all I'm asking. That you might have some other idea that we need to consider.

MR. BASKIN: Frankly, I agree with you, it's in our best interest as well as everyone's best interest, to have this diagnosis made as early as possible and this testing be widespread. We're all aware of the barriers that insurance companies have of trying to get messages out directly – direct to consumer. Kind of average marketing from insurance companies is one that's taken with a little bit of hesitation by the public. It's a little more difficult for us to initiate, but it is possible for us to partner – partner with clinics, partner with hospitals. I'm certain that CareFirst and I know that Aetna, through its foundation, does actually put monies out to support these types of efforts and –

DR. REDFIELD: Yes, like the Whitman-Walker band thing.

MR. BASKIN: Yes. There's charitable funds through both of our companies, I'm sure, and any large insurance company. And I know ours specifically being – are being utilized to address ethnic and racial disparities in healthcare and this would certainly fit the bill. So there are those opportunities. But what I'm basically trying to say is opportunities for us to kind of help, but partner with somebody who may be considered more acceptable to the community, to the membership.

DR. REDFIELD: Is there a way that the government side can help you all be more effective in doing – that's what I – we've asked you a lot of what you can do. My last question really is more about are there things that could be changed from the government side to make you a more effective partner? That's where I was trying to get at.

MR. BASKIN: Well, there's perceived barriers that probably aren't truly there. There's all kinds of – and I mean we're all aware of these things. They've all been kind of touched on at some point in time. But all this perceived barrier about being uninsurable – if you already have insurance, you're going to somehow lose your insurance. That's just – I certainly – we've mentioned that if you're uninsured and try and get an individual underwritten policy, that may bean issue for you. But certainly for an insured person –

MR. THOMAS: Well, it would be non-existent. You know that.

MR. BASKIN: Certainly for an insured person, those things aren't issues. There are still people that feel if they get a test that somehow or another the insurance company utilizes that information or passes it on somewhere or somehow shares it. I mean these things are illegal and quite frankly, unethical. And to the extent that the government has passed these types of regulations, whether it be in the states or federal regulations, it's not being believed, which makes it actually harder for us to do what we try and do to promote good care.

I mean, if we would attempt it promote this, to be honest with you, we'd be accused of something as opposed to welcomed as a partner in some way. So to the extent that the government can reassure the public – and I really look at this as a public safety issue, to be honest with you – it's just not been out there. I mean here's the – I started out with my comments by talking about the fact that that's something we don't talk about. Well, it's something we don't trust either.

And after 20-some years of this, we've gotten nowhere as far as I'm concerned. And maybe perhaps I'm talking more personally than for the company. But it is a barrier for us as a company to have that kind of atmosphere out there and that image that just makes it hard. But we are willing partners. But I agree with you, it's hard to find the venue and the right partnerships to make this happen.

MR. SCHMID: One last question.

MR. THOMAS: I agree completely. And I think your question touches almost a political one in the sense that when so millions of Americans have no health insurance, commingling with the lucky few that do, and fear of losing your job, but this really – I think this question is just rather political. And I think the most that we can do is ask for a change at the government level. It pains me to hear Dr. Primm talk about just prison inmates. That's a growth industry in our country, it seems. So I just – again that's just I

think – I'm speaking personally, but I think that the answer is at the voting booth. So thank you.

MR. SCHMID: One last question, John.

MR. MARTIN: Thank you. So this is a very helpful discussion, but there seems to be a little bit of discrepancy. So this op ed that Carl sent out to us, it's from a physician here in Washington, D.C. – it's not there, we got it by e-mail some time ago. It's from a physician here in Washington, D.C., who's talking about screening within the ER. So one of the things we talked a lot about is if we could screen patients who come to the ER, that may be their only source of medical care, we could perhaps pick up a lot of HIV. I believe it was in South Carolina where the study was done where they demonstrated that statistically.

So what he wrote is health insurers general pay for an emergency room basis based on final diagnosis. An HMO will pay a fixed amount for a sprained ankle. If this patient receives an easy-to-perform but unrelated HIV screen, the hospital is unable to recover the cost of that. And so that's what he's writing is the barrier there, to be unable to do testing in the ER.

MR. THOMAS: Jim, I'm confused again. (Unintelligible) – the emergency room where most of the uninsured get their care, Jim, they're not reimbursing for HIV tests? Is that – which is more related to Medicaid –

MR. MARTIN: But that means uninsured –

MR. THOMAS: – or private insurers?

MR. MARTIN: Well, that's the question here. I don't know. It says health insurers –

MR. THOMAS: Yes, I don't –

MR. MARTIN: – generally, but he may be referring to public payments. But the question I have would be private payers reimburse it?

MR. THOMAS: As far as I'm aware, that would be reimbursed.

MR. MARTIN: So it's not just –

MR. THOMAS: An ER visit is coded and –

MR. MARTIN: Yes.

MR. THOMAS: – et cetera, et cetera. But I don't know – to be honest, I don't know just what the numbers are, but I could find out since we have a division called

medical infomatics. It sounds very scary, and it's overseen by an M.D. here at the –

MR. MARTIN: We all like data.

MR. THOMAS: But I would wonder how ERs are responding to that when someone comes in for a sprained ankle and your 14-year-old teen and you're with your mother and you order an HIV test. I bet I bet that's not done a lot. So – anyway, that's my response.

MR. MARTIN: Yes. Well, right here at this place where they do have funding from other sources, 60 percent of the ER patients accept an HIV test, 75 percent told us they thought the ER was a good place and 80 percent would recommend it to a friend. But I think this is a unique situation where they have the funding, that they can apply it uniformly though all types of patients, and don't have the divergence of public and private payers.

MR. BASKIN: Well, let me just respond to the – it was a comment there about you pay a certain rate for an ankle sprain and then they do an HIV test and they're not reimbursed. There's a lot of semantics going on there, a lot of interesting interpretation of the way the hospitals get reimbursed. And in fact, contracts with hospitals take many, many forms. One such form is a global payment for emergency room that would be based on certain levels of severity or it could be one set average payment that – all comers, meaning that if you have a heart attack and you go to the emergency room, you may get reimbursed the emergency room the same amount as a sprained ankle and it's kind of an average type of thing. So there's a lot of different ways to do it.

But in doing so, if there is a global payment strategy, then a contract which has been agreed upon readily by both parties and theoretically a rate was negotiated that both parties would accept, one to pay and one to accept, whatever is done during that time is essentially reimbursed as part of that global payment. If a hospital is now adding new services that weren't there when they last negotiated, the next negotiation includes that. So it's rather naive to think that because a hospital performs an extra blood test that it didn't actually get reimbursed, and in reality it is being reimbursed as their global payment.

If a hospital is reimbursed on a more fee-for-service basis which is a different type of contract, which is literally we pay for each component of what you've done, then once again I'm not aware of anything, at least in my company – I'm once again going to say I'm presuming CareFirst as well – would stop that additional payment to go out for that test. So I'm a little – I just am a little concerned about whether that really is accurate or not.

MR. MARTIN: So just maybe for some of the other people here then who work in this type of setting – I don't – so fair to say global contract then there may be – ERs and hospitals may in incentivized not to provide the HIV test. If they work it into the next round, would they be more incentivized to do it or would they still – is this going to

be a barrier to testing going forwards? I guess that's my question.

DR. REDFIELD: Yes. And I think this finally I think got me were I tried to start. Because I think clearly in the individual person you've both helped me understand everything is reimbursable if you know how to do it. But it is these global contracts. And so it's really not the insurance industry; it's the disincentive. And this is why it would be really great if you do have the data. I know I'd love to see testing penetrants, and see over time how it's changing because it's just – it's determination of how effective the policy is penetrating. That – I suspect none of these individuals put this in the contract negotiations, and so the disincentive is really back at the hospital level.

That comes back to our first question where I find there our hospital is less reluctant to do it because, quote, "they're not getting compensated for it." Well, they are compensated. They getting global – they're going to have global contracts with everybody. They just decided they didn't put this in their original formula and this is a new cost – because I'm trying to still figure out what is it that we can do effectively to help CDC's recommendations get implemented. That's all we're trying to figure out. And it seems to me one of the realities, it comes down to the finances, but the finances may be buried in these global contracts, and again, how to incentivize that this gets included. And you mentioned one of the ways maybe to do it is to make it one of these measures because then people are at least measuring it. I think that clarifies for me where the reimbursement issue is. It's probably really on these global contracts when they are technically being reimbursed for it. It's their decision how to allocate the dollars that they're given.

MR. BASKIN: Well, just in defense of the hospitals just for a moment I would find it difficult to believe that the hospital and the emergency room setting is not doing the test because they're under a global payment and therefore trying to trim their costs as much as possible. I'm honestly going to give them the benefit of the doubt on that one.

And frankly it's not that things couldn't be contracted another way, but understand the complexities of when you're contracting with a hospital, you're contracting for thousands upon thousands upon thousands of services, and they are not negotiated line item by line item. And actually the hospital prefers to have a global payment in most instances, and in fact it's a joint agreement as to whether to do that. It's not an overbearing – it's not like the insurance company comes out and says, "You've got to do it this way." It's what works for both entities.

So to the extent that hospital says, "Geez, I want to open up an HIV testing clinic," I can't believe there's any insurance company in this country that wouldn't be willing to talk to them and say, "Well, how can we make that so that it's not a disincentive for you to do that?" But those conversations, they're welcome. They are entirely welcome.

MR. MARTIN: I think we – yes, we're coming from, we know the testing is not being done near to the extent that you would envision it to be done. And so what are the

barriers that are doing that, that are causing that problem? This has given some guidance I think, of where to go with – (inaudible).

MR. SCHMID: Right. Well, I want to thank all of our panelists. I think they've done an excellent job of presenting more information. And as we said, this is one of the barriers, one of the major barriers to implementing CDC's policies. And I think we heard some positive news from the private insurance company today. And I think we'd like to further investigate some of the information. And I think we heard that we have a long ways to go in the public financing arena for reimbursement, and that's where most of people with HIV are, as we discussed.

And maybe in the future, and maybe this could be in the domestic subcommittee, our future meeting, but if it does rest with Congress, maybe we need to hear from some congressional staffers or members of Congress. If it does have to do with the states, maybe we could bring in some state Medicaid directors. But I think this is an issue that the committee is going to continue to look into.

But I want to thank all of you for being here today. It's been very helpful. Thank you. (Applause.)

MS. MCGEEIN: This concludes our programming for this morning. We'll break for lunch now and come back into session at 1:00 p.m. I will once again advise the members of the audience that we have limited – they have limited accessibility. They can make it to the cafeteria and back. They can make it t the restrooms and back. But security will prevent you from going off the floor for the moment. Thanks.

(Break.)

MARILYN MAXWELL: Good afternoon.

MR. : Good afternoon.

MS. MAXWELL: It's great to be with you. Welcome to the afternoon session of our first day at a PACHA meeting. At this time, we'd like to welcome our next speaker, Dr. Nora Volkow. Dr. Volkow is the director of the National Institute of Drug Abuse at NIH. NIDA supports most of the world's research on the health aspects of drug abuse and addiction. As a research psychiatrist, she pioneered the use of brain imaging to investigate the toxic effects of drugs and their addictive properties. Dr. Volkow spent most of her professional career at the Department of Energy's Brookhaven National Laboratory where she has held several leadership positions including director of nuclear medicine, chairman of the medical department and associate director for life sciences. Dr. Volkow is going to speak to us today on crystal methamphetamine epidemic.

Thank you and welcome.

NORA VOLKOW: Thanks very much. (Off mike.) It's a pleasure and opportunity to speak to you about the importance of methamphetamine addiction and the HIV/AIDS epidemic but in general more about drugs than the HIV epidemic. Of course methamphetamine puts sense of urgency.

One of the things that we've been all of us very unfortunately disillusioned with was the negative trial for the Merck vaccine for HIV/AIDS because we were all looking forward to the possibility of generating a vaccine which would be incredibly capable of course in preventing drug use. The failure of this vaccine sets us back and the concept – it highlights how difficult it is going to get a vaccine for HIV. In speaking with immunologists, it's not straightforward, and we may never have a vaccine in the next 10, 15 years. So we need to look at other strategies that we can do to actually prevent the HIV/AIDS and that's prevention, prevention, prevention, and this is where my presentation comes around.

Drugs, from the beginning of the HIV epidemic have played an extraordinarily important role in its dissemination. It's been estimated that at least 30 percent of the cases of HIV from the inception of the epidemic until now have been accounted by drug use, except that that accounting has been specifically focused on injection drug use. By using contaminated material, drug users are at a very high risk of infecting themselves, and this is recognized. It's a national and international problem.

Then there's another aspect which has been much less investigated which is the use of drugs themselves produce during intoxication a change in the mental state of the individuals that can favor behaviors that increase their likelihood of getting infected with HIV. On top of that, there is some evidence that certain drugs may produce physiological changes in our bodies that facilitate that infectivity with HIV when having a sexual transmission with someone that – sexual interaction with someone that is infected. And finally, we've come to recognize that the combination of HIV and drugs is actually quite deleterious and it can accelerate the progression of the disease.

This is just some epidemiological data to show how really the whole trajectory of the HIV epidemic is changing, and particularly all of the vectors associated with the disease. In around 1997, we see a dramatic decline, this is the number of cases, of eight cases and death, so these reflect – (unintelligible) – numbers of death cases here, and this is since the inception, and that's 1985 to 2004. You can see the dramatic decline in the number of deaths and this is very much in part associated with the antiretroviral therapy which has been very effective in decreasing the number of people of getting AIDS. At the same time, I think equivalent, as important as the antiretroviral therapy is that the number of cases has gone down of new infections, and this has to do with effective prevention interventions which is something that as bad as the HIV/AIDS epidemic is and devastating, we have to recognize we can prevent it. We know the vector and we should be able to prevent it. So there's been advances both in terms of the treatment as well as the prevention.

Initially, the HIV epidemics were subscribed very much to men having sex with men, and that still continues to be the number one mechanism for infectivity of HIV/AIDS. The number two case was injection drug use, and you see it here, and interestingly in the United States at least we have been very successful in decreasing the number of people that inject drugs who became infected, and that has to do a lot with the introduction of treatments for these individuals, which for the most part reflect individuals that are injecting heroin and to a lesser extent, individuals that may be injecting cocaine or methamphetamine.

Unfortunately, there is another area where we are not seeing decreases, but we are actually seeing increases despite the success in prevention in other areas, and that is individuals getting HIV out of heterosexual contacts. And what's unique about this group is two things about them. First of all, 50 percent of the new cases of HIV now are related to individuals that are 25 years or younger, many of whom come out of having heterosexual sex, and the other one has to do with the fact that many of these heterosexual contacts are done under the influences of drugs, whether it is alcohol, marijuana, cocaine or methamphetamine, that facilitate behaviors that otherwise a person wouldn't engage on, whereupon again, highlighting the importance of the involvement of drugs on the HIV epidemic, not just on the injection drug use, but actually on the utilization of drugs that can favor risky sexual behaviors.

And the importance of this vector, not just use of drugs based by themselves increasing the risk of getting HIV as highlighted by this study that was just published by – (unintelligible) – in 2007 on a large cohort of individuals in New York City. These were actually two cohorts of subjects, one of 2001, 21 subjects that were attending treatment in a New York Clinic, and the other one represented 450 subjects that were not involved in treatment, were just recruited by advertisement. And what the investigators were doing was actually addressing the prevalence rate on these individuals that were drug users and were dividing them into those that were current injectors versus non-injectors, both in the group that actually was receiving treatment for drug addiction as well as in the group that was not receiving treatment for drug addiction.

And what you can see clearly is that it does not make any difference in terms of prevalence of HIV where you are injecting drug use or you are not. The prevalence rates on both groups of subjects are extremely high. Thirteen percent for injection drug users, 12 percent for people that are taking drugs but not injecting them in this cohort. In the other cohort that is not actually even receiving any type of treatment for drug addiction, current injectors is 15 percent and individuals that are not injecting or taking drugs is 17 percent. It's close to one in every five subjects has HIV positive. And that gets you an indication about how extraordinarily important drugs are in the HIV/AIDS epidemic.

Now, why could that be so? And I basically stated to you there are two mechanisms by which drugs, just intoxicating yourself with drugs, can increase the likelihood of getting HIV/AIDS. One of them is that drugs decrease normally what we call the (brakes ?) of our brain, that is, the areas of the brain in the prefrontal cortex that allows us to control our emotions and our desires. When you get intoxicated, the

functions of those areas goes down. Interestingly, the areas of the brain involved with limbic functions responsible for sexual desire go up, and this just illustrates those effects; this is the effects of intravenous methylphenidate, it's a stimulant drug, less potent, much less potent than methamphetamine but having similar pharmacological actions. And what you are just actually doing in this study is recording the sexual desire when individuals are give a placebo versus injection of the stimulant drugs, whether they are non-drug users controlled subjects or they are regular cocaine abusers.

Regardless of whether you regularly abuse drugs or not, just being intoxicated with the stimulant drugs, such – and as I say, this is less potent than methamphetamine – just by itself with no sexual stimulation, just giving the drug will increase sexual desire in the subjects. Now, when you put these together with the concept of people take drugs not just in a laboratory condition but actually in the case of methamphetamine explicitly when they are going to be going to social environments with the possibility of sexual contacts, there you can see that the interaction of just the increase in sexual arousal becomes – could be very, very problematic.

What do we know about the neurobiology? Well, what I'm showing you here are brain images of activation when an individual is sexually aroused. And the way that these studies are done, you use functional magnetic resonance imaging and you expose subjects to in this case a sexual video. The subjects report feeling sexually aroused and the degree of sexual arousal is correlated with activation of these areas that are circled here which are the limbic areas of the brain that include the famous amygdale, the temporal (pole ?) and the hypothalamus. Those are all areas of the brain implicated in instinctual functions and what we call the limbic brain, here illustrated more or less here in green.

When the subjects are brought back to the laboratory and the investigators say, I don't want you to get sexually aroused, you can do that, you can control your desires. We all know that. And that we do that by cognitive influence. The cognitive influence in our brain is the frontal cortex. And what you see here is the subjects are shown exactly the same sexual video, but the investigators have told them before they showed them the sexual video that they don't want them to get sexually aroused. Yes, and the subjects are able to not feel sexual arousal even though they are seeing the video, and you can see also their brain does not activate in the limbic areas of the brain. Interestingly, it activates into the prefrontal cortex, this areas of the brain here, where you are actually – this area here sends connections, anatomical connections to the limbic brain that actually can inhibit its function. And to the extent that you can activate these frontal cortical areas of the brain, you can inhibit the function of the limbic brain and you can regulate your actions.

Well, that very interesting balance between the primitive parts of our brain that deal with instinctual behaviors and the cognitive parts of our brain that allow us to exert cognitive control such that we can exert free will and regulate our actions, and we can say no, even though we may want to say it but it's socially inappropriate or it would be risky, that is the prefrontal cortex. That's the proper balance. And that balance is totally and completely disturbed when you get intoxicated with drugs. And these are actually images

of the brain, summarizing the effect of in this case alcohol intoxication in a group of subjects, 20 normal controls which were given a moderate dose of alcohol. And what you see are different slices of the brain, and in blue are the areas that get deactivated when a person gets intoxicated with alcohol, and in red are the areas of the brain that get activated when the person is intoxicated with alcohol.

And what is striking is how basically, is these two areas that are balancing get opposite effects. The prefrontal cortex, exactly the area, exactly the same area that was able to get activated to inhibit that gets deactivated in the persons that are intoxicated with alcohol. This is the – (unintelligible) – of prefrontal cortex all in blue. And the areas of the brain, the famous limbic frame area, this is the amygdale, the area that got activated when the subjects were sexually aroused, this is the temporal (pole ?) which was also activated when they get sexually aroused, the nucleus accumbens that I didn't show it there, but also the hypothalamus, all of these areas get activated by alcohol. So you have exactly the opposite pattern of effects that you would want when you want a person to make a decision whether they indeed want to engage in a sexual relationship or whether this could be detrimental for their health and they shouldn't do it.

So that's what we know about it. So yes, indeed, the use of drugs goes way beyond intravenous drug use, but it actually has to do exactly with the effects of the drug in changing our mental state and how the brain functions. But it's also clear that the combination of – for those that already have HIV and taking drugs can be very deleterious, and there are many, many studies showing that. I just want to show you one that illustrates the deleterious effects on the brain of human subjects for a particular marker, a protein that is very important in our brain, to actually enable us to initiate movement or motoric operations, for cognition, for motivation.

This is called the dopamine transporter which marks the famous dopamine cells. When you damage these dopamine cells, when you kill approximately 80 or 85, that's when you start to develop what we call Parkinson's disease. And it's a very unfortunate disease for those suffering for it because by destroying these cells which are responsible for initiating action, these patients literally cannot initiate movement and they are trapped in their own bodies. The way that you treat these patients with Parkinson's disease is giving them medications that can boost dopamine in their brain, and by activating dopamine systems, they can move again. The dopamine, however, as I say, is not just involved with initiation of movement; it's involved with initiation of a wide variety of behaviors and that's why it's so fundamental for motivation.

So these images here represent the concentration for a protein that serves as a marker for dopamine cells. This is a normal person, and the colors represent the concentration of this marker. This is a patient with HIV, and you can see the decrease in the coloring red here which is the areas which have the highest concentration of this marker is going down. So this is quantified, 17 subjects and 15 with HIV. These basically have no evidence of neurological symptoms. They just show a decline in these markers of the dopamine cells. And these are patients that also are HIV but are also abusing substances, in this case specifically cocaine. And you can clearly see that the

combination is much more deleterious. You see it in the images, you see it in the quantification.

Again, putting forward the concept that unfortunately what happens with HIV is that the virus targets cells in the brain. It can (leave ?) in a latent phase affecting cells in the brain and otherwise the person can be perfectly normal. And indeed, this has become one of the most challenging things to do when you are treating someone with HIV because the medications don't go into the brain. This is one of the last repositories of the presence of the virus in the human body. Incredibly important for pharmacological therapeutics if we could actually target medications that could get rid of the virus in the brain. But combining it with drugs actually just accelerates the deterioration of the effects of the virus in the brain.

Now, let's come back to methamphetamine, because that's what I was asked to (call in ?). I basically illustrated how drugs, all of them, whether it's legally like alcohol or illegal, are deleterious to the brain. But methamphetamine stands even I would say one step above those deleterious actions for a wide variety of reasons. Methamphetamine being a stimulant, of the stimulants that one that's the most potent of all of them, one of the things I showed you with another stimulant that was much milder, that it increases sexual desire. Well, methamphetamine does that even in a more effective way, and this is recognized in men having sex with men to the point that they basically describe that when they want to have sexual interactions, particularly when they are interested on engaging in these risky behaviors, they may actually take methamphetamine to facilitate this behavior. So exactly what you don't want them to do and they want to do, and whatever cognitive abilities that they may have or concerns about it, if they want to basically get rid of those concerns, get rid of those inhibitions, they'll take methamphetamine, and it works, unfortunately.

The use of methamphetamine being such a potent stimulant also produces more significant disruption into brain function than other drugs. And among other things, is that people that get addicted to methamphetamine, which happens faster than with other drugs of abuse – in fact, for example, the studies that have looked – how long does it take you to become addicted to cocaine, which is very addictive, which is approximately three years, studies that have looked at methamphetamine report that you can become addicted in less than one year. So here you have one of the consequences these people becoming addicted to drugs are much less likely to take their antiretroviral therapy as indicated, which among other things could have deleterious consequences because it can promote the emergence of resistant strains.

In animal models, methamphetamine increases the replication rates of viral particles, so we believe that this may also be facilitated by – use of these drugs may also facilitate the replication of the virus in humans, but again, this is at the animal level. It's very difficult to demonstrate that in the human brain. We don't have the – (unintelligible) – to look at it.

And again, one of the other things that happens when you chronically take methamphetamine, the ability of your brain to properly exert cognitive operations gets disrupted, and then, that in turn even when you're not intoxicated, can lead you to poor judgment and to engage in behaviors that otherwise you shouldn't.

So speaking about methamphetamine, you asked the question and we've seen it in the news, how bad of a problem do we have with methamphetamine vis-a-vis the number of people that are affected, and very important, how is the trajectory of that methamphetamine epidemic? And here we are really in a very interesting situation because on one side, indicators of prevalent rates of methamphetamine appear to show that the methamphetamine abuse in our country is stable and it certainly has not increased between 2002 or 2006 – or 2001 and 2006. And there are two major surveys. There actually three major surveys and all of them agree on this.

One of them is funded by the National Institute on Drug Abuse, which is the one that I'm showing you here, which is called "Monitoring the Future." It's a particularly important survey because it targets high school students and it is during the adolescence years where you see the highest risk for drug experimentation and initiation. So this surveys gives a very good pattern of the extent to which a drug will be problematic in our country. The other survey, which is the one that is done called the "Household Survey," surveys people that are 12 years or older, but the results are very similar to the ones that we are reporting here on "Monitoring the Future." And the final survey is the one that is done by the CDC that also surveys individuals of all ages. And again, three surveys have not seen a pattern of escalation.

Now, let's look at the prevalence rates. If you look at the age range of high school kids, 12 to 17, it is a little bit less than 1 percent, which is more or less somewhat equivalent, slightly lower than you see a prevalence rate for this age group on cocaine, which is 1.2 percent. The rate goes up in 18 to 25 years of age where we currently have a rate that – it's a little bit less than 2 percent, and this increase from 12 to 17 to 18-25 corresponds to what you see with any pattern of growth. And indeed, the highest prevalence rates across any life span occur exactly on this age range. The highest rate of experimentation occurs here, so they experiment and then they go later on to repeated drug use at this age. And so approximately 2 percent of 18 to 25. say 1.8 to 2 percent. are using it. Twenty-six or older, you see the decrease, and again, that reflects very much the patterns for other drugs of abuse.

So overall, we see prevalence rate that is not negligible. I would say that having a prevalence rate on average across all ages of approximately 1 percent is not negligible, one in 100 persons, because it is a devastating disease in terms of the addictiveness and the toxicity. And it is nonetheless not as high as you see with cocaine and a little bit lower than you see with heroin. But on the other hand, what we're seeing, and that's the issue of the paradox, and I think that even though the numbers are as they are, to me are higher than they should be, you want them lower, we're seeing other indicators that are telling us that even though the numbers here look for us like stable, stable, stable, stable, indicators of seeking treatment, methamphetamine treatment admissions, because

individuals in detoxification program or even more worrisome vis-a-vis the magnitude of the problem, numbers of admissions into emergency room because of problems associated with methamphetamine, all of these have gone up.

So here you have this paradox on the one – the indicator is telling you that it's stable, but look at the significant increases in terms of the number of admissions for treatment related to methamphetamine as well as admissions for emergency rooms related to methamphetamine, as well as epidemiological surveys indicating that the number of methamphetamine abusers in states that in past did not have such a serious problem is dramatically increasing; in other words, methamphetamine which was at one point limited in the west states of the United States and some of the central states is now becoming much more disseminated throughout the whole United States and unfortunately, throughout the world. We have some countries in East Asia where the number one drug of abuse equivalent to marijuana is methamphetamine.

So here we have a problem in our hands, we have countries like Mexico where methamphetamine – people didn't even know methamphetamine existed five, six years ago have some states like Colima where methamphetamine is being produced evidently that is the number one drug problem currently in five years, an escalation on the problem of methamphetamine.

So in light of these studies, to me I would say that we do not have the epidemic problem of methamphetamine under control, because if we had it we wouldn't see these escalations, certainly in the United State, not to say I'm not touching the international because I think that international we are actually seeing a very rapid growth of the problem of methamphetamine throughout the world.

Now, in the United States, this increase in the number of people seeking admissions or in the number of emergency rooms, may basically very well reflect the fact that we've seen also a shift in the pattern by which people take methamphetamine. Normally, when you take – initially people took methamphetamine by the route of orally, and that was known for many, many years, but when you take the drug orally, it is much less addictive than when you take it by smoking or injection. Why? Because the drug reaches much higher concentrations and its effects are much more addictive, and I can answer if you have questions on that. And we are seeing a shift in the pattern of route of administration from less addictive to more addictive forms of administration for methamphetamine.

So what do we concern about methamphetamine, and for those of you that are looking into your displaced hard copies there, there's a slide here. For many years, we have shown from all the drugs of abuse the one that produces greater toxicity is methamphetamine. Of all of the drugs of abuse, the one considered most addictive is methamphetamine. And it is directly associated with behaviors that increase the risk of infection of HIV and Hepatitis C, which actually creates a big burden on morbidity and mortality. And the other thing that makes it unique, it's very easy to manufacture and you can actually do it in your kitchen sink, and there are recipes in the web so you can

actually get going, and that makes it incredibly difficult to control because it is not that you necessarily have to buy it from your drug dealer, you can manufacture it. And while in the United States this is something that has been more or less under control because they have controlled the supply of precursors, that is not the case for most countries in the world.

This is just to illustrate the toxicity effect of methamphetamine. Methamphetamine, like all of the drugs of abuse, increases dopamine except it does it by huge, huge amounts, and when you produce large amounts of dopamine from the dopamine cells, this is damaging to the dopamine cells and can kill them. And indeed, here you have a normal control, again the marker that I had shown you for dopamine cells. This is methamphetamine abuser. And the type of damage I showed you before, HIV plus cocaine, the type of damage that you see by methamphetamine alone is even greater than you see by the combination of HIV and cocaine. So methamphetamine is particularly disruptive to dopamine cells. And this loss of this marker is associated with disruption in motor activity as well as memory, so it has cognitive and motoric consequences; so in other words, it damages your brain leaving the person at the disadvantage to actually go back into a productive lifestyle.

This is just another marker of brain activity, a normal control and a methamphetamine abuser showing how – this is a control and methamphetamine abusers in the brain. You can actually look at that and mark directly which areas of the brain, using that technology, have less activity. And interestingly, you can tell them during early detoxification or late detoxification. This is nine months with no drug use at all, and you can see these areas of the brain here. If you were a neuroscientist, you will jump and I said, "Oh, my God." This is an area that you don't want to be dysfunctional, this area here. This is the area of the brain that gives excitement, that makes you interested on things. If I damage this area of the brain in an animal, the animal will basically lose interest on the basic behaviors, behaviors even of survival. So if I can damage these, one, the animal will not be motivated by eat, will not be motivated by social interactions, will not be motivated by sex.

So what you're doing by chronic use of methamphetamine is really destroying the area of the brain that is key in motivating a wide variety of behaviors, and that's a long lasting effect of methamphetamine, a key component. Anything that we do in terms of treatment or rehabilitation has to consider ways to try to integrate the function of these areas of the brain. The person that has this disruption, of course, wants to still get some level of excitement in their life. They will get it if they take drugs because they are such potent reinforcers, but they also would go at extreme behaviors in order to get some level of gratification.

Now, that's where we can come in in many other ways to sort of say, prevention, prevention, prevention, prevent drug use, prevent HIV. If you treat drug abuse, you can prevent HIV. And this is an old study, it's 1993, it's 14 years of age, but again, it just illustrates how dramatic the treatment of drug addiction can be in the prevention of HIV. This is the rate of seroconversion in individuals that – for HIV in an 18-month period, in

individuals that were heroin abusers, intravenous drug users, that had no treatment versus those that had either a partial treatment or a continuous treatment. In 18 months, there was a 20 percent seroconversion of HIV in individuals that were injecting drugs that did not receive treatment. Look at the dramatic reduction. It's basically less than 2 percent in those that receive continuous treatment. So this is exactly where we can make a dent on the HIV epidemics, prevent the HIV epidemics, and it requires a multi-prong approach, but a key element in that multi-prong approach is prevent drug use, treat drug use.

So what do we have for methamphetamine treatment? I wish I could stand up here and tell you we have a wide variety of methamphetamine treatments just like we have for heroin. We've been pretty successful on heroin treatments. We've been also successful in nicotine treatments. Methamphetamine we have much less so. Most of the interventions that we have – in fact, the only interventions that we currently have for the treatment of methamphetamine are behavioral interventions of which there is one called the Matrix Model that uses a multi-prong approach that involves brute therapy as well as cognitive and motivational treatment for the methamphetamine abuser has shown the greatest likelihood of success. And the next slide actually shows some of the results of the efficacy of the Matrix Models. This is – the numbers of days of methamphetamine use at baseline approximately was close to 12 days in a month. After treatment, this has basically been reduced by less than half. So the Matrix Model works, it's not a panacea. It does not work for all subjects. But it can definitely benefit many individuals.

In the meantime, of course we are aiming at developing medications, testing medications. Our budget is limited because it's very expensive to get new medications into the clinic. It's approximately half a billion to a billion dollars, which all of our budget. So what we're trying to do is partner with pharmaceuticals that may be interested, but there are not many interested, but we're trying to make them interested, or using medications that have been developed for other purposes like for example, bupropion is a medication that has been developed as an antidepressant which also has been shown to be beneficial for the treatment of nicotine addiction. And what was shown is a benefit, this is the number of days or equivalent days of people that are clean when they are in blue which is on bupropion. So it shows some benefit bupropion in preliminary studies for methamphetamine abusers, but again, it is not going to be the panacea. We're actually aiming at multiple strategies for the treatment of methamphetamine addiction, and I can go into it if you ask questions.

So clearly what we know, and it's actually what makes common sense, but is clearly documented by scientific research, is that we need to develop strategies for preventing HIV/AIDS in all of its modalities. And we can take another approach which was funded by NIDA which indicates that a way that you can make a major impact in the prevention of HIV is by screening interventions. And you will say, well, why would screening improve the HIV epidemics or prevent HIV? Well, 25 percent of those people that have HIV don't know it, and yet they account for more than 50 percent of the infections. So what does that tell you? That if a person does not know that they are HIV, that they are less likely to be cautious in terms of risky behaviors. That's one of the

things that it tells you. Ergo, if you are able to document their infectivity, you can do an intervention to teach them strategies such that they are less likely to transmit HIV to others. But also incredibly important, you can offer them treatment that number one, will increase their survival, but number two, will decrease their infectivity; thereupon the extraordinary importance of making screening a more universal process.

In fact, these are studies that clearly document the benefits for the person that is infected himself or herself, while at the same noting that it's not just that you're going to be increasing the life expectancy of the subjects. And the costs are actually equivalent to the cost of screening for other things like colon cancer or breast cancer. But you're going to decrease the HIV epidemic because you're going to recognize this individual, you're going to be able to treat them, and by treating, you will decrease their infectivity.

The other thing that is very exciting about screening is that now it is possible to do HIV rapid testing where you can get the result in less than 20 minutes, which is very important because a significant number of people that went to get tested, actually one-fourth of them who test HIV that are positive fail to return to receive their results, so they never know what the outcome is. This can now be avoided because you get the results right there, is very inexpensive and it's not complicated, so you can train individuals in non-medical settings to be able to perform this test making it much more widely available for people to be able to be screened.

The way that I view it, so having said all of this again, go back to my basic ABC – ABC to me in HIV is prevention, prevention, prevention. You ask me, DEF, it's prevention, prevention, prevention. I think that the fact that we have medications that can help individuals has been incredibly useful, but the bottom line is HIV is still the number one cause of morbidity and mortality worldwide in individuals that are 18 to 45 years of age, and that is not decreasing. So how do you do it? Well, we have the examples of what we've done in the United States last century. If you are asking me, and many people agree on this one or also, what was the most effective intervention that we used last century? Curiously, it was the prevention interventions, smoking cessation.

Smoking cessation which was a big success. It was not perfect. We still have 15 percent of all adults in this country smoking. It basically brought it down from 45 percent. As a result of that, there was a dramatic decrease in morbidity and mortality associated not just on cancer but from cardiovascular diseases. And again, if you just look in terms of numbers of people that have been saved out of the smoking prevention intervention, as well as the cost in healthcare that has been saved, it is a gigantic impact of this intervention.

So if we have been able to do it with cigarette smoking, my perspective is we should be able to do it with HIV/AIDS. And we have to face the notion that we should be able to do that prevention whether we get that illusive HIV vaccine or not, we have an urgent need to do prevention interventions, that can put a stop into the HIV/AIDS epidemic. And with that, I thank you for your attention, and now I will be happy to answer any questions that you may have.

MS. MAXWELL: Thank you for that most informative presentation. Questions?

MS. VOLKOW: There are questions in the back it seems like.

MS. MCGEEIN: I have one. On page 9 of your slide, most effective preventions.

MS. VOLKOW: Yes.

MS. MCGEEIN: Is this with one – this is the slide I'm looking at. Is this with one episode of exposure or is this because of –

MS. VOLKOW: No.

MS. MCGEEIN: – multiple episodes?

MS. VOLKOW: Multiple episodes.

MS. MCGEEIN: Okay. Thank you.

MS. MAXWELL: Yes. Carl.

MR. SCHMID: Thank you for your presentation. You have a budget I think you said of over half a billion dollars, right, for HIV?

MS. VOLKOW: No, no, no. Our budget is a little bit less than $1 billion, of which $300 million go for HIV and drugs.

MR. SCHMID: Okay. Thank you.

MS. VOLKOW: Three hundred million.

MR. SCHMID: And you said there's only one behavioral intervention right now for crystal meth.

MS. VOLKOW: No. There are many behavioral interventions. I said that the one that's most promising is the Matrix Model.

MR. SCHMID: Okay.

MS. VOLKOW: There's motivational interventions, incentive interventions, group interventions. There's a wide variety. But the most effective is that one that we call the Matrix Model.

MR. SCHMID: Okay. And how do you interact with – NIDA does the research, SAMHSA does a lot of the treatment programs and CDC does a lot of the actual –

implement the prevention programs. So I'm just wondering how you interact with both of those agencies?

MS. VOLKOW: Well, historically, we had a long history of interacting with SAMHSA and we have very different ways that we interact. One of the things is we do (braided ?) funding whereupon we actually take their funds and our funds, bring them together and fund investigators that are both from the academic as well community treatment programs. That's one of the ways, so we give grants that actually maximize the likelihood of having individuals from both communities.

The other thing that we do is we have a clinical trial network whose function is actually to take a research product and bring it – determine its efficacy and effectiveness in a community treatment program. Those that are actually found to be effective, then they are taken to a group that is basically formed, half of the group is people from NIDA and half from SAMHSA, to transform that product into something that will be disseminated across all of SAMHSA into community treatment programs. So we transform it and maintain its sustainability.

And the third one is we constantly have educational seminars to bring the information that we have out of research into the SAMHSA activities. And that, for example, includes bringing the directors for the different states into our annual meeting which is "Blending the Sciences" to bring them up to date with evidence-based findings that they can then implement. So we have a wide, wide variety of activities with SAMHSA.

With CDC, it's newer and we've actually started with them on projects. Specifically now we've very interested in changing the culture such that we know that screening is very valuable. And CDC took that information to say, screening should be universal at least once in your lifetime, and if you're at high risk, it should be done periodically. The concept is that you can ask a person and they say, "I don't want to be tested," so one of the next projects in that clinical trial network that then will go into SAMHSA organization is exactly how do we approach the treatment community programs such that they can start to evaluate screening and what are the outcomes. And CDC is working with those on that, so that will be a common partnership.

And we've generated a series of meetings, again, to try to get information. We're very, very interested in trying to find out how to approach different cultures and communities because what may be valuable in an Hispanic community, may not necessarily be appropriate for a Native American or an African American, so we've involved the CDC. So now our HIV screening program we're directly working with them.

MS. MAXWELL: Beny?

MR. BENY PRIMM: Dr. Volkow, I just want to congratulate you on a most beautiful presentation, and to also ask you a question about the physiology of amphetamines and methamphetamines on the erectile function of males.

MS. VOLKOW: Yes. And you know, it's interesting. One of the things – and again, I do not – a lot of the work that has related to enhance sexual desire that occurs with methamphetamine has been more of an anthological type methodology, so the anthologists go out there in the community and interact and live with these individuals. And one of the things that they've complained is that methamphetamine in fact may interfere with sexual performance. So as a result of that, what is described out of these studies is that it is not uncommon for individuals to mix Viagra with methamphetamine, and so they have the enhanced sexual desire and they can overcome the adverse affect that methamphetamine may have by being a vasoconstricting agent. So this in turn poses further risk because as Viagra can produce cardiovascular pathology, and the combination of methamphetamine which also can produce arrhythmias with another drug, from that perspective cardiac risk is heightened by it.

DR. PRIMM: It's been said that male sexual behavior, particularly men who have sex with men, often changes under the influence of methamphetamine where men are more apt to have receptive anal sex because of the inability to have an adequate erection to have an insertive form of sex.

MS. VOLKOW: And there's also the issue they too also try to compensate with the use of Viagra, but I did not know specifically about the issue of the changes in sexual behavior themselves on a given individual. But yes, it is – and the thing that is interesting – many things are interesting – but that effect of methamphetamine appears to be secondary to its ability to increase dopamine so dramatically. So you can see the same effect if you give drugs that can increase dopamine, and that enhancement of sexual desire, except that methamphetamine does it more intensely and for a very long period of time. The duration of methamphetamine goes for hours.

MS. MAXWELL: Ed.

DR. GREEN: Yes. Thanks for a very interesting talk, and I wish I had hours to just ask you lots of questions, so let me restrict it to a couple of questions but start by asking for a clarification. It seems like in your third slide, you're showing evidence that whether the drug use is injecting or non-injecting it's a roughly equal risk factor.

MS. VOLKOW: Yes.

MR. : Is that right?

DR. GREEN: So that would suggest that it's not needles per se, but rather the disinhibiting effect, the clouding of judgment effect is actually is more sexual transmission than we might have thought, if you eliminate needles but you still have

drugs. But even with that third slide, I would that the type of drug is important. Is this only talking about stimulants like cocaine and meth?

MS. VOLKOW: These results to my knowledge has only been shown so unequivocally with a large sample for cocaine. This is cocaine.

DR. GREEN: For cocaine. This is cocaine only.

MS. VOLKOW: This is cocaine only. I would expect that similar number would come about with methamphetamine because it's a stimulant drug.

DR. GREEN: But not opiates.

MS. VOLKOW: But I do not know about heroin, I would not know how it would work with heroin.

DR. GREEN: Anyway, that's a very interesting and important finding. If you could make some comment about what you see as the effect of this needle exchange programs unless that's a sort of taboo subject. And the last question is, it's my understanding that if we're only looking at injecting drug use that HIV prevalence has decreased in the last decade in this country, and if so, why?

MS. VOLKOW: Yes. The injection drug use – and that's one of the things that we have to consider, this pertains to New York City and the United States, where the campaign really of educating people about the dangers of using contaminated needles has been going on for many, many years, where you have easy access to needles whether they are given for free or you go into a drug store, they are very, very cheap. I do not know that that will be – I would actually be surprised if you get the same situation in a place where you cannot get needles and where a high rate of those needles is contaminated. So I think that these numbers pertain to the particulars of that city.

We know – multiple studies have been done vis-a-vis the impact of interventions for syringes in drug abuse and addiction, and you probably are aware of the results. There was one study in Canada interestingly that has shown that the exchange of syringes in fact increase the rate of HIV, and that's the only study that has shown negatives. And that study was done at a period in time when the rate of cocaine abuse was increasing. So that's the only study where the exchange of syringes have been shown to have a negative effect. What we –

DR. GREEN: Can I ask you about – the Institute of Medicine, med analysis funded by the Gates Foundation, that the results were available a year or two ago. I'm trying to remember what – I thought the bottom line was as far as needle exchanges, while it may have various benefits, it was not shown to impact HIV incidents.

MS. VOLKOW: What it shows though in that study is that by itself, it requires to be – (unintelligible) – in the context of a treatment intervention. So the combination of a

needle exchange problem with treatment for the person that's addicted is an effective way for preventing HIV. So what they are saying is you should not just think the obvious things in a vacuum. You actually need to intervene with treatment. The other aspect about the case of heroin injection is that we have very effective treatments, and that's why I say I wish we had the same for methamphetamine or cocaine where we don't.

MR. : (Off mike)

MS. VOLKOW: Buprenorphine and methadone work, and they are pretty dramatic. And indeed, one of the things that were very interested and sort of I think that part of the aspects are interested on worldwide, is I love to, and this is what's sort of crystallizing, I'm trying to engage in our international research to generate the heroin vaccine. Because if we could generate the heroin vaccine, which actually in animal models has been developed as effective both for morphine and heroine, a person that would want to inject a drug will not be able to get any high, and that would be a very effective intervention for helping individuals that are addicted to heroin worldwide.

DR. GREEN: Would that be a one-time treatment or is this like naltrexone where it has to be continuous?

MS. VOLKOW: Well, with naltrexone we're working also – we're working in long – treatments that can last very long. That's why I say internationally. Because if you are in rural China, is going to be incredibly difficult for a Chinese person to go on a daily basis to get their methadone. It's also going to be unrealistic. And so if you can get, for example a naltrexone – and the problem with naltrexone in the treatment of heroin abuse is it works, but people just stop taking it. So we're aiming now at the naltrexone that's a Depot naltrexone that lasts at least six weeks. So you go and you may not like it, but you cannot stop taking it. And that way, you can manage populations that may not have easy access to a medical community. With naltrexone, we're seeing effectiveness, the Depot naltrexone, for six weeks. With a vaccine you can aim – based on what we have, there's some experimental data showing positive effects of two nicotine vaccines with positive signals. We are also working with a cocaine vaccine that has a signal that's approximately eight to 12 weeks, so the idea is to be able to cover a longer period of time.

DR. GREEN: In all cases, it works by blocking the pleasure centers?

MS. VOLKOW: No. It blocks by destroying the drug, just like with any vaccine. You generate antibodies for heroin or you generate antibodies for cocaine or you generate antibodies for nicotine.

DR. GREEN: So the immune system destroys the drug?

MS. VOLKOW: The problem and the challenge is just like with the HIV vaccine of course, it's not so formidable of a problem, not everybody mounts the antibodies, so you need to get an antigen to which you couple your drug that is strong and powerful

enough to generate sufficient antibodies that last long enough. So we've been successful, for example – we funded now for many years a company that has developed monoclonal antibodies against methamphetamine, and it works, so you can put – but in terms of its effectiveness, it's been useful. You have someone that gets into the emergency room intoxicated with methamphetamine which can lead to cardiovascular toxicity. You can actually give the antibodies and reverse the effects of methamphetamine. But those monoclonal antibodies have a relatively short duration, one week or two. But it's that type of thinking and trying to get something that's longer lasting that we could actually eventually utilize.

MS. MAXWELL: What's the most common mode of methamphetamine use: oral, smoking or IV?

MS. VOLKOW: It depends. Actually, when it is abused by people that are addicted, smoking. For people that – a lot of people take methamphetamine for sexual reasons. They take it orally. We've known for at least four years that truckers, people that drive trucks for many, many hours without having to sleep, abuse methamphetamines also, because it's a stimulant, it keeps you awake. They take it orally.

MS. MAXWELL: Beny.

DR. PRIMM: Dr. Volkow, I'm very concerned as an anesthesiologist relative to giving a vaccine that would block the effects of heroin and morphine. What would we use in cases of severe and acute pain and so forth that would be as effective as these analogues?

MS. VOLKOW: Well, you are an anesthesiologist, so you know much better than I that the wide variety of opioids that are available. And what's interesting, which is not a case for naltrexone, if you have naltrexone, that will block all of the opiate receptors, so whether you're working with Demerol or you're working with fentanyl, or you're working with hydrocodone, whatever, you're going to block them with naltrexone, not with a vaccine. The vaccine is only going to target heroin and morphine. The problem is, and that's why I say it may not work very well in the United States, is that in the United States you have a wide availability of prescription opiates, so a person that's addicted to heroine gets the vaccine, they'll go out and take OxyContin, they will go out – in China, in a rural community, that person will not be able to get OxyContin. So it's not a problem that – but on the other hand, that Depot naltrexone could be an issue on someone that requires a surgery. That's absolutely correct.

MS. MAXWELL: Ram.

DR. YOGEV: What you are showing me is something which really bothers me for a long time is in the Ryan White which is the biggest one which we're here for treatment, the one who would suffer the most in the cut and very limited is the mental health. (Unintelligible) – epidemic which is growing. What are your agency and other agencies doing to make those treatment available to this population?

MS. VOLKOW: To individuals with mental illness. Yes, and you're touching obviously perhaps of the populations those that are most vulnerable, and indeed, in the United States as well as worldwide, but I know the statistics in the United States, the individuals that are at greater risk of taking substances are those with mental illness, whether it is a psychosis like schizophrenia or depression or something of a learning disability.

One of the things that has been unfortunately very much eroded in the clinical treatment in the United States is that psychiatric treatment has been divorced from the treatment of drug addiction. Fortunately for other countries, that's not necessarily the case. In some European countries, the treatment is very well integrated. Not in the United States. And indeed except for a few providers like – (unintelligible) – most – even in academic centers – do not integrate it, like they don't integrate in any way the HIV treatment with the drug abuse treatment. And as a result of that, you have a person that's taking drugs, tests positive, it's sent to a completely different place and it's lost in the process.

So I wish I could have better responses to use. We are identifying as an area that needs to be addressed, and so we are providing information from services research to document the value of integrating the treatment of both, which will again, require that we change the educational system at the specialty level such that psychiatrists are trained to treat both the addiction as well as the other psychiatric diseases, which is not right now what happens in the United States. I don't know where you come from but –

DR. YOGEV: You see, the issue is that I think that as a committee, we need to discuss how to do exactly what you just said, the integration. I can tell you in Chicago we are trying to shy away from these patients because they're becoming expensive and there's no place where to – to direct them to, and in the Ryan White the minimal is there. So it's not sufficient for the epidemic which you are showing which might affect HIV. So I think as a committee, we need to look into – all the things which you are showing us, that there are of some success. Even a 60 percent reduction is great. But to do that, we need to find the funding and recommend for it.

MS. VOLKOW: Yes, I know. And I would appreciate – we're working with of course the American Psychiatric Association as well as the American Medical Association to try to facilitate the integration of treatment, and that implies integration of the treatment of drug abuse in psychiatry but also the involvement of the medical community and the recognition, evaluation and treatment of drug addiction which it basically has washed its hands of. As a pediatrician or as a general practitioner, most physicians do not evaluate – (unintelligible) – they are not get reimbursed for that. So anything on those lines – to me it's very clear cut – change in policy that would have a dramatic effect in the outcomes.

MS. MAXWELL: Our last question will be from Beny.

DR. PRIMM: Okay. Dr. Volkow, I'd like to go on record as saying to this audience that the Addiction Research and Treatment Cooperation where I founded that organization and still executive director, we have integrated (four ?) comorbid diagnoses, certainly mental health and of course substance abuse treatment of all kinds and it's flourishing and doing quite well. There's a new building in the (Hollam ?) community that's really named after me that the whole sixth floor is designated just for the treatment of mental health problems associated with addictive behavior. Thank you.

MS. VOLKOW: Well, I'm glad to hear that and I congratulate you for that.

MS. MAXWELL: Thank you, Dr. Volkow.

MS. VOLKOW: Thanks to you all. Bye, bye. (Applause.)

MS. MAXWELL: At this time we welcome Dr. Bernard Branson who is the associate director for Laboratory Diagnostics in the division of HIV/AIDS prevention in the National Center for HIV/AIDS, viral hepatitis, STD and TB prevention at the CDC where he also conducts research into HIV prevention strategies. Dr. Branson has been the chief architect for the CDC's activities surrounding new technologies for HIV testing including rapid HIV test. And Dr. Branson has been involved in providing HIV care, counseling and testing for more than 20 years. Welcome Dr. Branson.

BERNARD BRANSON: Thank you. I'm going to speak somewhat about the adoption of CDC's recommendations but I did want to start out to at least correct on misstatement that was made earlier this morning when Dr. Primm asked about doing RNA testing on a patient of his, that in fact, a part of CDC's new recommendations to include the process of doing RNA testing when acute HIV infection is a possibility so that is part of the new recommendations and I think it follows in very well with the question that you were asking in our seeking to diagnose people early.

DR. PRIMM: Thank you very much, Bernie.

MR. BRANSON: I'm going to start out with presenting some examples from the field on the adoption of HIV testing and CDC's recommendations. We anticipate that we will have more representative national data probably not before the middle of 2008 with respect to actual numbers of people tested given the nature of the data collection systems. The first example was actually a published one which started in San Francisco Public Health, and as you'll notice from several of these examples, a number of jurisdictions initiated the process of implementing CDC's recommendations when we distributed the first draft of the recommendations in May of 2006.

In San Francisco, the required separate signed informed consent in their health – (unintelligible) – and in their clinics, and it required that if a specimen was submitted to the laboratory without a special consent as part of the requisition that the specimen be rejected. They changed that requirement in May of 2006 and then they compared their rates of HIV testing and the new diagnosis before and after the change, and what you see

here with the blue line is the time period when they changed the requirement, and so testing which had been on a slight increase took a relatively abrupt increase after the change in the informed consent requirement, and they went from a diagnosis of 20.6 HIV positive tests per month in their health (system ?) to about a 50 percent increase to 30.6 HIV positive tests per month just as a result of that change. This was the first of the (ecologic ?) data at least that supported some of the parts of CDC's recommendations that were intended to try to make testing more realistic and easier to conduct in healthcare settings.

The state of New Jersey is another example where the Health Department has begun to assist rapid HIV testing in their emergency departments. They started a pilot project in March of 2004 actually, but now they are up to supporting HIV testing in 23 emergency departments. The Health Department provides HIV counselors and test kits and they offer counseling to the patients in the EDs while the rapid HIV test is running. As of August, 2007, they've tested nearly 16,000 people. Because they are using rapid test, 15,700 and 98.3 percent received their test results. They identified 384 HIV positive people that 2.4 percent overall rate compares with a 1.7 percent rate in their publicly funded testing out of emergency departments. Of those, 280 or 73 percent were new positives, and so some individuals are coming back through the emergency rooms who are not in care who do get tested again, get identified again and get anther opportunity to refer them back into care.

The next project that I have some data on is from the New York Health, New York City Health and Hospital Corporation. This is the largest municipal hospital system in the United States. They established a goal to increase their testing which had been at the baseline of about 55,000 tests per year in their entire system from 2003 to 2005, and also to increase the number of patients who learned the HIV status earlier. This is all conducted in New York State, and in New York they still have a two-part state mandated consent form which must be signed for all HIV testing. But the evidence basically in their first year of implementation, fiscal year 2006, they went from 58,000 to about 92,000 tests. More recently, as of June 2007, they arrived to 132,000, nearly 133,000 tests in their whole system, but importantly, and the number of HIV positive persons they identified in their systems more than doubled from approximately 700 per year up to about 1,500 per year in '06 and 1,600 new HIV positive diagnosis in fiscal year 2007. And these are all unpublished data from these different sources.

Another example comes from the JPS, the John Peter Smith Health Network which is a large public house for the system in Fort Worth, Texas. They also initiated primary point of care HIV screening in their emergency department. They started using the rapid test here back in 2004 for the people in the sexual assault network and then again started a more expanded HIV testing program here when CDC's draft recommendations came out in May of 2006, and I show this to indicate that their data runs from October to September according to their fiscal year and most of this expansion has been in their emergency department.

So you see basically the overall increases in the testing that they have done there from 648 HIV positive individuals in fiscal year 2005 up to 981 in '06 to 910 in the first nine months of fiscal year '07 on track to achieve the approximate diagnosis of 1,200 individuals. Interestingly here at this institution, they also kept track of the most diagnoses of the people who were diagnosed HIV positive, and the number one diagnosis was chest pain, the number two diagnosis was seizures and the number three diagnosis was abdominal pain. So at the current time, doing an HIV test is part of the standing orders for all patients who come to this emergency department with the complaint of chest pain and the basis of the experience they've had up until now. Obviously, those diagnoses represent the kinds of patients who are coming to their emergency department facility, and so that a lot of people are being diagnosed when they have conditions that are unrelated and that otherwise would be suggestive of HIV disease.

CDC did conduct several demonstration projects in emergency departments, and I want to go through a description of three of them that were published in June in MMWR. In two programs in Los Angeles and New York, the emergency department's screening programs were counselor based for the counselors offered and performed the rapid HIV test and also provided pre and post-test counseling. In the third program in Oakland, the test was offered by the triage nurse, the testing was done by the emergency department staff, usually the nurses who also disclosed the test results after performing the test.

So in these three emergency departments, they also saw a large number of patients during this time period, was all the same one year time period between about 50,000 and 70,000 patients. They were able in the two counselor-based programs to offer testing to 1,700 patients and 1,500 patients compared to 31,000 patients who were offered testing in a program that was staff based. The people who accepted the proportion as very high in the counselor-based programs but considerably lower in the program. However, the absolute number of people who accepted testing was still considerably higher in the staff-based screening model. People who were actually tested, almost everyone who accepted in the counselor-based model was tested because of other – (unintelligible) – in the emergency department, only 6,000 of the 16,000 people were able to be tested in the staff-based model, but the bottom line is that they identified approximately of the same percentage, around 1 percent of HIV positive people, but that was only 13 people in the Los Angeles ED, 19 in the New York and 65 in Oakland emergency department. And so this we felt is again some evidence that the models that make testing more routine and rely on routine staff in order to conduct the testing have a significant impact on identifying more HIV infected persons.

In Oakland as in several of the other programs, we are encouraging the programs to conduct patient satisfaction surveys in order to make sure that people agree with the process of HIV screening, and so of the HIV positive persons, 57 of the 65 completed the survey, all of them said they were satisfied with the process and 96 percent of them felt that the result disclosure was private. Of the HIV negative patients again, 99 percent were satisfied with the process. A slightly lower percentage, only 91 percent felt the disclosure was private. In this institution as in many others, the patient was often separated only by curtains and they would very often deliver the HIV negative test results

to persons when they were just in the cubicle, only taking the persons with positive results off to a private setting when it was necessary in order to do that, to disclose an HIV positive test result.

So we were interested to find that the patients' (possession ?) of privacy was maintained despite their testing and disclosure of negative results in a variety of busy clinical areas in these emergency departments. I think earlier and in fact someone quite from Jeremy Brown's program here at George Washington University Hospital Emergency Department. They set out an opt-out screening program in their emergency department after CDC's recommendations came out in September, and in their first three months, between September and December of 2006, 7,000 persons were offered HIV screening, again, 56 percent accepted, and we're seeing this in most programs between 52 and 60 percent of people offered screening routinely accepted.

Again, 41 or 1 percent of those persons were HIV positive. They also offered a patient satisfaction survey, and this was given both to people who accepted the HIV test and to people who decline the test, and of those people who were administered the test overall, 84 percent said they would recommend HIV testing to a friend if they went to the emergency department, and similarly we're looking at about 74 percent of people said they agreed or strongly agreed that the emergency department is a good place to perform HIV testing and only about 11 percent – I'm sorry, about 14 percent of people disagreed that the emergency department was a good place in order to conduct HIV testing. We are encouraging most of our programs now to conduct this kind of assessment with patients in order to make sure that they feel positively toward this expanded testing similar to the way most providers seem to do it.

I want to spend just a moment talking about policy support for expanded HIV testing. In the first of these which we consider are important was from the American College of Emergency Physicians. This is the national emergency medicine specialty society that has more than 25,000 members, practitioners of emergency medicine with 53 chapters representing each state in the districts of Columbia and Puerto Rico. Their policies cover many different areas and are distributed to all of the American College Emergency Physicians members to address key issues and illustrate important concern. They issued their policy with respect to HIV testing and screening in April of 2007, which states as follows: first, the early diagnosis and treatment for HIV can prolong life, reduce transmission, has been demonstrated to be a cost effective public health intervention. They felt that HIV testing in the evaluation for acute care conditions should be available in an expeditious and efficient fashion similar to the testing and results of other conditions.

But HIV screening which is for asymptomatic persons, when deemed appropriate by the emergency physician must meet the following conditions: first, it has to be a practical and feasible for emergency department settings and it cannot interfere with the primary acute care mission of emergency departments. They recommended the offer based on the local prevalence and the medical needs of the community integrated with the resources of the entire healthcare system, and that it must adequately address patient

confidentiality, state – (unintelligible) – requirements for informed consent, provider training and the need for counseling and (legalist ?) care.

They did reemphasize that it has to meet local and state requirements, and I think there's already been some discussion of that here today, and it must be contingent upon adequate funding to meet the (added ?) operational and personnel costs for sustainability. So while this is a supportive statement of expanded screening in emergency departments, it highlighted I think the important problems of making sure that there were compliant with state and local requirements, and also dependant on the sources of reimbursement in order to cover the costs for testing for the many patients who are uninsured.

This is our – (unintelligible) – so far of the places that have enacted legislative changes since 2006. I noticed there was a handout of the AP story saying nobody had done anything since last year, and that is actually not the case from the evidence that we've done this review, so that states that have explicitly removed written informed consent requirements that include Iowa, Illinois, Indiana, Louisiana, Maine, New Hampshire and New Mexico, the legislation has passed both the assembly and the Senate in California and has gone to the governor's desk awaiting signature, and there is legislation under discussion at the current time when it has been proposed in both New York and in Massachusetts.

The states that have specifically passed legislation enabling opt-out prenatal testing include Georgia, Iowa, Illinois, Louisiana, Nevada, Rhode Island and Tennessee, and again, it's passed both House and the Senate in New Jersey and it is waiting the governmental action. So that this I think represents for us a surprising number of places that have taken action since we issued our recommendations just in September in 2006 to get legislatures, especially in large states to move as quickly. Yes, sir.

DR. MALEBRANCHE: I wanted to ask what worked in getting that moved so quickly? Like what happened?

MR. BRANSON: What I can say is that we provide technical assistance on request, so we don't have all details of what happened in those areas, but I think the thing that was most instrumental in the places that moved forward was some very strong support from the medical society, so that for example the California Medical Association was a co-sponsor of the bill together with the AIDS Healthcare Foundation there in order to do that. I think similarly in Illinois, the Medical Association got together and they partnered and sort of struck some negotiation with the community based organizations, but clearly I think that provider organizations moving forward made a considerable difference.

There is a continuum of state laws that is being maintained by the National Clinicians Consultation Center. This is a HRSA funded program at the University of California San Francisco and so this website ucsf.edu/hivcenter, you can click on your specific state, it will take you to a summary of what requirements and either statute or regulations are, and then they have behind that the specific statute or regulation, and in

many places it is not a statutory barrier as has been pointed out but there are some regulations and a large number of jurisdictions for example I just received information from Missouri where they have specific regulations for non-clinical settings, in other words for HIV testing programs that have one set of requirements that are different from the recommendations for their clinical settings and they sent our a clarifying letter to all of the providers in their state to let them know that they believe their regulations are completely consistent with CDC's recommendations for opt-out HIV testing.

CDC has been attempting to provide assistance to priority jurisdictions, and one of the ways of doing that in order to get these recommendations implemented has been to conduct a series of strategic planning workshops and these are very much sort of grass roots levels where we recruit teams and individuals from hospitals usually including nursing, laboratory, emergency department and very often risk management in order that the plan for HIV screening in the institution. The format of these are to provide basic information about screening, and then one of the most effective parts if actually bring in people who are already conducting successful screenings programs in this kinds of environments in order to do our lessons from the field, question/answer session, then each of these teams does a strength/weaknesses opportunities and threats analysis, participate in some practical nuts and bolts workshops about how to do the screening and then for the institution they develop an individual strategic plan.

We are following up with each institution at six months and 12 months in order to gage what their progress has been in implementation, but in the series of the workshops we've completed in Los Angeles, Miami, Chicago and Boston, Los Angeles and Miami were the first two in Jackson Memorial and UCSF and UCLA are all conducting HIV screening now in their facilities, and we're seeing similar movement in the other places. There are additional workshops right now scheduled in Washington D.C., New York City and San Antonio and eight more are planned for the jurisdictions that are funded under CDC's new initiative.

CDC has established cooperative agreements with certain healthcare professional organizations including the American Academy of HIV Medicine, the arm of the American Hospital Association known as the Health Research Education Trust, the National Medical Association and Society for General Internal Medicine, these are designed to promote the extension of HIV screening and also the developments of some standardized materials that can be used in each of these kinds of practice venues in order to provide the recommended information for patients.

This is one example of the thing that is up and running from the Health Research and Education Trust which is specific for emergency departments, it's an entire website called edhivtestguide.org, and then basically it has the list of all the kinds of resources that are available here, and many of these related to information for patients, delivering tests results, documenting results. They are all in downloadable forms either in Microsoft Word format or in PDF format so that institutions can use these relatively standardized forms to provide their own specific information on that, and we see our other implementation guidance specific for individual venues following a very similar pattern

to this, so that we'll be able to have resources that can be shared across these different venues but still have some specific resources tailored for individual circumstances and assuring both cultural competence and understanding for low-literacy patients.

CDC did implement for 2007 the president's HIV testing initiative making $35 million available for testing in priority jurisdictions, and I'll show you a list of those in just a moment. In addition, we executed an interagency agreement with HRSA to provide $1.75 million for provider training which will be done by the established network of AIDS Education and Training Centers. Until now, most of the scope of the AIDS Education and Training Centers has been train providers to deliver increasingly sophisticated HIV care. This initiative is designed toward working with other providers in order to get them to start thinking about HIV screening and implementing the HIV screening.

There was another $750,000 for national organizations to deliver provider support, and $1 million to evaluate more broadly the adoption of the recommendations, and then $4.1 million for social marketing campaigns including one called "One Test, Tow Lives" devoted to prenatal testing. "Prevention is Care" is a social marketing campaign for delivering HIV prevention services for HIV infected persons who are in healthcare settings, and then a third one for marketing routine testing to healthcare providers in a variety of venues.

This is a list of the 23 funded jurisdictions. They received money in 2007 in order to implement HIV testing. These jurisdictions actually represent between 82 and 85 percent of the locations where the black AIDS cases were reported in the United States in 2005, and so we particularly tried to target this initiative in order to have it integrate with our heightened national response to the African-American epidemic in the United States, and the national organizations that were supported include the University of Washington to develop a web-based continuing medical education program, the professional, the American College of Obstetrics and Gynecology to develop tool kits for professionals, the National Black Alcoholism and Addictions Council to work with substance abuse providers, the Public Health Foundation to develop implementation guidance for STD clinics, the health research and education trust, again for implementation guidance, and the AETC National Clinicians Consultation Center.

One thing we felt was important is that if people were identifying more HIV infected people, that providers who may not have expertise in HIV needed somewhere to refer them and someplace to call for advice. And the National Clinicians Consultation Center maintains a telephone hotline where people can call for clinical information as well as providing referral information. Similarly, the AIDS Education and Training Center, National Research Center maintains the national repository of education materials, both informational materials for patients and educational materials for providers, and then the National Evaluation Center is working with individual programs, in particular in helping to evaluate patient responses and reactions to the expanded HIV screening.

So for us at CDC, our priorities and our next steps include number one, securing additional endorsement by professional associations. One of the issues in terms of making this standard a care is that CDC makes a recommendation, but it is very important that professional associations endorse these in order to basically making it much more binding. This is very effective with the prenatal screening recommendation. When the American College of Obstetrics and Gynecology came out with their expert opinion thesis, said everybody should be doing this. They have already come out with an endorsement saying that all women who are being seen in obstetricians' offices should be screened for HIV consistent with CDC recommendations. We feel this endorsement fits in with working on the issue of third-party reimbursement and we're continuing to work with different groups on addressing third-party reimbursement.

Similarly, we've been responding to requests to continue to help develop practical material for providers and information materials they can use with their patients and obviously to continue to conduct evaluation of this program in order to see exactly what the uptake is of CDC recommendations and see if we can identify both examples of best practices and continue monitoring for any potential adverse effects and some people have raised concern about a large change in the nature of screening with changes in both the counseling and the informed consent procedures.

I would like to acknowledge a large number of people who provided what was mostly unpublished data on all this implementation right now, because this is still very early in the course of getting information together so that from the New York hospitals, from Forth Worth, New Jersey Department of Health, (Alameda ?) County, and GW University Hospital and in particular, NASTAD, the National Association of State and Territorial AIDS Directors who has been maintaining pretty much a registry of the changes in legislation as the individual states reported into them, they have been sharing that information with us.

Thanks very much. (Applause.)

MS. MAXWELL: Thank you Dr. Branson.

Questions? Beny?

DR. PRIMM: Bernie, I'm concerned about maybe I'm confused, and it's not uncommon for me to be confused that there were $45 million appropriates I thought for to fight HIV among African-Americans campaign. Is that true, or was it 35 million that you put forth?

MR. BRANSON: Thirty-five million dollars went after the states, and the other money went out to support those efforts including what I listed there having to do with provider training in those area, making materials available to clinicians, consultation center so that the additional money, the difference between the 35 and the 45 was to provide the necessary resources for them to be able to actually implement the – (unintelligible).

DR. PRIMM: Well, it was reported this morning that this money was found in CDC by Dr. – (unintelligible) – and I'm wondering is that going to be a continuous program like this or this is just a one-shot deal, some states did not for example, like Mississippi and Alabama, did not get any money where there's great problems, or how will these states continue to get their money? Will it be a competitive for grants again or what?

MR. BRANSON: Obviously, we are dependant on appropriations, and so we are hopeful that there will be continuation of this money. We don't have a guarantee that there will be a continuation. So when this money was announced, it was announced as one-time money with the possible expectation of continuation depending on continued appropriation and perhaps Eva Margolis (ph) can address this?

EVA MARGOLIS: Thank you very much. Just to clarify, the money was – (off mike). Thank you. (Laughter.) The money was put into our fiscal year 2008 base, so the money will not be one-time dollars. It was put out as one-time – we put it out before the FY08 budget was submitted and it was for a three-year cooperative agreement.

DR. PRIMM: I'm also wondering why the numbers were reduced from 1.5 million to one million in terms of the people to be tested. I asked that question – (off mike).

MR. BRANSON: We put out a request or an expectation that 1.5 million people would be tested. We then received proposals from the different states which came up to just about I think 1.2 million people that they were proposing testing. We feel that we would like to begin leveraging this process in order to achieve a higher number than that, but until we get started, I think it's going to be very difficult for us to tell – I think what was in their proposals was their best guess of what they could accomplish.

DR. PRIMM: Last question. Would that be an RFP to – ministers met in New York this past Monday and Tuesday, over 100 of them met with the National Medical Association and ministers and members of Congress, five members of Congress attended that meeting. Will there be, and this bunch of money that you have adequate amounts to now maybe fund efforts on their part to do some testing within churches in all of the United States which I think is just tremendous.

MR. BRANSON: The bulk of the money that we put out at this point in time was to go towards expanding testing in medical settings, but up to 10 percent of those funds could be used to retesting for programs in non-clinical settings, and so we see that as a part of the subsequent announcements that we do like our usually CBO announcement plus a continuation of this would be potentially usable for activities like you're speaking of in non-clinical settings like churches.

DR. PRIMM: We just need to get that information out there so people can know about it and begin to focus in on those dollar if that's possible.

MR. BRANSON: Great.

MS. MAXWELL: Ram.

DR. YOGEV: First, a question about the rapid testing. For more than 10 years, we know that if you do two rapid testing with different methodology it's as accurate as doing the western blot, yet the CDC has continuously recommended to do a test and verify it with a much more expensive test which takes longer to do. Is there any move of trying to resolve it really right there and then by recommending those tests in – (unintelligible) – and Columbia and – (unintelligible) – even in Texas in the late '90. The two tests are working as good. Is there any progress in that direction?

MR. BRANSON: We have several cooperative agreements now evaluating the use of those tests, and also in December of this year will be the HIV Diagnostics Conference. There are proposed algorithms for both point of care confirmation and new algorithms for laboratory confirmation that will be discussed at that meeting in December. However, there's also the recent publication that came out from some workers in Uganda using that multiple rapid test together which showed that its specificity and confirmation was only about 92 percent. And so before we make a specific or explicit recommendation across the country, we need to look at the exact combinations of tests we have here to make sure they are as accurate as the western blot.

DR. YOGEV: The other question is in the CDC budget to about $30 million incentive to state will fulfill the criteria of the CDC of opt-out, and one of the reasoning – and the last (money ?) went to the Appropriation Committee that there is no state to fulfill those criteria, therefore there was specifically prevented CDC to use those funds. As of Thursday, I know of one state that Illinois fulfills those criteria and the two questions: one, is that money frozen or is moved to something else, and two, done this changes now that I hear from you that California and I know that Illinois is doing is would it be something to reconsider?

MR. BRANSON: Just a couple of points, but I think Eve perhaps can perhaps address those specifics on the budget.

MS. MARGOLIS: Okay. Yes. The money actually was not in CDC's budget for FY2007. We were actually prohibited in congressional language from spending that money. In FY08 we don't have a budget yet, so it's yet to be seen whether or not we're going to get funding for that. If we don't get funding for that, we're going to have to cut the state HIV prevention dollars because there's no other – that's where the funding will come from if we don't get new dollars. Regarding your question about the eligibility, the way that language was written, just having a law or regulation isn't sufficient enough to qualify for the money.

I don't have the exact phrase in my head, but you have to actually show intent to implement the policies, the policies in place so that it's not just a state giving lip service

and passing the law. They actually have to take steps to implement it. So we've been asked that question many times about how many states are eligible and it's really hard to say. We know who definitely may not be eligible. Well, actually we don't even definitely know that because the absence of a law or REG, a state could go ahead as long as they had a policy in place. So really the only way we're going to know who's eligible is put out an RFA and find out who it is, and we're not going to do that if there's not – depending we're going to wait and see what the congressional language says on that section of the law.

DR. YOGEV: Just a quick clarification. If certainly in the CDC budget and then they say don't use it, that money is completely taken away or those 30 million are transferred to something else?

MS. MARGOLIS: The 30 million was actually never in CDC's budget. The way this section is written in Ryan White it says it comes out of CDC's prevention budget, but it was actually never in our budget.

MS. MAXWELL: Bob.

DR. REDFIELD: Thanks for all you do. Two questions: one came up a little bit today when we talked to the third-party pairs, we had Blue Cross Blue Shield here, we had Aetna here. Were you in the audience at the time?

MR. BRANSON: Yes.

DR. REDFIELD: So you heard the comment about sort of the vagueness of recommendations. I know in the Defense Department when we started routine diagnosis in the context of sort of an annual education thing, the first time we did it, for the first couple of years we did it annually, and then we recommended it every two years. Is there any thought to try to get a little more prescriptive with CDC's recommendations particularly at this stage in terms of trying to move this forward?

MR. BRANSON: First of all, one big part of our intention with the recommendations in terms of the nature was to eliminate the requirement for medical necessity protesting, because a big – (unintelligible) – that we heard from most providers as well as from a lot of the people in the ED workshops is that if you have to demonstrate medical necessity, in other words that a person is eligible for HIV test, they either have to be sick, or there's not only a procedure code for the testing, but it has to be associated with the diagnosis code, and only applicable diagnosis code was lifestyle associated problems which is not something most people want reported to their insurance company. So by having a broad recommendation, we felt that if it was screening across the board, it would allow for people to begin to do reimbursement without requiring medical necessity, and to date, the claims that have been denied have been denied because they have not had the requirements of medical necessity, and so some people are contesting them.

With respect to the second question about the frequency to repeat screening, our recommendation was based on the cost effectiveness analyses which said, to the threshold that we recommended, the 0.1 percent demonstrated prevalence or yield of screening, that was effective across – (unintelligible) – but one-time screening in the country, and without getting some information on where the yield of screening would be, we thought that we didn't have the factual or the data basis in order to proceed with the recommendation for a periodicity for screening. It was a topic on which we convened the consultation. I think it would be probably similar to the military which should be an evolving recommendation.

DR. REDFIELD: Just a quick follow up. Can I do a quick follow-up? It sort of puts in perspective because again, I think the leadership to CDC's put out on this and your own personal involvement is obviously enormously appreciated and it's something that needs to be done. Earlier on, I sort of suggested I'd love to see the year 2008 to be the sort of the year of diagnosis rather the day of diagnosis, because we are since we rolled the HIV test in '85, we're almost 22, 23 years into it and still somewhere between a quarter and some people even say more, some of those ER data might even suspect might even be higher than 25 percent of Americans don't know they're infected. Just sort of as a reaction in terms of what we need to do here.

Mara (sp) reminded there's 300 million people in the United States. I assume again, I'm not a – (unintelligible) – heartbeat, but let's just say two-thirds of them reach that recommendation of 13 to 65. If we got a test for $5, we're still talking about $1 billion a year just to run a testing program. If we assume about a third of people are uninsured, now we're talking about $300 million a year program. If we really believe this is important, and I happen to be one of those who really believe it's important, that's a treatable preventable epidemic, it seems that we need to now take the policy recommendations and get it resourced through the public sector and the private sector, to try to move so that again, all Americans have the opportunity to know if they're infected or not.

It really is going to be somewhere between from a public side it's going to be, in view, somewhere between $500 million and $1.5 billion to make sure that the poor and the uninsured get the same benefit of our public health recommendations as the rich. It's more of a comment that maybe you want to react to it, because I know you're working the best you can within the resources, but now it's to translate that war into a broader public policy.

MR. BRANSON: Obviously, we would like to have resources to see this implemented. We are working and sort of coming up with something because I want to be careful when we stir about calculations like the 300 million U.S. population, about 45 to 48 percent of people say they've already been tested in the U.S. and there's about 16 to 21 million people who are tested each year already in the United States so we're doing a lot of testing that's already out there. What were talking about is going incrementally, and while I would like to see – the Bronx is about to announce an initiative to be the first burrow that knows its status.

Oakland is doing the same thing in terms of being the first city, so people are moving forward. The other side of it is that the people in these emergency departments where they're having 100,000, 120,000 visits a year are terrified that they would be expected to test everybody in the first year, and so the other side of that is to allow them to recognize that we're looking forward toward incremental implementation so that we're not going to attempt to overwhelm any of these service providers by trying to have them do all of this within 2008, so although that would be sort of a desirable slogan, I think we'd like to see move a little – (unintelligible).

MS. MAXWELL: Carl?

MR. SCHMID: You've been very busy for the last two years since these recommendations have been put out, and I guess my question is the implementation because it is already been implemented but you haven's put out all the implementation guidelines yet for the different healthcare settings, and I guess as a community (we ?) representative, we want to make sure that confidentiality is maintained, that information is presented on HIV/AIDS, that it is truly opt-out as you recommend, that there is linkage to care and that debating non-state laws there's informed consent and prevention counseling. So I guess I'm a little concerned that it's being implemented but the guidelines aren't out there yet. So I guess what is your timeline with the implementation of the guidelines and developing all these materials?

MR. BRANSON: I want to be careful about two things. One is that CDC doesn't pretend to know how this should be done in every healthcare setting out there. In developing the emergency department guidelines there are a large number of site visits, we did a bunch of demonstration projects with them so that we learn from those experiences, and each one of the other implementation guidance is being developed similarly, so for example, the Prevention Training Centers, they work with SCD clinics as doing it for STD. The Society for General Internal Medicine is instrumental as being the author behind the part four primary care settings.

And so I don't want to create the image that CDC is now going to tell everybody how they should do their job because we think that we're learning this from the people who are doing it, and so each one of these workgroups who is developing the drafts of the implementation guidance has got very active representation from the people. They've also received the fundamental principles that I think maybe the community groups have gotten together, fundamental principles that should be present in part of each of this counseling and testing programs, so that we have several drafts of this implementation guidance. They're being reviewed by an editor. We plan to get commentary from them in other places, but just sort of a (slide shift ?) that CDC is not going to issue implementation guidance in all these places we're coordinating its development with the people who are actively doing these programs.

MS. MAXWELL: Freda.

DR. BUSH: Thank you. Actually Carl asked a portion of the question that I was going to ask, but I'll follow that up with the example on page two of what's going on with the emergency department in New Jersey, it specifically said that counseling was offered while rapid HIV testing is done. So I was wondering exactly how was it implemented, if you can recall? Was it seen as a barrier while they were waiting, and what type of counseling was done at that particular time? Was there literature given, especially to those who were HIV negative? You mentioned they were treated a little different from the positives, so that would enlighten us.

MR. BRANSON: In Oakland there were – I'm sorry, so the New Jersey example when counseling was provided at the same time, that started before CDC's recommendations came out, and so the program was set out to deliver the classic or traditional prevention counseling and testing where separate counselors would go and approach people in those emergency departments but give them the same kind of services, is not quite what CDC is recommending at the current time. So they would receive prevention counseling and testing.

Many of the emergency departments were at first reluctant to have people there because they essentially thought that they were going to get in the way, and so as they became accustomed to having people there and realize that there were a lot of their patients spending an awful of time waiting anyway in the emergency department and there was plenty of time to offer this additional service, they were welcomed a lot more and it became a lot more acceptable to the people who were providers in those circumstances. Our only concern is the same that I showed with the example from Los Angeles and New York is that the counselor-based models are able to reach such a tiny fraction of the people who need to be tested in those environments, and the idea is how best to balance those two means which is to try to identify the people who need to be diagnosed with HIV and provide counseling when it could be beneficial and that's a balance everyone is trying to work out.

MS. MAXWELL: Beny?

DR. PRIMM: Bernie, I wanted a little bit more clearance of the use of the RNA testing that you talked about as a preamble to your speech to get some clarity when it could be used and how did you suggest it would be used?

MR. BRANSON: Our recommendation currently is carefully worded and it says that when acute HIV infection is a possibility that you should do an RNA test in conjunction with an antibody test in order to diagnose acute HIV. The Public Health Service treatment recommendations say that for a person who has had a high risk exposure and who has symptoms of a viral syndrome, they should be tested with an RNA test together with an antibody test.

Right now, what we're trying – Eric Rosenberg for example in Massachusetts General is looking for acute HIV infection specimens, and he went to its hospitals laboratory and looked at everybody whom a – (unintelligible) – test had been done

basically and tested those, and 1 percent were positive for HIV RNA. They had undiagnosed acute RNA, so that a lot of people with viral syndromes are going through these environments and not being tested. On the other hand, because of the cost and the complexity of the RNA test, we don't necessarily recommend that everybody who has a viral syndrome be tested.

And so right now, I think our recommendation be similar to that of the U.S. Public Health Service that a person who has had a risk exposure similar to the woman that you described earlier this morning in the example that you gave and some symptoms consisting with the viral syndrome would get an RNA test.

DR. PRIMM: Would that be good for prisons too, and then who would pay for it? Those are the –

MR. BRANSON: Well, in prisons of course, usually is the correctional system health system that's responsible for the cost, and these other environments, that's exactly what we're looking at, it's one of the reasons we're not recommending this to be done on everyone. It's simply because it is so expensive. One other correction is that there is one qualitative RNA test that's approved by FDA for diagnosis. I know that mentioned today had to do with the – (unintelligible) – or the viral load test but there is a qualitative diagnostic test that's approved for HIV diagnosis for acute infection or for confirmation.

DR. PRIMM: Okay. What is that test?

MR. BRANSON: It's APTIMA made by Gen-Probe, qualitative RNA test.

DR. PRIMM: Thank you, Bernie.

MS. MAXWELL: Raymond?

MR. GILMARTIN: We touched on this a little bit earlier in the discussion I think but what would you say are the most significant obstacles or barriers that have to be overcome with this whole program?

MR. BRANSON: Well, we hear back from providers in terms of the most significant obstacles and this is what they report doing these workshops that we've been attending and it's been very instructive, and they say that the most significant obstacles for them had been in the states that have regulatory or legislative barriers, those barriers which impose too much of a requirement on them to be able to process the people who are coming through, and then the cost related issues. Several people have looked at the patients coming through and they looked at the issue of if they can recover reimbursement from some of the third-party patients, how much of the uninsured can they cover.

We had to specify that CDC's money could be used to support testing for uninsured patients, but we do want the – (unintelligible) – get used to the idea of

spreading this out among the others. We've been working directly with the state, Medicaid medical directors in order to get reimbursement from the Medicaid program, so New York for example has already announced their specific reimbursement strategies and levels for screening in those kinds of places, but I think those are the two biggest barriers that have been identified for us.

MS. MAXWELL: John?

MR. MARTIN: I think my comments are – (off mike) – other people – (unintelligible) – caught in the middle here. First off, thank you very much for your presentation. It really shed a lot of light on the issues we've been discussing all day, and it's clear that you're making a lot of progress on a lot of various – but the concern of course is the scale of the problem, and you talked about getting leverage, Bob talked about the cost, and you made the point about being incremental, and it's clear that the total dollar amount together when screened would not go on forever, and so spreading it out to some degrees is important. However, I think we're also concerned about how the epidemic into communities has kind of gotten away from us and it should not be too incremental, in other words.

And so my question is just sort of if you can give us some insight of how it's happening at the federal level to coordinate all these activities because it's obviously exceptionally complicated, hard for us to understand even though we talk about it all day, so what's going to happen between now and the end of the year and over 2008 to address Bob's point of making 2008 the testing year that will do the best we possibly can?

MR. BRANSON: I think that we're taking actions at as many levels as we can. We have continued to meet with HRSA, with SAMHSA and we work with the other areas for which they are responsible. CDC has been attempting to take some of the lead in working this through, but I think that it's important to sort of recognize that primarily, we saw our recommendations as being recommendations for providers and we did not intend to set up an entirely yet new structure of counseling and testing that would be publicly funded. We basically recommend the flu shot every year, but we don't pay for it for everybody in the country, and I think that what we would like to do it try to make sure we get the other sectors involved and not view this all as being a strictly federal responsibility.

MR. MARTIN: Yes. That's really clear. That's the leverage part and you mentioned the – (unintelligible) – third-party payers. We're here to talk about 35 versus 45 million when the numbers' magnitude versus the magnitude above that. But the program has had some sort of the responsibility to create the environment where that's implemented and who's trying to make that happen.

MR. BRANSON: We count mostly on our partners in order to work with Congress in order to try to get that money for us since we can't seek it directly.

MS. MAXWELL: David.

DR. MALEBRANCHE: I had a question that was slide 15 on – it's the last slide on page five. I know you can't bring it up, but it basically was a slide that looked at the three different ED demonstration products and compared projects between Los Angeles, New York and Oakland. And I noticed that the number of patients, they were all in the high in tens of thousands. It was 47,000 for Los Angeles, 72,000 for New York and 65,000 for Oakland. But then the number that was actually offered testing was so disproportionately higher in Oakland and I didn't know if you would shed some light on why that was or kind of what happened was the targeted screening based on risk profiles and the other one and then they just screened all comers in Oakland or how did that work, because that number just seemed – it's outrageously different.

MR. BRANSON: I'm sorry if I didn't make the point clear enough because that was exactly the point I was trying to make sure that sort of hit home. The difference was that when you had counselor-based model and it was only the counselor who was offering testing, there was only so many people they could do that to, whereas in the other models were staff models and everyone who came through triage was asked, do you want an HIV test and everyone who was in the emergency department would either follow up or would perform the testing and it quite clear that the staff based model was much more productive both in offering the testing and in performing the testing.

MS. MAXWELL: Dr. Branson, you had mentioned that about at least 48 percent of people in the U.S. have been tested?

MR. BRANSON: They say they've been tested.

MS. MAXWELL: Does that include blood donors too?

MR. BRANSON: No.

MS. MAXWELL: Okay.

MR. BRANSON: No. This is for the National Health Energy survey where they have an annual question: have you ever been tested for HIV and then they also ask have you been tested in the last year, and that number has been suddenly increasing, that people would say they're ever been tested and that does not include blood donors.

DR. PRIMM: Bernie, probably just a comment. One of the most successful testing programs going on is that in Oakland with Marsha Martin and of course Rendell – (unintelligible) – and Barbara Lee. Very, very interested in which whole thing, and as a consequence of that, they have now been organizing and I'm sure those numbers are going to be even be more astronomical than what you have and it's because of a concentration of important people being involved in the issue, getting tested themselves, stepping up and so forth. That works and that's what's happening, and Marsha's out there now and she's making it work even better, so I think that to show that slide of then before she got out there, you can now imagine what's going to happen after.

MR. BRANSON: We're looking at it as a model, but clearly, the local community leadership, there's also been involvement from the corporate sector there with Lee Meistrauss (ph) and others who have gotten involved and really supporting these kinds of activities, and we see this very much as a model for what other communities could do.

MS. MAXWELL: Any other questions?

MS. MCGEEIN: Just that we promised Dr. Branson he'd be off because he has a plane to catch.

MS. MAXWELL: Okay.

MS. MARGOLIS: Can I just add one other comment because a lot has been dais about CDC finding money and I don't want to leave the committee with the impression that we just have $45 million laying around to move all around, but the way the budget we got in FY07 was a continuing resolution from Congress and there were some projects that were ending, and there was a new one that was starting up and there was an overlapping budget period and there were some cost saving there, and decisions were made within the agency on where was the best place to put that money and we wanted to put it to presidential initiatives that had not received congressional funding and so that is how the $45 million came about. So I just wanted to let the council know that, since it sounded like we just kind of found money lying around.

MS. MAXWELL: Thank you. And Dr. Branson, thank you for that great presentation and safe travels to you. (Applause.) At this point, we are going to take a 10-minute break before our last presentation.

(Break.)

DR. MAXWELL: Okay, we'll go ahead and get started for our final session. And we have Dr. Lisa Fitzpatrick, and I'm sure they saved the best for last. That's what they always say. Dr. Lisa Fitzpatrick is a director of the Caribbean regional office of the Global AIDS Program. She is responsible for all global AIDS program activities in the 21 Caribbean country in HIV prevention, care, treatment, surveillance and infrastructure development, provision of medical and epidemiologic advice and consultation as a national and internationally-recognized expert in HIV/AIDS. Dr. Fitzpatrick. Thank you.

DR. LISA FITZPATRICK: Thank you. Good afternoon. I realize I'm what's standing between you and the door, so I will talk to you for about 25 or 30 minutes and then give you an opportunity to ask questions. Excuse me.

I have one correction to the bio. The job she described is actually my former job. As of two weeks ago I have moved on from that position. And I'm actually on vacation.

(Laughter.) But when I heard –

DR. MAXWELL: We appreciate your dedication.

DR. FITZPATRICK: – about the opportunity to come and talk to you about this, I gladly accepted, because I think it's a very important topic that few people know well. And I actually think I'm the person at Health and Human Services who knows the most about what's going on in the Caribbean right now so –

DR. MAXWELL: What is your current job?

DR. FITZPATRICK: I don't have a job. (Laughter.) I'm resting. So a much needed break. You'll probably agree after I finish my presentation.

So I was asked to give a talk on the HIV/AIDS epidemic in the Caribbean. There's a lot to say but because there is, I decided to cover everything in a very general way and let you ask more specific questions because I wasn't exactly sure what it is you wanted to know about HIV in the Caribbean.

Can we move this?

So just a brief overview. I'll talk just a few minutes about regional context to set the stage for you. I will then give you a brief overview about HIV/AIDS in the Caribbean and talk about some challenges and opportunities, and then open it up for questions.

Oh, what did I do? Yeah – no, it's fine now.

So to orient you, there's a map on the table. I don't know if you have the map. You have the map. In case you need to refer to the map throughout the presentation. There's some confusion about the different countries in the Caribbean, what's considered Caribbean and what's not, so it's always helpful I think to show a map. You'll hear me refer to the OECS. That stands for Organization of the Eastern Caribbean States, and it's really the six little islands off to your right. So the Organization of the Eastern Caribbean States are those six islands, and they've decided to form a federation. So they use a single currency. They're also trying to develop political and regional strategies for those six countries, so just so that you understand OECS.

The regional office for CDC was based in Trinidad and Tobago. We have a few people there still. But now the regional HID-AIDS offices for USAID and CDC are both located in the United States Embassy in Barbados. And then we have two – (inaudible) – programs, bilateral programs in Guyana and (Haiti ?), denoted by the yellow circles. And most of the Caribbean –

DR. PRIMM: From Anguilla all the way down to Trinidad – (inaudible) – in front of me?

DR. FITZPATRICK: No. Anguilla is part of the British territories –

DR. PRIMM: Oh.

DR. FITZPATRICK: – so it's –

DR. PRIMM: What are the – (inaudible)?

DR. FITZPATRICK: It's Antigua, Balanika, St. Lucia, Grenada, St. Vincent, St. Kitts.

And when people work – generally when organizations work in the six OECS countries they often will also extend their support to Trinidad and Tobago, Surinam, which is actually down in South America but considered Caribbean because they're English-speaking, and then also Barbados. Barbados is not considered OECS, but a lot of times there's program communization that includes Barbados.

Most of the Caribbean is English-speaking. There are a few French-speaking countries. We don't work in most of the French-speaking countries. And as you'll hear, most of the countries we work in are English-speaking because of our collaboration partners. I mentioned the two bilateral programs. Guyana, also in South America, but considered Caribbean because they're English-speaking. And then Haiti next door to Dominican Republic, also English-speaking. A few French speakers in Haiti, but by and large most of our work is with English-speaking collaborators.

So if you have any more questions about geography, just bring me back to the map.

I just want to talk to you a little bit about context. And the reason I'm showing you pictures from Carnival is because I think Carnival is so deeply embedded in the psyche of Caribbeans that it really spills over into lots of the – of the activities, of the – (unintelligible) – of the countries. So there's a Carnival in almost every Caribbean country. And it also will help you understand a little bit about why it's difficult to implement some of the prevention programs in the Caribbean. I would encourage you to participate in Carnival any time. It's a very eye-opening experience, by the way – very educational.

A little bit about the region. There's striking diversity within the region. Ethnic and culturally diverse. I talked a little about there are Spanish-speaking, there's French-speaking, there's English-speaking, and then there are couple places that speak Dutch in the Caribbean. So it's very diverse. So there's no one size fits all for anything in the Caribbean.

Economic disparities. You may hear some of the countries in the Caribbean are very rich. I think the mostly commonly-thought-of country is Bahamas, when they think

about the wealth that there is in Bahamas. But I'm here to tell you there is extreme poverty in the Bahamas and throughout the Caribbean.

Political calaloo. Calaloo is a dish in the Caribbean that's made with – actually, I can't tell you everything that's in it, but it has greens and spices. And it's a mixture of lots of different things, and it's a dish that you can find throughout the Caribbean. So we refer to lots of things as "calaloo" as a figure of speech. The point I'm making here is that every country considers itself autonomous. So it's different when you're trying to apply regional strategies throughout the Caribbean because everyone wants to say, "Well, we're different," when in actual fact in many ways they're very similar. So there's absence of regional consensus.

Economies of scale. We think the Caribbean – if they would band together, they could accomplish lots. But again, because there's this tug-of-war between being autonomous and working together, so it's a bit of a struggle.

Limited human resources. I think that goes along with some of the economic disparities, and it limits our ability to implement programs because we don't have the human expertise in the region or enough bodies to do the work.

And then there's an – (unintelligible) – for slower pace. So we may want program implementation to happen faster, but it's difficult if your partners are leading the way and they're okay with something that might take a month here may take a year in the region.

They say a picture is worth a thousand words, so I just put this picture in to show you that there is disparity. The building on the top is a building in Trinidad and Tobago. The next street over, I took the picture on a street in Trinidad and Tobago, and on that street you'll find homeless people, you'll find poor people, you'll find dilapidated housing. On the top right, that's the building where the Ministry of Health is housed in St. Kitts, and you can see the level of disrepair in that building. But if you go a few miles from the building you'll see an elaborate resort.

So what's the story with HIV/AIDS in the Caribbean? I'm going to talk to you just briefly about the players, who are our partners. The epidemiology, and I have "as we know it," because there are so many data gaps in the Caribbean.

So I don't know how much you know about the Caribbean, but you probably have heard that the Caribbean has the second highest rate of HIV in the world. And I'm not sure that's true. And the reason I'm not sure is because we don't have a lot of data, consistent data, in the region. But even so, there's a low overall prevalence. However, I think if we were to look for concentrated epidemics we could find it. So Surinam is a great example. Surinam has a public health department with an outstanding epidemiologist. So she has conducted studies in men who have sex with men and commercial sex workers over the last five years.

And to her surprise, she found that the MSM – this study was done in 2004, the initial study. Or sorry, in 2003. And she found that the MSM population had a – (unintelligible) – prevalence rate of 18 percent; CFW's (sp), 24 percent. So she repeated the study a couple of years later, and the CFW rate was 22 percent but the MSM rate was about the same. She took the information to the minister of health to say, "Look, we have a problem," and he said, "Well, it's a good thing it hasn't gotten any higher." So that gives you some idea about the disconnect between the political will and the leadership and what needs to happen in the region. And I think if you were to look for concentrated epidemics you probably could find them because general prevalence information really isn't telling us very much.

There's pervasive stigma and discrimination throughout the Caribbean. It's very tangible. People lose jobs, people lose homes. It's frightening actually. There's HIV/AIDS resentment throughout the region, and this is because, as you'll see, the region is fairly wealthy when it comes to HIV/AIDS resources in dollar amounts; however, it's not the primary health priority at the moment. Similar to us, it's chronic diseases.

And then I've already mentioned data and technical gaps, which I'll talk a little bit more about. I wanted to give you a snapshot of the funding scenario in the region. Most of the money in the region is from external donors. I have a question mark by (PAHO ?) because to my knowledge we don't have a funding estimate from PAHO that outlines how much money they have in the entire region. The USG or U.S. government money, although it's 130 million, 80 percent of that money or more is allocated to two bilateral programs in Guyana and Haiti, and the rest is spread between the donor groups that I have at the bottom, CDC, HIRTA (sp), USAID, Department of Labor, Department of (inaudible) HRSA and Peace Corps.

So I just wan to say a couple of words about the two major players when it comes to HIV in the Caribbean. The Caribbean Epidemiology Center – has anybody heard of CARREC (sp)? Okay. CARREC is considered to be the CDC in the Caribbean. So they're the agency that's tapped with epidemiology surveillance, laboratory support, throughout the region. And they are parented by PAHO. So it creates a bit of a difficult dynamic sometimes because PAHO really makes decisions on behalf of CARREC, but CARREC is on the ground in the Caribbean executing and implementing programs.

Now, to get back to English-speaking. Most of our collaborations in the Caribbean are with English-speaking countries because CARREC is the major player when it comes to HIV and AIDS in the Caribbean. However, they're getting some backlash from some of the non-English-speaking countries and they're having discussions now about how to be more inclusive. But countries have to pay into the CARREC system in order to receive services, or that's the way it should work. HIV funding comprises 60 percent of the CARREC budget, which is a problem that's becoming increasingly visible because of chronic diseases being the highest priority at the moment.

The second part I want to tell you about is the – (unintelligible) – Caribbean and

HIV/AIDS partnership. This is an organ of Caribbean community, which is – we call it CARRICOM (sp), but it's equivalent to our U.S. Congress. So the Caribbean community has prioritized HIV/AIDS as an important issue, so they PANCAP, the Pan-Caribbean AIDS Partnership. And it's a collaboration between all – among all the stakeholders in the Caribbean. So whether you're an external donor, whether you're a researcher, whether you're a public health department, locally, externally, if you're interested in working in the Caribbean they ask you to buy – not buy into – but to commit to this partnership. And really, it's about collaboration and harmonization of efforts, which I think is critical when you have so many donors and so many players in the region and so many countries that insist on acting autonomously. So they have a regional framework, but I have to say they're – they're still working the kinks out in the regional framework because although they have priority areas, each area was not assigned to a specific agency or group, so it's difficult to know who's doing what. So they're working on harmonization. But the idea of PANCAP has been highlighted as a You and AIDS best practice, and I think it's a good idea. I think all over the world there's a need for better harmonization and collaboration when it comes to program implementation. Excuse me.

So just a few words about the epidemic. And I don't have a lot of statistics and data for you from the region. And the reason is because the Caribbean is not a region that traditionally systematically and consistently monitors, analyzes and uses data. But hopefully that's changing over the next several years. But the leading cause of death between those ages 15 to 44, and I think it sounds a lot like here in the U.S., is HIV. The new infections, all these statistics were compiled by You and AIDS in 2005. Every two years or every three years You and AIDS compiles the statistics around the world and disseminates epidemic profiles. You can find all those information on the You and AIDS website if you're interested. But I think the important point about the data triangulation exercise that You and AIDS does is that the data they use are only as good as the data that they're getting from the countries. And so sometimes the countries don't have the most accurate information. Which means that we're not sure how relevant or how valid these estimates are.

I have a question mark by "women." Fifty percent of the new infect – 51 percent of the new infections were thought to be in women. The question mark is not to say that that's not true. The question mark is, when you hear that the rates of HIV are increasing among women in the Caribbean, it's because I think the strongest programs and the strongest infrastructure in the Caribbean is in PMTCT. So because you have a captive audience with mothers who are already coming into the system it's easy to test them, rather than going out and finding people who may have other risk factors.

This is just to give you a snapshot of some of the high-burdened countries. So the ones in blue, Bahamas, Belize, Guyana, Haiti, Trinidad and Tobago, are though to have the highest rates of HIV. I have Cuba in pink. I also gave a one-pager on Cuba. I don't know if you have it. Okay. I gave you the one-pager on Cuba because as you can see here Cuba always reports the lowest rates. And we don't have a program in Cuba for obvious reasons. But we do have what we call an ambassadors prevention program. There are eight U.S. embassies – or nine U.S. embassies in the Caribbean. And Cuba has

a U.S. embassy, so they come to the ambassadors prevention program meeting every year. And what was explained to us last year is that the data coming out of Cuba are suspect, and the reason they are is because there's – I'm trying to figure out the best way to say this. Cuba does not want the rest of the world to know what's really happening in Cuba. So the data that are coming out are the data that were allowed to be released. So we really have no idea if this is correct. But you'll see in the You and AIDS fact sheet Cuba continues to do well. Cuba has always had a low prevalence, but I would just take that with a grain of salt.

For those of you who wanted to see some data, it's always nice to have a little bit of data. So in 2005, there was a behavioral surveillance survey conducted in the OECS. And these are the groups that they surveyed. And as you can see, they're pretty young people, in-school youth, youth on the block. And I wanted to show you some of the findings. These were the striking findings I thought. HIV general and prevention knowledge was poor among in-school youth and taxi drivers. And so these are questions like, "Can you get HIV from a toilet seat? Can you get HIV" – what – "How can you get HIV?" basically. It was those types of questions. "How do you prevent HIV?" So you can see 27 percent were unable to identify misconceptions about HIV in the in-school year. There's a high degree of HIV-related stigma. This I think is appalling. And I think if we would survey more widely throughout the world you may find similar degrees of stigma. But 1 to 8 percent were accepting of people with HIV. Early sexual debut, up to 30 percent were sexually active before age 15. And then of concern to the CDC program, poor HIV testing uptake, because that is one of our areas of focus.

So I'm going to talk a little bit about data gaps. As I mentioned, regional consensus is pretty absent in the Caribbean, so we don't have regional strategies that have been implemented, although it would be nice. Because it's early to learn, I think, from one program to another about their successes and failures. Epidemiology and surveillance, data collection, care and treatment, general prevention, PMTCT. I think the region would benefit from regional strategies on all of these things. And we've been working with CARE (sp) to develop those but it's not so easy to implement, particularly when countries want to use the information to their own satisfaction.

I think I'm not going to cover the rest of that.

HIV testing. This is a high priority for the USG team in the Caribbean. But we don't have a regional strategy for scaling up HIV testing. One of the problems – and I would say this is – bullet number 2 is the biggest problem we're seeing right now, is that the region endorses a laboratory-based strategy. I was not here for Bernie's presentation but I'm sure he must have talked to you about all the new modalities in rapid testing and why it's important to expand testing. Well, we've been shouting those same messages in the Caribbean, and it's not going over quite so well because the region endorses a laboratory -based HIV testing strategy. So we have three countries, Guyana, Surinam and Trinidad, who actually have implemented a rapid testing algorithm in several of their clinics and it's going really well. So one of the things we hope to do is model some of these programs in other countries to see what the acceptability, what the feasibility is like.

There are many people trained in the region in traditional VCT (sp), the traditional model where you bring the person in, you counsel them extensively, test them, have them come back for their results. But unfortunately in the Caribbean sometimes it can take up to four weeks to get your results.

I'm not going to say much about laboratory capacity other than to say this is a big gap in the region because we need technical support to build laboratory capacity. There are no accredited labs in the Caribbean, including at the Caribbean Epidemiology Center which is the public health institution that should provide laboratory support.

A laundry list of things we still need to know more about. But I have at the top of the list migration impact. And I have it at the top of the list because this is I think a critical area for the U.S. to study. What is the impact of people moving so fluidly across our borders? People coming from the U.S. to Puerto Rico to the wider region, people leaving the region, easily coming to the U.S. New York City I think and Brooklyn, there's a large population of people from Trinidad and Tobago, and they move freely between Trinidad and New York. Some problem with Guyana moving to other places throughout the region. So it's an area that we don't know a lot about.

We also have anecdotal information about the Bahamas epidemic being affected Haitian migration. But we don't have data to substantiate that. It would be nice to look to see what are the demographics of the new cases in Bahamas? So we actually have talked between the regional programs, and the Haiti program, the – (unintelligible) – program in Haiti about Haiti about conducting a collaborative study, but then we were told that it's difficult to do such a study because we can't use Haiti money in Bahama because of the parameters around – (unintelligible). So this is one of the challenges we've run into, and it would be very nice to be able to devise ways for the regional programs in the rest of the region to benefit from the – (unintelligible) – dollars in the region.

And then the rest of the areas we need to know about, risk factors and transmission routes. We don't have a lot of information. I suspect this MSM activity, the behavior here, I think it's higher than 12 percent. But again, I think it's concentrated epidemics but because of the stigma and discrimination in the region it's very difficult to obtain this information. We had a failed study two years ago because people were not interested in being tested.

(Unintelligible) – coverage. Spotty, but many countries offer free HIV therapy. There's a variety of combinations that are used, and we can't say from one country to the next, okay, this is the standard regimen, this is the standard regimen, or these are the three regimens that they use in this country. But these are all data gaps that we need to get a handle on.

And then finally, I'll mention prevention efforts. You'll see most at-risk populations somewhere later in the presentation. This is a high area of focus for USAID

in the region. Again, it's related to knowing where the risk is. It's thought that there's very little IDU transmission in the Caribbean, except for Puerto Rico. I have no idea where that comes from because I haven't seen any data and I haven't seen anyone looking for it. It may be true.

This is Morochas (ph) Bay, by the way, 30 minutes from my old house. I was never there. (Laughter.)

So why aren't we seeing more data and impact from the region? So it took me almost two years to figure this out. But we have a very fractured regional response. Just lack of coordination. So while we have over $300 million in the region, it's not coordinated. So I'm afraid there is extensive duplication of efforts. And I mentioned to you PANCAP (?) in the very beginning. That's why PANCAP is critical to the success of the HIV/AIDS – t stopping HIV/AIDS transmission in the region. Because I think they are in a powerful position to coordinate the efforts, to know who's in the region, who's doing what.

I've already talked about lack of systematic data collection, monitoring and use.

And then poor human resource capacity. The brain drain in the Caribbean is similar to what I saw when I worked in Africa. It was very shocking. And most people actually come here, particularly nurses. And Trinidad and Tobago has recently engineered a contract with Cuba for healthcare providers, and so now lots of Cubans have moved to Trinidad and Tobago to provide healthcare. So another issue to put into the migration pot. What will be the effect of moving Cubans throughout the rest of the region to – how does that impact the epidemic.

So, this, by the way, is a retreat that I took my staff. We had a team-building exercise. It was fabulous. Here's where – (unintelligible).

This is a quote I like to use often because I think it applies to so many things. And while it seems that there are lots of challenges in the Caribbean, where there's a challenge there's always an opportunity.

So we've had to refocus and think about what our goals are and how we can actually address some of the root causes. And so now because USAID, CDC and HRSA are the biggest players in the region on the U.S. government side, we've thought about our goals. And we would like to develop a regional public health leadership, because I think there's sluggish program implementation because people aren't trained in public health, they're not trained in data collection, and a lot of times they're not trained in the specifics of clinical monitoring and so on. And I think that all gets back to public health leadership and program management.

And we've like the availability and access to strategic information. Strategic information I hope you've heard is this new term that we're using to refer to surveillance, epidemiology data, monitoring, evaluation and information. Any information that you

need to improve or to drive your program.

And this is a big area also for CDC for obvious reasons. USAID is taking the lead on expanding our prevention program. The CDC is providing support to improve the PMTCT (sp) response in the region.

I'm going to skip that.

I put this slide in here because I thought you might like to see a little tactical use here. You can see a sign by the secretary. This was a strategy we used to try and help move the testing agenda forward. And it was actually Bill Steiger's (sp) idea. I met with him to tell him about the challenges we were having. Of course, we can't improve surveillance activities without knowing how many people are infected, and we can't know that until we get people tested, and that's why CDC wants to improve testing, but everything is so slow. And he said, "Well, since you talk to the prime minister all the time, why don't we send a letter endorsing rapid testing." And I thought it was a brilliant idea. So they followed through and they sent it down and I waited and waited, and nothing happened. But it's okay, we tried. And these are the kinds of strategies that we have to use all the time. As a matter of fact, we have a phrase called the triple C. It stands for conspiring to convene a coincidence. Makes you very tired though. Your brain never shuts off.

So I'm going to wrap up, but I wanted to just give you a snapshot of what the U.S. government is doing in the Caribbean and where. Because there's also a lot of confusion about who's working where, what we're doing. And as you can see, I mentioned earlier that our efforts in the region are fragmented. And the USG is really not much better. We're trying, but it's difficult when, again, country solidarity, politics in the region are coming into play. People who have been there for years, external partners and internal partners, have been there. It's not easy to come in and reorganize the entire scenario.

So as you can see, each U.S. government agency really works in a different place, but most of the action is in the OECA. Why is that? I'm not sure. I think it's because they're smaller countries, there's less infrastructure in those places. It's seen as a place that needs a lot of support, which is true. But I also think that because they're now a federation, theoretically you should be able to intervene at the federation level and have everything circled down to the countries, but guess what, that doesn't happen either. But I would say we are making some headway on the testing front in the OECS, particularly because they have a global fund and we've been providing some technical expertise.

You probably also noticed the absence of Puerto Rico and U.S. Virgin Islands. It's because as far as we know, our mandate in the region is not to focus on Puerto Rico and U.S.V.I. because they are U.S. and we were told that because they're U.S. they will be handled with a different pot of money rather then PETFAR money.

So I think I have one more slide, and it's issues for you to consider. U.S. is part Caribbean. So do we need a broader collaboration? And I think we do. I've already

talked about the migration border issues, how is it contributing to the race of HIV in the region. Do we need to strengthen our technical, financial and infrastructural support? In the region, money talks. I think that's true around the world, but particularly in the region. He who has the biggest purse carries a lot of voice. Is stronger USD public health leadership role warranted? I definitely think this is true also. I's certainly worth considering, because HIV is not the highest priority anymore. It may be on par with chronic diseases, but it's falling.

Will support for U.S. – for regional prevention – (unintelligible) – yield benefits to the U.S.? This gets back to the migration issue. If you conduct strong prevention in the Caribbean, does that lead to – are we going to see better prevention or reduced transmission in the U.S.? Feeds right back into migration border issues.

And then given the data gaps and migration challenges, is the current USD funding scheme appropriate? And by that I mean, as I told you, most of our money in the region is in Guyana and Haiti. But what about the rest of the region? There was a delegation, a high-level delegation that came up to talk to Washington on Capitol Hill – I'm sorry – the White House a few months ago about this very issue. And they come to us all the time asking us, but we – our hands are really tied, so we have to stick to the program and talk about what we can offer with the amount of support that we have.

So with that I'll close. I think I talked longer than 30 minutes, but let me know if you have any questions.

DR. MAXWELL: Thank you, Dr. Fitzpatrick. I have a question. You mentioned that in the Caribbean about 18 to 27 percent of the population is ever tested with only 10 to 17 percent that know the results of the test. How can that be? Why does that happen?

DR. FITZPATRICK: It's because of failure to return for test results. Because even in the study – this was a controlled situation. They conducted rapid testing but they didn't give results back. That was part of the study protocol. So they relied on people to come back for their test results. But even though that was the study, I think that's pretty indicative of what happens in most of these programs where you have to wait two to four weeks to get your results. People are lost to follow up. I think it even happens here at home. Maybe not to that degree but –

DR. MAXWELL: Ted?

DR.GREEN: Yeah. I'd like to make a comment and ask a question or two. First of all, you said that – just a correction, I lived Surinam and I speak the national language and it's not English. The official language is Dutch, and the lingua franca is a Creole – (unintelligible). That's the one I speak.

I think you're right in suggesting that these are mostly concentrated epidemics. I think that was what your slide and what you were suggesting. And to look at Surinam, the example you gave, pretty high rates of – among MSM and commercial sex workers,

and yet 1 percent national prevalence. The Dominican Republic was estimated by You and AIDS to be 2-1/2 percent. Then USA did a population-based survey and found it was slightly less than 1 percent.

One question is, are you aware of any countries that have had population-based – (unintelligible) – surveys other than the DR? And secondly, I raised this question earlier about whether for Caribbean immigrant groups in the U.S., if we have AIDS prevention materials in French, Dutch, any of the Creoles, like Haitian Creole? So those are two questions.

DR. FITZPATRICK: The second question, not to my knowledge.

DR. GREEN: Well, there must be materials in Haiti. Why couldn't we, you know, bring them here and use them in Miami and Boston? I live in Boston. A lot of Haitians there.

DR. FITZPATRICK: Oh, I'm sure that could happen, right, Eva? Yeah, sure. That's no problem I wouldn't think. I don't know the extent of the materials that are available in those countries. But if we have them and if they're U.S. government property there's no problem with that.

DR. GREEN: Are you aware of any countries – yeah.

DR. FITZPATRICK: Yeah.

MR. : Population-based surveys –

DR. FITZPATRICK: The population-based survey. Jamaica did a population-based survey some years ago, but I haven't seen any recent data. And when they did that survey, I can't recall the number, but it was in their range, 1-1/2 to 2 percent, so it's still low. But I don't know of any other countries that have done a population-based survey. They're very expensive, as I'm sure you know, so.

Any more questions? Well, see, as I said, I'm standing between them and the door.

DR. MAXWELL: Any other questions for Dr. Fitzpatrick?

DR. PRIMM: Lisa, I know you. Thank you so very much for coming, and thank you for all of your collaboration with me that you've done when you were there in – (unintelligible). I really appreciate that.

I'd like you to say something about Puerto Rico, if you would. And I know there is lots of exchange. People go to Puerto Rico to get treated from the other islands in many instances, and go to Florida. What about that trafficking back and forth for treatment?

DR. FITZPATRICK: Again, Dr. Primm, I'm sorry, I can't say anything about Puerto Rico because we – the extent of our relationship with Puerto Rico is having Puerto Rico provide some support, and it's minimal support, to the rest of the region for anti-retral viral drug resistance, which is something we actually have tried to back away from, because I think as you saw there are much more important things I think the Caribbean should focus on. But having said that, that is the only – that's the only technical area that we've worked with Puerto Rico. And pretty much, again, it's because our understanding was with PETFAR dollars, they were not to be used collaborating with U.S. territories, in the U.S. None of our activities are in Puerto Rico, so I really – I'm sorry, I don't have – if that's what you wanted to hear about, I probably could have looked that up, but I can't say much about Puerto Rico.

DR. PRIMM: You also tried to do testing on certain islands with cooperation from – (unintelligible) – technologies. What happened to that project?

DR. FITZPATRICK: Yeah. We were designing a study in four countries to look at the acceptability and feasibility of oral rapid testing. And in two of those – the countries were Haiti, Guyana, Surinam and Trinidad and Tobago. And in two of the countries we received permission from the minister of health – the ministry of health to conduct the study. The other two, we're still waiting for permission to do the study. The study is also still in clearance at CDC, but that should be coming through any time. So I think it's just a matter of time. Probably another month or two. But again, it depends on what's happening at those ministries of health. They all seem very willing to be in the study. The collaborators on the ground at the clinic sites. But it's the ministries of health who have to approve.

DR. PRIMM: And who is your replacement, so that we would be able to know that individual for contact with correct?

DR. FITZPATRICK: My replacement is Dr. Shirley Lecher. She is not on board just yet. She is an HIV vaccine researcher from Walter Reed. Walter Reed? I think so. So that's L-e-c-h-e-r. But again, you could probably funnel those kinds of questions through Eva and she could give you the information. I'm not sure how long it will take Dr. Lecher to be on board.

Eva could probably also address your question about Puerto Rico.

EVA MARGOLIS: Well, I'm not sure I can really answer your question. I – (off mike).

DR. MAXWELL: Is your mike on?

MS. MARGOLIS: (Off mike, laughter.)

(Inaudible) – leave it on?

I just wanted to confirm that Puerto Rico does get the domestic HIV prevention dollars, and we have a project officer for Puerto Rico. It has been an area that we have struggled with over the years. And some of you may be aware. I mean they've been in the newspaper recently. HRSA has had issues. There's all kinds of problems with the healthcare service delivery program in Puerto Rico. The FBI has been involved. Several years ago they had difficulties getting their prevention funds out and they asked us to compute their CBO dollars for then, which we have. So money is going to community-based organization for prevention. I can't say much more about what's going on there because I don't have the specific details. But I know we did provide for PACHA information on the number of cases in Puerto Rico, but as far as being able to comment on contributing factors back and forth across the border, I really can't. I'm sorry.

DR. FITZPATRICK: I think that underscores though the need to improve the collaboration between the U.S. territories and the rest of the Caribbean. Because we really have not tried to foster or develop relationships, because really those are the parameters of our funding, and it's something that we have no control over so –

DR. MAXWELL: David.

DR. DAVID MALEBRANCHE: Lisa, what do you think would be the best solution, I mean given PETFAR and their focus just on Guyana and Haiti? Because it sounds like you're almost suggesting there should be some kind of separate program. Do you think that would be better, or do you think in the preauthorization of PETFAR and kind of revamping that, that more Caribbean nations should be included? What do you think would be the best –

DR. FITZPATRICK: Yeah.

DR. MALEBRANCHE: – the best approach.

DR. FITZPATRICK: Thanks for asking that, David. I think it's important to assess what's really going on in the Caribbean and looking at where the data gaps are, and I'm not suggesting at all that we should take funding away from Guyana and Haiti. I'm suggesting that there is a broader need for support throughout the rest of the Caribbean. I show that there are at least five or six other countries that have a high burden, but because of the way PETFAR funds are allocated, it's based on GDP, it's based on the amount of resources in a country, and so some of the countries may appear to have more access to wealth, but when you get to the infrastructural problems and you look at what's happening in the health sector, there's a lot of poverty, there's a lot of need, there are a lot of gaps. So that would be my suggestion, that if PETFAR is re-authorized, there's a need to critically look at what's happening in the region and what the needs are and if the current funding strategy makes sense.

DR. PRIMM: Do you think, Dr. Fitzpatrick – first, you've let the federal government now, so you would be able to answer –

DR. FITZPATRICK: Not yet.

DR. PRIMM: Well, you're on vacation. You're on – whatever. (Laughter.) Could you comment on how well you think the funds that are provided to PETFAR in Haiti and Guyana are helping the cause? Are they being adequately disbursed and spent toward prevention and care of that patient population who –

DR. FITZPATRICK: Mm-hmm.

DR. PRIMM: – may be suffering from this disease? Can you comment on that?

DR. FITZPATRICK: I can comment a little bit on that. I think the PETFAR dollars have been a tremendous benefit to both those countries. The numbers of people who are now on care is far – far exceeds what they would have been able to do without PETFAR dollars. I think the money is allocated according to the parameters that are set forth in the PETFAR legislation. And you probably know that a certain percentage of funds for the bilateral programs have to be spent on treatment, a certain percent has to be spent on prevention, and so on and so on.

And so if your question is what do I think about that, I think that also deserves a second look, because some countries – again, it's not a one size fits all. There are some countries the governments are already paying for medication, so it doesn't help to have PETFAR money to pay for medications when you could pay to develop infrastructure or you could pay to expand prevention programs or expand testing or build laboratory capacity. So I think it deserves a look at what each place needs rather than saying these are the parameters. And I know it's easier for reporting. We've had these conversations. It's easier to say to Congress, "Okay, 80 percent of the money was spent on medications and now we have 2 million people on drugs because of that." But realistically and practically, it doesn't always work that way. And I think it's important to consider the context on the ground when making those decisions.

DR. MAXWELL: Any other questions? Dr. Fitzpatrick, we want to thank you for going above and beyond the call of duty and coming in on you vacation to give us this great presentation, and we wish you the best. Thank you.

DR. FITZPATRICK: It was my pleasure. Thank you. (Applause.)

DR. MAXWELL: This concludes our meeting. We will reconvene after – we'll reconvene tomorrow at 8:30. And Marty has some comments.

MS. MCGEEIN: Like you thought you could get out of here without them. I will draw your attention to the agenda for tomorrow morning. At 10:15, that particular session is billed as a listening session, and the purpose is for you to share with our guest your thoughts on the epidemic, on what you do for a living, and how those two intersect. Okay. All-righty.

DR. MAXWELL: Could you give us just a little more insight so –

MS. MCGEEIN: Unlike our usual, there won't be a presentation. There won't be a presentation followed by questions. It will be what's called in Washington a listening session. It is – I believe Mrs. Clinton calls these a conversation. It is designed to be a conversation with the PACHA members as opposed to a prepared speech followed by Q&A.

DR. PRIMM: I prepared in draft form a resolution that I'd like to be considered, and I added to my draft anything that anybody suggested as I circulated it to each member of PACHA. And she's just finished it. I would like each one of them to take it if they would, and have a look at it, and then mark it up even more if that were the case.

MS. MCGEEIN: Okay. Apparently they're sending around – I will simply remind you that these have to be cleared through the domestic – or the international subcommittee and then brought back to the full committee –

DR. PRIMM: Sure.

MS. MCGEEIN: – tomorrow afternoon.

DR. PRIMM: Sure.

MS. MCGEEIN: So –

DR. MAXWELL: So we will address yours in the –

MR. : We will address it –

DR. MAXWELL: – domestic.

MR. : – in the domestic.

DR. PRIMM: Thank you. Marty?

MS. MCGEEIN: Yes.

DR. PRIMM: That's why I gave it to everyone present here, so that they would see it, and international and domestic, so that I could get some concurrence if I could from everybody. That's why I did that.

MS. MCGEEIN: Okay. Thank you.

DR. PRIMM: Thank you.

DR. MAXWELL: Okay. Everyone have a good evening and we'll see you tomorrow.

MS. : We have a bus.

DR. MAXWELL: A bus apparently at 4:20 downstairs, but usually they're down there a little bit early.

(Cross talk.)

DR. MAXWELL: Yeah, you actually could walk.

(End of day one.)

MR. GILMARTIN: Well, good morning everyone and welcome.

So, I'm pleased to be sharing this role with Marilyn and I find out that a significant part of the role is telling the bus driver to leave – (laughter) – executive decision. Exactly. Well, with such a distinguished group it's a pleasure to have the opportunity to do even that and speaking of a distinguished group, we'd like to being by recognizing one of our colleagues who – for his very important service and we have some, and also is part of this, as I recall from that last time, is that we're calling upon you to make some comments based on your experience and some you'd like to – suggestions you'd like to pass along to the rest of us, so I look forward to that.

So, Ted, if you would come forward, we have – (inaudible).

MS. MCGEEIN: Absolutely, for the wonderful four years that you have shared with us, and the not quite year that you've shared with me, we would like to thank you for your service, the Presidential Advisory Council on HIV/AIDS. Here is a note from Secretary Leavitt, your certificate of appreciation from Secretary Leavitt, a little remembrance from Secretary Leavitt – (laughter) – a remembrance from President Bush – (applause).

We need to shake hands.

(Pause, off-side conversation.)

DR. GREEN: Oh well, I was afraid I was going to be late this morning, the traffic was backed up and because I'm on my way to Africa later today, I was given the great honor of having a parking space for today underneath the building, but the traffic was terrible and then it took a while getting in.

I just jotted down the outline of, you know, thinking back over my PACHA experience. I was asked to serve in 2003 and what was going on then is I was devoting my every waking moment to trying to tell the world about a model of prevention that's

different, that was and still is different from what we do in most of the world. What we do in most of the world for sexually transmitted HIV is promote condoms and various ways – treat the treatable STDs, voluntary counseling and testing, and that's just for the sexually transmitted part.

I was, I actually started to work in AIDS before the USG became involved in AIDS outside the United States, which started in, I think, mid or late 1986 with the AIDS Comm and AIDS Tech projects. I was working in condom social marketing for family planning and the first thought anyone had is, oh, well, we need to quadruple our efforts to get condoms out there and have people use them consistently. I mention that because some people have accused me of being anti-condom, but, you know, for three years I was working in condom promotion for family planning. We began to do it for AIDS prevention and I got to use existing funds to do quick studies of sexual behavior, I was working in Nigeria, Liberia, and the Dominican Republic.

Flash ahead to 1993, I went to Uganda for the first time and lo and behold, the incidence and prevalence were coming down in Uganda and condom social marketing was just getting off the ground. It had hardly done anything outside the capital city, and yet incidence and prevalence – we now know that incidence started to come down in the late '80s and they only really began their prevention program in 1986, so I thought, well, this is the story of the century. Here's the first success story, at least the first success story in Africa, in fact it was the first anywhere, and the most dramatic to this day, and I knew it wasn't coming down because of condoms and that's what everybody thought and hoped and expected. The company that I worked for, as a condom social marketer, was the same company that had the contract with USAID to promote condom social marketing in Uganda.

Anyway, I, as an anthropologist, I just, you know, quickly went around and spoke to nurses and doctors of STD clinics, various officials, traditional healers, traditional birth attendants, I just quickly talked to everybody and said, what's going on? And what I heard was – and I saw the evidence for it – the government had developed its own prevention program. It didn't wait for Western experts like me from Europe and America to come and tell them what to do; they quickly mobilized themselves and promoted monogamy; fidelity, if you're in a polygamous marriage, fidelity within that – not having multiple partners, that was the main message. And the church was very much involved, which is unusual in AIDS prevention at that time. It's still not that common, even with PEPFAR and things you may have heard; it's still not that common.

So I thought, wow, the world's really going to be happy and – I found out a couple years later that the cost of the program at that time, that was so effective, was 23 cents per person per year. So, I thought, wow, I've got a great story and the world's going to be so happy, but the world wasn't happy because we had a lot invested in the way we were promoting AIDS prevention and there was a lot of politics and there was a lot of ideology and right from the get-go, people thought that I was a partisan in the culture wars in the United States: condoms versus abstinence.

And I was saying, you know, this is not about abstinence or certainly not about abstinence only, it's mostly, it should mostly be about whether we really try to actively discourage people having multiple sex partners or not and delay of the age of first sex is an important factor, but it's not as important because it only affects a relatively small segment of any population, you know, at the age at which teenagers begin to come – become sexually active. And to this day – (chuckles) – you'll hear, abstinence only doesn't work, as if that is the discussion, and it shouldn't be.

Well, I came back to Uganda a few times – well, actually – no more biography. PACHA – so, in 2003, I was getting my message out. I was asked to testify in Congress twice and then twice after that, but 2003 twice that year; brief White House staff, I was in public debates, I had op-eds in four newspapers including the New York Times and the Washington Post. I was controversial and making a lot of enemies among my colleagues, who suspected that I had somehow become a religious conservative. And when I joined PACHA, we had a diverse group, then as now, and there was liberals and conservative, and I'm a liberal, but conservatives liked my message and the liberals were suspicious.

But unlike some other boards I've served on, the people at PACHA for the most part – in fact I can't really think of any exceptions of close-minded people – people in PACHA were willing to look objectively at the evidence and find common ground and some people that maybe thought I was a little bit crazy at first, I think we – they've come to respect me; I've come to respect them – and I promised Marty I wouldn't make any invidious comparisons with other advisory agencies, but this has been a good one.

Some of the highlights – Secretary Tommy Thompson invited a few of us on the international committee to come to – to come on a trip to Africa, four countries including Uganda. And all of the leading people in AIDS, the head of U.N. AIDS, PEPFAR, which just started, and the number two at PEPFAR was Mark Dybul, who is number one, I think he's coming today, Richard Feachem, Tony Fauci, Peter Piot of U.N. AIDS, all the leading people in AIDS were on that trip, either for all of it or some of it.

So I had a chance to meet those I haven't met. A couple of – there were a couple of senators, and we had the CEO of Pfizer – Hank McKinnell on PACHA, and we had the CEO of Merck on that trip. It was a great opportunity to meet powerful and important people in the world of AIDS. I wish I had time to tell you about – I'll just tell you very briefly. We come to Uganda and Uganda was chosen of – among the four countries because of its great success in AIDS prevention. And we had four days there. By the third day, there was no mention of any kind of prevention that was not a medical device. In other words, the whole thing has sort of become medicalized and commoditized if that is a word.

You know, they were talking about trials for vaccines and future of vaginal microbicides, and nobody was talking about the ABC program. And this is just to show that Uganda sort of drifted away from their original indigenous African response to AIDS, and because of the foreign donors – I know this is sort of heresy – but the foreign donors wanted to fund what they wanted to fund, and what they're used to funding –

promoting fidelity, monogamy, partner reduction, and abstinence or delay of sexual debut was not something that then or now, with the exception of PEPFAR, foreign donors were comfortable funding, for reasons we don't have time to go into.

I'm writing a new book called "AIDS and Ideology," and I explore this. So a couple of us on the trip complained, and all of a sudden the Uganda government was happy to talk about their ABC program. They were used to Europeans and Americans not really wanting to hear about this.

Well, the next highlight was when Hank McKinnell, two and half years ago, whenever it was, one day in a meeting of the full council said, you know, what would be interesting is to – apart from any considerations of political feasibility, economic and financial considerations, what would it take to bring HIV incidents to zero. The new infections next year and globally, what would it take to have no new infections.

And I seconded that idea, and pretty soon – and almost immediately we're talking about bringing in this person, that person. I said, let's do something different. There is enough experience around this table. Let's draw upon what we know. And let's not bring in people because you can bring in people that, you know, you have reason to believe will promote this, and reason to promote that.

Let's just draw upon our wisdom and experience, and come up with – and we ended up writing this monograph, this 99-page – I think it was – monograph, achieving an AIDS-free generation, and that illustrated what I was talking about the ability of PACHA to be objective about the evidence, and some people ended up supporting things they didn't really support at the beginning of this exercise. So it was a successful exercise in people from – with diverse experience to diverse political views focusing on the evidence, and I was proud of that.

Then maybe the next highlight for me was and is the white paper on PEPFAR-2 or PEPFARther, as we're calling it, which we're – well, we have a draft. We have a draft that has actually been over – gone over several times by the international committee. And there again, there were some pretty sharp disagreements at the beginning of this exercise with new – there were new people in PACHA, and I was thinking, oh, we did. We finally achieved consensus. We had this book and some of the people who saw things the way I see them left, and just new people – oh, we have to go through this all again. But once again, I don't know if we're just lucky in PACHA or somehow – but whatever reason, we were able to go through a similar process, but even in more depth. And we had the Institute of Medicine evaluation of PEPFAR as, you know, looking over our shoulder because that'd already been done and released.

And maybe I'm not supposed to make any kind of invidious comparisons, but I – (laughter) – but I will; I'll stick my neck out. I think our white paper is much more evidence-based, and I believe it's – you know, it's gone to the full committee now, is that right?

MS. : After today's – (inaudible) – meeting is over.

DR. GREEN: About to, yeah.

So again, we had people with divergent views. Let me mention why we have divergent views. I think, apart from politics, we have two basic types of epidemics: generalized and concentrated. And in most of the world is concentrated, which means the three universal high-risk groups for HIV infection – gay men, injecting drug users, and commercial sex workers – that's where you find most of the infections, and it varies among those groups. Like in Africa, there aren't many injecting drug users, but there is commercial sex. And it doesn't make much sense to promote monogamy, fidelity, or abstinence to a commercial sex worker.

But in like manner – everyone recognizes that, but in like manner, to go into an African village and talk to a primary school, and some students could be up to 15 years old or so, and most of them haven't started to have sexual intercourse, if the only thing you have in your toolkit are condoms, you know, treating their STDs and clean syringes, which I know is not U.S. government policy, but other donors, that's not really appropriate for people who are not currently at risk.

And I think if all of our experience is in Thailand or some country with a concentrated epidemic, you can't quite wrap your mind around the importance and effectiveness of promoting not having multiple sexual partners. And Uganda was only the first country to prove that when governments and NGOs and FBOs promote monogamy, fidelity, not having multiple partners, and abstinence appropriate to your target audience, their age and whether they're currently at-risk or not, that it works, that if you promote it, you get higher levels of those things, and that has a big impact.

And where we are right now, we have about seven countries in sub-Saharan Africa where we have documented HIV prevalence decline in every country, without exception, about five years before we see this change of prevalence – and what's happening is a change in incidence, the rate of new infection – we see a significant decline in the proportion of men and women who report more than one sex partner. So that's not a randomized controlled trial, but that is the next probably most persuasive type of evidence, a consistent associational pattern.

I think I probably don't need to go on any longer, probably used up my time, but I want to – let's see, I think we've mentioned advice. I wasn't thinking about giving any advice, except to keep in mind that there's all this common ground, no matter how – a lot of passions run high when talking about HIV/AIDS for a number of reasons that I think we all know. Passions run very high, and when there is disagreements about AIDS, it can get quite personal and heated.

My experience at PACHA has proven that people from diverse backgrounds and political viewpoints can come together objectively, looking at evidence, and the way to

do this is to be friendly, respectful, open-minded. For example, like my friend Ram here, who united different views but, you know, I think we both learned from each other.

And then also to keep the mind that what is needed for AIDS prevention differs, whether we're talking about generalized or concentrated epidemics. One reason is that in generalized epidemics, where HIV is in the general population and not in definable high-risk groups, it has never been possible, whether for family planning or for AIDS prevention or STD prevention, it's never been possible to achieve high levels of consistent condom use in any general population. It has been possible in high-risk groups. That's not to say we shouldn't promote condoms to everyone, but we have 25 years of AIDS experience and 50 years of family-planning experience telling us that you're going to need something else in addition, not instead of, but in addition to condoms for general populations.

So with that, I'd like to thank everyone, all my colleagues in PACHA for being good colleagues, and the various leaders and directors and administrators for treating me very well. And I'm sorry to be leaving, and I've had a great experience here. Thank you.

(Applause.)

MR. GILMARTIN: Well thank you very much, Ted, for those remarks. Whitey's (sp) informed me that our speaker, our 9:00 speaker, has not yet arrived.

MS. : Five minutes.

MR. GILMARTIN: Five minutes. So if we think it's appropriate, maybe we just can have a conversation with Ted as well in terms of what his experiences had been, and some reactions. On that trip: It wasn't the CEO of Merck who – which I was, but it was our head of Europe-Middle East and Africa, Per Wold-Olsen, who is I think, you know, the government of Romania practically credits him personally with helping provide access to HIV/AIDS drugs to deal with a problem that they were having, so he was very committed. But he met John Martin on that trip, so that was a very fateful trip in which they established a relationship that led to a working relationship between John's company and Merck in terms of being able to put together combinations. So it sounds like it was a very important event.

The other thing I would just add to your comments is that, you know, based on my comments that at my first meeting at how Merck has been involved with Botswana. So the president of Botswana was here in Washington and meeting with the press in a roundtable setting. And he was asked – and of course the program in Botswana includes prevention, which is condom distribution and education of, you know, in schools about talking to kids about how to prevent HIV transmission.

And so to your point, he was asked what I would consider to be a leading question about abstinence; more or less, to have him answer, yeah, that's a ridiculous approach. But he actually came back, he said, no, it's very important, and it's very much part of our

program. At the same time, it wasn't a question of either/or; it was both. And I think that gets lost, unfortunately too much, as you were saying before, in the whole discussion. So it's great to hear how effectively this group has been able to come together and hear different viewpoints, and perhaps develop some different perspectives as a result of listening to one another.

Yes, Ram. So why don't we just pitch in, rather than formally call in on everyone.

DR. YOGEV: I'm sitting on this committee now almost three-and-a-half years. Most of the members who left before you, I was really sorry on a personal level. I think the committee's going to do is the intellectual capability that you brought in, and never yielded without asking why. And that's a great, great asset that we're going to miss. So thank you for what you did. I wish you'd stay another six months so I can leave first.

(Laughter.)

DR. GREEN: To comment from Ray's remarks, I have an opportunity to make a presentation in Botswana at the end of November to high levels of the government and to parliament about some of the newer findings. You know, it's not just having multiple partners; it's having multiple and concurrent partners.

And in southern Africa, in and around South Africa, a lot of marriages are interrupted by the men migrating to South Africa to work in the mines, to work in the cities; I mean, it's the only really industrialized country in Africa, and it's a big magnet for labor of especially men. And they leave their wives in the village for months or years at a time. And in addition to having casual sex with a non-regular partner, not infrequently – it's not most, but a significant minority of men and even of women establish an ongoing relationship, the man with somebody where he's working, and the wife eventually with a man in the village who helps pay the school fees to the children.

And it turns out that since HIV is actually difficult to transmit through normal, heterosexual intercourse, it's these ongoing concurrent relationships that are very risky, and it raises greatly your chances of encountering somebody in the high-viral load period soon after infection, when the viral load is higher than it ever will be again. And so some of the people that were resisting the ABC approach – and that's been so politicized we probably need to dump it and come up with – in fact, I did come up with something.

You've all heard E equals MC squared; I've been saying E-squared equals MC-squared. E-squared is epidemic squared, a hyper-epidemic, is due to multiple concurrent partners, that's one MC, and lack of male circumcision, the other MC. So that's a little mnemonic aid to – (laughter) – this is why these are the two main reasons that HIV rates are so high in and around South Africa: lack of male circumcision and having multiple concurrent partners.

Anyway, I hope this really comes off, and I have the chance to speak to the folks in Botswana. And I lived for four years in Swaziland, which is the only country that has higher infection rates than Botswana, and they have similar issues of absent husbands.

DR. PRIMM: Ted, speaking of male circumcision, what is your take on that for the problem in the African-American community in the United States?

DR. GREEN: Well, Beny, I think you've asked me this before, and I'm afraid of sticking my neck out in an area that I'm not really grounded in the evidence. My understanding is that circumcision is – and by the way, the reason we say male circumcision – like what other kind is there – in some Muslim areas there's what they call female circumcision. And that's another matter, and it's also called female genital mutilation. Beny, when I say circumcision of course I mean men. My understanding is that it's less common among African Americans than among white Americans, and the free-randomized controlled trials that we've had, that have now turned everybody around and saying, yes, this is something we need to promote, I personally would only be comfortable promoting it in Africa because that's where all the trials were.

But you've heard what people have come here from NIH and so on, CDC, saying no, no, there's evidence that it's important for gay men; it's important for everyone. So theoretically, increased circumcision of black men theoretically ought to reduce chances of HIV infection.

I'm sure you've all heard that the major reservation about this is that it might promote a false sense of security, and men might take more risks in their sexual behavior than they would if they weren't circumcised. But that's true about using condoms; it's true about a lot of things. If you reduce the risk are you going to, as they say, compensate for that reduced risk by increasing your risky behavior, which actually happened in the United States among gay men after anti-retrovirals became available. We saw levels of risky behavior actually increase.

So my only answer is that it theoretically should help. I know it's a very sensitive issue, but it's not mixed up in religious beliefs. In Africa, and in the Muslim world, circumcision can be part of your religious belief. But I don't know of any religion that says don't circumcise.

Anyway, that's my short answer – my long answer.

DR. BUSH: Ted, I would like to thank you also for I guess the zeal or compassion of which you were so energetic in getting the truth of what was going on in what you observed in Uganda, even at the risk of, you know, like you said when people began to question your motivation. So I appreciate you for persisting.

And I wanted to venture out a little bit and ask you, I guess, when you mentioned E-squared equals MC-squared. Beny asked about the male circumcision component, so

I'm going to ask about the multiple concurrency, and if you had any comments about its impact in the African-American community.

DR. GREEN: Oh, in the African-American community. Yeah, you were asking me – we started to talk about this yesterday, and then we got interrupted; the meeting started or something.

Well, having multiple concurrent partners is a high-risk factor whether you're African, African-American, or Polish. Whoever you are, it's a definite risk factor for the several reasons, but mainly because it's difficult to transmit HIV if you have ongoing relationships. And also, people in ongoing relationships don't use condoms; I mean, a few of them do, but it's rare. And there've been studies that show that for people that are married, or living together, or just having an ongoing sexual relationship, no matter what you do, no matter how much you beg, plead, and give them free condoms, you're not going to achieve significant levels of consistent condom use. So that's another reason that multiple concurrent partners are having that as a risk factor; you're not going to see a lot of condom use.

Now, we don't have a clue – (chuckles) – really, how to discourage these. I think what happened in Uganda – and I'm going to Uganda this evening, again, with an express purpose of trying to explore the concurrency factor. We know the prevalence went down, we know that the proportion of men and women reporting more than one partner went down significantly, but we don't know about concurrency versus the other kind of casual sex with a non-regular partner.

What I think I'm going to find – and this is only speculation at this point – is that there was a lot of decline in casual sex; you know, one pickup sex worker or something like that. I don't know in the situation I described, sort of a stereotype of a man having sort of a second wife, but he's not married to her, and maybe even his wife, who's neglected and not living in the same location, having an ongoing male sexual partner – I'm not sure how many of those ongoing relationships were ceased; I suspect not many.

But I think what did happen is that young people entering young adulthood, where they might have the mobility and the flexibility and the finances to have a second sexual partner, that maybe they didn't enter into those relationships. So it was sort of preventive rather than, you know, people saying, oh, concurrency is a real risk factor so, you know, either leaving the wife or leaving the girlfriend. So we're going to explore that, and then set up some, you know, surveys to try to measure more accurately what's going on.

Oh, by the way, there is a – in Botswana, I'm pretty sure it's Botswana, Population Services International, with money from CDC, is going to do a randomized-control trial to try to isolate the multiple partners, whether concurrent or irregular, to try to isolate that factor and measure how determining is that versus condoms and other things. So that's something I've been wishing we could have for a long time.

MR. GILMARTIN: In Botswana, they cite that as one of the major issues that they have because, you know, the way it was described to me was people have concurrent relationships at three different locations, which would be the cattle posts, the home village, and place of work.

DR. GREEN: So that's E-cubed equals MC-squared.

(Laughter.)

MR. GILMARTIN: So I mean, and they are monogamous relationships in each one of these locations, as described.

DR. GREEN: But they're multiple, concurrent monogamous relationships.

MR. GILMARTIN: (Inaudible) – concurrent partners, which they saw as a major contributor as to why HIV infection spread.

DR. GREEN: Yeah. Is Merck – do you have a hand in this study?

MR. GILMARTIN: I don't know for sure, but I don't think so. But I can't say that for sure. It's been about a year-and-a-half or two before I was –

DR. GREEN: Yeah and this is just recently come up, this funding, this opportunity.

MR. GILMARTIN: But they're very – you know, one of the things that's impressive about the country, as you've seen in other places, that is the commitment throughout the country to really battle this because they are fighting for their survival and those infections.

DR. GREEN: Yeah. And by the way, Botswana – Africa in general challenges what we think we know about AIDS. I've also gotten in trouble with my colleagues by pointing out that maybe it shouldn't be this way, but we see an association in Africa between greater wealth, greater education, and higher infection rates. And the general thinking is, oh, it's poverty driving HIV infection rates, and I mean, that's sort of intuitive. If the woman has no money, she needs to get into a relationship with a sugar daddy or turn to commercial sex. This is what is widely believed, and there were people in PACHA who were saying, you know, we shouldn't be doing A, B or C; we should be raising economic levels through financial, you know – something that would raise income levels.

Well, yes, and that would help a lot of other diseases; it would improve reproductive health, it would improve tuberculosis. But in Africa, so many things are different than outside of Africa. We see this association – and Botswana and South Africa have the most money going to AIDS programs of anywhere in Africa. They have the highest levels of income and education. Women are more powerful than compared to

– I was in West Africa, in Muslim West Africa in January, Senegal and the Gambia. Women have far less power there, and we all think that, you know, more female – women's empowerment would lower rates.

I'm all for ending poverty, increasing women's rights, and I've worked in women in development; I've worked in that field. But it's just very tricky, the relationships between the things that we are promoting, and we should promote them, but we need to look at the relationship between that and HIV more carefully in Africa because it keeps confounding the outside experts.

MR. GILMARTIN: Well, thank you very much, Ted, and thanks for everyone else's comments as well. Clearly by the comments we're all going to miss you, and best wishes on your trip this evening, and if you have an opportunity, pass on my regards to some of the government officials there as well. Thank you.

So turning next to our first speaker on the agenda, welcome, sir.

IGOR V. TIMOFEYEV: Thank you.

MS. : A victim of Washington traffic. (Laughter.)

MR. GILMARTIN: Yes, which – yes.

So Igor Timofeyev, who is director of immigration policy and special advisor for refugee and asylum affairs at the department of homeland security. He has served as an associate legal officer to the president of the international criminal tribunal for the former Yugoslavia; he has also clerked for Justice Anthony M. Kennedy of the U.S. Supreme Court. So Igor, please.

IGOR TIMOFEYEV: Thank you very much.

(Off mike.)

Okay. All right, I think I'm wired.

To Chairmen Maxwell and Gilmartin, members of the Presidential Advisory Council for HIV/AIDS, thank you very much for inviting me to be with you today. And I'm honored to speak to you about an important initiative of both President Bush and the Department of Homeland Security to facilitate travel of HIV-positive individuals into the United States.

I'm particularly pleased to see members of your domestic subcommittee, such as Carl Smith (sp), who invited me to speak to them about a month ago on this very issue. And I must ask for their indulgence as some of what I have to say will sound familiar.

As all of you know, on December 1st – (audio interference) –

So as all of you know, on December 1st, 2006, on last World AIDS Day, President Bush has announced an initiative that forms an integral part of this administration's effort, dedicated to ending discrimination against people living with HIV and AIDS. The president directed the sector of Homeland Security to initiate a rulemaking that would propose a categorical waiver for HIV-positive individuals who seek to travel to the United States on visas of short-term duration. This rule seeks to create an easier and faster process for these people to come to the United States on short-term visas. What the rule would do is it would offer authorizations of short-term, non-immigrant visas and also temporary admission for foreign individuals who are currently inadmissible solely due to their HIV status.

As such, the rule would provide for a more streamlined process than the one that currently exists to authorize these individuals to enter the United States as visitors, for either business or pleasure, for up to a period of 30 days. In a nutshell, HIV-positive people who wish to travel to the United States for short visits would no longer be required to seek admission under the more complex, individualized, and case-by-case process that exists under the current policy.

The rule seeks to accomplish this change in a way that, for the imposition of requirements derived from the current practice, would minimize potential costs to the United States government and the risk to public health. This proposed rule is currently being developed by the Department of Homeland Security in close collaboration with our counterparts at the Department of Health and Human Services, and also the Department of State. In the latter, we are working together with both the office of the global AIDS coordinator and the Bureau of Consular Affairs.

As with any regulation, the rule would have to be approved for publication by the Office of Management and Budget, and we're in close communication with them as well as with the domestic policy and homeland security counsels at the White House. This had been, and continues to be, a very collegial process, and the draft rule has already benefited significantly from the comments we have received from our colleagues in the inter-agency.

While the proposed rule is not out yet, I anticipate that we will see it officially published very soon, and by very soon I mean within days and not weeks. So it really will be coming, I expect, in the Federal Register quite shortly.

At this point, once the rule is out we will be looking forward to receiving public comments on the rule, and I hope that the listening session we will have later today will also be a fruitful precursor to that process. I expect that once we have received and reviewed the comments from the public, we will be in a position to issue a final rule – and I take a breath before I say this, but not too deep a breath, I think by the World AIDS Day, and if that proves impossible then by the year's end.

So we really – we have a cooperation with OMB. We have managed to put this rule on a fairly fast-tracked, accelerated process, but hopefully still one that will enable the public to react as it should to this initiative.

So why is this rule necessary? What does it seek to accomplish and how does it build upon our experience in adjudicating waivers from HIV-positive individuals who seek to come to the United States? To answer this question, we need to look at the current statutory framework, at its history, and at the current practice concerning issuance of visas to HIV-positive individuals seeking to visit the United States.

Let me turn to the statutory framework first, since its inception in 1952, the Immigration Nationality Act provided that foreign nationals who have any, and I quote, "dangerous, contagious disease," close quote, are ineligible to receive a visa and therefore excluded from admission to the U.S. The statute did not specify which diseases would fall into this category, but left that determination to regulatory action.

In 1987, by statutorily mandated regulation, HIV was added to the list of dangerous, contagious diseases that indeed makes an individual inadmissible to the United States. Accordingly, foreign nationals who were infected with HIV have been rendered ineligible to receive a visa.

In the early 1990s, the Department of Health and Human Services, which is charged by statute with determining what constitutes a communicable disease of public health significance, considered a regulatory amendment that would have removed HIV from the list of those diseases. In response, in 1993, Congress amended the immigration law to expressly specify that, open quote, "infection with the etiologic agent for Acquired Immune Deficiency Syndrome," close quote, shall constitute a communicable disease of public health significance.

This statutory change introduced an explicit prohibition against HIV-positive individuals who seek to travel to the United States. And this prohibition was made immune from a regulatory amendment. To date, infection with HIV is the only medical ground of inadmissibility that is written into the immigration statute, as opposed to being left to regulatory discretion.

While this prohibition is therefore both harsh and unambiguous, it is not inflexible. The immigration law gives the secretary of Homeland Security discretionary authority, subject to certain restrictions and conditions, to approve the issuance of a visa and temporary admission into the United States of a foreign national who is otherwise inadmissible. This authority extends to instances where the inadmissibility is based on health-related grounds, which includes the HIV infection.

How does the process work? People who wish to come to the United States on a temporary basis, such as for business purpose or for pleasure, must file an application at the U.S. consulate abroad. As a part of that application, the individual must answer whether he has any communicable diseases of public health significance, which includes

HIV. During the subsequent interview, a consulate officer will ask the applicant questions concerning his application to determine whether to recommend that applicant for a health-related waiver of inadmissibility.

This recommendation is made on the basis of the guidelines that have been developed by the Department of Homeland Security, and its predecessor agencies in consultation with other relevant government agencies, such as the HHS. Normally, the recommendation would go through a level of supervisor review right at the consulate. This is a part of the waiver process that is administered by the Department of State in the course of its normal – the charge of its normal duties of issuing visas, reviewing and issuing visas.

After this process is complete, if the consul officer recommends a waiver, that recommendation is forwarded to a special office within the Customs and Border Protection, a component agency of the Department of Homeland Security, that is charged amongst other things with the determination of which individuals must be admitted into – or may be admitted into the United States. That office, which is called the Admissibility Review Office, would review the recommendation to determine whether it conforms with the guidelines for waiver issuance. If it does, the office will make the decision to issue a waiver and that decision will be communicated through the relevant consulate abroad to the applicant.

What are the guidelines that the State Department's consul officers and now admissibility review officers follow while considering these waiver requests? Currently, this review is done on a case-by-case basis and it employs a balancing test which involves several factors. In general, when considering whether any waiver of statutory inadmissibility, whether for health-related reasons or for others, should be issued, we consider – and we must consider – three factors: the risk of harm to society if the applicant is admitted, the nature of the basis for inadmissibility, and the nature of the reason for travel into the United States. Again, these are general criteria that would be applicable to any kind of immigration waiver.

Guided by these factors, we have developed a series of more narrowly targeted criteria to guide the exercise of discretion with respect to waivers for foreign nationals who are HIV positive. These criteria were first developed in a series of guidances and instructions in the last 1980s, so that was not only well before my time at the Department of Homeland Security, it was well before the creation of the Department of Homeland Security itself. And these criteria were issued by the former Immigration and Naturalization Service, which had authority with immigration matters and by the Department of Justice of which the former INS was a part.

As is almost always the case with immigration, there are not – these criteria are not straightforward and simple. There are actually three different sets of criteria: one that applies to any request for an HIV-related waiver, and two that address more specific situations, and I will describe those shortly.

The criteria that would apply to any request for a waiver of HIV-related ground would require that the consular officer or CVP officer consider three factors: first, whether the danger to the public health represented by the applicant is minimal; second, whether the possibility of a spread of infection is also minimal. And third, whether the applicant's admission will result in any previously unauthorized cost for a government agency in the Untied States, be it local, state, or federal. To approve a waiver, our officers must find that the formative factors – the danger to the public health and the potential spread of the infection – are not more than minimal and that there will be no cost to government agencies to which the agency had not consented before.

Then the second set of criteria applies to situations when an individual wants to travel to the United States for a visit of short-term duration, one that would not exceed thirty days. In addition, the individual must present a reason for travel that would qualify as a public benefit for the United States and one that would outweigh any risk to public health that his travel may pose. Such public health – public benefit could include, for example, attendance at an academic or health-related event, conducting business with the United States, visiting close family members, or traveling through the United States in transit to engage in similar activities in a third country. Such transit also may not be greater than five days.

The supplemental set of criteria was developed in order to provide for more streamlined decision making in this specific category of cases where there is a discernible public benefit reason for an individual's travel to the U.S. And it reflected also common sense experience that an HIV-positive individual who wants to come into the United States for a short period to visit his relatives, to teach in a university, would not normally present a danger to public health.

In addition, we have developed a third set of policies, one that addresses instances where an individual wants to travel to the United States to attend a scientific, professional, or academic conference. That is, in itself, of a public interest. Such a conference event must first be designated by the secretary of Health and Human Services. And in these situations, an individual who has HIV will not have to go through an individualized waiver review process because his attendance of such a designated event is already deemed to be a sufficient public benefit to justify a waiver. The period of admission authorized under this event-specific set of policies is shorter than under the more generalized criteria I described and must not exceed 10 days.

Over the years, we have granted waivers under this set of procedures for an individual to attend events such as the Salt Lake City Olympic Games, the U.N. General Assembly special session on HIV/AIDS in 2001, various universal fellowship or metropolitan community churches events, and the 2006 Gay Games in Chicago.

I should also add that our criteria require HIV-positive applicants for admission to establish that they're aware of the HIV-positive condition, that they have received and are following adequate medical counseling, that they are current under medical care and are traveling to the United States with a supply of drugs as is medically appropriate and one

that is adequate to cover the length of the anticipated state. The applicant must also demonstrate that he has adequate medical insurance or other financial means available to him to cover anticipated medical expenses during his stay in the U.S.

Now, what is the experience that we have gained during some 20 years, almost 20 years of reviewing and adjudicating the HIV-related waivers? I think this experience has shown to us that both DHS, and before DHS's existence, the Department of Justice, have consistently approved recommendations from consul officers for non-immigrant visas to aliens who are HIV-positive where the following set of factors has been present: first, where the applicant sought to travel to the United States for 30 days or less, for a purpose consistent with a business visit or a tourist visit classification, or was in transit to go through the United States to a third country; second, the applicant has received medical counseling; third, the applicant was in compliance with medically advised behavior and medically prescribed treatment protocols; and finally, the applicant was able to demonstrate availability of an adequate supply of medication, if any were prescribed, and therefore was not likely to require assistance resulting in any cost to any level of government agency in the United States.

Also, with the help from our colleagues at the Department of Health and Human Services, we have gained great understanding and expertise regarding the threat to the public that is posed by HIV-positive individuals. In particular, we believe that the current policy we have adopted has provided adequate protection to the public health of the United States and that individuals who have HIV, who aware of their medical conditions, receive appropriate medical counseling, are in compliance with medically prescribed treatment and medically advised behavior, have presented little risk to the public health in this country.

So based on this experience and as added knowledge, the administration began thinking about how to further simplify and streamline the waiver process. In particular, we looked at the event-specific waivers that we issued – the third category of waivers I described – and we wanted to see whether we could approve – whether we could develop a set of further streamlined process that would involve – that would be based on that sort of set of policies or group waivers. And we face the challenge of trying to see how we can simplify a waiver process that involves at least two government departments – Department of Homeland Security, Department of State – and also on many occasions such as with event-specific waivers, also Department of Health and Human Services.

So in short, we wanted to develop a set of policies where a consular officer would be able to analyze a visa application, look at the appropriate factors to consider, and if satisfied that these criteria are met, will be able to issue a visa outright without a further review by our admissibility review officers. So in that sense, the process would emulate, would be based on this third set of event-specific policies that I have described where there is the visa – a consul officer is able to issue a visa outright without the further individualized review by our CVP officers.

The obvious benefits of this policy is that applicants who wish to visit the United States for short periods of time would be able to get the applications approved more quickly without this additional step of review. What we did is we look at the legal possibility of doing so and even though, so far, all the waivers that we have – we have effected in this area have been done on a case by case basis; there is nothing in the immigration statute that would stop the secretary of Homeland Security by also issuing a waiver through the rulemaking process.

So based on that legal conclusion, we have decided that this is a rule that we can put forward and develop. And again, as I mentioned before, and as I know on last December 1st, President Bush announced this initiative and directed the secretary of State to request from the secretary of Homeland Security the initiation of that process, which Secretary of State Rice has done on June the 6th, requesting that the Department Homeland Security grant the limited waiver of inadmissibility under the Immigration Nationality Act to person who are currently inadmissible to the United States solely due to their HIV-positive condition.

More specifically, Secretary Rice recommended the waiver for persons who seek short-term, technically called B-1 and B-2 visas; these are the visas for business and for pleasure, which includes tourism. And she specified that his waiver would apply to people who did not have active, contagious, symptomatic infections associated with HIV or AIDS.

So my department, the Department of Homeland Security, shares the president's and Secretary Rice's firm commitment to enable, on this categorical basis, the admission into the United States of HIV-positive individuals who do not have such active contagious symptoms, and to enable those – that admission in instances when these individuals want to travel for short visit to the United States and do it for a permanent, streamlined process that employs standardized criteria as opposed to the current case by case individualized process.

Because the rule is not yet out, I am somewhat constrained in terms of speaking of what will be in the rule, but I think the rule will capitalize on the policies that we have currently developed, on the knowledge that we have gained through administration of those policies. It would take into account a lot of advice that we received from the Bureau of Consular Affairs, that will bear a greater burden – or at least a greater workload in terms of reviewing and determining those applications, and also from the Department of Health and Human Services, which has done a lot to inform us with the latest medical opinion.

And certainly we are looking forward to comments – once the rule is out, for comment from the public and from, you know, really individuals and organizations such as yours which have a great deal of expertise, a great deal of knowledge and can really inform us on how best to formulate and to shape this rule.

I, perhaps, if there are specific questions about the rule, I may be able to address it throughout the question and answer, but again, until the rule is out, which I expect will be very shortly, I will be – I will have to be somewhat limited in what I can say. So, thank you very much. If there are questions, I'll be happy to take them.

MR. SCHMID: Thank you for coming back and visiting us, and thank you for the good news that we will see the proposed rule very soon. We're very pleased to hear that.

I guess, you know, when you spoke to the domestic subcommittee, many of us said, you know, this is a law that needs to be changed. So I wanted to put that on the table, but I know you are preceding based on current law, but I would like to put that out there that I think we should look at changing the current law.

But given that we have to live with the current law, I do have two questions. One is, I believe now when people are given a waiver, case-by-case, it is stamped on their passport through a numeric code that they have HIV. Is that going to continue under this? Is that, first of all, correct, and will that continue under the waiver? And the second thing is – and this is just because I'm not so knowledgeable on all these issues – does everyone who enter the United States have to obtain a visa? And this is, I know, you know, pertaining to people who have to get a temporary visa. So my question is, if they don't have to, you know, how are you going to deal with those people?

MR. TIMOFEYEV: With the people who don't have to get the visa? Sure.

Well, I can't comment on the law, so that's – (laughter) – the law is out there, and in part that's why I sort of wanted to stress that this is the one specific instance where the statute very unambiguously constrains us, constrains HHS. So we tried to see what we could do within the law. And just in that sense, I would say that this categorical waiver we propose is, while there is a precedent and there is certainly the legal authority for that, it is a somewhat new departure. I mean, this is the first time in which, when the secretary of Homeland Security has proposed doing a categorical, fairly sizeable, categorical waiver. So in that sense, I think we should appreciate that it is quite a noble element that we're introducing here.

In terms of what is currently being stamped in the passport, I believe that the only notation that is done is that there is a waiver granted on a specific section of the INA, which I think is section 98212-D3A. So really there is a notation on the passport, but it's not a notation that says this is the HIV waiver. It just specifies the ground, the statutory authority under which the waiver is granted. And that statutory authority is not HIV specific; it's a waiver that can be granted for medical, for health-related inadmissibilities. So in that sense, that's how it's currently marked.

Under the rule, what we anticipate is we will develop probably similar process when there is a notation in the passport. The reason for a notation is very obvious: We want to communicate to our customs and border patrol officer who will do the actual admission that this is a waiver that is issued for 30 days; it's issued pursuant to particular

regulatory authorization from the sector of homeland security. There is a transparent process by which the officer would be able to identify it, but it's not one where that would identify HIV or AIDS. If concern is about sort of stigmatizing, that is something that we certainly want to avoid.

We actually looking at the possibility – and I speak on somewhat tentative terms – of seeing if we can maybe do away with the notation altogether, and communicate that information from the consulate, the consul offices, who issue the visa through the electronic database. There is something called the consular database, through which our CDP officers have access and into which the information can be entered. I say tentative because there are technical issues involved that sort of depend on interoperability of two government databases, and how that information can be communicated. But really, our hope is that we eventually can move to this, and maybe even at the time the rule's implemented, to a system where that information will be communicated electronically. So then, if indeed it seems easier, we will do away with the notation in the passport, and just communicate electronically.

I mean, speaking in general, the State Department slowly has been moving towards a more electronic system which engenders a lot of opposition, not just there but also elsewhere from people who are used more to a kind of old-fashioned system of flipping through a passport and seeing what the information is there. But we're slowly beginning to rely on the fact that there is more information, and more specific information, we can communicate more effectively through the electronic means.

And in terms of the people who don't require visas, that is true. If you come from what is called a visa-waiver country – most of Western Europe, United Kingdom, France, others, also I believe Australia and a few other Asian countries – I think only about six countries that not within Western Europe – and also Canada. Canada is not a visa-waiver country, but they also don't require visa. Normally, you don't require a visa if you come from that country to the U.S. for a short visit; the problem is that once you have a ground of inadmissibility under the immigration law such as the HIV infection, then you're not admissible to the U.S. and you have to get a waiver from that inadmissibility.

And that is why even people who apply, say, from the United Kingdom and who have HIV do have to go to the U.S. consulate there, fill out a visa application, specify that they have this condition which by law makes them inadmissible, and get the waiver. So in fact, the consulate where we process the greatest majority of those waivers is indeed our consulate in London. And through the outreach that the consulate has conducted where there is groups – for instance, there is groups in London, United Kingdom, it really informed the public that if you do have that condition, even though you're within the visa-waiver country, you do have to go and actually get a waiver from that inadmissibility.

DR. MALEBRANCHE: Thanks for coming back, Igor, to bring up this topic.

I wanted to ask because I heard about the part of the waiver wouldn't be included for people who showed evidence of some kind of communicable disease or opportunistic infection. Was that part of it that I heard? Like, the waiver wouldn't be offered to those folks that seemed like they were suffering from something. Did I mishear that?

MR. TIMOFEYEV: Yeah, the way that we're designing this – and this was present from the beginning; this was, as I mentioned, was present in Secretary Rice's request for it – is that the waiver not encompass people who have the active contagions and sort of symptoms of the disease. So if what your question is, you know, what kind of symptom will disqualify someone –

DR. MALEBRANCHE: Yeah, well, my question is about like, the only opportunistic – and it's not even an opportunistic infection per se, would be something like active tuberculosis, that would create an immediate threat, Things like microbacteria, thrush, you know, any kind of other Cryptococcus, is not going to present an immediate threat to somebody else if they're suffering from that unless their immune system is compromised as well. So again, it kind of gets back to Carl's point about the law kind of being a little bit interesting, and maybe a misunderstanding of what is exactly communicable unless somebody's having direct sexual contact with somebody.

So I'm kind of wondering where we're going with this, with regards to all that because the waiver is good, I congratulate you guys on moving forward with that, but the law seems to me to be inherently flawed, unless someone else can add something more to that, another communicable disease that would present a threat on a plane or immediately to other people, what that would be.

MR. TIMOFEYEV: I mean, I think there were two parts to your question, and I'll defer to this group on the more medical, you know, medical understanding. But it is right that the law quite strictly specifies HIV infections, in that sense to the extent that HIV infection is different in terms of, you know, its communicable nature and the public health danger that it presents. I mean, again, I defer to you, but we're constrained by the law in that we have to address that.

And I think when the law speaks about the communicability, it's not speaking just in terms of travel on the plane or travel on the train across the border; it also speaks about the communicable nature while the individual is in the United States. So that may be different from tuberculosis.

DR. MALEBRANCHE: But you could make that argument with an assumption about Hepatitis B, Hepatitis C, anything that's sexually transmittable. So that's – you understand where I'm getting at with this?

MR. TIMOFEYEV: I think so. What I guess my response is, you know, there is –

MS. MCGEEIN: It's the law. If we want to change the law, that's a different issue. But it's –

DR. MALEBRANCHE: Yeah, that's probably what I'm getting at, is that what can we do to change that law because it's an archaic law.

MS. MCGEEIN: I don't think we necessarily disagree with you, but it is the law.

MR. TIMOFEYEV: As I said before, you probably remember, as I said when I spoke to the domestic subcommittee, as a member of the executive branch it is my duty to execute the law. So I kind of defer to others on the question of whether or not it should be changed and how.

But I just want to address, briefly, maybe what is also part of your question. To the extent that someone who has HIV comes to a consulate, and then the question is well, does he exhibit active symptoms. And some things – again, this is something where we would have to develop based on the medical opinion, you know, sort of guidelines and instructions, education for the consul officers, again, capitalizing on really what is being done now.

But if someone has a rash, or he has a cold, and these are really not symptoms that actually indicative of a high, you know, communicability, I don't think that that individual will be precluded from receiving the waiver. So it really will have to be – there will have to be a discretionary process that the consul officers determine to see whether or not such an individual can get in.

MR. GILMARTIN: Well, thank you very much.

MR. TIMOFEYEV: Thank you.

(Applause.)

MS. MCGEEIN: I just want to make a point that Igor made at the beginning of his presentation. I'm going to make it again more strongly. When this MPRM (?) comes out, that he is working 24 hours a day, and has been for months, on, it is going to come out with a very defined but relatively short comment period. So I will send an email out to all of the loyal PACHA fellows that indeed, it is in the federal register and the comment period is X, whatever it turns out to be because you know, there really is a desire to meet the needs of the community.

MR. GILMARTIN: (Off mike) – brings many years of public service, both inside and outside of government, to the public health arena. And from June of 1995 until July 31st, 2001, she served as a member of this advisory council on HIV/AIDS as an appointee of the 42nd president of the United States, President Clinton. So in 2003, she was appointed by Mayor Bloomberg to serve on the New York City Commission on

HIV/AIDS; and now in 2007, she was nominated by Governor Eliot Spitzer to serve as a member of the New York State Public Health Council.

So welcome, Ms. Fraser-Howze. Welcome, it's a pleasure to have you with us.

DEBRA FRASER-HOWZE: Thank you very much. Good morning, everyone.

I am very pleased to be here. I want to thank, first, Dr. Beny Primm, who's the vice-chair of my board at the National Black Leadership Commission on AIDS, for giving me an opportunity to speak to you, and I'm going to say hi; and thank you, David, who also participated in the national conclave.

There was something that is not in my bio, and I don't know why, and I have to go back and ask my office why: While I did serve on the commission under President Clinton, I was also asked to be reappointed, and served on this commission under President Bush for the first year, and probably because at that time we did have subcommittees, and I was chair of the subcommittee that focused on communities of color. So there was a need to do some transitional work, specifically because of the staggering numbers in our communities. So I'm glad – this is déjà vu. I'm home; I'm very, very happy to be with you today.

You know a little bit about us, when we were founded. We're 20 years old. That makes us the oldest and largest black AIDS organization working on policy and community development in the country. Our focus is a model that would include, starting first with the clergy – and it's a 20-year-old model so it's nothing new, starting with the clergy and then putting around them a number of people in the community that make things work, that will give them the information they need to move forward. And that includes elected officials, social policy experts, medical business and media leaders.

These groups are now called affiliates, and we have them in nine cities across the country, and we're working on eight additional cities. They do undertake public policy on the local level. Their focus is to develop new resources for communities of color. And they also look at very specific policies, when policies seem to be out of whack.

And I'm going to give you one short example of Ronald Johnson, who I see is here, who's been a founding member of my board, he's in the audience. Years ago in 1988, we discovered that there was a law in New York City, who has a division of AIDS, that said that when a person is sick with AIDS, they will send out a homecare attendant. The homecare attendant is there to care for the individual who is ill.

We had homecare attendants actually going out, caring for the individual who was ill, but the disease had changed. The individual who was ill was no longer a gay, white male individual; it was now a black woman or a Latino woman with three and four children. So these home attendants, following their rules, would go out and attend to the person who was sick, which was the mother. They were not allowed to fix breakfast, dinner, or lunch for the children, care for the children in any way, but to focus on the

individual who was sick. That was the law; that the regulation for that particular program.

And in understanding that the policy had not changed, and nobody maliciously didn't change it; the epidemic changed. This epidemic is evolving and expanding on a daily basis. The decision was then for the ministers to go in, look at that policy, and go back to government and do all they could to change that policy. We've been doing policy like that around all kinds of issues including needle exchange, which is probably the worst issue to deal with in the African-American community because they were absolutely against needle exchange. We've been dealing with issues like that for the entire 20 years of this epidemic.

I'm giving you some of that history because I want you to understand that this national conclave on HIV/AIDS policy for black clergy did not come out of air; it comes from a 20-year foundation of the clergy doing just this type of work. And in order to begin with this, we had to ask ourselves two questions, or base this on two premises. And one was, what would you do if you had no fear? Around 20 years in the epidemic, clergy have been around this epidemic for 20 years. You've been doing some things well, some things not so well. BLCA is a policy organization, so we're not doing program, and you know, we're not doing very specific programmatic pieces; we do mostly policy and developing new resources, and bringing people together to do that on local levels, and then on a national level. But what would you do if you had no fear? You the clergy, you the people that we go to, to both save our souls and save everything else – so, you know, the leaders and the leading institution in the African-American community.

The other thing was that we started with the premise that we are not bankrupt. We've seen these affiliates work all over the country. We've seen new resources; we've seen the clergy, you know, join with local elected officials, join with local health departments particularly, and work with the health departments and the elected officials to do major programs like testing, get policies out, resources in the community so that they could go out and promote that everybody in the community should be tested. So we knew that this worked.

I'm going to attempt to go through this with you because I have to confess to you that my grandson did this PowerPoint for me last night because I'm technically challenged. (Laughter.) So I explained to him that Uncle Beny got me speaking at this President's Advisory Council on AIDS, I need some help; and Michael got up and went with it. So I'm not even sure I know how to turn on the –

MR. : (Off mike.)

MS. FRASER-HOWZE: Okay. Turn the page. Oh, okay. Thank you so much.

So when we brought the clergy together – there's something that you should know because this will not be on the slides unless he did it and didn't tell me. We asked

the clergy for a very specific statement: How would you open this up? Let me take you back a little bit before that.

Dr. Calvin O. Butts III – Reverend Doctor Calvin O. Butts III, is chairman of our board of directors. He reached out to Bishop T.D. Jakes. I don't think that people really know that in our community, there are different factions of ministry; that all black clergy are not the same, absolutely not. We have a very conservative wing of black clergy groups, we have a more liberal wing; we have what we call activist preachers, the progressive preachers; we have an unbelievable mosaic of black clergy in our community. And to make the mistake to think that they're all the same is deadly. You can walk in there and speak about one issue and get absolutely cut off, and they'll never invite you back again. So you have to be very, very careful. It pays to ask somebody who knows who's who in the room.

So you should know that the pairing of these clergy, the traditional activist clergy and the mega-church clergy leader, was different. So they had some things that had to be worked through just to sit down together, theological perspective. But when they did the heavens opened up and it showed us, again, that we are not a bankrupt community.

When they agreed to work together and call in ministers from all over the country, we started with an invitation of 50; we ended up with 168 ministers and medical leaders, with the likes of Creflo Dollar and, you know, you've got T.D. Jakes, you've got Creflo Dollar, you've got Fred Price's children, you've got Eddie Long; you have a number of ministers that you probably know about because if you look at The Word Network, or glance through it every now and then, they're all over The Word Network.

We're talking about ministers that, you know – and other end the Calvin Buttses of the world that have the traditional church, the mainstays, the Adam Powell churches, that write the Martin Luther King kind of history in our community; that have, you know, standing-room-only attendees in their church on Saturdays, and do other work in the community as activist clergy. And then you're talking about the mega-churches, somebody like a T.D. Jakes, who has 16,500 parishioners coming into him every Sunday morning, and that's just one of the churches that was there.

We're talking about a good 3.5 million African-Americans that we're talking to by just talking to them in the room, and we're not even including their television ministries. So we have to really understand the power that these folks bring to – 168 people brought to the table. In addition to that, we were joined by the National Medical Association. The National Medical Association, in August of this year, declared that HIV/AIDS was a state of public health emergency in African-American communities. They released this statement at their convention, and they released a policy document that looked at very specific areas of concern, and solutions to those areas of concern.

They officially, in August, turned that document over to the National Black Leadership Commission on AIDS, who was at that time putting together this conclave of black clergy, and asked that BLCA take this to the black clergy, and have the black

clergy ratify what 30,000 African-American physicians said needed to happen on HIV/AIDS. We were then later joined by the National Conference of Black Mayors, the National Caucus of Black State Legislators – we were then joined by a number of individuals, but the two core groups in this were the clergy and the medical providers.

What would you do if you had no fear? In the spirit of our historic role of advancing prophetic social justice ministry – this is the clergy – black clergy is stepping forward to play a stronger leadership role in advocating for theologically sound HIV/AIDS public policy. Working with the National Black Leadership Commission on AIDS, we have determined to live up to the biblical mandate that calls us to be the light of the world.

With faithfulness to this calling, we must compassionately embrace those who are infected with and affected by HIV/AIDS. Through life-affirming ministry, we are committed to caring for the physical, mental and spiritual needs of all people in our communities who lives are being devastated by this insidious disease. Just as African-American clergy fervently came together 50 years ago to fight for civil rights, we are banning together today to bring an end to HIV/AIDS and its potential to obliterate our community; to combat this plague which is claiming five to 7,000 lives per day worldwide and is destroying black families and killing black men and women at a disproportionate rate of genocidal magnitude. Then, they go on to their very specific recommendations.

What you should know before I go over some of those recommendations is this: They came together to ratify the policies of the National Medical Association, so this is not something that – they as clergy know that they're not medical providers. They left there with a new law; they created and wrote a new law. They invited every political person that they felt they needed, from Representative Charlie Rangel and Representative Townes on the health committee, and James Clyburg, to talk to them about educating other elected officials about what needed to be done.

And then this sharing of information – okay, do I do down? Okay.

One of the things that they agreed that they would definitely – I'm sorry, did I mess something up? My grandson told me, don't touch anything – (laughter) – just ask somebody to push the buttons, Grandma. Okay, yes. Okay, thank you. He told me somebody would help me – (laughter) – he said, you're going to the President's Advisory Council, for god's sakes, somebody will help you. So good, this is good. (Laughter.)

They promised to aggressively seek that every person in their sphere of influence, and I think that I discussed with you what their numbers looked like, got tested for HIV. And that is a critical piece of what we need to do to end this epidemic in our community. They're going to promote HIV awareness and they're going to make sure their congregations are equipped to address the issues factually.

It's not just, you know, we want to talk to you, and everybody should sit around and sort of hold hands, and sort of worship on getting this thing corrected. We want you to know how many African-Americans are infected, how the disease is transmitted, how you protect yourself from this disease. And, yes, that's going to involve some tricky conversations in the black church; they're going to have to talk about condoms in the church, they're going to have to talk about a lot of things. They're ready to do that, and they've been doing it for a while. They're ready to move on.

They're also ready not to let other religious leaders in other communities make a decision about what they know is affecting their community more than any other community. And they're joining, along with their partners, which are the 30,000 black medical doctors in the country, make them more affirmed that they are taking the right stance. This is something that this administration has focused on, and they're right there with it, the ABC model. But of course, they've added D: Don't engage in risky behavior.

Of course, there was a lot of discussion at the meeting about this. A lot of discussion to sort of move folks, not just with the ABCD model, we have D but we actually went to E, F, G – (chuckles) – and had both long periods of discussion. But they were very clear that it would be the ABC model, they agreed with it. There're nothing wrong with telling people to abstain, you know, especially young people. They don't see anything wrong with it, and I don't see anything wrong with it. And in a sexually transmitted disease, it is absolutely ridiculous to think that this is not something that you do. In our community we embrace that, particularly for our young people. In fact, I'm a black woman over 50; I'm in one of the highest new-rising rates of new infections in the country and I could tell you that I have abstained, whether I want to or not. (Laughter.)

So that whole discussion about sexual activity is revved a little more than it actually is going on in the community. They found that also, that in our community, we're not more sexually active than any other community; in fact, we're probably a little more conservative. So those are the things that they did agree to. Next slide.

They are calling on the president and congress to declare this a public health emergency. Now, this is not the first time this was asked for. This was asked for in 1998, I believe it was, when I was on this presidential council, and we went to then-President Clinton and asked him to declare HIV/AIDS a state of public health emergency. He would not do it; he declared that HIV/AIDS was a severe and ongoing crisis requiring emergency federal intervention, which allowed a group of folks to work with some legislators and have the minority HIV/AIDS initiative created that gave some relief to communities.

Right now, we're talking about testing all of these people of color in the community, and we haven't fixed anything. So they're getting tested and going into a system that's broken, and it's going to be a lot of them in the system that's broken. And the concern is now, we need to stop for a minute, understand the emergency proportions that we're in: one in every 50 black males and one in every 160 black women estimated

to be HIV positive; that's a catastrophe in the United States of America. So we need to stop right now, look at this as a public health emergency, and then begin to actually respond to it for the emergency that it is.

A national AIDS plan, I'm sure that you heard about that, the fact that we don't have one for this country. And hopefully it's this body that moves us closer to having a national AIDS plan. But we certainly need one, and we need one that is succinct. We talked about what the components of an AIDS plan would be, and that is how they got into the actual writing of a piece of legislation. They said, you know, it is not unusual, you know, we had Floyd Flake there who was a former Congressman Floyd Flake, Reverend Floyd Flake, head of Allen A.M.E. Church, and we had passed the buck there who is the head of Abyssinian Development Corporation, the home church of Adam Clayton Powell, who probably wrote more laws – who did write more laws, before and since – you know, than any other congressman that was focused on the uplifting, particularly of people in communities of color.

So they looked at what that meant. Now, these ministers are ministers of great means. They have not little flocks but huge ones, and made some decisions based on their knowledge, and as you can see, with the act, including measurable goals, timetables, specific objectives for their national AIDS plan, these are not a group of ministers who are unknowledgeable about the system. Next slide.

They want to look at the historical treatment of African Americans – that is going to be one of the pieces of the act, and – look at how that plays into making priorities in how we move forward. And let me just say this to you, that one of the biggest problems that I have seen in the 20 years that I have been doing this work, in responding to African-American communities, is our absolute mistrust of the public health system, for good reason, good historical reason. Again, we're not bankrupted as a community, and we're also not ignorant as a community.

Part of our tradition in our community is an oral tradition, brought on because we had no other choice. But that oral tradition is so strong and those discussions and the stories, and those realities of those stories based on fact, like the Tuskegee experiment, have not gone away. And we as public health officials, should not sort of roll our eyes in the air every time we hear it because it has a true and real impact on saving the lives of these African Americans who are in need.

They also talked about endorsing some very specific legislation that is already out there like Maxine Waters's bill that talks about prisons and testing and discharge. It is something so basic, you know. I don't need to go into it with you about what is going on in the prisons and the guys are being discharged and they're coming home and having sex with their wives, their girlfriends, and infecting them because they are having sex in prison – next slide – and there is not any real follow up. Next slide.

So they did call – they are calling on – and I'm not here to ask you this specifically, but we're asking you to look at this and understand their feeling of their need

to call on – you should also understand that this is a very bipartisan group, full of both Democrats and Republicans. These clergy are not in one camp. Next slide.

They believed that – I think that we are repeating – I think that we are going over the same slides once again. But you can – if you can keep going and let me see if they are – go ahead – all right – yeah, okay. I think that – I think that Michael did a very good job. (Laughter.) Thank you, Michael. Thank you for Grandma. I give him an applause. Thank you very much.

MR. GILMARTIN: Thank you also.

(Applause.)

We have time for question or two. Does anyone have a comment?

REVEREND HERBERT LUSK II: Yeah, I – I want to get her attention.

MS. FRASER HOWZE: Sure.

REV. LUSK: Yeah, I just want to commend you on what you're doing. I'm very excited about what is taking place. I'm part of that mosaic that you talked about. I'm Reverend Dr. Lusk.

MS. FRASER HOWZE: Hi, Reverend Lusk.

REV. LUSK: All right, one of the things that I noticed as I looked at some of the information – and Dr. Butts is someone who I'm very familiar with. T.D. Jakes is someone I'm very familiar with. The TD evangelists, the social entrepreneur faith-based leader – Dr. Butts is. I just think – and you may already have done this, but what I did not see is I did not see leaders of major denominations. I didn't see Blake (?), Church of God and Christ. I didn't see Bill Shaw, who was my president.

MS. FRASER HOWZE: Bill Shaw was absolutely there from the beginning of the meeting to the end of the meeting, as was the president of the Progressive Baptist, as was – I mean, we have – we ensured that we invited Thurston. We invited the leaders of all of the major denominations and they were all there except Blake who had a scheduling conflict. But he is absolutely on board.

REV. LUSK: Well, let me just embellish for this council.

MS. FRASER HOWZE: Yes.

REV. LUSK: These individuals, these leaders of denominations are very powerful men. And even more powerful than the people that you'll see on TV. You're talking about – you're talking about Dr. Shaw who has –

MS. FRASER HOWZE: – 8.5 million.

REV. LUSK: About 9 million. We say nine. We are bragging 9 million. We probably have about 7 million – (laughter) – about 9 million individuals that they can talk to on a given Sunday morning is the message is accurately shared. The second thing would be Blake, somewhere around 6 million.

So what you're doing is just fantastic. I just wanted to commend you on it. We just also encourage you to continue to – and even as you present this, to mention these guys and to get these guys out in the front. They need to be in the front of this.

MS. FRASER HOWZE: Yes.

REV. LUSK: Bill Shaw needs to be on the front of this, and Blake needs to be on the front of this, and Thurston needs to be on the front of this. So keep doing your work. God bless you.

MS. FRASER HOWZE: Thank you. Thank you, Reverend. God bless.

DR. GREEN: Yeah, I also want to greatly commend you for the work you're doing. I work at the Harvard School of Public Health, and I have been very involved in African AIDS and some Caribbean AIDS, and one of the things I have come to do is help mobilize and show the impact of faith-based organizations in Africa on the terrible epidemics there.

A couple of questions: What can somebody like I do to help from the outside – what can the – what could PACHA do? And lastly, I wonder if you're linked up with the – I'm not sure of the exact name, but the National Association of Black Pastors' Wives.

MS. FRASER HOWZE: Yes, Vivian Berryhill.

DR. GREEN: Yes, Vivian Berryhill. She is a friend of mine. We went on a trip to Africa –

MS. FRASER HOWZE: She was on the planning committee of the whole event.

DR. GREEN: Great, great. That answers that. But then – so what can PACHA do and what can a non-black pastor like myself do?

MS. FRASER HOWZE: Yes, we are actually right now pulling together an advisory council to this endeavor. I found that we needed an advisory council. Many of my Republican friends came to me. Some white Mormon from Utah – (chuckles) – came to me and said how do I get involved in giving some support to this and helping – helping with this. And we came up with the idea of having an advisory council that will work with us, that will work with the ministers to move this. Some of the other mega preachers as well have asked as well how to get involved.

How can PACHA be involved? The best of all worlds would be that PACHA would endorse the conclave. I'm not asking for PACHA to endorse a specific piece of legislation because I used to be a member of PACHA. I know you can't do that. But to endorse the concept of the conclave, the fact that these ministers are on their own coming together, representing millions and millions of African Americans, and endorse the concept of the moving forward. That would be something that we would very much appreciate that we can say that the president's advisory council – and we would help to work on the wording of that, but that would be very helpful to us.

MR. GILMARTIN: So I think that is a good summary statement to conclude this session. I know that many of you would like to be engaged in the conversation.

MS. FRASER HOWZE: I will be here.

MR. GILMARTIN: But we have lots – thank you, everybody, for helping arrange this and orchestrate this, and thank you, Mrs. Fraser Howze for your presentation and for joining us for that.

(Applause.)

(Break.)

MS. MCGEEIN: PACHA members, if you'll please take your seats.

MR. GILMARTIN: I expect a few members are getting their last-minute chance at the coffee – (laughter) – and will be with us in a second. So we'll just give them a minute or two.

So the next item on our agenda is a listening session. And being new to the group, but having heard at the first meeting that I attended that one of the things that we wanted to have the opportunity to do was express viewpoints sort of in a more discussion or more free-flowing framework, rather than the kind of structures of listening to a series of presentations. So it's in that spirit that we have arranged for Anna Mitchell to join us as part of the listening session. And Anna is an associate director of the Domestic Policy Council, where she works on healthcare policy and has a particular focus on domestic and international HIV/AIDS issues.

And the Domestic Policy Council coordinates the domestic policy-making process in the White House. And it also offers policy advice to the president. It also works to ensure that domestic policy initiatives are coordinated and are consistent throughout the federal agencies. I'm sure not an easy job necessarily to do.

So Anna's role with us today basically is to listen to us. And it's an opportunity for us to express viewpoints, opinions – and so, we're not in a Q&A-type mode; it's more to gather and take information back. And I think, given her position, we can be very

effective in drawing together our viewpoints and so on in passing them along. And of course that provides us an opportunity downstream to have a continuing contact point as well, as is needed. So with that, I'll just open the floor. And I'd like to run this in a discussion mode and not be too formal about calling on people and lining people up for responses. But just to initiate a conversation –

ANNA MITCHELL: Actually, Raymond, I just wanted to –

MR. GILMARTIN: Sure.

MS. MITCHELL: Thank you for that warm introduction and express my gratitude for all of you that are here today and serve the administration and serve the American people working on these issues. It's good to see some friendly faces, both here at the table and also out kind of in the audience. When Marty asked if I would come do a listening session, I jumped at the opportunity because we haven't had a chance to do this yet. And I'm very much eager to hear what you want to make sure we're aware of, what we're doing well, what we're not doing well, what we could do better, and really use this as a starting point moving forward.

MR. GILMARTIN: Okay, excellent, good. So, begin.

DR. YOGEV: There are so many issues I don't know where to start. (Laughter.) It goes without saying that the president should be really congratulated on what PEPFAR is all about. It's an unbelievable change. And I have to admit in public I was not in favor of this president until he did that. And now, I think that's his legacy. My issue is while we're doing so well internationally, somehow we forgot the domestic agenda. And it goes in different levels.

I'm involved in research through the NIH and it's almost disheartening to see how much of the funding of the NIH, which was not increases, you know. And it's a problem by itself. It's diverted in this specific area to the international. And domestically, it become to the point that we are going to lose the ability to do an appropriate research. And especially, I'm a pediatrician, so especially in pediatrics, for some bizarre reason, there is a notion that pediatric AIDS in the United States is over.

While it's true that a number of new cases is really cutting down nicely and the recent CDC recommendation report will change it even more, we still have to deal with somewhere between 15 and 20,000 kids who are growing, and all they expertise of what to do with patients who have multiple exposure to those drug and resistant and new issues with discovering they're getting more and more diseases that we didn't expect they will have because it become a chronic disease. And funding to that is cut below the minimum.

So I would appreciate if somebody will look into the whole issue of how we spend the money for research on those issues, domestically and internationally. And the same one – I'm sure that some of my colleagues will join me in much better English in

the forum – is what we are doing with the clinical level? We are always limited on funding and every other day there is a cut because there's less in the Ryan White; there's less in something else.

So our patients are getting to the point – our ability to several points, get to the point that we are studying – (inaudible) – less and less. And I'll give you one small example. Because we're doing so well – and none of us – 10 years ago, if you had told me that I have a kid who's going to be adolescent and go to university, I would laugh in your face. Well, now the average age, age of infected kid in the system that follows them, is around 16 years.

When they reach to 18, in my state, for example, Illinois, and I don't know if it's in other states. Medicaid is stopped unless you have a handicap. So now, we spend all of our good time and hours and effort to avoid them, avoid the patient to get AIDS because they have nothing. At then, at the age of 18, we cannot do almost anything with them. So we're getting a growing population of adolescent who are a little bit handicapped because unfortunately, this disease is affecting their ability to such an extent that they are not as well-prepared to go into the world. They have no work, cannot get insurance because they already preexisting condition, even if they go there. And yet, there is no governmental agency to help us to take care of them.

MR. GILMARTIN: Okay, thank you. Ted?

MR. GREEN: Yeah, I'd like to sort of the idea that Ram expressed. It's something we've been discussing in PACHA over quite a period of time, which is the special risks of African Americans, Hispanics, and we should add, Native Americans, and this began to coalesce yesterday into something specific when Dr. Primm started to draft language for proposing something like a domestic PEPFAR with the word emergency in it: legislation, funding, policy to address on an emergency basis the spread of HIV in minority communities. So it's sort of a domestic PEPFAR and maybe Dr. Primm would like to say more about that.

DR. PRIMM: I certainly would. I think that's what is necessary in this country to show that we are as serious about this disease entity and territories as we are in the rest of the world. I think when we look at places where money is being spent, in North Korea and everywhere else, that we are under great criticisms in the African-American community about, well, what's happening here? What's happening here in the United States?

There is an example of what could happen. The prison system, for example, in California, has been sort of demanded to be taken over by federal jurisdiction because it was so bad. I think this ought to happen in Puerto Rico where things are so terribly in times of people getting diagnosed, getting tested, getting treatment to people and not being able to spend their moneys adequately to take care of the people. The federal government ought to step in and do something about that problem, with people dying like they are. Same thing in the African-American community.

I think a domestic PEPFAR would be the ideal thing to do. I think we need, as recommended by the clergy that just met, I think you might have been in the room while Debbie was talking. We need a plan. We don't have a plan. And if we don't get that plan, this administration is under I think great scrutiny and criticism because of the lack of a plan. And so, I feel very strongly that the message should be taken back to the Domestic Policy Council and certainly to the president that that is a great feeling out here and great sensitivity about this issue.

MR. GILMARTIN: Barbara?

MS. WISE: I speak to young people. I've been speaking to them about the last four years. And I've met several – I'm HIV positive – and I've met several young people who are HIV positive and have kept in contact with many. And as I'm watching them grow and I'm so excited how healthy they've been and how people have worked so hard to help them be that way. But it is – I'm watching them hit the college age, 18, and starting to hit college. And what do they do? You know, how do they get health insurance? And they're already trying to navigate how do they discuss this as they go into college to their roommates in the dorms.

And you know, I mean there's a lot of issues already and I just want to give them support. And if we've already worked so hard to help them stay healthy, can we figure out a way just to help continue that for them and navigate this piece? I think that would really be something that we could do. Thanks.

MR. GILMARTIN: Thank you, Barbara. Reverend Lusk?

REV. LUSK: I don't want to take the discussion away from the young people because it's very important. What you've said is extremely important. But I want to just piggyback on what Beny had to say and also what Ed had to say regarding the African-American community with the numbers the way they are. I mean, I don't know at this point in the administration what can happen, but I think it would be important to our country and also important to the legacy of our president.

The group that met in New York – significantly to start somewhere would be just meeting with the group. I mean, just his presence, you've got the bully pulpit. And we use it every Sunday morning, we reverend doctors do, to get things across and to bring attention on things that are important. And some type of visit, some type of gathering, some type of rally of some sort would be a beginning.

MR. SCHMID: I'd like to echo and support everyone's call for a national AIDS strategy and a heightened awareness and response to the domestic epidemic. But in addition, the president and the administration can do something now. You know, it would be nice if we – if he would announce a strategy, but absent that, you know, we do have the power of the budget. And he could propose annually, and he still has to deal with this year's labor HHS bill and I know you're working on next year's as well.

So I would just make a pitch for the CDC. You know, we have, they're the center that's dealing with prevention activities. And their budget has not gotten that much of an increase, though they did get an increase this past year, the HIV component. But it's just, you know, we need more money for those problems because the need is so there, is so great. Especially, you know, when we hear that the incidence rate may be higher than what we currently have.

And then the same – you know, we've been talking in the last couple of days about testing, increased testing, which is something that we have to do since there's so many people undiagnosed. But then, once they find out that they're positive, we need to make sure that there's care and treatment for them. And, yes, some of them will have private insurance. Others will have Medicaid, Medicare. But then, you know, many will fall to the Ryan White CARE Act. So just a pitch that we need increases there as well, with people living longer, you know, they're going to need the care and treatment. And I congratulate the administration for proposing some increases and let's hope that they come to fruition this year and for next year as well.

MR. GILMARTIN: Thank you.

MS. FLUCAS: Good morning to you. I would like to see more of the help with Ms. Barbara. We see a lot of issues going on with our young people. If we don't help talk about the language, about the condom use, and about the body parts – because I looked at a textbook that my 13 year old has and not a lot of information about HIV and AIDS are put into the textbooks. You see limited information about it. But if we're going to try to talk to them about abstaining from sex, we have to first get them comfortable with their bodies.

Because by the time we get to 18, we don't want to talk about sex – oh, shh, behind us. But I think that is a very important issue that we have to first get them introduced to the language to talk about sex and HIV and AIDS in order to stop the spread. Because becoming infected at 19, there were issues that went along from my teenage years that would have probably changed some of the behaviors if I would have got the information at an early age.

MR. MARTIN: Excuse me, thank you for joining us today. It's great that we have the opportunity to talk to you. And I think throughout the government, the federal government, there are a lot of really good things going on with what the CDC and the NIH have done for a lot of years. The concern though is that – we all feel it and it relates to what Beny's talking about, that need for more leadership.

And with the administration having about a year to go, we all have the concern that there may not be the urgency. But in fact – and it's kind of a mystery to me. It would seem to me that within this year, there's an opportunity to set a stronger path. We have an epidemic and some minority communities, especially the African Americans,

that's gotten out of control. And it's clear that that's happened and that with the power of the federal government, we'd like to see a much stronger response to that.

And maybe on your Domestic Policy Council having, bringing in some more people that have a lot of experience addressing these types of issues to help rally the various parts of the government to more effectively deal with these programs, whether it's to start to build a national plan or to better leverage that the CDC is doing to make testing more universal and part of routine medical care.

But what we'd like to really see, all of us, is a considerable effort in bringing out the leadership of this and the coordination of those activities. Thank you.

DR. MALEBRANCHE: Thank you, Anna, for coming. I'm going to be stepping out on a limb here, and I don't think this has been mentioned already. But we need a national plan. (Laughter, chuckles.)

MS. MITCHELL: I've got that one down.

DR. MALEBRANCHE: Did you get that one? Okay, good. I just wanted to say that, you know, to kind of – (chuckles) – to kind of echo that. I can't beat that drum enough and I think – you know, PEPFAR is just an amazing template and it's just strange that we have done such wonderful things internationally and we still have kind of sub-pockets

And just listening to Ted talking today about issues of sexual concurrency and those kind of issues, those issues are documented as being part of what's driving the epidemic among African Americans today in the United States. And there's some literature supporting that. So I think some of the dynamics internationally do translate into what's going on over here.

In addition, while we're focusing on a national plan, I think – you know, a lot of our discussion for the past few PACHA meetings have been on HIV testing, HIV testing, HIV testing, HIV testing. And I want to remind the president and everybody that's in the White House that's dealing with these issues, that we've had adequate testing for syphilis and gonorrhea for years. And we've had, we've been able to eradicate or treat, completely knock out syphilis or gonorrhea in an individual who comes up positive for it. But yet, epidemics still keep coming up.

And in my experience, I'm a clinician who deals with HIV and internal medicine. I also do a lot of speaking with churches, teenagers, college students. The one thing that I've noticed is a generational divide. And I do notice that there's a lot of misinformation. I think when we look at pockets – and Reverend Lusk mentioned this – about focusing on the youth. And I think the youth, it doesn't always hit home with them.

So while we've been beating this drum about education, another generation has come up. And because they don't see people around them being impacted with HIV or

living and getting sick or dying from HIV, we need to keep up a sustained educational plan as well that traverses all economic strata as well as racial and ethnic groups in the United States. That has to be part of the plan because if we just keep testing, it is kind of similar to just telling me to just not have sex because they don't the education on why or how. With this stuff, they just kind of are told certain things.

The same things need to be done with seniors. And so, we're looking at sub-pockets of the epidemic. No one wants to talk about the senior community. At Grady Hospital in Atlanta, Georgia, we diagnose someone with HIV who's over 60 at least once every month that I hear of. And so something is missing in the translation. And it's not necessarily just that these people aren't getting tested, but I think, while we're focused on testing and treatment, those are great things, but the other component has to be sustained education and prevention if we ought to follow a national plan. So I just want to kind of put that out there as well.

ROBERT KABEL: I would like to just accentuate what some of what David said ad John that actually as – and Carl's discussion of the appropriations process as the president, the White House, develops the last budget to be delivered to Congress sometime in January, you might really – and falling back on the information that we've had – that there's insufficient funding for testing. That a lot of hospitals and other places are ready for testing, but there just isn't sufficient funding for it.

And the other aspect of AIDS in America is that the educational funding has really subsided and it's taken a back seat to treatment, which is important. But the president could make a great statement in his budget and then build the campaign around it in his final year, for testing and education around domestic HIV and AIDS.

MS. WISE: Yeah, I think also that education piece is very important. And I've been really looking at that closely in terms what education is being offered to counselors who counsel people for testing or when they get their test results. And I think we do need to develop a deeper base. We have a lot of protocols and steps set for, you know, people who are doing risk reduction. There's been a lot of research, a lot of resources invested in those approaches. And I think we could also invest a little bit and look at some resources and actual protocols and steps on more than just saying no.

You know, if people want to do A or B, what are some other skills that we can really develop for a person who is choosing those options. And to start educating young people because there's 53 percent of the young people that are waiting to have sex. And so, how do we keep those young people safe and get them education before they get this.

REV. LUSK: I would just like to just add. I guess I'm pretty much saying the same thing everyone is saying. Other than, this is not only the right thing to do in terms of putting emphasis on what's going on in the minority community, but it's also a tremendous opportunity.

And I've been fortunate enough and blessed enough to have had some personal involvement with our president. You know, he's visited my church two, three times. I've met with him, had private conversation with him. And you know, I don't think what I know about the man – I know he cares. I mean, I'm not under any illusion about that. He's a caring person.

And I personally would like for other people in my community to know him the way I know him. And I think that this issue presents an opportunity for him, not only to do the right thing, but also to add to whatever legacy that will remain for him.

MR. GILMARTIN: Just, you know, most of my experiences have been in African and sort of the international arena. But one of the things that one does not hear much about in the U.S., and it may be because I had as much involvement. But the idea of public-private partnerships in addressing AIDS in other parts of the world has been a very important element. And that's included from school (?) companies; that's included faith-based organizations, non-governmental organization.

And the theme that we always were using was the fact that no one in an institution on its own can deal with this issue, that it really does require a partnership. And just listening to the presentations this morning, such as in the suggestions that you made, Reverend Lusk, is whether or not there is a new opportunity here for partnerships that perhaps was not available before.

And so, picking up on some of those themes may be, you know, a way forward here and address these issues in a way that's different than we've done it before. Because there's a lot of emphasis on what the government should do. And that's an important role, and the funding is an important role, but, how to engage communities along with the government as well. And I think we've seen a good presentation, demonstration of that this morning. So there may be a big opportunity here that wasn't available before.

DR. PRIMM: Yes, let me, a good example of what you're just talking about is what happened at that clergy conclave. Pharma was there; Abbott was there, Pfizer was there and great, great, support. I mean, and I've been asked by other people, why weren't we notified? They would have been there. So the twinning and the tripling and the quadrupling, and all that kind of thing, is happening out there.

But what we're talking about also here is that if the president said that, if the president talked to – had a talked to the people like Herb is talking about, it makes a great deal of difference from that bully pulpit. His presence or his recognition, for example, of Mutombo, for his good work, what he did in Africa, was an incredible kind of thing for the African-American community. It would be for an announcement of a plan now to focus on that issue, an announcement of certainly – you could call it PEPFAR if you wanted to, whatever you want to call it, but we've got to do something about this issue in these communities that are suffering in our country that are not seem to have the attention.

And I know he cares. And I know you care at the White House. And you know, this is a two-way street, too. I mean, we've been talking to you and everybody's said something. I want to hear something from you – (laughter) – quite frankly, if you could, if you would.

MR. GILMARTIN: Well in fairness to Anna, she's here to listen and so on. Looks like you're raring to go –

MS. MITCHELL: Well, you guys have given me many important and insightful points to take back. I appreciate your passion, your work on this issues, and you're absolutely right; the president cares deeply about HIV issues and AIDS issues both at home and abroad. And I think he has a consistent record on that. And it's great to work for somebody who cares as much as he does because that trickles down from the top. And I have to commend my colleagues over here HHS because they are also busy at work on these issues.

And I know a question I often get when I meet with groups is, you know, what's going on with offices, a national AIDS policy. Why is there no director? No one is paying attention to these issues. And that couldn't be further from the truth in the sense that you have dedicated individuals working on these issues every day on behalf of the administration, on behalf of Americans in both our domestic efforts, but also our international efforts.

And while we continue to search for a director to head up that office, in the meantime those responsibilities are carried out within the Domestic Policy Council, myself and other colleagues I have there as well as colleagues over here at HHS. So I know we're very busy. And I think you've heard from speakers over the past day and had some discussions about what some of the issues are. I know Igor talked about the (waiver?) rule we're working and hope to get that published soon for comment.

And I know that Ambassador Dybul is, I think, next on your docket. And he's going to talk about PEPFAR reauthorization. But you guys raised excellent point about our efforts here, domestically and – Carl's right that the timing is pretty much on point here as we start to think about what we're going to tee up in the next budget request that we send to the Hill. So I just want to reassure everyone, that's one of the reasons I wanted to come to you, is to show that there is a person over at EEOB working on these issues. There are quite a few people over there that spend a lot of time thinking about this and reaching out. And like I said before, I hope that this can be the beginning of a conversation. And we can look at some of the ideas that you've put worth and how we can put them into practice or, you know, use them as a starting point.

MR. GILMARTIN: Okay, very good. Thank you very much. (Applause.)

DR. GREEN: Ambassador Dybul is not here. I want to pick up on a comment – And I've been eager to go; I want to clarify that. I bet she's eager to get engaged in the conversation. (Laughter.)

MS. MITCHELL: And one thing that I would add, too, is that the feedback and perspectives and expertise and personal perspectives that each of you lend to this issue are so critical. And when we talk about kind of a comprehensive effort, there are a lot of different pieces that go to that. There's a role for the government; there's a role for the private sector; there's a role for NGOs and faith-based. And all of these pieces working together is really how you tackle as big as and as complicated sometimes as HIV/AIDS.

DR. GREEN: I would like to pick up on a comment that Barbara made, which is that 53 percent – I think the figure is 53 percent of high school American teens have not become sexually active yet. It wasn't that way 20 years ago; it was something like 45 percent. It has crept up. And I mention this because two of the rallying cries for people working in AIDS for a long time has been, we're all at risk and teenagers are going to be sexually active; we've got to face it and make sure that they have condoms.

And I want to state for the record, especially since this is my last meeting, that if we go by the best survey evidence from Africa, that a majority of African teenagers who are unmarried are not yet sexually active. Actually, the measure we – well, the measure we have is, have you had sex, sexual intercourse in the past year. In every country in Africa, a majority of African teenagers have not been sexually active in the past year. And it's – like America, like the United States, it's moved up because of fear of AIDS probably. It ranges from a simple majority in countries like South Africa to 85, 90 percent or higher in some very conservative countries in Africa. So I mention this because our approach has mostly been risk reduction. This administration has added risk elimination and I second what Barbara was suggesting, which is that in addition to just the abstinence or the abstinence message, we need to find programs that help empower teenage – especially girls to resist peer pressure and boyfriend pressures to become sexually active when they don't want to be.

We have actually some good programs developed by UNICEF, developed by African NGOs of life skills and empowering and focusing on future goals and ambitions. So I just wanted to say for one last time that we need to look at both types of target audiences: those at risk – and anybody having sexual intercourse with more than one partner is at risk — and those not currently at risk. We need to find ways to help them remain not at risk.

MR. GILMARTIN: Okay. We have a little more time if anyone has another thought. I think we've hit the major themes and – (applause).

MS. MITCHELL: Thank you very much.

DR. MAXWELL: I just wanted to make a comment. Ted, and something that you said, certainly we know without a doubt that concurrent partners is a major risk. I certainly don't want us to lose focus of, even if it's your first time, if you're with an infected person, that still puts you at risk. Many people may practice what we call serial

monogamy, which is not protective, too. So, you know, I don't want us to lose sight of that –

DR. GREEN: I totally agree. There's two types of risky, multi-partner sex. And having, changing partners often, even if it's monogamy, it's serial monogamy and that could be risky, too.

DR. MAXWELL: It's so amazing how young people think they're doing such a good thing and that they're following all of the rules. And they'll tell you, I'm just with one person. But just with one person for two weeks? For six months? For nine months? I mean, they just think they're doing the greatest thing that they're monogamous.

MR. GILMARTIN: So we are pleased now to have our next speaker with us on our agenda, Mark Dybul, the ambassador, as you know. Particularly this group knows, serves as the United States Global AIDS Coordinator, leads the implementation of President Bush's emergency plan for AIDS relief.

From March to August of 2006, just to give you a bit more background, he served as acting U.S. Global AIDS Coordinator. And prior to that, he held the position of deputy U.S. Global AIDS Coordinator and assistant U.S. Global AIDS Coordinator. So moving up, you've been moving up in the world. (Laughter.)

But before that, he served on the planning taskforce for the emergency plan. So you were an architect and then you had a chance to become engaged and implement it as well, and was a lead for HHS for President Bush's International Prevention of Mother and Child HIV Initiative. So Mr. Ambassador, thank you for joining us.

AMBASSADOR MARK R. DYBUL: Thanks, Ray. (Off mike) – and that partnership. We have really moved past. And this is part of the president's overall development agenda. We have moved past donors and recipients to true partnership, which the only way that we're going to succeed. And it's actually the only rational approach. There has been almost this notion and still does exist, I'm afraid, of, oh, we're over there to help these poor people.

That is not what the president's development agenda is about. That is not what the American people are about. It really is a partnership of supporting people on the ground. And that's also the only way it's going to work, in terms of transformation. It's really a change in how we've approached the world and I think a fundamental piece of why PEPFAR has succeeded.

You're all aware of the dollar amounts and how significantly they've increased. President Bush called for a $15 billion commitment; we'll actually exceed that depending on how the '08 budget comes out, somewhere between $18 and $19 billion over five years. That's the largest international health commitment in history dedicated to a single disease. It is currently the largest global health program in the world. So it gives you a sense of the scale and the rapid scale-up.

I do think it's important for us to note, also, that we've increased at a pace that others aren't following. Right now, we're providing about as much as the rest of the world combined. And I think we need to recognize that, going forward, we cannot succeed in this global epidemic unless more people respond. Also, importantly, this slide shows that we have a bilateral and multi-lateral component. The Global Fund is a key part of how we operate. And in fact, we provide about 30 percent of the resources for the Global Fund. Some people say we should give more or less. I think the important thing about this slide is that it shows our percent, relative to bilateral, is not remarkably different than most of the rest of the world. The reason we look so different is because we have so much money that is going towards the bilateral program.

There's a misconception about PEPFAR which I don't think most people in this room have and that is that it's only 15 countries. It's not. It's 120 countries. And you can see in blue where PEPFAR is active. But we have 15 focus countries shown in red, 12 in sub-Saharan Africa, Guyana, Haiti, and Vietnam. And I think it's important to note, still these 15 countries have half of the disease in the world. So we are in an area where we have half of the resources in the world and we're also focused on where half of the disease is located.

One of the most important things about PEPFAR and the president's vision for this and for all of development is that it's not just about money. For too long in development, all we talked about was money and what money we were contributing to disease. The president said, we're going to commit a lot of money, but we're going to get results. And those results were, as you know, the two-seven-and-ten goals, to support treatment for two million, to support prevention for seven million, and to support care and treatment for 10 million, including orphans and vulnerable children.

I did want to point out that – well, I'll talk about that in a second actually. I think what I'd like to begin with is prevention. You know, there have been some pendulum swings lately about, oh, we should just be doing prevention or we need to move more from treatment. We need to be very careful about prevention swings. The president got it right and the Congress got it right. You need to combine prevention, treatment, and care. You can't have an effective prevention program if you don't have care and treatment. And you can't have an effective treatment program and reduce the need for treatment if you don't have effective prevention.

So the president got it right and Congress got it right when they did this approach. We're going to go through some results very rapidly so you can see them. But I want to begin by saying, the reason that we have so many results is because of the pace at which we've moved money. Over the first three years of PEPFAR, we are 94 percent obligated and 67 percent outlayed, or what would typically be called expended. I challenge any governmental or non-governmental, particularly start-up, to get anywhere in that ballpark. People are generally happy with 30 percent obligation and three percent expenditure in the first three years of an initiative. So that's why we've seen such rapid pace, because the money is moving so quickly.

In terms of prevention, prevention has always been the bedrock of the PEPFAR program. We cannot keep pace and treat ourselves out of this disease; prevention is key. There are still as many new infections in the world as there were 10 years ago, just as there are just as many new infections in the United States as there were 10 years ago. But we have had great success. And that success is based in a very comprehensive approach. This pie chart shows how our resources are distributed: about 46 percent, 47 percent go for treatment; about 29 percent go for prevention, if you include counseling and testing – and it's a nicely distributed set of resources. Counseling and testing is about 7.8 percent, PMTCT around 7 percent. Sexual transmission is about 12 percent, of which 7 percent is for A and B and the 5.2 percent for C.

I think everyone should be aware that the United States, since PEPFAR has begun, the United States government has provided 1.67 billion condoms. As Peter Piot has said, that's more than all other countries combined. The important thing is, it's done in the context of a rational approach, which includes A and B now, which it didn't used to, because in generalized epidemics, which is where we're working, you need A, B, and C. And the day – I came to this as a treatment specialist, not a prevention specialist.

But as you look at the data, they are just overwhelming. Every place that's been looked at: Kenya, Zambia, South Africa, Ethiopia, Botswana, Namibia, Uganda, importantly. Everywhere where we've seen stabilizations and declines, it's been based fundamentally in A and B, also C, but if you look at the data, it's actually a little bit more for the A and B components. So we need to stick with what works.

And we need to do that in reauthorization. In terms of sexual transmission, well, we went over the data. In addition to the condoms, we've supplied A, B, C prevention messages to around 61 million people. Now, we need to step it up a bit and we can talk in the question and answer about some of the innovative stuff we're going to be doing around prevention as we move forward.

I just wanted to show you some of the data. Most of you are familiar with this in terms of the impact of A and B – A, B, and C. These data are from Kenya, where they saw 30 percent reduction in HIV over a five-year period, 30 percent reduction. You can see that the bulk of that change, in terms of behavior change, was, A, people who reduced or delayed their sexual debut. Multiple partnerships went down dramatically, a 50 percent reduction, particularly among men. And at the same time, we saw some increase in condom use, although not a lot. The reason for that isn't that condoms don't work; the reason for that is that for too long, all we did was condoms. So we kind of already hit our peak. What we're trying to do now is have a more balanced approach. And that's having a significant impact on the prevalence rates.

If you look in Zimbabwe, an article published in Science magazine, we saw the exact same thing. And to be honest, this is not the result the authors thought they would have. And they'll tell you outright. But now that they've seen that, they are some of the biggest promoters of A, B, and C. It's from London, actually, where these data were

done and published. And it was clear that reduction in partners and delay in sexual debut are the greatest, some of the most important indicators. I was just with Allan Rosenfield up in New York; I think most people know where Allan comes down on a lot of issues. He told me, they just did a meta-analysis and it's clear to them that delay of sexual debut is one of the most important things in terms of reductions in prevalence where we've seen successes. So I think people are starting to understand the need for all of these approaches. But we need to stick with them as we move forward.

There are some areas we need to step up, such as prevention for positives. This is something we're doing in the United States. We have to be careful about how we say this because there's no intention and we cannot stigmatize. But only an HIV positive person is capable of transmitting the virus to someone who's negative. And so, we've got to get people into care and treatment who are HIV positive to teach them effective approaches to avoid HIV/AIDS. And we're really stepping up our activities there. I think it's important to note, however, that where we're seeing a lot of HIV transmission, in terms of positive people, are in discordant couples, couples where one is positive and one is negative. And that's a very different population. While we have had great success in increasing condom use among casual partnerships in Africa and here, we do not have much success among regular partnerships because it's viewed as a lack of trust. That's true in the United States and it's true in Africa. I may even have some data on that depending on where we go.

We're also dealing with cross-generational sex, a very important problem in virtually every country in sub-Saharan Africa, where older men are preying on younger girls. And you can see how many more young girls are infected compared to boys. And that's largely, we believe, largely because of trans-generational sex. Now, importantly, one of the things we've trying to do, and I think this is something that we need to understand as we're talking about this and one of the reasons people are harping on prevention these days is, you know, we can show treatment results pretty rapidly because you can show numbers. And you can do it almost on a monthly basis. What we're talking about in prevention is changing human behavior. And it's very difficult to change a 25-year-old's behavior; it's much easier to get to people while they're young.

And so, a lot of our prevention activities are generational, cultural change. And you can't see those changes in a year, but you can predict that they'll be successful based on the existing data. And part of that generational change is going to be how boys and girls interact and how men and women interact. And one of the things about ABC programs is we're getting in early and teaching boys to respect girls, and teaching boys and girls to respect themselves so that they'll delay their sexual activity.

And that, actually – we're starting to see tremendous changes on an anecdotal basis; it's going to take awhile to – in how boys treat girls. And we also have a lot of programs targeting this approach, targeting changing how boys and girls interact, which will reduce sexual activity. We've got right now, in our last year, about 830 interventions which somehow relate to gender issues, at a total of $442 million. We can skip that one for now.

This is about multiple concurrent partnerships. There are two types of partnerships we deal with, as I mentioned. One is casual partnerships – and we're seeing remarkable reductions in frequency of casual partnerships, particularly among young men. However, there is another problem in sub-Saharan Africa and that is a cultural issue about multiple concurrent partnerships, where it's normal for a man to have multiple partners, not necessarily wives, but multiple partners, particularly when they live in different areas. And I'm not going to get into this. But it just shows these networks of interaction between regular partnerships. And that's one of the things that's going to be most difficult to change because it's a much deeper part of the culture than casual partnerships, but something we're going to need to tackle because, as I mentioned, discordant couples, where one is positive and one is negative, is becoming one of the most pronounced issues.

I also want to mention, because this is misunderstood, in many cases, in several countries, there are more women positive than men in multiple concurrent partnerships or in discordant partnerships. It's not always the man who's positive and the woman who is negative. This is a very important slide to us because after 20 years of social marketing, you see absolutely no change in condom use in regular partnerships. And again, that's similar here than it would be in Africa.

I think, I just saw something in Ghana, which really brought this home to me. I visited a great program where we support women in prostitution. They are almost all using condoms now; they have 90 percent condom use. But then they showed me some data showing they have 90 percent condom use, but they say, I have a 20 percent prevalence rate. And that didn't make sense to me. If 90 percent of them are using condoms all the time, why are 20 percent infected. And what they told me is, the women in prostitution will use condoms when they're with their clients, but they will not use them when they are with their regular partners. And that's the scope of the problem we're up against.

So we have a lot of programs now trying to identify discordant couple and then try to get them to use condoms in those regular partnerships and also be faithful; we don't want them going around spreading it to others. But it's going to be really hard. And the best success we've had so far is in Rwanda, going from 13 percent to 15 percent use. But that's not enough. So we've got to think intelligently. And we're actually thinking about male circumcision and some other approaches with these folks.

PMTCT is a very important issue to us and a very important part of where we are. President Bush had a mother and child initiative before he had the broader picture, and it's something we're very focused on because it's something we can avoid. So far, we have reached six million women through PMTCT programs and have probably averted around 100,000 infections. I think it's important to look at these data that show the scope of coverage in the focus countries.

There are still countries that have a long way to go. But I think it's important that five of the fifteen focus countries have actually already achieved the objective of the mother and child initiative, which is 50 percent coverage of PMTCT over a five-year period. So we're already there is five countries, but we need to go a lot further. Botswana is a great success story. They had, as you can see, very little coverage, well, relatively good coverage, but it almost doubled over the course of the last three years. And they did it because they changed their policies. They went to opt-out testing and they went to use of rapid tests. And because of that, and simply because of that, they were able to double their access. South Africa will never get over 50 percent if they don't change their policies. And so, going forward, we need to work with policy change; it's not a matter of just programs; it's policy change.

I wanted to show this because safe blood is a part of what we do, too. We've gone from 37 percent clean units to 53 percent clean units in the focus countries, which I think is a great advance. Some countries actually now have fully clean blood supplies because of PEPFAR.

I want to shift to treatment a bit and I'm not going to spend a lot of time there because most people here about the treatment successes. You know that, through March of last year, we were supporting 1.1 million people in treatment in sub-Saharan and one million in sub-Saharan Africa. When President Bush announced PEPFAR, 50,000 people in all of the sub-Saharan Africa were receiving treatment. That's the type of scope and scale we are seeing. And again, this isn't because of Americans; this is because of people in the country doing the work.

Here is the trajectory. This is a trajectory we're seeing across all of the countries, but also in each country. And importantly, it's not just about numbers and treatment; it's about life years saved. So far we have supported the saving of 3.5 million life years. Now, why is that important? Because people are staying alive to take care of their kids so they don't become orphans, they are staying alive to contribute to the economy, they are staying alive to become peacekeepers. It's not just about getting people into treatment; it's about transforming the society because of the treatment and, importantly, creating hope. And I think that is probably the greatest thing about PEPFAR, is it's created a hope that cannot be overcome.

Here is the numbers that I think are most start: a 1200-fold increase in treatment over three years – rather extraordinary. And this just shows graphically how that is accomplished. Three years ago – basically dark green is good; light is bad. Three years ago this was the percent coverage in the focus countries. This is where we were last year. And so rapid movement to national coverage.

I think an important part of why we have succeeded is the rapid use of generic products through the FDA process. So far the FDA process has approved 51 generic products for use in the focus countries, first time in history that we're doing this as a government, rather extraordinary. The first approval for the three-in-one combination for pediatrics, which will be essential as we scale up our pediatric programs, is through this

FDA process. Importantly, for those of you on domestic issues, there are three generics now available in the United States because of this process. Hugely successful program, and it's one of the reasons we've been able to scale up our products. But at the same time, we are ensuring that we wouldn't give a product to an African family we wouldn't give to our own family.

In terms of care, I am afraid most people are forgetting about care and we cannot. The orphan situation in Africa is one of the most tragic. Our goal, again, is to support care for 10 million people including 2 million – including orphans and vulnerable children. We have scaled up in care similar to treatment – 4.5 million. This is actually – it's about a six-month lag from the treatment results. So we're certainly much higher. And we have actually supported care for 2 million orphans and vulnerable children.

An important part of what is going on in PEPFAR is more than those numbers; it's what's happening beneath those numbers. And it's mainly about building the capacity of local organizations. Eighty-three of our partners – 83 percent of our partners are local institutions, are local organizations. That is critical because we're talking about transforming societies, and we can't do that from U.S.-based organizations; we have to build the capacity and build the local environment. We have supported 25,000 care and deliver sites in the first three years. That is expansion of the sites. And I think it's essential to understand that much of what we're doing is building systems.

There is a lot of criticism saying we don't build systems because we focus on prevention care and treatment numbers, but it's just not true. There is an evaluation of our treatment sites. As you can see, the U.S. government was providing 92 percent of all of the capacity-building work that was going on in those treatment sites – 92 percent.

And as you can see, we're actually doing more in the public sector than in the private sector. We may not directly fund the private sector because of governmental flows of money, but we support private institutions to support the capacity building of local institutions.

One of the hot topics these days is are we drawing from the other health systems so that we can do HIV/AIDS activities. And the data right now are a resounding no. A lot of people are talking in terms of opinion but all of the data right now point to the fact that what we're doing is building health systems, not just for HIV/AIDS.

A study was conducted in Rwanda to ask the question: With a massive infusion of AIDS resources, what happened to the rest of the health system? So they looked at 22 non-HIV/AIDS indicators, health indicators to see what happened to them. Seventeen of them went up in a statistically significant way. All right, 17 of them went up and nine in a statistically significant way. Family planning went up in a statistically significant way. Anti-natal care went up in a statistically significant way. Use of laboratories went up in a statistically significant way.

If you look at hospitalizations, this is actually an old number. There was a 30-percent reduction in hospitalizations for general health. As many of you know, 50 percent of hospitalizations in many countries are for HIV/AIDS patients. If you care and treat them, you don't have to put them in the hospital anymore. We saw the same thing in this country. If you reduce hospitalizations by 30 percent, you just enhanced the capacity of the health system by 30 percent because nurses and doctors and physical space and laboratory space is now freed up for other types of health care. So we are absolutely expanding health systems.

And if you look at a couple of pictures, it tells you why. On the left, you see what a laboratory used to look like, on the right a renovated lab. You couldn't do anything in the lab on the left, but on the right, you can now do a lot of things. And while you might have an AIDS clinic twice a week, you now have a laboratory for your health clinics the rest of the week. And so they are – we're seeing an increase in use of laboratories for non-HIV/AIDS indicators.

A waiting room on the left, renovated on the right. Now, who wants to sit in the waiting room on the left? No one. So people don't come to clinic and don't feel comfortable coming to clinic. Now they have a welcoming environment. This is a clinic we didn't renovate; we built completely. We just opened it in Tanzania, Secretary Leavitt did. Beautiful clinic that is building capacity in Tanzania. What I like about it is there is a nurse in there and we are also paying the nurse's salary.

Bill Gates reflected this when he wrote an op-ed recently in Newsweek basically talking about the important work of PEPFAR in building capacity and supporting what is going on in the communities. We're also building supply chains and services that just didn't exist before. If you build a supply chain for AIDS drugs, you can send TB drugs out, and that is precisely what we're doing, 120 different products and commodities. We are building warehouses. We're creating a capacity that never existed before.

Now, as we look forward to where we are going to go, we also need to think about how we do things, and we need to think about our indicators because our indicators drive – a lot gets derived from our indicators, and we're taking a new look at our indicators. We have to have output indicators, which is how many people in treatment, how many infections did you divert, how many people in care.

But we're looking at a new approach to indicators that move from assessment and planning to impacts. So ultimately, as in this country, we want to know if treatment reduced morbidity and mortality. We want to know if treatment increased the economy because people were able to work and productivity went up. In behavior change, we want to know if boys are treating girls differently, not just the number of infections averted. We want to know if people are reducing their partners and changing their behaviors. And so we're going to have a new generation of indicators that will be available in January. Not surprisingly prevention is the most difficult for this, but we have every technical working group working with stakeholders to develop a next generation of indicators.

So that is where we have been. I think where we're going is the next phase of PEPFAR. And as you all know, President Bush called for a doubling of the original commitment to $30 billion. So already going from what was the largest international health initiative in history to doubling of that. Importantly, he called for new goals. We should never commit dollars without goals, and the goals are to support treatment for 2.5 million people, so going from two to two and a half to support prevention of 12 million infections, so going from seven to 12 and supporting care for 12 million, including 5 million orphans and vulnerable children. We have a very specific orphan goal this time.

You can see there is a bit of a shift towards prevention. We're almost doubling the prevention goals, versus a 20 or 25 percent increase in care and treatment. That makes sense. We needed grasp massively expand care and treatment so that you could do more in prevention. People won't get tested if there is not treatment. We know that from this country. You can't identify HIV-positive people if you don't do testing, and no one is going to get tested if they don't do treatment, which means you can't do effective prevention.

If in discordant couples, if there is no treatment available, a woman has absolutely no chance of getting a man tested. So it all fits together in a very progressive 10-year look, and the president, again, is leading the world in a rather extraordinary way. If we get that $30 billion, the American commitment to global AIDS for a 10-year period will be around $50 billion.

We are also looking at things in a different way to some degree. We are certainly going to continue our services. We are not going to back away from supporting prevention, care, and treatment in the countries where we have done the work. But going forward, we're not – with new money, we're not talking about focus countries as much anymore.

What the president said is we're going to develop partnership compacts, which means we're going to go work with countries that want to tackle their own epidemic. And what that functionally means is if we can save two lives with one tax dollar or one life with one tax dollar, we think we ought to go where we can save two lives with on tax dollar. And that means the countries will do things to fight their own epidemic, including resource commitment. Now, in Mozambique, they are not going to be able to commit a lot; in South Africa they will; in India they should be able to as well.

So we need to talk with the countries about their resource commitment to match our resource commitment. And not – not match, but contribute. And not necessarily just for AIDS; we also want them to be increasing their health system, so we need to work with them in the countries.

But we also need them to have a policies and practices that will save more lives, such as workforce policies that allow task shifting so that we can get to more people with prevention, care, and treatment services, such as rights for orphans so that they are

protected legally, such as gender equality, rules, regulations, and approaches, so that men aren't misusing women, such as having opt-out testing because we can save many more lives through PMTCT if we put a dollar where we have opt-out testing than where we don't.

But it's going to be different in every country. This isn't an MCC-type partnership compact; it's more working together in partnership, expanding our partnership with the countries as we move.

I want to end with this group by just saying what the American people have done through President Bush's leadership and strong bipartisan support is nothing short of a miracle. It is without a doubt one of the most significant humanitarian efforts in history. It is building hope where there was none. It is transforming individuals, communities, nations; in the case of Africa, this transforming a subcontinent. For those of you who have been there in six-month intervals, the change is extraordinary. There is a sense of we can tackle our problems.

And we are part of a broader development approach. President Bush has doubled resources for development, quadrupled them for Africa. It includes the Millennium Challenge Corporation, the president's malaria initiative, the women's justice and empowerment initiative, the African education initiative, debt relief, doubling of trade, because ultimately – with Africa because ultimately that is the engine that will fuel development.

So we are part of a much bigger picture that is transforming people's lives. Importantly, people in those countries are also getting a new window into the hearts of Americans. President Kikwete from Tanzania and President Mogae of Botswana were just in Washington last month talking about what the American people are doing in partnership with their countries, in glowing ways and ways you couldn't possibly have envisioned three years ago. And we see this at every level, from presidents, to ministers, to tribal leaders, to individuals in their communities. They have a different sense of what the American people are all about.

Importantly, as President Bush has said, it's also good for the American people. It's very good for the American people and our character, and represents who we are, and Africans and Asians, and the people in the Caribbean are starting to see that; they are starting to see what we stand for and that we stand with them. And that is transforming a lot more than just development.

This work has just begun. This engagement in this noble and humanitarian effort has just begun. It is noble, and it is ennobling for us as Americans, and we look forward to working with you and everyone. And as President Bush has said, we're going to get a bipartisan bill to reauthorize this so we continue in this noble and ennobling work. So thanks very much, and I'm happy to take any questions you have.

(Applause.)

MR. GILMARTIN: (Off mike) – great. Thanks very much, and a great record of accomplishment. Congratulations to your leadership as well. So questions for the ambassador? Yes, Ed.

DR. GREEN: Yes, thanks for a great presentation. This is my last meeting at PACHA after four years, and I had the chance to address the council this morning and talked a lot about prevention and Africa and generalized epidemics, so it's great to have you reinforce what I was saying.

I would like to call attention to two things you said and then – and ask a question. You said – you pointed out that this is the greatest concentration of resources on a single disease ever, and you also pointed out that we're seeing stabilization and probably has declined in some countries in Africa. Of the 14 original PEPFAR countries, according to the data I have seen, we actually are seeing prevalence going down in seven of them, half of the countries.

Most of the people don't know this in the general public and even in the AIDS profession. And in the IOM evaluation of PEPFAR, that wasn't stated; it wasn't mentioned.

My question is, wouldn't you – I mean if prevalence were not going down anywhere and after $15 billion I could see how you wouldn't want to mention it, and I also recognize it's difficult to show that these programs rather than somebody else's programs are the reason, but why wouldn't we want to mention that we're seeing prevalence going down in half of the focus countries?

AMB. DYBUL: Well, we do, quite a bit. It's just a matter of whether or not anyone wants to hear it. And, you know, there was an op-ed recently in The Washington Post recently saying we need to stand up and say prevention has failed and that's where people's heads are at, and it's just not true, and we need to change the message – we say it all the time.

Now, we have to be careful in some of the evaluations because sometimes the drop, we don't know is a real drop; it's at least a stabilization because our ability to collect data has improved dramatically. One of the big problems is we're stuck with prevalence, which is really a look backwards, not a look forward. And as we put more and more people on treatment, prevalence could actually go up. So, we desperately need an incidence marker; we're almost there. We have a validated incidence marker which is being calibrated right now. And I think once we have an incidence mark, we'll be in a much better position to advocate.

But part of the – it's not that we don't say this; it's that people don't want to hear it. And – but I think it's a huge success story, it's a huge success story. Now, the prevalence needs to keep going down, you know, a 30 percent reduction in Kenya still has us at 10 percent prevalent, so we still need to keep going down. But I think we need

to talk about the fact, and we are talking more and more about the fact, of the great success that we're seeing in prevention, at the same time saying we need to do even more.

DR. GREEN: And maybe we should mention for the record that we have kind of a proxy for incidence in looking at prevalence in the youngest cohort, 15 to 19, because that's the group that would be least affected by mortality. And so, when we see that going down, we have a sense that we're really having some impact.

AMB. DYBUL: And we do have mathematical models, so where we see the reduction in prevalence in Kenya, we actually have incidence that looks exactly the same when you do the mathematical models. It'll be much better when we can actually show it through incidence markers and we're going to have them soon. And we've actually been storing samples over the last couple years, we were allowed to, so we can go back and look at that in an effective way.

But it is an issue and I think there's been a lot of progress, you know, in a recent floor debate, every member regardless of which side of the aisle they were on, talked about the importance of abstinence and fidelity. Could you imagine that three years ago? Inconceivable. And that's where we are. We have Chairman Lantos talking in the reauthorization saying, it's going to be important to have an abstinence and fidelity component. And people are talking about prevention, but I think we need to talk about successes and not just throw our hands up in failure. We're kind of repeating what we did in treatment; oh, treatments is impossible, we can't possibly do it. There was a sense of despair. Now, everyone's talking about how great treatment is; we need to do that in prevention.

But we also need to be better at prevention, we need combination prevention. We need to hit kids everywhere they are, we're talking about combination prevention now. We've got lots of great programs, but they're not all in the same place. So, you'll have a great faith-based program in one place or a great school-based program in one place, or a great program that works with sex workers or women in prostitution in another place, but they're not all in the same place. So, we actually have activities to do that so that you get people everywhere they turn, not just one or the other places.

We also need to get in the 21 century; we're still doing stuff we were doing, you know, and methods we were using 20 years ago, so we need to advance ourselves a little bit too. And we've got some great projects that are happening that we hope to announce soon to deal with it. But I couldn't agree with you more.

MS. : Please identify yourself.

DR. YOGEV: Ram Yogev from Chicago. There's no question that it's a miracle. Just because you mentioned the program, one thing which came to my attention just because of one of your people, your technical assistant mentioned, it's only 6 percent of pregnant women that are prone to getting ARV to find out that mother-to-child

transmission program are beautiful and separated and you're right you increase them, but separated from the care. And one – you know, from the experience of the United States, we reduce it if you deal (?) with mother-to-child transmission, the best you can get is 50 percent. If you put in care, you're going to get to 80, 90 plus percent. Are there any constant effort to make sure that mother-to-child transmission will also give care to the women as part of the whole gestalt?

AMB. DYBUL: It's a great question, Ram, and you're absolutely right. We need to move from short course therapy to full course therapy and we actually think we're missing a lot of PMTCT work that's going on because what's happening in most countries is the pregnant women are getting referred to testing – to treatment sites and we're losing them in terms of our data collection in the PMTCT sites. And I've seen clinics where this happening.

We actually have tried to collect data on pregnant women receiving anti-retroviral therapy; the problem is the data systems are capable of doing that right now, but we're building them so we can. There are concentrated efforts, very strong effort, to get us to that point. Botswana is going to be there very soon, and you know, in three years they got from 50 percent to 90 percent. Their national transmission rate is 4 percent, it's approximately what the United States has. And they're working on this, Nigeria is working on this, we're working with every focus country to have practices and policies in the ministry that allow this type of approach. Some people are doing innovative stuff that's even beyond what many people in this country would do, which is to give women regardless of CD4 cell count anti-retroviral therapy for 18 months through the breastfeeding period.

So, there are a lot of efforts. I think we're missing effective programs, but we're not doing enough. The other thing is, we're just – we've got to get policy change towards opt-out testing or we're not going to get anyone into these programs. And we have to have rapid tests used rationally, not the way many people have used them. But you're absolutely right.

DR. PRIMM: Mark, I wanted to ask you a question, I don't know whether you would go this far or not, but I'm going to ask the question. What is your opinion about expanding PEPFAR and making it also a domestic focus because particularly in certain communities and expanding it, certainly, in the Caribbean, which is you know, our really our sandbox, America's sandbox is the Caribbean. And we had a report yesterday about what's going on in the Caribbean and it seems as if certainly the two countries that are there that you're focused on may have shown some improvement but there are other countries there that need the help very badly.

I personally spoke to the president about this in a private meeting and he had indicated to me at that time that he would think about expanding it in the Caribbean. I, now, am talking about expanding it to include a domestic PEPFAR for the African American community and Puerto Rico. It's just incredible to me what's going on there, that it's just as bad as sub-Saharan Africa.

AMB. DYBUL: It's going to be easier for me to address the Caribbean question. I couldn't agree with you more on the Caribbean action and that's why we're not talking about focus countries for the next phase; we're talking about where we can have greatest impact on a dollar for dollar basis. And I personally think that the Caribbean is a place where we can see action in a holistic way across the Caribbean. You know, Guyana and Haiti when we started to have the highest prevalence rate in the Caribbean, we need – we have a pretty robust program in the DR because Haiti and DR are on the same island and it's not good to have one and the other and we're actually doing more and more across the island. I was just in Haiti and saw some of that. But I think we can do more in the Caribbean region, if the Caribbean region wants to step up their fight as well.

You know, the Caribbean has done rather well, although there's still a lot more that can be done. They're one of the regions with stabilizations or declines in infections. We're seeing the same types of behavior change in the Caribbean region at some countries. We've seen come countries expand their care and treatment close to what would be considered universal access, although that's a terrible phrase. But more can certainly be done and we think it can be done in a more regional way.

We actually have a regional program now, particularly for training, and because of the mobility, we think it's an area that's ripe. So, we'd like to work with the Caribbean region in the next phase and actually this year we might do more of this. In 2008, we're looking at doing more of this across the region.

In terms of the United States, I'm going to leave that to the Department of Health. Even though I work for the Department of Health and Human Services, I'm in detail to the Department of State, and in the Department of State we only deal with the global problem of HIV/AIDS, so I'll leave that to Martin, those who work on the domestic side to think about that. Certainly from a legislative standpoint, that would not be, it couldn't be PEPFAR in terms of what needs to be done for the domestic issues, we'd leave that to the committees that deal with – Health and Human Services and other committees that deal with that, and to the department.

DR. PRIMM: I understand that you can't, but what I'm thinking is, the epidemiology that we are saying in the African American community parallels that that we see elsewhere. And wouldn't this call for something of that nature and that hasn't been effective as you have talked about it in miraculous terms today. I mean, that's the kind of thing we need in our community too and that's why I asked you the question, not that you would say, hey, it would work, but a PEPFAR would work I think or something like that.

AMB. DYBUL: The only thing I would add, you know, the president in his State of the Union address two years ago talked about this issue in the State of the Union. I mean, I think you all around this table know what – I mean, I have friends that have worked for 20 years who'd say they would beg for a single line in the State of the Union for 20 years and he talked about this issue in the State of Union. He talked about the

need to increase our efforts in the African American community, particularly to get some testing so people can be provided with services. He talked about some of our vulnerable populations, such as prisons, so there's definitely some focus on this, I'm just not engaged in that.

MR. GILMARTIN: If I could make a comment and I'll ask – having had a chance to see in Botswana, as you know, first hand the kind of progress that's been made. The other thing that came through your talk on partnerships was the fact that, I think that the success is the result of a new models on how to approach HIV/AIDS that could have application here as well as they could have in other parts of the world. So, I know it's not necessarily within your scope, but it would be great to – maybe you want to take this Mike – how do we capture the elements or principals of success that are embedded in those outcomes so that we can transfer that information?

And some of the things that you've found have been sort of goes right against the dogma that people have had all along. Even on testing, for example, on opt-out, which you talked about, you know President Mogae was criticized in the international community, by civil rights groups saying he's violating human rights. Yet, when given the opportunity, people took advantage of it and it had a dramatic impact of the fact that people knew their status, so.

There are a lot controversial areas here that the model might be able to cut through and demonstrate here if you go this direction, here's the benefit and the result of that. So, I'm just making a statement.

AMB. DYBUL: But I think it's actually an important one and Ray of course is being modest because a lot of the success in Botswana is because when he was MERC he got it all going and there are great lessons. And we are actually starting. Kevin Fenton from HHS who oversees, from CDC, who oversees the domestic AIDS program, we've actually begun talking about how we share lessons learned back and forth because we have lessons to learn from them here, there's some lesson that can be learned across as well, and some of them are opt-out testing, some of them are adherent. The Africans actually do a much better job at adherence than we've done.

There's a lot of good opportunities – and that's what we're trying to get through from this partnership; it's not just us going to help these poor people, it's actually – I mean you always, some of you have been over there, some of the most intelligent, creative people you will ever – I mean, you meet a hero a day when you're out there. And that's the kind of thing we need to be learning from.

MR. SCHMID: This actually ties in with what you were just talking about in measuring outcomes and later today we're going to be considering a recommendation for PEPFAR reauthorization, it's going to – we're talking one of the elements discusses the need for monitoring evaluation research. And I'm just wondering, in your opinion, how much should we be spending on that? It's definitely – you mentioned it in your presentation, it's definitely an important component, but how much should we be?

AMB. DYBUL: How much is a tough question. I can tell you what we should not have is a set amount. So, I've heard people propose 10 percent should be spent on monitoring eval; well, that's more than we spend on orphan care. Do we really think that we should be doing more in terms of that than in orphan care? I don't think – I mean, we know how to do this stuff. It's true we need to refine and improve and we need what we're calling public health evaluations. And we were about, I think, 5 percent, 4 percent, or 3 and half percent of our resources for monitoring an evaluation.

We could recognize it wasn't working that well, and so we've actually changed it to public health evaluation to look at broader issues and there's some things we're collecting that no one else can; I mean with 2 million people in treatment and 10 million people in care and these massive prevention programs, we're the only ones who can really look at some of the outcomes and markers and other things. But in terms of the scientific questions, that belongs to NIH. I don't have the staff and do not want the staff to try to create such a program. We should not be doing that. This is one of the dangers going forward with PEPFAR, because of its success, people are trying to get us to do everything and that's actually a bad model. It will destroy our focus and it will make it much harder for us to get the good work done.

And we happen to know how to do good prevention, care, and treatment, but we need to do monitoring and evaluation and these public health evaluations to do anymore. So, I would strongly encourage you to not put in a percent or an amount, but to encourage the work to be done, to make sure that we're doing it. And that's what we're trying to do with these new approaches with public health evaluation. We're bringing in NIH and CDC to help us. We actually have our new director of that in my office is someone who's a CDC economist, a fantastic person who can help us evaluate the costs and the other pieces of care and treatment. His deputy's going to be a part time detail from NIH and then we have an interagency group to work on this, so there's no question we need to do better at it and we're putting the systems in place, but the notion of a directive around this, I think, would be extremely hazardous and it's not our core competency and we ought not be doing it beyond what I think we're trying to; that belongs to other parts of the U.S. government.

MR. SCHMID: Just to clarify, the – what NIH does in this area, is that part of the PEPFAR budget, or is it outside the PEPFAR budget?

AMB. DYBUL: Both, when OMB submits as is mostly – our budget is one of the most complicated things you'll ever see. There are actually about eight different spigots of money that go in to make up the total dollar amount you see for PEPFAR. We actually unfortunately lots one of the spigots last year because the malaria money used to be part f our overall amount. But it's – the amount that comes from the global AIDS program, which is from the HHS budget which is about $140 million and includes child survival and health at around $350 million. It includes some of NIH's money for global vaccine and microbicide and other work.

It includes the global find, it includes a bunch of these small State Department spigots, FSA, CESF, and that includes the biggest peach, which is the global HIV/AIDS account. So, some of the money is technically there but we have completely stayed out of it and we need to stay out of it. Tony Fauci and NIH ought to be managing that money, not us. And so, we leave that to them to manage. And that's the way I think it should be.

And then with the 3.5 percent I told you is just within the programmatic budget to do the programmatic evaluations that need to be done, and that's about, last time I saw the numbers, 3 and a half percent, which I think is about right. That's a lot of money when you're looking at budgets the size we're seeing. We just need to use it better.

The other thing we were seeing is, you know, a lot of our partners were doing evaluations; we never knew about it, that's why we have this new international implementers meeting. And what we saw was everyone was collecting data on the same – the exact same question and we didn't know about it. And they were collecting in a way that you couldn't aggregate it because it was collecting data from data, that's insane. You know, we're duplicating effort, first of all, and therefore not looking at questions we could be looking at, and then you have all these data pieces that you can't put together to answer one coherent question. And that was the point of this new public health evaluation approach, to bring all the pieces together and maybe in a year we'd come back and say, look, we actually need to spend more on it. But that doesn't require an earmark; what it requires is us to rationally look at the program and figure out the best way to do it.

DR. MALEBRANCHE: David Malbranche from Atlanta, Georgia. I appreciate the comments, especially about the complexity of sexual behavior between partners and the condom use, it mirrors – I do some behavioral research here in the States and what people say about how they choose to not use partners – condoms with their single or their serious partners, but then with casual partners are more likely to use condoms so it reflects that tremendously.

I had two questions, there was one slide that you actually had up that you went over briefly that I think had CD4 counts and outcomes and I want to know if you could tell us about that. And the second question was, I was wondering if you could speak a little bit more about some of the programs that you've seen in the countries that work on the issues of masculine socialization or masculine empowerment for young men? I mean, you read a lot and you see in the literature a lot about indicators of what it means to be a man, and sometimes in this country as well as other countries, you know, sometimes getting an STD is considered a right of passage for being a man.

Can you talk about some of those things because sometimes we talk about how women are getting infected and we just look at men as vectors of transmission, and I'm interested a lot of time in my behavioral work about how the men are contracting it and what can we do with that, so I wanted to know if you could speak a little bit on what you've seen there too?

AMB. DYBUL: Yeah, no, I think that's an incredibly important issue, how we do that. I can tell you about a couple of those programs, can you tell me again what precisely you wanted on the first part?

DR. MALEBRANCHE: Just as far as like outcomes, as far as CD4 count, what you guys have been seeing up to this point.

AMB. DYBUL: So, that, the reason I passed over that is those are not actually the good data I want and I know are out there and we're trying to collect right now. That was just on the increase in CD4 cell counts in the first 12 months of treatment so we know people are taking their drugs and the CD4. The important data that I know are out there because I'm talking to our partners and we're actually accumulating now – I just asked Bill Pop to do it – is, what is the CD4 cell count at entering? What is the CD4 cell count at diagnosis?

To me, that's the most important piece because you know, when Ray started his program in Botswana, they were saying 30 percent of people die in the first three months because everyone is coming in on deaths door. But now, what they've seen is that's not happening anymore. People are coming in earlier and earlier and we all know, you need to get – that's why the care piece and why everyone in the world is forgetting about care is so important. You need to get people in care programs when their CD4 cell count is 600 so you can monitor them until it gets down to 250, 200, whatever the country's guideline is to treat them optimally or we're not doing effective treatment.

We also need people in the care program so we can teach them to practice safe sex so that they're not transmitting the virus. So, that CD4 cell count at entry, I just talked with Bill, he's got it and others have it and that's what I want to collect, so I don't – that one's not surprising. CD4 cell counts go up when you start treatment.

In terms of what we're doing with – I think this is one of the most important areas and when we actually had a gender consultation on how we could do a better job at dealing with the deep cultural issues of gender as it relates to our program. I mean, we can't change the – PEPFAR can't change the cultures of these worlds, but we can deal with some of them. One of the key elements that came out from groups working on gender is get to the men because the men are actually the ones preying on the women and there's a limit to how much negotiating a woman can do in the circumstance, a real limit, whether it's A, B, or C.

So, like some of the better programs I've seen are the Men as Partners Program in South Africa. It's an extraordinary program that teaches young men, particularly those that don't have access to school and other things, that it's not macho to abuse women, that it's actually right to respect women. And that's cool, that's macho. And it's been an incredibly successful program, you know, there are data now on how men and boys have changed their view towards women.

There's a program with the Maasai warriors in Kenya, similar to the STD, you used to prove you were a man as a Maasai warrior, basically you'd all get together at age 14 or 15, I can't remember, and one of the mechanisms by which you prove you deserve to be a warrior is by raping as many women as you could effectively. And we intervened in a program and now that's radically changed to teach them, no, you prove that you're worthy of being a warrior by respecting a woman and that's radically changed some of the behavior there. These are some of the important programs I've seen that try to deal with it.

But I think ultimately – these are kind of doing catch-ups; these are trying to get to 25-year-olds and 20-year-olds that are currently – we have a great one in Nigeria doing the same thing and college kids started it themselves to teach boys that you should be waiting for sexual activity. You know, the reason they did it, they did a study and when they asked all the incoming freshmen, 80 percent of the boys said that they've always had – or that their friends have already had sex, but only 20 percent of them actually had, so it's a sense of, you know, yeah – (chuckles).

So, they actually started a program to identify them, to teach them, you know it's okay, it's actually cool to continue to not have sex. So, that's – these are the types of programs but once of the most important things we're doing, I think for the long term, because this is a generational thing, this is not – it's hard to change behaviors of 25-year-olds, 30-year-olds, God knows for me a 50-year, 40-year-old, it's not so easy. But if you can get to kids when they're young and teach them to respect themselves and respect others and respect women, that's these life skills programs that we're putting into – Botswana's doing a national scale-up of life skills programs. We've been working with them for three years and we're going to support that, we're already supporting it. We're doing this in multiple countries.

That's how we're, for generations, going to change this and that impacts on boys' and girls' behavior towards each other. So, we're not only going to impact their sexual behavior, we're going to impact gender equality, and you know, I was in a high school in Botswana where we started to do this early, as one of the pilot projects, and if you go into most high school in Africa and you have the boys and girls together and you ask questions, only the boys are going to answer, because that's the way the system works. In this high school, the boys could barely get a word in edgewise and the girls were talking about how they wanted to doctors and nurses and be teaches and be an engineer. That is – that's how we're going to change this stuff.

The problem is, I think what we're doing is, you know kids are in school only for so long. Kids are in their faith community for so long and then they leave or there's a point at which they don't listen to their elders anymore, so we've got to get them at every place and there are a lot of kids who have access neither to, in the slums and other things, to school or to faith-based organization, so we need programs that reach them as well. We need them all in the same geographic area or we'll make progress that will not succeed.

And that's what we're working on, this combination prevention to mere combination treatment where we're doing all of the things in the same place. But, you know, that's why I think Ted's point is right. There's so much success out there, but we're not going to see it; we're not going to see it on six-month intervals, the way we can see treatment. And we need to avoid these pendulum swings of oh, just go back and do this, or – and without treatment we're not going to have effective prevention.

REV. LUSK: Yes, my name's Herbert Lusk from Philadelphia, Pennsylvania, congratulations on all the good news that we've heard. My organization, Stand for Africa, is in five countries in Africa now and I just want to reiterate the hope that we see when we go there. I'm going there now somewhere between two and three times a year in the last five years. I'll be meeting with the Tanzanian president in December.

Two questions; the first one is your new partners initiative, you're going to continue that? Very good, and for good reasons; obviously there's some good things happening and you've got to bring new groups in and we're constantly pushing new groups in, I want to repeat that again, new groups in, include my group. But then, the other question is how do you deal with the comment made by a president of a country like South Africa, for instance, the president mentioned that the drugs themselves, the medicines themselves, are contributing to the AIDS problem. How do you guys approach that? How do you deal with that?

AMB. DYBUL: It's a very good question. And it's always good to see you, Pastor Lusk, I mean you got in early and have been involved in Africa for a long time and it's been so important for the work and we are going to continue the new partners initiative. You know, it's taken a lot of heat, but we think it's essential because there are a lot of partners out there that are doing good work that need to be brought into the government. And we can't succeed and scale up without them.

One of the things that's been, we've noticed, as a lot of the new partners don't have the skill set yet for responding to U.S. government grants and for the reporting for the U.S. government grant, which is a complicated thing. And that's led to a cycle of people who know how to do that keep getting all the money.

So, we're actually going to put out two new approaches for – to provide technical support to help build the capacity of partners so that they can compete on a level playing ground because right now they can't. And we're going to do that now because we recognize that we're just not doing enough to support partners' ability to play out – we're not trying to make them win a grant; we're trying to have them on a level playing field so that they can effectively compete if they have a good program and show their program's effective. So, we have some work to improve it and we're working on that.

You know, South Africa this year is going to commit probably $800 million of their own dollars to HIV/AIDS; we're going to commit around $600 million. They have by far the largest anti-retroviral, national antiretroviral program in the world, hundreds of thousands of people now getting treated. And a lot of that is through public sector

programs that we're also supporting. But political leadership's important and it – we could probably be further along in a lot of countries if there were the type of political leadership that President Mogae, President Kikwete, and others have shown.

So, what we need to do is work with political leaders and do work with political leaders to get those political statements. And the president of South Africa has actually been very good in terms of budgetary support and has changed dramatically in public statements around these issues. But we think we need to do more.

The other important thing is, political leadership is not just presidents and governments. There's a limit to how much people listen to public health officials and presidents and – you've got to get to the leadership at every level, which is the local leaders, the church leaders, the people everyone listens – the traditional healers, the people listen to at the local community. All health is local and we've really got to build that – and we're spending an awful lot of time and resources to build that leadership locally as well, so if we have problems at a higher level, there is that local support there that will keep going. But it's a very good question and that's why – one of the reasons we're in the State Department.

MR. GILMARTIN: (Off mike) – one last because I think you wanted to ask a question, too? I'll defer to you.

DR. BUSH: My question had to do with how much of the disease, I guess, is attributable to one of the slides that you had talking about trans-generational sex. And I know at one time there was the myth that a virgin would help cure an older man. So, I just saw you kind of run past that and I was curious, especially when David brought up the question about behavior in men and the gender issue.

AMB. DYBUL: The fact of the matter is we don't know for sure, and it's different by country and different by region of country. But what we do know is that younger girls in a lot of countries are five times as infected as the young boys, and there are two reasons for that: one is trans-generational sex of the older men preying on the younger girls. The other is, and there's actually been a study on this which is fascinating, the young – the young boys tend to travel in packs that are highly sexually active and they are the ones who are transmitting a lot of the virus in some areas, particularly in college age kids, high school and college kids, whereas most of the boys aren't. So, it's a mix of these things, we believe, but we're not sure.

Fortunately a lot of the old myths are dying away as people become educated. It's one of the reasons care and treatment are so important because as you medicalize a disease, as we saw in this country, a lot of the old knowledge and the old stigmatization goes away. The churches have become very involved; you know, there were some churches that taught that it was a curse from God or something else. What is amazing is their brethren and sisters in the cloth have actually gone after them and said, you've got to stop saying this stuff and changed the way they behave. And they get together to do that. The Coptic bishop in Kenya, who actually is for all of South Africa, Southern

Africa, actually goes to talk personally with pastors and others who have said this, to say, look I have diabetes, do you think I'm cursed from God? I'm a bishop.

So, as we medicalize the disease, as people understand the treatment and care and also the prevention components, a lot of that's going away. And there's been great success. A church that taught polygamy in Zimbabwe now teaches monogamy because of HIV/AIDS. So, a lot of these barriers, both cultural and others, are starting fall away because of the success and the expansion of prevention, care, and treatment programs. So, it's still there, to some degree, there's still people who believe, you know, the CIA introduced HIV, you know – but the percents and the not – it's really dramatically down. And I think a lot of that is because of the hope that's been created.

You know, when people see the opportunity, when people see that they can control their lives and – a lot of these older myths just start to fall away. So, lots more work to do but good success.

MR. MARTIN: Mine was just a comment that I could have made after you left, too, but it has – (laughter) – it has to do with the leadership thing, the point you brought up, that the president, that you have done a fantastic job and it's created this miracle. And the money could have easily been wasted and it's been very effectively spent and it's accomplished a lot. So, in a way I'm just thinking about the resolution that Beny has put together about domestic issues. The passion you talk about, the knowledge and the leadership on this international stuff has been so essential for the success. And we can contrast that with when we – you talked, so the various prevention programs. It's fantastic and it's music to all of our ears.

Another example would be the, we've got to get these countries to do opt-out testing whereas here in the United States, we hear we're waiting for the states, you know, it has to be their initiative and so it's a – in my mind, it's a very dramatic difference of the leadership and style and I know there are aspects of it, that there are reasons for of course. But I think, just any way we think about this resolution, that to really recognize what this leadership has meant to the international effort. It has indeed been a miracle that you've accomplished. Thank you.

MR. GILMARTIN: Thank you, Mark. Terrific, great to see you. Thank you all, thank you very much.

So, we're going to break for lunch at this point and we have lunch on the fourth floor. I'll wait for Marty to come back to give us the details here.

And so – well this is – hold on everybody. Oh, he's just saying goodbye. So, this is a working lunch that we have and will take place on the fourth floor and –

MS. : Can you turn that off?

MS. : Yes –

MR. : You're going to describe the details.

MS. MCGEEIN: This is, as you know, we recess for lunch now. We'll reconvene at 2:00. The domestic subcommittee will be meeting in room four – or conference room 443E. The international will be in 422F. There are people at the top of the elevator and at the bottom of the elevator. And if you get lost, just call for Nancy, she'll head out and find you.

(Break.)

MR. GILMARTIN: All right. I will call us to order. And the sequence we're going to follow is first, the international committee to present a document that we have been working on for quite a period of time and continue to work on actually over the last two hours or so and made some final changes. So we're putting that up on the screen so you can see the recent changes that we've made and then open for comment. Then, we'll move from the international to the domestic committee after that. So Bob, would you lead us off on the international committee to report?

DR. REDFIELD: Thank you very much, Ray. As I think everybody in the group now has had an opportunity to look at the white paper that we've prepared related to the PEPFAR reauthorization. I know I talked to Carl yesterday; there are some additional recommended edits that you've made that you're – we can either comment on them or some of them are, I think, factual updating of numbers that we talked about, which I thought was very helpful, very useful, so that we have – because when Bob Archer (sp) and I started this document, it was about nine months ago, I think, or a year ago. So we're going to update some of those numbers.

And I don't know if we want to go through Marty specifically or whether the committee will allow us to take the updated numbers from Mark's presentation from a couple of weeks ago and just edit them in, okay, because they're not contextual; they're just updating the numbers. So I'd like to have the discussion really on the content issues that people think if there's omissions that they feel that or if there's still an emphasis issue. And prior to doing that, I'd like to just go through some of the changes that our own committee, again, has recommended to the document, largely from an emphasis perspective and so everyone here could just be familiar with the changes that we're recommending to be included in the document, too. So, okay.

MS. : A little technical difficulty over here.

DR. REDFIELD: I think I can do them without people seeing. If we want to go to the document, the major and – the major changes that we had recommended under the executive summary – it's really going to be executive summary recommendations. We look at recommendation number four and there was a lot of discussion – I know Carl brought this up yesterday to me from the domestic subcommittee perspective –

MR. SCHMID: Those are my views; it wasn't from the domestic committee.

DR. REDFIELD: So Carl brought up, from his review, that the question of whether or not there was the issue of operational research, research should be included in our perspectives of this document. And I had tried to raise the point of view over the last year and a half that PEPFAR is a highly successful program, but it does need to be guided. And the mechanisms that we have to guide it are to evaluate it and in a sense, to try to determine what are the parameters that would help it be guided more clearly. And the term we use for that is operational research so we felt that it's important to highlight – and again, I don't mean to be negative and I wouldn't say this if the previous ambassador didn't use this in his own speeches that it was a ready, fire, aim approach and again, you know, in a sense justified because of the urgent need to get people on therapy. We think at this stage it needs to be a ready-fire-aim approach, and so, bringing in some – strengthening the evaluation and operational research. If you read the document carefully, you'd see that there was sometimes a little confusion, I think, in the way it read, whether it went from operational research to more developmental or what we could call more just developmental research.

And so, we have recommended some changes in item four so that the document that you have currently, we would just eliminate the last sentence suggesting that some of this money be used for developmental research so that there's no confusion. The purpose of the research allocation in this document is to optimize standard practice and to monitor and evaluate. And I think that's the contextual change. I don't know, Ray, if you wanted to make a comment because you sort of used an analogy that you had in industry to try to do the distinction.

MR. SCHMID: Yes, just to that point is that, you know, that in my former world and even in terms of the material I'm teaching now to (pressly minute?) about the BMBAs is making the distinction between what goes on in operation and what goes in a research organization. So in the document, we tried to make that clear that was PEPFAR is an implement or an operational entity and as an operational entity, needs to do the research on how to optimize its operations. And so, there is aim and fire as opposed to – and particularly, as Bob has pointed out, once we start scaling up from thousands of people to millions of people, being off a little bit on your findings on thousands of people is not as serious as when you scale up to millions.

So therefore, this research is very important. But also, not to confuse the mission or the focus of the organization as an operation, we're advocating that they stay focused on the operational research to optimize. And that although other new research, original research and developmental research, needs to be done, it should be in another entity and not part of the PEPFAR initiative.

So that's a distinction that we made in four. And we did that by dropping the, in effect, the last sentence of four. We had substantial discussion over that and there are different points of view on that, but sort of as a majority came out on that point.

DR. REDFIELD: Yeah, it wasn't a unanimous perspective, but I think it was definitely a consensus perspective. And so, that was the major change in the recommendations. There was some wording changed to item three.

DR. YOGEV: Before you leave four, a major change on the 10 percent.

MS. : (Off mike.)

MR. GILMARTIN: Yeah, if you could.

DR. YOGEV: Please because we did address that.

DR. REDFIELD: All right, point number three was – in the executive summary was changed completely. I can't see where we are.

DR. YOGEV: Can you go to point four?

MR. : We're on four.

DR. REDFIELD: All right, number four reads, the office of the global aids coordinator, OGAC, should be encouraged to invest substantial annual funding to support research. And the final sentence that's now highlighted was deleted.

MR. GILMARTIN (?): And we wanted to also use the word, I think, operational research, right?

MS. : So in the first line, allocation to support operational research?

MR. : Yeah.

MS. : Okay.

MS. : So the 10-percent advance?

MR. : No, that's gone.

MS. : It's going.

MR. : We're working with two different documents here, sorry.

MR. : What happened?

MS. : There was some translation problem.

MR. : Okay.

MR. : But we had a document –

MR. : Put the word operational –

MR. : So the first sentence essentially reads, the office of the global aids coordinator, OGAC, should be encouraged to invest substantial annual funding.

MS. : To support operational research.

MR. : And that's substantial annual funding as well.

MR. : And then, we get rid of that.

MR. GILMARTIN: I guess the thinking on that is that we didn't feel that we should be that prescriptive.

MR. : And then, item three there was wording changes. And if you want to read it?

MR. ANDERSON (?): PEPFAR should continue to promote rational, evidence-based, targeted prevention depending on age, circumstances, and risk profile. Therefore, abstinence and delay of sexual debut, mutual fidelity between partners, reduction in number of casual and concurrent partners, correct and consistent use of condoms, open parens, known as the ABC model, closed parens, should remain the priorities for PEPFAR prevention programs in areas or regions with generalized epidemics and as a strategy for general populations everywhere. And the last sentence now reads, in addition to primary emphasis, other available interventions must be considered as back-up strategies. And the absolute last sentence was removed.

MR. : Yeah, it was the last sentence. It was restructured. Do you want to – I guess for people to see it, I don't know if you're going to type it in there or –

MR. ANDERSON: PEPFAR should continue to promote rational, evidence-based, targeted prevention depending on age, comma, targeted prevention, targeted prevention, depending on age, comma, circumstances, comma, and risk profile, period. Therefore, abstinence and delay of sexual debut semicolon –

DR. YOGEV: Just take the ABC out – (inaudible).

MR. : Yeah, you don't need to retype the whole thing.

DR. YOGEV: Just take the ABC out – (inaudible).

MR. ANDERSON: It begins, therefore abstinence and delay of sexual debut, mutual fidelity, right, and then everything – after the word condoms and then parenthetically known as the ABC model – (pause) – should remain the priorities for

PEPFAR prevention programs in areas or regions with generalized epidemics and as a strategy for general populations everywhere.

MR. : Then we took out the last sentence –

MR. ANDERSON (?): Now, number three ends with the sentence, in addition to primary emphasis, comma, other available interventions must be considered as backup strategies, period.

DR. REDFIELD: Must is a pretty tough word.

DR. GREEN: I was thinking should because –

MS. : We'd like to stay away from the must word.

MR. : I'd prefer to say the word should there.

DR. REDFIELD: So is there any discussion, concern, since again everyone had the chance to read the document, but since we changed the context of how we're summarizing the recommendations, it's important to give people an opportunity to see if they're comfortable with the way we've framed that. Okay? And I think those are the major recommendation changes. Bob, is there another one – there was a minor wordsmith I think on number 10.

MR. ANDERSON: Number 10 now reads, to ensure the sustained availability of new drugs and formulations for pediatric patients – oh, I'm sorry. In the executive summary, page two.

DR. REDFIELD: There it is.

MR. ANDERSON: To ensure the sustained availability of new drugs and formulations for pediatric patients, pregnant women, and adults living with HIV infection, OGAP should develop long-term strategies that fully engage the creativity, development, and market capacity of the pharmaceutical industry.

MR. GILMARTIN (?): You know, from a technical detail, pregnant women is kind of redundant. There are other women besides pregnant women.

DR. REDFIELD: So those are the major changes and some minor edits within the session that discusses the research component, just to reflect, you know, taking out the area of investigator-initiated to reflect the consistency with the recommendation and also to be non-prescriptive in terms of the amount of money that was invested in the operational research.

So if the committee would concur, we would just make those editorial changes that we have. But in the interest of time, I didn't go through them. They just reflect

those major changes that we made in recommendation number four. And is there any other –

DR. YOGEV: We suggested and we agreed that you're going to add the – (inaudible).

DR. REDFIELD: Yeah, I was going to bring that up. Any other comment other than anybody have? The second area that we wanted to and the question can be discussed whether it becomes an independent recommendation of if it becomes one of the discussion areas. If you look at the document, if you take a second to look at it, how it's formatted. When we get to the challenge – page seven we sort of get to the challenges. And we talk about the challenge to optimize best practice, the challenge for the use of modern evaluation, the need to build human capacity, the need to increase availability of therapeutics for children and infants – childrens of all ages, the need to look at expanding support within the Western Hemisphere and the Caribbean. The need to expand end-of-life and palliative care services because the reality is, as you saw, even though we're making progress, we still probably have one out of five people in need of therapy not receiving therapy although, again, I'm very optimistic that this program, by the end of the next cycle, can get close to getting a majority of people on therapy that need therapy by today's standards. Although, it's likely that the standards of therapy will change over the next five years so that it may, in fact, be that all people with HIV infections. So we'll always be playing a little catch-up there.

But in those contexts – and then we talked about the need for administrative procedures and the need for sustainability. It seems like one of the areas that we didn't comment on that there was some discussion in our committee and again, was whether there's a need to have a separate paragraph at least, even if it's not a recommendation that's discussed, to emphasize the need of the program to continue and development and improve ways to empower women in these countries – dealing to empower women in the context of not only their own treatment and prevention and care for HIV infection. So I don't know how people feel.

It wasn't addressed as an independent item. We had some discussion at this international subcommittee at lunch about it. There was, I think, a general consensus that the document would be strengthened by adding a recognition that we need to continue to develop, that that plan needs to continue to decide to develop programs that facilitate and empower women, particularly as related to HIV care, treatment, and prevention. So just open that up. Carl mentioned that also to me as one of the things he felt was a deficiency, the document, that it didn't mention it anyways. So I just throw that out to have some discussion for –

Carl, you brought it up. Maybe, you'd like to –

MR. SCHMID: Yeah, well I appreciate you guys' discussing it, but I do feel that the document was absent. It didn't talk about that at all. And I think that's a very important issue, particularly in sub-Saharan Africa and Mark – Ambassador Dybul talked

about it as well today. And I just think, as a recommendation as PEPFAR gets reauthorized, to recognize what they're already doing, but to continue to do that, to empower women. And we could come up with some other language as well. But I would be interested in seeing what other members of the committee –

MR. GILMARTIN: I think our sense was that was something that we had left out; we should add something along those lines.

MR. : I would agree. It would be under the challenges section as well. Were you planning on putting it or –

DR. REDFIELD: That's what I was thinking, to put it there like we did, to have a separate paragraph that this is a challenge, and important challenge. We need to continue to – we need to recognize this is a key issue and we need to continue to focus on this. And again, depending on how people fell, we could take a sentence out of that and put it as a recommendation or we could at least have it in the text of the body. I was thinking more of having it in the text that we recognize it and, you know, just have it as one of the elements. Because not every single thing that we listed in here did we put. We tried to keep the recommendations down to 15, you know, just because we wanted people to sort of read the key recommendations.

But again, I'm open if the committee feels differently. If it's in the context of the document, you know, what I'd like to ask is that we can develop that paragraph to recognize that. And really, almost along the line of almost what Carl just said, but putting it into language, that this is an important thing to recognize and that the PEPFAR program needs to continue to look at how empower women in these areas, particularly of HIV prevention as well as getting access to care and treatment for HIV infection, and that we see that as an important component, that continues to need to be expanded. I mean, that's more or less what it would say. And put it in under the needs, under the challenges areas.

MR. : Yeah, I think that's the appropriate – for me, that seems to be the appropriate amount of emphasis that needs to be on it.

MR. GILMARTIN (?): I have an actual on this as an approval. So, would you like to move this?

DR. REDFIELD: Yeah, I would like to request that with those editorial changes that we stated we'd make in terms of updating the numbers, adding the paragraph on the empowerment of women, and modifying the text to correspond to the recommendation changes that we made on number four that we'd be able to do that internally and request that the document be approved by the full committee to be forwarded to the secretary for the administration's use.

MR. GILMARTIN (?): So we have that motion on the floor. Do we have a second?

MR. : Second.

MR. GILMARTIN (?): Any further discussion? All in favor say aye.

(Chorus of ayes.)

Opposed? Carried. Thank you very much. Thank you, Bob. Thank you committee, full committee for your comments. Okay, now we're ready to move next to the domestic subcommittee.

MR. SCHMID: Thank you and thank you, Bob, for incorporating a lot of those suggestions into the final document. The domestic committee is presenting three resolutions for the four committees' consideration, and if we could get those. But the first one is having to do with addressing the crisis in Puerto Rico. The subcommittee has been, has expressed an ongoing concern with the situation in Puerto Rico. We've heard comments from the public, the full consul, but also at our last domestic committee meeting, we did have a representative of the governor's office and also a member of the community as well.

So should I go and read it since this is all new to? It's on the screen I know the – well I guess the members of the full consul have seen the earlier draft and you can see how we did make some changes. But we go through and address some of the issues and I do not know how much money has been returned by the commonwealth in those years. That is a question mark and I hope we could incorporate that number, if HHS could get that number.

MS. MCGEEIN: I'm sure that it is gettable.

MR. SCHMID: Okay, if we can't then I suggest that we say it has returned millions of dollars if we cannot get the exact number that they have returned.

MS. MCGEEIN: (Off mike.)

MR. SCHMID: So I'll give a moment for everyone to look at that.

DR. REDFIELD: One of the comments in item four, you might say, since we don't have the numbers, that they received the amount they received and you could either say returned or you could say had to return, you know, millions of Ryan White funding over the last five years. So like you said, just either returned or was unspent and returned, or something like that – time to emphasize, you know that – but I agree. I would probably take the number out if you're not positive of the number?

MR. SCHMID: Yeah, the inspector general number for San Juan is a quote from the inspector general's report. It's just the commonwealth is the number I don't know.

MS. MCGEEIN: The five-year period ending in '03. We're now in '07. I will accept the 6.5, but I think in talking about the crisis – (inaudible) – the numbers are not –

DR. REDFIELD: If it is that out of date, you know, over five years, you might want to just say, whereas they received money and have had to return, you know, a significant portion of these Ryan White dollars unspent or something like that because I have to admit, if I see that there was a problem five years ago, I don't understand why I'm – I'm trying to think of who is going to read this and say, wait a minute, you know.

MR. SCHMID: Okay, so we could change that to reflect that both the commonwealth and the city of San Juan have received X amount of money, but they have returned unspent funds in the tune of millions of dollars – there are millions been like that. Hopefully with the full committee will give us the latitude, too.

Any other comments from? Okay, hearing none then.

MR. GILMARTIN: Yeah, I guess I will.

MR. SCHMID: Thank you.

MR. GILMARTIN: Is that, and you can put that forward in a motion that this resolution –

MR. SCHMID: Okay, I move that the full consul adopt the motion as amended.

MR. : All right, a second to that.

MR. : I'll second.

MR. SCHMID: All in favor say aye.

(Chorus of ayes.) Any objection? (Pause.) Okay, motion carried. Thank you.

MR. GILMARTIN: Thanks, Carl.

MR. SCHMID: Okay. Our second resolution has to do with the information that is given to patients when they are tested. And we wanted to make sure that they be given information about – when they are given information about HIV/AIDS that they be given information – I'll just read it – "On the behavior practices of primary risk avoidance and risk reduction we developed and be given to the person who is waiting for an HIV test during the window of opportunity. And I would call on Freda if she wants to add anything on this? If the – we've all seen it on the domestic side so I guess I would – looking for comments from people from the international committee.

Any questions?

MR. GILMARTIN: All right, so would you like to move that one as well?

MR. SCHMID: Yes, I'd like to move that the full council adopt the resolution as presented.

MR. GILMARTIN: And a second, please?

MS. : Seconded.

MR. GILMARTIN: All in favor say aye.

(Chorus of ayes.)

MR. GILMARTIN: Opposed? All right, thank you.

MR. SCHMID: And the final resolution has to do with when people are presented with HIV counseling that if – when they do choose abstinence that they be given ample information about abstinence and that they have – including trained counselors and skills developed and materials presented to them. Any – does Barb – you want to talk about this one at all?

MR. GILMARTIN: Okay.

MR. SCHMID: Any questions?

MR. GILMARTIN: Any questions?

RAM YOGEV: I have one. It's not clear to me, the way it's written, how the person choses abstinence. Did he receive all options or the discussion was only abstinence and then you give him whatever you say? I think by that we are beating what we are trying all the time to say, is we need to educate the whole and then if they choose this one. So, I would like to see where is – the principle key is to educate for ABC, whatever, if a person choose abstinence, which I am very much in favor.

And then to – I mean, it suggests that abstinence is the only thing which you are going to do, which I think beats the effort.

MR. SCHMID: I think that's an excellent suggestion.

DR. BUSH: So, like – oh, number three whereas a person presented with the options chooses abstinence as a personal goal, be it resolved?

DR. YOGEV: Yeah, just to put what other options – I like the idea that we don't give up education and we need to encourage this, but education should include abstinence and obviously according to the age – abstinence, be faithful, what other options, condom, whatever, and then if he chose abstinence. See, this is too generalized, so for example, I

will never tell you to teach a kid at age of 10 to use a condom; I think it's wrong. You should talk to him about abstinence, if at all, after you've taught the education. If he grows and is sexually active, you know at the age of 15, what is that number, 50 percent I think are sexually active in high school, you need to give them everything. If you are sexually active, don't jump from one to the other; be faithful and then if you decide to use, the way we chose, here's a condom; that's what you do with it.

If he then chose to be abstinence, I have no problem with what you say, but I want to see that going in direction of age-oriented, intellectual – or not, maybe it's sort of wrong word, but you know – level of understanding what we're teaching and if abstinence, we give them what to do with it.

MR. SCHMID: So, Ram, do you have any suggested language. I could see something changing that third whereas to something like, whereas when a person dot, dot, dot, when –

DR. YOGEV: The second one – whereas the goal setting is focus on the age of who you're counseling which will include abstinence, be faithful, condom. What was the deal? I like the D this morning; it was great.

DR. PRIMM: Don't do risk behavior.

DR. YOGEV: What? Don't do risk behavior, thank you.

DR. PRIMM: Risky behavior.

DR. YOGEV: Yeah, risky behavior. And then, whereas the person is choose abstinence, that's the person's choice, which I respect, go ahead and do whatever you say.

MS. WISE: When I wrote it, I was thinking in the first one we addressed age and development level. In the first whereas.

MR. SCHMID: And I think that goes well with what he says.

MS. WISE: And then the HIV client-centered, then you would have – you'd have the client and then, so then it's all up to the client and then if they choose abstinence.

DR. YOGEV: You see, whereas personal goals settinG in the focus client center counseling, which will include all, everything, then it would –

MS. WISE: What if they are little?

DR. YOGEV: That's according to the culture and to the client age, culture, whatever, language, sex, whatever. And add over their – or you have the age.

MS. WISE: Which can, maybe can include, instead of will? Can include?

DR. BUSH: So, this adding an – after include – ABC, just or ABCD, just let's you know that they have all of the choices in front of them and they choose abstinence, then we need to support them and help them succeed that.

MR. SCHMID: That is the thrust, I believe, of the resolution.

DR. BUSH: That is the thrust.

DR. YOGEV: But it's not here, when you put can, can include, that tells me –

DR. BUSH: It will include.

DR. YOGEV: It should include.

DR. REDFIELD: I think again, as you get back to can, if it's an 8-year-old person you're evaluating, I think that you're going to – this is the whole issue of being sensitive to culture. There are some cultures that are, you know, they're sensitive to age, and I think that's what Barbara's trying to do is trying to make this that it's not whether or not everyone has to learn X, Y, and Z. But when somebody does say, listen, I'm into this A thing, okay, she's trying to say that, you know –

DR. YOGEV: I hear you, you have an excellent point. Maybe an appropriate, just appropriate portion of the ABC according to client, culture, you see –

MS. WISE: Appropriate to the clients?

DR. YOGEV: But, before they're just appropriate sectional to ABC or they really, you see what I'm saying?

MS. WISE: Up top at the first whereas?

DR. YOGEV: Yeah, on the first one, by that you're saying what Dr. Redfield so appropriately pointed out, that there is – I cannot ask a Catholic priest to teach condom, it is to be fair not to –

MS. WISE: Right, so, I agree. I see what you're saying. So, whereas one of the – provides –

DR. YOGEV: We're saying you need to consider everything, choose it according to what you do, and if you chose abstinence, then go – then it's fine with me.

MS. WISE: So, it's provide services that are appropriate?

DR. YOGEV: Provide services –

MS. WISE: – A, B, and C that are appropriate to the client's culture, language, sex?

MR. SCHMID: I think I just got lost.

DR. YOGEV: Guidelines is to provide ABC services –

MR. SCHMID: ABC services, right.

DR. YOGEV: – that are appropriate level of – and by that you put what – Dr. Redfield is absolutely correct, you can then take it out in full. And then if you choose, and then I'm not sure if you need –

MS. WISE: And then we can take out the other –

DR. YOGEV: Number two.

MS. WISE: – number two, the ending part of number two.

DR. YOGEV: Right, exactly. You can combine number two and three together, you say well, whereas personal goals set in focus client center if the person choose.

MR. SCHMID: Yeah, I would also like to see the – in the final that ABC be spelled out. Okay, I think this is an excellent change. Thank you for that.

Any other – Jose?

DR. JOSE MONTERO: I got one question. ABC, if you're talking about someone's risk grouping IV drug use, you're not going to attack something – ABC's not enough. It's risk – well, that's risky behavior, I mean because you're not going to capture that.

DR. YOGEV: So, so – that's a point which –

MS. WISE: But we're talking –

DR. YOGEV: The situation was put in so nicely. You put abstinence, be faithful, condom and whatever was the D, don't do – so services according to culture, then a person chose of which – you see because the first thing which will happen is those who are so sensitive to abstinence only will right away jump when I say, you are only abstinence only and we say, no, we say everything. But if the guy chose abstinence, educate him how to do it right.

DR. REDFIELD: The recommendation's not trying to be exclusive of individuals that use IV drugs, okay, it's just trying to be a recommendation relating to when you

relate abstinence, be faithfulness, and condoms, that, for those individuals in their own personal choice, choose abstinence, the following. And I think it's worth emphasis, I think it's worth emphasis because historically, we've had maybe over-emphasis on the condoms and so now it's important to have sort of a balanced emphasis. Allow people the ability to figure out which one of these prevention strategies is the most appropriate for them and then begin to try to reinforce those strategies so that they can be effective for those individuals.

MR. SCHMID: Any other comments on the proposed resolution?

So, I would like to move that the full council adopt the resolution as amended.

MR. GILMARTIN: All right. A second?

MS. WISE: Second.

MS. : (Off mike) – be faithful.

MR. : Be faithful – (off mike).

MR. SCHMID (?): It's not condom services either. (Laughter.) Yeah, we'll work on this.

MR. GILMARTIN: We'll work on this. All right, so we have a second for this?

MS. : Second.

MR. GILMARTIN: Would you like to second this, Barbara?

MS. WISE: Yes, I'd like to second this please.

MR. GILMARTIN: Any further discussion? All in favor say aye.

(Chorus of ayes.)

MR. GILMARTIN: Opposed? Motion carried.

MR. SCHMID: Well, thank you. And we did have another resolution that we began to address that we unfortunately did not have time to complete and that was the one authored by Dr. Prim calling for a domestic PEPFAR and a year of testing. We are disappointed that we didn't get to address that but the subcommittee has agreed to continue to work on that and we will discuss it in our domestic subcommittee meeting and present it at the next full meeting next March. So, thank you very much.

MR. GILMARTIN: Good, thank you very much to both subcommittee chairs for an excellent outcome.

The – we now move into the public comment phase of our meeting and I'll turn over the chair to Dr. Maxwell.

DR. MARILYN MAXWELL: Okay, for this final section of our meeting I have a list of those that have signed up for public comments. Public comments will be held to three minutes and you'll be given signs at one minute and 30 seconds.

Our first public comment will be from Greg Smiley.

GREG SMILEY: Here we go, okay. My name is Greg Smiley. I'm the director of public policy for the American Academy of HIV Medicine. We represent MDs, DOs, nurse practitioners, and physician assistants specializing in HIV medicine. And I just wanted to make a quick public comment about the need for better reimbursement for HIV screening, that you referred to yesterday's panel and I've got some great positive responses from Aetna and CareFirst. I think that we've still seen from our CDC workgroups that we've conjoined of clinicians from different disciplines around the country from OB/GYNs, family physicians and so forth, that there isn't enough adequate reimbursement for screening and so we're not seeing as much uptake of the CDC recommendations because of that.

NASTAD, which is the National Alliance of State and Territorial Aids Directors, just had convened a meeting in January of emergency departments, and they reported that, again, the biggest barrier to emergency departments taking up HIV screening was the need for better reimbursement for that. So, we did hear some positive news yesterday from Aetna and CareFirst, but some other conversations that we had had with other private insurers and HMO organizations had really not come on board yet for the need for screening. I'm citing, like, the U.S. Preventative Services Task Force and their recommendations to not necessarily recommend HIV screening is a reason to not also reimburse for it.

So, we had come up with some potential solutions that the council and other organizations should look at, making available the need for reimbursement of the screening and we decided that like, CMS could issue a dear state Medicaid director letter to all the state Medicaids and say, these were the guidelines, say, and this might be a good option for you to take up reimbursement. Relevant medical societies, such as ours, could convene a meeting of the state Medicaid medical directors, a lot of the state Medicaid programs have specific medical directors that give them advice, and so we could bring them together and then, you know, discuss the need for screening.

The Health Resources and Services Administration could and should change their policy to require that community health centers offer HIV screening as a part of their communicable diseases screening requirement and work to ensure that such centers have adequate resources to cover screening services and test kits and so forth. AMA has also been discussing a CPT code for screening and we wholly encourage them to adopt that.

And then finally, private insurers, such as – well, other private insurers besides Aetna and CareFirst should follow their lead and reimburse for HIV screening and the AMA and the Association of Health Insurance Plans should consider convening a meeting of major insurers to discuss the needs for that. So, hopefully, you can maybe take that up in your next meeting as well. Thank you very much.

DR. MAXWELL: Thank you, Carl?

MR. SCHMID: Yeah, I just wanted to make a comment that we – I should have said this when we were closing – that one of the issues that we're going to continue to look at in the domestic committee is this reimbursement issue. Do we have written comments, by the way, of their now? That would be great, thanks.

DR. MAXWELL: Okay, our next comment will be from Suzanne Miller.

SUZANNE MILLER: Hi. Good afternoon, my name is Suzanne Miller, public policy associate for the AIDS Institute. Today I would like to comment on the urgent need for a national HIV/AIDS strategy in the United States. After more than 25 years of this disease, the United States is still without a comprehensive outcomes-oriented and evidence-based national plan to effectively and proactively respond to the HIV/AIDS epidemic.

An effective, comprehensive national HIV/AIDS strategy should do several things. Among them, one, set ambitious visible and credible prevention and treatment targets and require annual reporting of progress made; two, identify clear priorities, responsibility, and accountability for action and encourage interagency coordination; three, prioritize the needs of groups most impacted by and at greatest risk for HIV; four, the need to address structural and social factors that increase vulnerability to infection, such as poverty, housing, and incarceration; five, scale up federal funding for HIV prevention, treatment, and research programs; and six, incorporate many sectors of society into the development of a national plan, including government, business, community, non-governmental organizations, faith, research, and people with HIV/AIDS.

We are at a critical juncture in this epidemic; while after 25 years we have made some gains as a nation in the areas of prevention, care and treatment, and research efforts, this epidemic is unfortunately far from over. The rate of new infections has plateaued at more than 40,000 per year for the past 15 years, and we are hearing that CDC will soon release a much higher estimate of new infections. Additionally, an estimated half of all people who know they're HIV-positive do no have access to anti-retroviral medications.

African Americans, Latinos, and gay men continue to bear the brunt of this disease while federal funding for HIV prevention, care and treatment programs, and research efforts continually fail to keep pace with actual funding needs. Furthermore, we cannot pull back on our commitment to finding a vaccine and ultimately a cure. While the U.S. has positioned itself as a global leader in biomedical research and the fight against HIV/AIDS abroad, we have failed to adequately respond to the epidemic here at

home. We can no longer demand a national HIV/AIDS strategy of other nations we provide support to while ignoring the need for one at home.

I also wanted to say that more than 180 organizations across the country have signed on to a movement demanding a national AIDS strategy and you can go and visit their website at www.nationalaidsstrategy.org and sign on as an individual. And we also ask that PACHA make the development of a national AIDS strategy a priority by passing a resolution. Thank you.

DR. MAXWELL: Thank you, Ms. Miller. Next we have James Sykes.

JAMES SYKES: Good afternoon, my name is James Sykes, the global advocacy coordinator for the AIDS institute and today we would like to provide public comment on the reauthorization of the president's emergency plan for AIDS relief and biomedical HIV/AIDS research. Four years ago the president began a bold initiative to provide care and treatment to 10 million people infected and affected by HIV/AIDS. As we approach reauthorization of this landmark legislation, the AIDS Institutes respectfully offers public comment in two key reauthorization areas for your consideration and hopefully inclusion of them in your advisement to the president.

First, at the threshold of PEPFAR reauthorization, we know that approximately 24 million more people have become infected with HIV since the program began despite its successes. It is obvious that we cannot treat our way out of this pandemic. There's a need for an enhanced emphasis on comprehensive, evidence-based HIV prevention. We know the epidemic is rapidly increasing in ASIA and other regions of the world, often driven by intravenous drug use. Comprehensive HIV prevention must include needle exchange and referral to HIV testing, counseling, and substance abuse treatment.

The AIDS Institute also asks that you advise the president to consider removal of the abstinence-only earmark in the light of the Institute of Medicine's findings of the ineffectiveness of such programs. At the same time, the HIV prevention program must include expansion of comprehensive and evidence-based ABC approaches to minimizing the sexual transmission of HIV and other sexually transmitted diseases.

Secondly, reauthorization needs to be carefully planned with an emphasis on sustainability. The AIDS Institute supports a reauthorization of at least 4.5 – $5.4 billion per year as a floor, not a ceiling, as recommended by the global advocacy community. The goals of the program – of the program expansion in sustaining current programming are both important to continued success of PEPFAR.

A final comment regards ensuring continued biomedical research to find improved life-sustaining anti-HIV drugs with increased accessibility worldwide as well as here at home. The AIDS Institute asks this body to convene a meeting about the important topic; the need for new drugs is well known as we see clear evidence of biological resistance and the lack of new classes of anti-HIV drugs being developed. The AIDS Institute encourages such a meeting to include scientists, clinicians, the National

Institutes of Health Officials, World Health Organization representatives, non-governmental organization representatives, people living with HIV/AIDS, and the private sector, including the pharmaceutical and biotechnology industries.

Two goals of such a meeting is to bring increased public awareness to the need for continued research and to generate a consensus about ways in which key stakeholders may move forward in the pursuit of improved HIV therapies. Thank you very much.

DR. MAXWELL: Thank you. Next we'll have Mr. Ronald Johnson.

RONALD JOHNSON: Thank you and good afternoon. My name is Ronald Johnson. I'm the deputy executive director at AIDS action council here in Washington, D.C. We are encouraged by the expressions of support for a national AIDS plan that have been made at this meeting, including the support for the concept of a domestic PEPFAR. Core elements of a national AIDS strategy must be addressing the HIV/AIDS epidemic in communities of color.

Human – geographic and population and human disparities that cut across and go beyond communities of color must also be addressed. You've heard the sound recommendations this morning that emerge from the national conclave of black clergy. Yesterday was Latino HIV/AIDS Awareness Day and I bring to your attention the call for action for a Latino AIDS agenda and the upcoming summit meeting in January to adopt a Latino AIDS agenda. It's important to realize that plans that target highly impacted communities are completely compatible with an overall national AIDS strategy.

Indeed, the advantage of calling for a national AIDS strategy is that it can encompass the various specific plans that are needed to end this epidemic. A national AIDS strategy must enhance, not obscure, our ability to address specific population and geographic disparities and disproportional impacts, particularly in communities of color that continue to mar and characterize this epidemic. That is a way to be truly effective in ending this epidemic, and that needs to be the focus of a national AIDS strategy. Thank you.

DR. MAXWELL: Thank you very much. Our final comment will be from Marsha Martin.

MARSHA MARTIN: And I've got to do a show and tell.

I'm Marsha Martin, director of Get Screened Oakland and I bring you greetings from a former colleague of yours, Mayor Ronald V. Dellums, who some of you might recall was also on PACHA at one time.

I want to share with you a little bit about an initiative that's underway in Oakland. Indeed, Get Screened Oakland, it is building upon the successes that we had an opportunity to experience in Washington, D.C., and is part of what I would describe as a growing movement of municipalities undertaking this effort to expand screening for HIV

and expand the opportunities for people to know their status, getting care of they're positive, and understand HIV transmission and work to prevent transmission if they're negative and stay healthy that way.

A couple of things I want to point out to you and I think it would be valuable for PACHA to consider having a discussion on municipal responses to HIV. And the idea of a municipal response is, of course, where you bring an entire community together using executive leadership, community leadership, you know, all the sectors to come up with a plan and then work collaboratively to mobilize and execute that plan.

That is 25 years into the epidemic, a new conceptualization; it's happening around the globe. We have mayors and provincial leaders and district leaders engaged in HIV, but the United States, it's really been 20 years since we've had the kind of executive leadership. And as we look to routinize HIV screening, steps to making that success is to be able to bring everybody into a room and to work with people collaboratively to make that happen.

And, yes, it's important to find about who's going to pay for it, the insurance companies, et cetera et cetera, but if you don't have an entire community engaged in this conversation, it doesn't work. So, an important part of the next step, as you look at routinizing HIV screening, is to have this discussion of community-wide efforts. If John Martins were here, I would also then tell you about the public-private sector part of this. Get Screened Oakland is fully a public-private sector operation; 75 percent of the funds that work Get Screened Oakland came from the private sector.

California is a county government-based public health system; our city does not have its own health department. The mayor, showing his leadership, has committed local budget dollars to make this work and to match the private dollars; so, public-private partnership, bringing it together to make an initiative like this work. Gilead is supporting us in the Bronx, Gilead is supporting Oakland, Gilead is supporting Baltimore, Gilead is supporting Los Angeles; there are communities around the country that are engaged in this municipal, get everybody together in a room to talk about expanding HIV screening.

And I would encourage PACHA, as they begin to look at the issue of a domestic response to HIV to not forget the cities. And we remember that PACHA came to Washington, D.C., and met and heard from local leadership around what's going on. We would like to extend you the same invitation to come to Oakland. Mayor Dellums would be thrilled to host his colleagues in the Presidential Advisory Council and would like to invite you to really take a look at a community in the shadow of San Francisco and what they are doing to try to respond to an epidemic 25 years later. And the materials I passed out to you, you will see the new social marketing campaign just kicked off in October where the mayor is standing up inviting people to get screened for HIV, where the mayor is fully behind this initiative.

Understanding what you all have talked about is the role of leadership, executive leadership, in engaging a community. We had it here in D.C.; it will happen again here

in D.C. now that Dr. Hader is in place. We have it in Oakland. We encourage you to come join us and we'd love to host you, thank you very much.

DR. MAXWELL: Thank you. We thank everyone for all of the public comments. This concludes our 34th full council meeting of the Presidential Advisory Council on HIV/AIDS and the full committee will convene again in March. Safe travels home everyone.

(END)