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TRANSCRIPT OF PROCEEDINGS

NATIONAL COMMISSION ON

ACQUIRED IMMUNE DEFICIENCY SYNDROME

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DEFINITIONS OF HIV DISEASE:

POLICY IMPLICATIONS

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Pages 1 thru 177

Washington, D. C.
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NATIONAL COMMISSION

ON

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DEFINITIONS OF HIV DISEASE:

POLICY IMPLICATIONS

Tuesday, December 10, 1991

9:15 a.m.

Embassy Suites Hotel
1250 22nd Street, N.W.
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AGENDA: [Continued)

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P R O C E E D I N G S

CHAIRPERSON OSBORN: We are pleased to welcome the next panel, who will be talking to us about confidentiality and civil liberties issues, and in this order: Nancy Dubler, Director of the Division of Law and Ethics at Montefiore Medical Center, Albert Einstein College of Medicine; Sally Perryman, Special Assistant to the Director of Policy for the New York State Department of Health AIDS Institute, and David Hansell, Deputy Executive Director for Policy of the Gay Men's Health Crisis in New York.

Welcome to you, and we look forward to hearing from you in sequence, and then we'll get a chance to interact, if that suits you.

MS. DUBLER: Thank you very, very much for inviting me and giving me the opportunity to share with you some of the thinking I've done over the last time on this possible new definition.

I'd like to talk about three things briefly. One is confidentiality. The second, you've labelled "civil rights" but I'd like to recast a bit and talk about civil rights as the issue of social justice. And finally, the issue of good ethics is only based upon good facts.

And in fact I'd like to start with that last and then return to the other two. There are a number of assumptions which underlie my remarks, one that this new definition will result in a bolus of names which will be reported. That also may result in a substantial drop in reporting thereafter as the definition catches up with its first announcement.

Two, it is going to result in a larger pool of cases reported earlier. Three, it will not necessarily result in more accurate reporting of cases involving women, IVDUs and adolescents. Four, the prime use of the definition has been in the past and will continue to be for reporting and for benefits. And finally, the definition may improve access to care, but may actually impede access to care if it is not finely tuned to the needs of special populations.

Well, good ethics depends upon good facts, and my sense of this new definition is that it continues to ignore or not to put sufficient focus on the particular problems of women, precisely because we don't know what they are. The research has been so scant and the clinical treatment in many places so inadequate that we really don't know what the incidence of pelvic inflammatory disease, vaginal candidiasis and cervical cancer is, for example, just to name three with

women.

Caregivers within the Bronx with whom I spoke before this presentation said that they have numbers of women they are treating who have disabling disease--PID or vaginal candidiasis--which isn't recognized now necessarily as a part of AIDS and will not necessarily be under the new definition.

Adolescents present a particular problem. We perhaps know less about them than any other group. Montefiore had the first adolescent treatment program of any size, and the caregivers there tell me that they are not really certain that the definition as it now stands is inclusive of the sorts of bacterial infections that they are seeing with adolescents. They honestly don't know.

They have seen more than 100 youngsters since the clinic began, but the pattern that has emerged from that care is not yet clear.

These groups--IVDUs, adolescents and women--presently have problems with access to care because they tend to be unemployed or underemployed. With adolescents in particular, they exist in a "Never-Never-Land" of private insurance coverage and access to Medicaid. They tend to be street people, and they tend to be women who are perhaps less

aware than the danger than other groups at risk.

Good ethics begins with good facts, and the tests that we now use appear to be quite reliable in terms of their judgment of whether someone is HIV-infected. I am told that the T-cell count is a much more difficult test; that it is likely to yield different results from different labs; that in fact it is much more expensive, much more difficult to confirm. And the question would be would we in fact have data that are as reliable if we shift to a new test as we have now.

The second issue is confidentiality. Confidentiality is an interesting doctrine in the law. It really has two notions, historically, in cases and in discussions in the literature. One is an absolute notion to protect the secrets of someone, and that is indeed how you see it from the Hippocratic Oath through the present confidentiality statutes.

There is a second notion, and that is an instrumental notion of confidentiality, that in order to deliver good medical care, you need to know the most about your patient, and the way to get the patient to come forward is to promise protection for secrets. That's not an absolute notion. It is a utilitarian notion that we'll do best if we proceed in

this way.

Those are both concepts of confidentiality which are important to physicians on the one hand and for public policy on the other.

The interesting thing about the doctrine of confidentiality is from its inception it has never been an absolute. It has always been possible to breach confidentiality for the good of others, for the public good, and that certainly in America has been codified in statutes that establish required reporting for diseases that range from infant diarrhea to HIV to other sexually-transmitted infections to TB. The last time I looked at the New York list, it was about 60 diseases that had to be reported, most of which are not, and those that are tend to be reported from clinics and not from doctors' private offices.

So there is a great difference in how this concept of reporting is complied with, and it tends to break down by race and class. If you are poor or if you are a person of color, you are more likely to go to a publicly-funded institution, and you are more likely to have data that is reportable actually reported.

It is interesting to note that when I went to look

last week whether there were data on that phenomenon, there aren't any. And I think that is so truly interesting because those of us who work in health care know that that's the case. If you go to a private doctor, venereal disease doesn't get reported; if you go to a clinic it does. But I was astonished that there really have been no studies that I could find--perhaps, Dr. Osborn, you know some--that demonstrate that. But it certainly is a fact of the health care system in which we work.

The breach of confidentiality for the good of public health has in the last years--well, actually, since the late 1960's--been accompanied by a new development, and that is the breach of confidentiality for the benefit of a particular person who is at risk from the individual who is reported.

The first case is one called Tarasoff v. Regents of California, which some of you may know, which held the state and psychotherapist liable for not reporting a dangerous individual to the intended victim. That model, which indeed has not been followed in the majority of States, most States assume they now follow, and certainly it has been the basis for many of the individual reporting obligations or permis-

sions that have been developed in various States.

It is my assumption, as I said at the outset, that this new definition will in fact result in earlier reporting for some. That, of course, raises the possibility that those whose names are reported at this earlier stage will in fact suffer greater discrimination if the reporting is not adequately protected. People who are asymptomatic and still in the work force, still covered by insurance, still part of society and not identified openly as persons with HIV infection, are much more likely to suffer, I would assume, the stigma if the data are not very, very carefully protected once reported.

The final issue that concerns me about confidentiality is the issue of the maintenance of the anonymous testing sites. I think, back to this notion of confidentiality both as an absolute and as an instrumental notion, we want people to come forward and be tested; that is still, I assume, where society is, and not yet at the point of mandatory testing. And the continuation of the anonymous test sites for these new tests seems to me to be extraordinarily critical as we proceed. The funding for those, I'll discuss in a moment.

The final issue I'd like to address is what is listed in your agenda as the issue of civil rights, but I'd really like to talk about as civil rights in the guise of social justice.

Social justice, or distributive justice, doesn't get a lot of play in American society although it gets quite a lot of play in discussions in medical ethics. It requires that those who are in need be provided for equally in the allocation of goods and services. There are especially discussions in health care, arguing that access to diagnostic and treatment care, access to services, equally for all, are the chief obligation of the health care system.

The second concept that emerges out of an inquiry into social justice is respect for persons. That principle demands that people not be used for an end which is at odds with their own defined self-interest.

The third concept which is contained in this notion of social justice is that of the equity of burden. It requires that all people bear an equal share of the burden and that none bear a disproportionate share.

Well, how does this all relate to this new possible CDC definition? My concern is that this is a definition

which will again disproportionately affect negatively the poor, IVDUs, and people of color for a number of reasons. It is not clear to me that the use of the definition will require funding for the ability to do the test. It is now possible, I think still in every State, for someone who wants to be tested to receive that testing even if there is a wait, a growing wait in some places, without payment, number one, and anonymously, if they choose, number two.

I am told that the test for T-cell count is much more expensive, and it is by no means certain that public funds will be used to ensure access to that test. If that is the case, then in fact certain people, those who have the ability to pay, will have disproportionate access to this new, "expanded" definition, and those who cannot pay will again be excluded.

But I think there is an even more important concern from my perspective, and that is I stated at the outset that the definition as it now exists seems to me to be used predominantly for surveillance and for benefits. What has happened practically in the old definition is that if you met the criteria, you were presumptively eligible, and the process of gaining access to benefits became commensurately

easier. But under the old definition, if you did not fit squarely within it, you were in fact as the world operates presumptively ineligible, and therefore people who did not fall squarely within the definition found it more difficult to establish their disability--for example, women with disabling PID--and therefore access to benefits and treatment became more difficult.

Since this new proposed definition runs the risk of excluding people who cannot pay for a T-cell count, and excluding people who may not fall squarely within its definition once the T-cell count has been done, I'm concerned that rather than increasing access to care, it may actually raise new barriers to care, especially, again, for women, for adolescents, and for IVDUs.

Federal funding formulas. Federal funding formulas now are keyed in large measure to the CDC definition. But in places like New York City where many of our population who are infected will not be able to pay for a T-cell count if it isn't publicly funded, it may not only work to the detriment of individuals gaining access to care, but it may work to the detriment of those areas that are the most severely affected by the epidemic.

Were we to exclude the poor and those areas with the greatest number of poor, it would be an extraordinary violation of our obligation to social justice. I think we should only consider this new definition if we are certain that it will practically make it easier for people to gain access to services. That, it seems to me, would be the only principle to justify a change in the definition, given that I think it also may be do harm.

Thank you very much.

CHAIRPERSON OSBORN: Thank you very much.

Sallie, welcome again. Good to see you.

MS. PERRYMAN: Good morning.

First, thank you for the opportunity to testify in front of you. I am going to piggyback on a lot of what you've already heard, so I'm going to be brief, or at least attempt to be--I always wonder when I say that what really will happen.

VICE CHAIRMAN ROGERS: We'll help you with that, Sallie.

MS. PERRYMAN: Thank you. I'm sure you will.

CHAIRPERSON OSBORN: I know the feeling.

MS. PERRYMAN: I need to go on record saying that

I'm not representing the AIDS Institute per se, that I'm here as a person living with HIV infection and also, I am very concerned about this CDC definition. One reason is that I am a widow, and my husband was HIV-infected, and he died in 1986 before the definition was changed, and one of the opportunistic infections he had at that time was wasting, and it was included in 1987. He was ineligible for access to care through Social Security. I see that pattern repeating itself, and I think it is very important that we stay focused on the fact that behind all the discussions and all the background information and all the science that we put on the table here, there are people involved. And those people are people who are women, those are people who are poor, those are people who are addicted, and they are not at the table, and they are also people of color.

Since I at some time have represented three out of those four categories, you have to know that I take this very personally. I can't help it. History has documented disparity in treatment for people of color and for women. We also have to realize that that reality still exists, and no matter how much we theoretically or try to set up formulas to count more people, in essence what is happening with this

definition is those same people will be undercounted, and I'll go on and explain that a little bit more.

The way they will be undercounted is that because before someone can take a CD4 test, they already have to access care. We always try to not couple the fact that we are dealing with the surveillance definition with the fact of how importance that is for access to care. Our system is so interwoven that we can't make a clear distinction that will give us a formula that will have us do one without hindering us on the other side. And that is what we need to be very cognizant of.

In fact, there will be no more inclusion. There will be a different way of defining the people who are already in care, so that you'll have greater numbers, but it will not include those people that you haven't included already, and that's the major point.

It will also kind of warn the health care population and the science population that they're going to have this many more people coming into care and kind of move our system toward setting up--if they can, and in a lot of instances, they are just not capable of doing that--setting up ways of making provision for people who are already counted. It

still will not include those people who are on the edge that have not been counted. And we still won't be ready for the onslaught of people to be served.

We talk about early intervention, and I personally don't see how that is happening. Right now, physicians are suggesting early intervention at a level of 500 T-cells and not 200. So if we're going to set a standard where we're going to include people at 200, where now the standard in medical practice is 500, how is that early intervention? I don't understand that. And who is the early intervention for? Automatically, by setting up that premise, if those people who are undercounted are allowed or get access, you're still setting a level that's less than what is already currently being established. So those are problematic areas for me.

And bottom line, how will the change in definition--and again, it's a problem of social justice--but how will that definition change the minds of those physicians who already don't want to see addicted populations, who already don't want to see people with AIDS. We're talking about social issues and trying to find a medical and scientific resolve for things that people have in their hearts and minds

There is discrimination--in 1989 in New York State, one-third of the discrimination cases were against health care providers who didn't want to service people with AIDS. Now, if that's the case, and we give them a T-cell count to use as a way to circumvent an HIV testing mechanism, what are we doing? Unless we know that there is enough human concern--because I don't know what else to call it--for people to respond in a positive way--and we cannot guarantee that--then CD4 testing is a back door to discriminate against people. And anecdotal situations already exist where that's being done.

In addition to that, many doctors in New York City now are not taking Medicaid. So what's going to happen to those people who have to depend on one or two CD tests to get a diagnosis, and the doctor is not taking Medicaid? I see the need for a definition change. I don't know how, and I don't know how to begin to suggest that be done. But I also see issues that are real life and pragmatic as to how to put that into effect. And if you neglect those, then we really have a problem.

As I said, all this is embodied in me in terms of being part of three out of four of those groups, so you'll

have to bear with me if I sound a little critical.

Our health care system is overburdened in New York State, and the onslaught of additional numbers of people--we have to resolve that.

The restricting of the definition will not alter these confidentiality issues, and it will not alter the discrimination issues. And it won't include the additional people we need to include, and it won't make preparations for those people.

Those are the issues. Now, I realize that we're talking about two different issues. One is access to care. But we're not really because one is predicated on the other. I know we're supposed to be talking about two different issues, but there is no way that we can separate them, and if we think we can, we're doing an injustice to people, and people who need the services the most.

I said I'd be brief, and I was.

Thank you.

CHAIRPERSON OSBORN: Brief and powerful. Thank you.

David, please.

MR. HANSELL: I also appreciate the opportunity to be here today. I think you have copies of a written statement

from me, and in the interest of time I'll try to highlight certain parts of it.

I think that there is a very difficult Catch-22 underlying this whole discussion, and Sallie just alluded to it. As Dr. Berkelman acknowledged yesterday, good surveillance depends upon access to care because any reporting system is clinically-based, any good reporting system, and requires access to the diagnostic service that gives rise to reportable information.

But conversely, access to care is dependent upon good surveillance because you can't target services to provide care unless you know where the need is, how great the need is, and who it is that is affected. That is, I think, a very difficult conundrum that makes this a difficult problem.

But I think it is an enormous leap of faith to assume that a simple change that in theory will add 50 to as much as 300 percent more people to the AIDS definition, the AIDS rolls, will actually do that in the real world. I don't think one can reasonably expect that a surveillance change will magically solve the access problems that are now keeping those same people out of the care system.

But query: Even if we only pick up some of those

people and get some of those people into care, isn't that better than nothing? And while I appreciate the appeal of that argument, I think the answer is no.

I think the answer is no because the proposed new definition would systematically exclude the same people who are currently left out of the system.

I think the answer is no because the new definition would systematically disadvantage the same areas of the country that are already medically underserved.

I think the answer is no because the proposed new definition would result in a weakening of the confidentiality protections in ways that have already been shown to keep people away from the counseling and testing system that is the gateway to care for most people.

I think the answer is now because the new definition as proposed would almost certainly result in a decoupling of diagnosis from presumptive eligibility for Social Security benefits, as Nancy said, and Medicaid, and hence would actually result in delays in access to treatment.

And I think the answer is no because the proposed definition if it were adopted would retard efforts to modify the definition in a way that would actually reflect the full

range of clinical manifestations of HIV among all populations. So I don't think the argument that this may be not perfect but better than nothing doesn't really hold up because of the dangers and the down sides that would be associated with it.

Not only is the CDC proposal faulty as a surveillance tool, but serious problems of confidentiality and discrimination could well result from using a diagnostic procedure in this case to define a condition reportable under the public health laws.

CD4 test results do not enjoy the confidentiality protections which many States have enacted for HIV antibody test results. Specifically, counseling and testing protocols, which provide for informed consent and create a mechanism to educate both the HIV-positive and the HIV-negative do not apply to CD4 tests in New York and, we believe, virtually all other States.

If there is any benefit to the proposed revision, it is the potential highlighting of CD4 counts as a trigger for early intervention therapy. Yet that potential would be undermined by the lack of accompanying counseling requirements and by the removal of the reporting obligation from the clinical setting to the laboratory.

The impact of case counts on funding formulae create an incentive for States to erode protections for confidentiality of those with HIV, moving inexorably toward lab-based reporting and even mandatory reporting. Already in New York, public health officials are discussing procedures for matching lists provided by labs of people whose CD4 test results are under 200, with physicians' records of their patients' HIV antibody status.

Obviously, this cannot be done anonymously, and it almost certainly cannot be done without serious intrusions upon confidentiality protections.

In addition, the proposal would encourage the use of CD4 test results as a surrogate for HIV antibody status, circumventing the entire structure of informed consent, pre and post test counseling and confidentiality. For those of us at GMAC and other service organizations serving clients for whom discrimination, confidentiality, and access to appropriate care are crucial concerns, this would be a very grim scenario.

Furthermore, the new definition would create no improvement in access to care for the HIV-infected. Probably the only benefit to an HIV-infected individual of receiving

an AIDS diagnosis now is eligibility for income entitlements and public pay or medical coverage. But this link is not unbreakable, and a huge increase in the numbers of people eligible via diagnosis will almost certainly force an uncoupling of benefits from diagnosis at Federal, State and local levels.

To date, presumptive eligibility has meant that anyone with an AIDS diagnosis who also met income eligibility standards was immediately eligible for benefits. Destroying presumptive eligibility based on an AIDS diagnosis, which is a likely consequence of the CDC's proposal, would subject seriously ill individuals to the lengthy and difficult functional disability determination process, a process in which those who do not have knowledgeable private physicians are at an extreme disadvantage and which can take months to complete. It would also mean substantial delays in their ability to qualify for Medicaid and potentially life-sustaining medical care.

Finally, the proposed revision would also have a detrimental psychological impact. Appropriate counseling, particularly emotional support and mental health services, does not necessarily accompany CD4 testing. Similarly, no

attention has been paid to the thousands of people who will in effect receive their AIDS diagnosis in the newspaper when the new definition takes effect, and their CD4 level converts them from HIV-ill to AIDS.

If CDC continues to move toward this change on its present timetable, the results could be disastrous. No improvement in surveillance, myriad problems of access, confidentiality and discrimination. The CDC has repeatedly refused to respond to these concerns about the case definition. They have refused to convene meetings at which they could learn the views of all concerned with the definition, including clinicians and members of affected communities. They have refused to respond to letters seeking open dialogue on the issue, and they are barreling forward with this proposal without seeking consultation or comment.

I very much hope that the Commission will try to slow down this juggernaut. CDC must call for comprehensive public comments both on the impact of this proposed change and on what changes would best serve all of the purposes for which the definition is used. And the public comment period must be expanded not just over Christmas, but for a sufficient amount of time to allow all of the issues that we have raised

in these hearings to be fully addressed.

Thank you.

CHAIRPERSON OSBORN: Thank you very much, all three of you, for very thoughtful testimony.

Let's take some time now for the Commissioners to interact. Harlon and then Don.

MR. DALTON: I have a couple questions. The first is for Ms. Dubler. I'm trying to understand just how far your argument goes. I thought I heard Ms. Perryman and Mr. Hansell say that the new definition would not include any of the folks who aren't included under the current definition.

I thought I heard you say something stronger, and it's something I didn't quite understand--namely, that the new definition would make things worse in terms of the poor and people of color because of inability for financial and access to care reasons to get CD4 tests.

The reason I don't understand that is because currently an AIDS diagnosis isn't simply a matter of having an HIV antibody test, which one can get anonymously, but in addition having some clinical marker, opportunistic infection, or whatever, and that requires access to care, and that requires money.

So it seems to me that for your argument to hold true, you must be saying that it is more difficult to get a CD4 test than it is to get a diagnosis of PCP or Kaposi's or wasting syndrome or whatever. And what basis is there for that?

MS. DUBLER: New York City in 1991. I just think that--

MR. DALTON: I'm sorry. I didn't understand that.

MS. DUBLER: New York City. How I see services now operating presently in New York and what I'm concerned about. What I'm concerned about is people now have pretty easy access to HIV testing, although they have tremendous--

MR. DALTON: But that's necessary under either definition, the current definition or the proposed. That's just step one.

MS. DUBLER: It is step one. The problems with access to care will remain the same, I would assume, unless we put more money into services, but the fact that people will not have access, based on lack of income, to this new test may place them at a disadvantage for gaining access to care.

In the perverse way services get distributed,

having an HIV-positive diagnosis is one of the ways of being able to gain access to care. If we come to rely in the same way on T-cell counts, which will be less available, I think it may actually limit access.

MR. DALTON: My question is will T-cell counts be less available than the kind of care that proves that one has PCP or--because people are obviously being diagnosed with PCP in the morgue, but you don't get an AIDS diagnosis for simply having an HIV test.

MS. DUBLER: Of course.

MR. DALTON: So if we're comparing the current CDC test for AIDS with the proposed test for AIDS, my question is whether you are suggesting that the proposed test, that poor people and people of color and women are less likely to qualify for an AIDS diagnosis.

MS. DUBLER: It may be I'm off on the wrong track, but my assumption merely is that now the diagnosis is a combination of the test on the one hand and the clinical findings on the other. If one of the tests becomes harder for certain people to get, it is merely my assumption that it will cut down on access.

I have no proof for it.

MR. DALTON: No, it's not a proof question. It seems to me, I guess--and I'll get off this then--it seems to me you are comparing both in terms of cost, access and in terms of confidentiality, an HIV test on the one hand with the CD4 test on the other hand. And it seems to me that the proper comparison is an HIV test plus care that results in evidence of an opportunistic infection or carcinoma or whatever on the one hand, versus HIV test plus CD4 test on the other.

MS. DUBLER: But do remember, as I understand it, under the CDC definition, a T-cell count of less than 200 is one of the definitions of AIDS. Is that not correct? Since that is correct, that requires access to that test, and it is precisely that access that I'm afraid will be limited on economic grounds.

MR. DES JARLAIS: I think Harlon's point is that a diagnosis of PCP requires access to care, too.

MR. DALTON: Yes. That's my point, quite simply.

MR. JOHNSON: If I could interject in this context, the difference is if a low-income person, for example, is ill with PCP, he or she can go to an emergency room, and the emergency room presumably will recognize the illness and

diagnose the person as PCP.

If a low-income person is HIV-positive, he or she cannot go to the emergency room and say, "I am here for my CD4 test." So there is going to be a very real difference in the introduction to the health care system. If you are ill, if nothing else, you can go to the emergency room. If you are just HIV-positive, you can't go to the emergency room and say, as I said, "I am here for my regular routine CD4 test."

MR. DALTON: Actually, that's very useful.

MS. DUBLER: Thanks, Ron.

MR. DALTON: Thank you. I take it in fact it's also easier to document wasting syndrome, for example, and to do so cheaply than to get a CD4 test. But thank you--you can speak out of turn any time.

The other question is for everyone. You call talked in different ways about concerns about confidentiality, and I am truly concerned about that as well. In particular, I guess Mr. Hansell made the explicit point that the problem with the CD4 test is that in New York and presumably in other States, they aren't agreeing with some of the confidentiality protections that HIV tests are--that informed consent may not apply to them or does not apply, apparently, in New York;

that pre and post test counseling is not required.

I guess my question is isn't that a problem whether there's a new definition or not, that is, insofar as CD4 tests are used for any reason, including for early intervention reasons, as you point out Ms. Perryman--isn't it important to attach to them the same confidentiality and other protections? Isn't there the same invitation, as Ms. Perryman pointed out, to physicians who don't want and treat to go ahead and take a CD4 test if you can get away with that even in a State where you can't get away with an unconsented HIV test; if you can do a CD4 test and then decide you don't want to treat that patient, that's a problem.

So isn't this something that States should be dealing with quite apart from the new definition of AIDS?

MR. HANSELL: I think the answer is yes, but I think there are a couple of reasons why it becomes a greater problem. Just a little background. New York's confidentiality law--and I think this is the format of most laws in the country--has two components. One is the protocol around HIV antibody testing, which requires pre and post test counseling and informed consent in the testing setting; and then protection for the information that gets created as a

result of the test, or any other HIV-related information about a person in a medical file. CD4 counts would certainly be covered by the latter part of this; that is, if they are in a physician's record, they would be covered as confidential information. It is not, at least by our interpretation, covered by the first part, which is the testing protocol, which is fairly specific to antibody testing, which is a problem.

The reasons why I think the problem becomes worse is that there is a strong tendency--to the extent that you highlight the CD4 test as a diagnostic indicator, there is a tendency to use that in lieu of HIV antibody testing. We have already seen that, for example, being done by insurance companies in California, the only State that still has a prohibition on insurers using HIV antibody tests as a condition of insurability for health insurance, and as a result a number of companies have started using T-cell tests instead.

MR. DALTON: But that's my point. So my point is why shouldn't there be pre and post test counseling--

MR. HANSELL: There should be.

MR. DALTON: --with respect to CD4 test already,

following your logic.

MR. HANSELL: Yes, there should be. I'm just saying it's more likely that will happen on an increasing basis if we move in this direction.

The other reason I think is that if this were to happen, as I said is already being discussed in New York, it creates tremendous pressure to move from clinically-based reporting to lab-based reporting, and that creates all kinds of opportunities for confidentiality breaches.

MR. DALTON: Yes, let me follow up on that because I'm the next State over, and experiencing the same situation of there being a lot of high-level conversation about moving toward lab-based reporting.

We asked questions yesterday of laboratory scientists about whether it is possible to do lab-based reporting in a confidential manner, and they made a reasonably convincing argument that it is quite possible, at least from the lab's point of view; that in States like Oregon, physicians if they choose to can send in blood samples with their name and "X10", let's say; the lab will report that "X10's" CD4 count is 200 or whatever, will notify the health department, and the health department will then call the physician and

say, "You have a Patient X10 with a CD4 count of 200"--or, let's say 100--"Is this AIDS reportable?" If the physician says no, that's the end of it. Now, maybe that's not the story. Are you imagining a different scenario, or are you saying that that scenario also concerns you in terms of breaches of confidentiality?

MR. HANSELL: What I understand is under discussion at least in New York City, from officials in the Department of Health, is something like that, which is that the information from the lab would be reported to the health department, the T-cell result, together with the name of the patient and the name of the physician ordering the test.

MR. DALTON: With the name of the patient?

MR. HANSELL: Yes, with the name of the patient and the name of the physician ordering the test. The health department would then contact the physician and request the HIV status of that patient, and that would be done without the patient having the knowledge or the opportunity to consent or not consent to the release of that information by the physician.

So I think that changes the relationship between the patient and the physician in a fairly significant way.

MR. DALTON: I would absolutely agree with you. I guess my question is is it your understanding that that situation that you are describing is required in order to do CD4 testing, or is that simply something that folks in New York State's health department are planning to do because they would like to get at the names?

MR. HANSELL: All I can tell you is that Dr. Polly Thomas, who is the chief epidemiologist in the New York City health department said she felt that was the only way they could accomplish reporting under the new definition.

MR. DALTON: Thank you.

CHAIRPERSON OSBORN: Don?

MR. DES JARLAIS: It is their present policy in New York to do CD4 testing under just code numbers, and I would not expect that policy to change. I certainly would expect the health department to try to do active followup to the physician to find out if it is a reportable case of AIDS, but I would not expect the present policy of doing testing under code numbers to change.

Actually, I wanted to ask both Nancy and David about--it seemed like you were comparing the HIV testing confidentiality procedures to the proposed new definition.

Again, similar to Harlon, I would think that the applicable law would be around the diagnosis of AIDS; that right now that information that someone has a diagnosis of AIDS is protected by New York law and I assume by laws of other States, and would not that law also then apply to a CD4 test under 200, that that would have the same confidentiality protections as a KS diagnosis or a PCP diagnosis or any of the current ways of defining AIDS?

MS. PERRYMAN: I'm going to respond even though it wasn't asked to me. CDC testing is used for other than AIDS diagnosis, and that's where the problem is. If someone has a low immune system or sugar diabetes or any of the other illnesses that the T-cell count is used for, that's where the problem comes in. It's not a specific AIDS-related test, so it may not be covered under the law.

My interpretation in doing confidentiality violations is it would be, but the two attorneys on either side of me disagree with that.

MR. DES JARLAIS: I'm asking those attorneys: Right now, if someone were diagnosed with AIDS under the new definition, wouldn't they have the same legal protections as someone currently diagnosed with AIDS under the current

definition? I mean, is there some change in the law that would say that it wouldn't apply to the new definition but would still only apply to the old definition?

MS. DUBLER: I would have to give a resounding "Maybe" because at least in New York, the definition is very integrated. The definition is dependent upon, in the law as it is now written, the relationship between clinical findings and an HIV test, and the law is very focused on the antibody test. And it might, but it equally might not. Would you not say, David?

MR. HANSELL: I think that's right, and as I said before, the other prong of the confidentiality law, which is this protocol surrounding testing itself, certainly does not, I think, cover T-cell tests. That is, there is no requirement for informed consent or counseling above and beyond any other lab test that a physician would order for a patient. But if we move ahead with this, obviously, the implications of the T-cell test are different.

DR. DES JARLAIS: Well, are you saying, then, that the procedures for informed consent for HIV testing should also apply to a biopsy for KS or a PCP diagnosis?

MR. HANSELL: Well, I think symptomatic conditions

and diagnosing an asymptomatic condition are very different. I mean, when you are presenting a patient with for the first time any indication that they may be ill with something like HIV infection, there is a different obligation to counsel that patient around those issues than there is when a patient comes in actively ill and knows something is wrong and wants to know what it is.

MS. DUBLER: I think that the protections for pre and post test counseling were very effective by the impact of the diagnosis on the particular person which, as David said, is just not an issue when someone is clinically ill, but is very much the same issue if someone is asymptomatic and going for a T-cell count for the purpose of using that as a surrogate marker, which is increasingly the way it is used.

CHAIRPERSON OSBORN: Did you want to make a comment, Dr. Berkelman?

DR. BERKELMAN: Yes. I'm going to confine my remarks to surveillance, and every State does have a law or regulation that does penalize anyone in terms of the confidentiality provision. These confidentiality laws do hold for any diagnosis of AIDS, whether it is the new definition or the old definition. They do hold for that, and people can be

brought up on charges if they release that or disclose that inadvertently or intentionally out of the surveillance offices around the country and the health departments. We have been through this obviously a lot in the last ten years, ensuring that those penalties are there.

So I think that the issues I'm hearing about CD4 counts really are related not so much to surveillance, but I agree with you, more to the issue of the use of it by an insurance company or someone else.

I also want to say that no CD4 test in and of itself will count as an AIDS case report. The health care provider does need to submit the case report form, and it does need to go through the provider system, the same way that it does now. This is not something, even if--and I know Polly Thomas is talking about using laboratory reports as a prompter to go to the physician. But if that physician says, "No, this is not an AIDS case; I do not choose report on this case; it is not an AIDS case report form," then that's it.

A CD4 count in and of itself is not an AIDS case report form, and the laboratory does not have the kind of information from which you could complete an AIDS case report form.

Even the HIV linkage--I have heard also the scenario what if an HIV reporting was linked with the CD4 list--again, the laboratories do not have that information to complete the details we ask for on the case report form, and the providers need to consent and cooperate to get that report in.

MR. HANSELL: Yes, and I think the question is--it clearly requires a linkage between the HIV result and the CD4 result to create a reportable case--the question is what role will health departments be playing in creating that linkage. That's the concern.

CHAIRPERSON OSBORN: We started a little late, so I do want to let this discussion which is quite rich going a bit, but I hope you can help me by being concise both in questioning and answering.

Dr. Konigsberg and Don Goldman have indicated their interest.

DR. KONIGSBERG: "Good ethics begins with good facts" is an interesting phrase, and one I think I'll remember for a while--one of those take-home things--and what I think we've been trying to do is to sort out the facts for the last two days, and I don't know whether I'm getting more confused

or less confused; I'm not really sure.

There are some troubling phrases, and I think Dr. Berkelman tried to clear this up a little bit. One of the phrases I heard earlier this morning was "shifting to a new test" and I also wrote down "circumventing HIV test"--I didn't put quotes around that, but somebody said that, and I think it's a similar thing. I don't think that's what the definition is all about, but if there is some fear about that, I think the Commission certainly needs to be concerned about it and comment.

Again, I get a little out of my field when I get into the clinical areas, but I can't help it. An AIDS diagnosis just cannot be made on the basis of a CD4 cell count under 200. If there is not evidence of HIV infection, it does not make AIDS, and it has been pointed out there's got to be more to it than that, although I will admit when you look at the CDC definition, the part that goes under 200, that isn't clear, Ruth. That may be something that perhaps ought to be cleared up about the clinical judgment aspect, that a CD4 cell count is part of a diagnostic workup, and unless I've missed something, we are not talking about a screening test here. It is a test that relates to the immune

system that is part of a diagnostic workup. Now, is there potential for misuse? I think the panelists this morning, and some yesterday afternoon, feel that there is, and that's something we ought to be concerned about.

But what I want to be sure of is that we're clear on what the definition is all about, the difference between surveillance and diagnosis, and the fact that the diagnosis is still the point. I think, Don, that's part of what you were trying to say.

Maybe there does need to be some things done with the laws in the State for confidentiality, and if there are abuses of the CD4 cell count as a surrogate marker, I would have some concerns. But I want to make sure that we do have good facts along with the good ethics, and somehow I'm just not clear what we're getting at at this point.

CHAIRPERSON OSBORN: Don Goldman.

MR. GOLDMAN: Thank you.

My experience and understanding is that most--and obviously there are exceptions--but most persons who are infected with HIV who are under care and do have access to some system do in fact receive T4 tests periodically. It may not be every six months, but most clinics that treat people

with HIV disease try their best within their limited resources to follow the CDC recommendations as to what the periodic and what the general guidelines in the medical community are as to what the T4 testing is.

I think just as convincing an argument could be made, given the fact that numbers of AIDS cases may drive economics, that in fact the provision of having the T4 test as part of a definition could well improve care by driving agencies and institutions and communities to increase their numbers by making sure there is adequate funding to provide such testing and doing it on an appropriate periodic basis.

So the argument could be made that way as well, and I'm not sure whether or not the case is convincing that there is any likely lowering of results or an access problem in that sense, because if the person shows up at the hospital, right now, the definition is based upon PCP or KS or some other opportunistic diseases which require access to care as well. So it's not going to make a difference one way or the other. And it's true you can't show up at the hospital and say "I want a T4 test," but if you go to a clinic, and you are part of a clinic, sometime during the year you are likely to get one.

MS. PERRYMAN: But if you're part of a clinic, and if you go to a clinic--

MR. GOLDMAN: But if you're not part of a clinic, you're never going to get diagnosed anyway.

MS. PERRYMAN: And that's what we're talking about. That's exactly what we're talking about. We're talking about the people who are undercounted because they are not a part of those systems.

MR. GOLDMAN: But that's a problem that we're going to have to get them into the system; it's not a problem of the definitional change, it's not going to have an impact--if somebody is not part of the system, and they're not diagnosed with pneomocystis pneumonia, and they're not diagnosed with KS, and they're not getting a T4 test, and they're not getting an HIV test, they're not going to get diagnosed one way or the other.

MS. PERRYMAN: But what we're saying with the definition is that those people who are a part of the system will be counted, and those people who aren't, where the problem lies, won't be.

MR. GOLDMAN: But the change in the definition isn't designed to solve that problem.

DR. KONIGSBERG: Right.

MS. PERRYMAN: That's true. And that's the problem. That is the nail-on-the-head.

DR. KONIGSBERG: That's a problem, but it's a different problem, one that the Commission has spent a great deal of time over the past two-plus years, which I know that Dr. Osborn also brought up with the President yesterday, the problem of access to care. It is extremely serious.

But I'm concerned that if we halt progress on trying to make the surveillance system more effective and more useful, while we're waiting to fix the health care system, we're going to wait a long time, plus the fact that this could conceivably contribute to trying to document the problem a little better. I don't know that I would share Don's optimism that it would actually lead to that, but I don't believe it would make it worse. And again, we're not going to fix access by not changing the definition.

MR. DALTON: But there is a very important timing question here, and I just want to be real explicit about this. That is, the case definition is tied to any number of other things. It is currently tied to entitlements. It may not be tied to entitlements, and we did hear what you said; I

understand that having a presumptive diagnosis of AIDS is a really important thing for people who want to get Medicaid or SSI or SSDI, and if we have a definitional system that doesn't allow for presumptive diagnosis, where you get your check right away while they are still investigating, it makes a real difference to people on the ground.

So the definition is currently tied to entitlements, it is tied to care, it is tied to reporting and all of these things, and the question is should CDC move forward with the change in definition without examining all those other connections, and if we assume that this definition will not be changed every year or every six months, then should the Commission take the position that before making this change, some other things should be ironed out or sorted out first. It seems to me that's what we've been hearing from panelists for the last couple of days.

In connection with that, I wanted to ask Dr. Berkelman, since you've had the temerity to sit around this table again this morning--one of the things that Mr. Hansell asked was that the public comment period be extended so that you could have conversations with people like him and Ms. Perryman and Ms. Dubler and Mr. Johnson and the others, and

they can hear from you. I notice you took this opportunity to talk to them about lab testing, to try to clarify what may be misapprehensions; shouldn't you also have the opportunity to hear from them? Is it possible and appropriate to extend the comment period and invite the kind of people who are sitting here and back there to engage in conversations around that?

DR. BERKELMAN: It is certainly something we can consider. The public comment is open now, and we certainly are open to listening now, and whether it needs to be extended is something we can consider as well.

CHAIRPERSON OSBORN: I think to focus Harlon's question a little bit, because I wanted to get back to that, too, I think what people are saying--and I'm sorry I missed some of the rich testimony yesterday--is that this is really even more complicated than we thought, which may be some of your reaction, too, as this kind of discussion goes on.

The simplest public comment for the moment would be to extend the comment period and give this very deep attention of this sort, or start working with the transcript of this meeting and formulate a way to talk some of these things through and resolve anxieties, as you have done in some

instances, and so on.

Is that a feasible form of a public comment, because in terms of the complexity of the issue, to put together an exhaustive brief or synopsis of some very important and complex testimony--I think we're all thinking aloud together here, and that is very important. That's what this Commission is supposed to do, and I'm pleased that we're doing it. But I am hoping that your answer would be yes, that actually could be an appropriate response, that the Commission says hey, this is even more complicated than we thought it was when we set up the hearing, and we would like to urge you to slow it down.

Is that a doable thing?

DR. BERKELMAN: Oh, I think it is certainly a feasible comment to make to us, and one that we'll consider.

CHAIRPERSON OSBORN: Good. Okay. Eunice, Don Des Jarlais and Don Goldman--and then I think we must move on. We're getting behind.

MS. DIAZ: I guess I've been very sensitive yesterday and today, too, listening to some of the testimony that links our concern for service delivery or entitlement types of programs with the changes in the definition. I just

wanted to say that the HRSA AIDS Advisory Council, now under some new leadership due to changes in people that have moved and others coming in, has looked at the need of discussing that at our next meeting, which will be either January or February, but looking at the specific implications or public perception of how this change in definition may affect HRSA-funded service programs.

Maybe Dr. Bowen in his upcoming testimony to us will discuss this, but it was an item of real concern to the members of the advisory committee, and we're hoping to devote a great portion of our meeting time to discussion on this issue in terms of service delivery, which is what basically what many of you have called for.

So I want to tell you that we are sensitive to that as a group of people advising HRSA for the service portion of it.

CHAIRPERSON OSBORN: Quickly, Don Des Jarlais, Don Goldman.

DR. DES JARLAIS: This is more to Ruth. The reason the Commission decided to hold hearings on the new definition is that we felt there was not an adequate public forum previously for discussing. Previously there was the OTA

meeting, which was a good scientific meeting but obviously not an adequate public forum.

When Bill Roper testified before us a month ago, he mentioned that the most important asset of the CDC is the trust and confidence of the public health community as a whole--it's not its budget or anything like that. This new definition and the process by which it could be adopted is really bringing up that question of the extent to which people affected by the HIV virus trust the CDC, so I think the process by which the CDC adopts a new definition is going to be much, much more important than the science it is using to revise the definition.

I would agree that the science is really pretty clear in terms of a need to revise a definition that was based on studies of gay men eight years ago, but the process by which CDC adopts a new definition is going to either increase dramatically or dramatically decrease its trust by the people affected by this, the whole AIDS epidemic. And he really needs to know that the process and the communication with people affected by the virus is going to be much more important than the science in terms of CDC's credibility on a new definition.

DR. BERKELMAN: I appreciate those comments; I really do. And I think that we all recognize that if we're going to have good reporting, good surveillance, we have to have trust, and if that trust is not there with the public health community, the surveillance will not accomplish what it is trying to accomplish.

So I do look forward to discussions with all of you on the panel and anyone else who is interested.

CHAIRPERSON OSBORN: A quick last question--Don Goldman.

MR. GOLDMAN: It's not really a question. Just in keeping with what we have said hear, Mr. Hansell, I'm happy that you mentioned the psychosocial impact on people of learning their new diagnosis via the newspaper. I'm also concerned about them even learning their new diagnosis and how they are learning it, even at their physician level, or where they know their CD4 test under those circumstances. I mentioned yesterday and I just want to repeat again today--at the end of the day yesterday, there weren't too many people here--that I think the CDC ought to be preparing guidance and resource materials for caregivers at both medical facilities and community-based organizations to assist them in ameliorat-

ing the potential psychosocial side effects and sequelae of the change in definition on that very population that you're referring to.

I think further--and although none of you mentioned it--that the ADA, which is an important bulwark in our fight against discrimination, does not become effective until for the most part, most of its sections, until June or July of 1992. And as I understand the proposed CDC definition, change is not to become effective until April 1, which precedes the effective date of the ADA by a number of months.

In order to give the CDC time to prepare and distribute and to prepare caregivers for the change in definition and to ensure that the change of definition does not precede the effective date of the ADA, so that discrimination provisions, to the extent that the ADA provides them, are in place when that change in definition takes place, it would seem to me wise, at least, if you are going to change the definition--and I think a good case has been made by the CDC for such changes on epidemiological grounds--that at least that change ought not occur until sometime over the summer after the ADA is effective and after somebody has some opportunity to prepare some guidance and resource materials

for caregivers to assist in some of those problems that we have identified.

CHAIRPERSON OSBORN: Thanks, Don. That's helpful. And I think we will be continuing some of these themes anyway because our next panel--and thank you, and please stay with us; we very much enjoy the opportunity to take full advantage of the rich resources that you all represent--our next panel will be talking about implications for care and services.

In this order: Dr. Stephen Bowen, Director of the Bureau of Health Resources Development, Health Resources and Services Administration; Theresa McGovern, Project Director of the MFY HIV Project, New York; Laura Thomas, ACT UP San Francisco, the San Francisco HIV Services Planning Council; Ted Holloway, an old friend of the Commission and our host at one very important time, who is District Health Director, Southeast Health Unit in Waycross, Georgia; and Ron Johnson, an old friend, Executive Director of the Minority Task Force on AIDS in New York. Welcome to you all, and if you could all give us your succinct opening comments, as you see, the Commissioners are not shy about interacting, and it is particularly rich for us if we can do that. So thanks for coming, and Dr. Bowen, if you'd like to start, please.

DR. BOWEN: Thank you very much, Dr. Osborn and members of the Commission, for the opportunity to give comments from the perspective of HRSA. We administer Titles I, II and III of the Ryan White Care Act. My bureau specifically administers Titles I and II. So that much of what I am going to say has to do with the impact on these particular programs, but the wealth of the discussion that was going on certainly will lead to discussion of client interactions as well.

I guess the first thing I'd like to say is that certainly the new guidelines will clarify and simplify the process by which clinicians and other health care providers objectively evaluate and classify persons with HIV infection for the diagnosis, and to the extent that simplicity is better, this is an improvement.

Obviously, one of the major impacts administratively that this is going to have on the Health Resources and Services Administration and the programs that we administer is that a larger number of people will be having an AIDS diagnosis sooner. There may be some change in the distribution of formula funds to States, but the most dramatic impact will be increasing the number of cities that are eligible for

Title I funds at a rapid rate.

The Congress, as you know, as put 2000 as the kind of magic number for cumulative cases above which cities are eligible for direct funding under Title I of the Ryan White CARE Act. Currently, there are 18 cities eligible. We anticipate that with no change in case definition for 1993, between three and nine--most probable number probably four or five--will become eligible without the change in case definition. The postponement of the proposed time for implementation means that we're essentially working up to the end of March of next year with the old case definition for that purpose. So it's not going to have any impact at all in terms of the number of cities eligible through next March 30th, and we will probably then have an approximate number of Title I cities eligible, in the range of 23.

Then, depending on which numbers you think are the most likely, we could end up with as many as 32 to 41 total cities by the following year. That's because there are now five cities that have more than 1,000 cases, there are nine cities additional that have more than 800 cases, and there are another three or four or five that won't make it next year under the old case definition that are currently above

1,500.

So I think it is fair to say that no one can really be positive as to what the number of increase in cases will be. There is variability in terms of the ability of surveillance systems to respond. We'll be moving more toward an outpatient rather than inpatient case surveillance system, and no one really knows how the system is going to respond in terms of the speed with which people are reported and are verified.

So the first and most obvious impact is in terms of the rapid increase in number of cities that are going to be eligible.

Second--

VICE CHAIRMAN ROGERS: I can't resist, Dr. Bowen--to be eligible for what looks like strikingly decreasing funds--and that's not your problem, but as I sit here, I think about that.

DR. BOWEN: I obviously don't know what future funding will be. There was an increase of approximately $30 million in Title I funds in the FY92 budget. The President's budget proposes no increase in 1993, and what the Congress does in a time of tight fiscal situations, we don't know. If

you had a situation with level funding--obviously, I think that's what Dr. Rogers is referring to--if you had a situation with level funding and increasing numbers of cities eligible, you would have cutbacks in the original 16 cities. That would be the inevitable consequence.

Going to an issue related to laboratory testing, since we do know--go ahead, Don.

DR. DES JARLAIS: Just to clarify that point, because it could be potentially important, is the funding based right now on the number of cases, or just whether or not you've reached 2,000?

DR. BOWEN: The 2,000 cumulative cases puts you eligible for Title I funds. And there is no linkage, obviously, of the budget process to that.

DR. DES JARLAIS: Yes, but among those 2,000, is money given out equally because everybody is at 2,000, or is it given out on whether you've got 2,005, which is 20,000.

DR. BOWEN: Fifty percent of the money is allocated on a formula which is based on the total number of cases and the population. So New York City gets substantially more than San Diego. The differences in order of magnitude were in the range of $850,000 to San Diego and about $15-some-odd

million to New York City on the formulate part. We're just talking about the 15 percent that's allocated by formula now. The rest of the money is allocated on the basis of a competitive application that is independently reviewed by an outside review panel of non-Federal experts in HIV-related care. The three factors that determine how much a city gets from that 50 percent of the money under Title I are, obviously, the level of appropriation, the review panel scores, and the original formula amount. We adjust the amount that each city gets up or down from that on the basis of their competitive application score.

The Congress defined what the need factor was by the formula, so we've chosen to take that as the basis and adjust it up or down based on the quality of the application as judged not by us, but by the review panel.

Any other comments on that?

Okay. My other comments have to do with what funds get used for, and some things about who may be eligible for service and the increased demand for services.

One of the things that I think inevitably will happen as a result of moving toward a more laboratory-based definition and a test that is expensive is that some of the

scarce prevention and care dollars will be used for testing. That is something that we have to take into account. It is not necessarily bad or good, but it is going to be a fact.

An important issue at the level of client service delivery is the increasing number of people who now will inevitably want additional care. Having a diagnosis of AIDS is a different thing than having a diagnosis of HIV infection. People with AIDS use more services, they come more often, they are put to the head of lines in scarce resource service delivery facilities whether they be primary health care or any of the other kinds of important social and support services that are defined by the Congress under the Ryan White CARE Act. People who are sicker and whose service providers perceive them as being sicker inevitably are put at the head of the line. This results in kind of a triage process and in a way kind of at least sets aside or tends to dampen the early intervention impact of the Ryan White CARE Act.

The intent of the Congress is to get more people into care earlier and to the extent that care is limited and resources are limited and the service providers don't have enough clinicians and other health care providers and social and support service providers to take care of the people,

people who are sick will inevitably get care first, and the early intervention aspect of this which can potentially prolong people's lives and reduce their immune system deterioration may be compromised. So I think that is one thing that needs to be considered.

There is also likely to be--at least to the extent that outreach efforts which are mandated by the Ryan White CARE Act--to the extent that those are effective, there will be an increasing number of people of low income who are disenfranchised for a variety of reasons either because they are homeless, because they have no insurance, because they don't have previous access to care, which is the target population for care under Ryan White. To the extent that outreach is effective in reaching those people and telling them that early intervention and care is available to them, and to the extent that they find out they have AIDS, there will be an increased number of people in the health care system, which is good, but the ability of the system to respond to that my having adequate resources is under question.

One final comment I'd like to make is that certainly the change in classification system should call more attention

to the epidemic in underserved communities, which I think is a good impact; and lastly, in terms of its impact on the surveillance system, I'm sure other people have made this comment, but to the extent that more people are involved in it, there is some question about increase in lag time in reporting, in the quality of the data that is reported, and the ability of a larger number of people to protect the confidentiality of individuals who are now going to be reported by a larger number of people who perhaps have not had the kind of training that they have had in, for example, hospital infection control people and physicians. I think there is going to have to be a considerable training and teaching responsibility as we move toward a more outpatient-based reporting system.

Thank you very much.

CHAIRPERSON OSBORN: Thank you, Dr. Bowen.

Theresa McGovern, thank you for being with us.

MS. McGOVERN: Good morning. I'd like to thank the Commission for the opportunity to speak with you today.

The HIV Project where I work provides free civil/legal services and advocacy to poor people with HIV. The majority of our clients are women and/or people of color. I

was invited here today, I believe, because I am lead counsel on SP v. Sullivan, a lawsuit filed in 1990 on behalf of women, i.v. drug users, and low-income people, generally charging DHS and specifically the Social Security Administration with discrimination in the disbursement of disability benefits.

MFY Legal Services began experiencing a deluge several years ago of poor, HIV-infected individuals who were unable to obtain health care, receive an AIDS diagnosis, or even get their HIV-related conditions attended to let alone obtain disability benefits. And when people are denied disability benefits, either at the Federal program or a local program, it is suggested that they get an advocate or an attorney, and that's when people come to our offices.

So I just want to kind of highlight that we are dealing with the people the system is not working for.

I'd like to take a minute now to illustrate what I am alleging here. I've noticed that you've had a lot of testimony about data and a lot of policy testimony, but very few descriptions of what people are actually going through. I realize that these can often be laborious, so I'm going to be brief, but I ask you also to bear with me.

I'd like to begin with "SP" our lead plaintiff in the lawsuit. She came into our office in early 1990. She had applied for SSI in 1989 due to recurrent painful pelvic inflammatory disease, headaches, shortness of breath, weight loss, dizziness. Her medical records showed a history of chronic gynecological conditions, pelvic pain and various other symptoms. Yet all over her emergency room records it read: "HIV-positive, asymptomatic."

Social Security also classified her as asymptomatic. We fought for two years to win her benefits. She had a hearing at which we submitted medical records documenting these conditions. She testified that she was unable to work, in constant pain. She lost the hearing. The judge found her not to be credible. These kinds of gynecological disorders could not, he ruled, support the level of pain which she described.

After another level of appeal, more data from doctors, and another hearing at the end of November of 1991, "SP" was found eligible, two years later. The large portion of these two years were spent homeless.

One can only conclude that to the Federal Government her life must be cheap. It is not, however, cheap to her

children.

Let me also tell you about "MC" who had the following medical history between 1981, when she believed she was infected, and June 1990, when she was finally found eligible, after three attorneys had helped her, for disability benefits, five years after she applied. Eight hospitalizations for pelvic inflammatory disease. Five hospitalizations for carcinoma of the cervix and ovaries. Five bouts of bacterial pneumonia. Recurrent urinary tract infections. Chronic yeast infections. Her records also classified her as HIV-infected and asymptomatic. No medical person even suggested an HIV test for her until 1988. No one certainly administered a T-cell count.

"MC" is dying now. She is lucky she saw any benefits at all before she died.

I will tell you lastly about "JG", who worked up until four days before she died. "JG" was a very proud Puerto Rican woman who took care of her own kids and everyone else's. She was being treated at an infectious disease clinic for PCP. She had been to the clinic one week before she died. She asked on that visit, I believe, about her chronic pelvic pain, heavy menstruation, abnormal gynecologi-

cal symptoms. The physician attending told her that these were not HIV-related, and that the clinic had no gynecological provider anyway. "JG" did not have time to find another doctor or to work up the nerve to question her doctor further about these gynecological conditions.

She died a week later, after waiting hours in an emergency room, of septicemia caused by massive pelvic inflammatory disease. I say again her life must be cheap to the Federal Government.

I and others spent this weekend preparing legal papers to bring eight new plaintiffs into the lawsuit against Social Security, eight more persons whose lives are cheap to the Federal Government. "BL" has a T-cell count of less than 100 since May of 1990. She also had PID, bacterial pneumonia, chronic cervicitis, to name just a few. She learned she was infected in May of 1990. No one bothered to test her or to talk to her about HIV before 1990. No one took a T-cell count. She didn't know PID or bacterial pneumonia could be HIV-related.

I could go on and on and on with case histories of women, poor people, people of color, people with a history of i.v. drug use who have faced years of neglect in this

epidemic, who have had years of these impairments--bacterial pneumonia, PID, pulmonary TB, chronic cervical abnormalities, genital ulcers, endocarditis--and no one has spoken to them about a T-cell test, an HIV test. Their physicians classify them as HIV-positive when they are tested, but asymptomatic.

This has grave consequences for access to entitlements, to housing, for transmission, for longevity of life.

I recently was invited to attend the workshop at the OTA where the CDC presented its reasoning for expanding the definition to include the T-cell count rather than add the various, very serious types of infections I described. While one might argue chronic yeast infections are not enough to confer an AIDS diagnosis, one cannot make such an argument about recurrent bacterial pneumonia, recurrent endocarditis, recurrent pelvic inflammatory disease, neurosyphilis, septicemia--the infections that are killing my clients.

The CDC says it is too cumbersome to add the symptoms at this late date, and the surveillance system must be simplified. We are operating in a scientific void regarding the natural history of this virus in women.

We simply do not know. I feel like the lives of my clients are cheap to the CDC. For the Federal Government to

say we don't know ten years into an epidemic is criminal. Then they went on to say that based on more studies of gay white men, a person is more likely to get a life-threatening illness at under 200 T-cells. Again, when they say "life-threatening" are they looking at T-cells in women like "JG" when they die of septicemia, or women with PID? People are getting KS and PCP over 200 T-cells. Data from the Mack study show that the figures are not so low.

As Ruth Berkelman testified, on one of their spectrum of disease studies, only 35 women had gynecological problems reported in the medical record. Therefore, this might not be such a problem. I have to tell you that often I am the first person to ever ask a client about their gynecological record. IDC clinics are not doing gynecological work on women. Women are being completely neglected in this epidemic. Therefore it is surprising to me that 35 women had evidence of gynecological evidence in their medical charts.

To try to represent people and advocate for people and try to get women gynecological care at this point is a nightmare. Thanks to the current CDC definition, there are no gynecological providers. Underdiagnosis, misdiagnosis, devaluation, and inability to access entitlements. It is

fundamentally unfair to name the symptoms of one population but attempt to catch other populations only as they are dying.

My clients get AIDS at 300 and 400 T-cells; I know this. I see that there is absolutely no reason to leave out things like recurrent septicemia, PID, TB, when there is immuno compromise. This is AIDS. No one can tell me it is not AIDS. It is killing people. These are not people who would have died but for HIV infection.

I don't think you can say "We don't know--it is poverty, it is drug use, it is lack of access to health care." We do know. In the Eighties, the number of young women who died in urban cities for unknown causes has skyrocketed. People were not dying in these numbers before of these diseases. It is the role of HIV. It is AIDS, whether you call it AIDS or not.

Although I am not on the entitlements panel, I'd like to spend the rest of my time very briefly discussing Social Security, since that is what I've worked on--

CHAIRPERSON OSBORN: Excuse me, Theresa. Could I make a suggestion--the next panel will be involved in that discussion, and perhaps that might be something we could put off until the presentations have been made, if you don't

mind, so that we can keep our focus on this topic for now.

MS. McGOVERN: Okay.

CHAIRPERSON OSBORN: Thank you for your impassioned caring about people, and if you don't mind, we'll defer the other comment.

Laura, thank you for being with us, and welcome.

MS. THOMAS: Thank you.

HIV disease is a very complex issue both medically and in the social, political and economic fields, and from my perspective it is impossible and unrealistic to view any part of it as an isolated element. I understand that the definition is intended as an epidemiological tool. However, I feel like it has and will continue to have a huge impact on the ability of individuals to access services and the ability of organizations to provide services.

First of all, I feel like the definition does need to be changed, and I want to briefly express my disappointment with the proposed change. It is based on biased and incomplete research on the natural history of HIV disease in women. It uses a lab marker that is, in my opinion, better used to chart the trends of an individual's immune suppression rather than to make broad epidemiological distinctions, and

which has limited availability for many people with HIV.

It will continue to leave out women and injection drug users and will not give us an accurate picture of the reality of HIV disease in America.

In terms of the definition's impact on service provision or accessibility, we all know that funding often follows the numbers. We also know that there are huge barriers to care for people with HIV, such that many people will never get CD4 counts done nor adequate treatment for their HIV-related conditions.

I do not think the proposed definition will help anyone gain access to CD4 testing. It will only record those already in the system of care. In fact, it may scare people away from testing for reasons of confidentiality, especially health care workers, who may feel that their jobs are perhaps more in jeopardy.

Before the CDC attempts to implement this change, it needs to adequately fund and train surveillance staff nationwide and not do this at the expense of seroprevalence studies. It also needs to subsidize the cost of CD4 counts which, as we heard yesterday, often run in the range of $100 to $200 and may go as high as $600.

Since anyone with a CD4 test has obviously come into some contact with the health care system, I do not think the new definition will bring anyone into the system nor reduce any of the social, cultural or economic barriers that keep people out of medical care. People in rural America, those in prisons, in inner cities, women, and injection drug users will continue to be shut out of an overworked and underfunded system.

From a San Francisco perspective, another issue is our campaign for early intervention. We are projecting that the educational campaign encouraging people to test, to monitor their health and to intervene early in the course of their HIV disease will bring more people into the health care system and the social service system than the definition change.

The problem other than the increased demand for services is that until now our message has been that if you take care of yourself, if you take your Bactrim, your AZT, you will not get AIDS, and you will be able to stave it off. Obviously, we can no longer be telling people this as there are many people who have been able to stave off major illnesses who are under 200 T-cells, for whom that message of

"Take care of yourself, and you'll be able to stave off AIDS" no longer holds.

I do want to point out that early intervention is also in some ways predicated on cheap, accessible and reliable CD4 counts. That's also certainly a cornerstone of that campaign.

An AIDS diagnosis can improve an individual's access to other, nonmedical services, however, once they have been able to enter the medical system. Many service agencies use a diagnosis as entry criterion for housing programs or emergency funds, for example. In San Francisco, we recognized that the current definition was inadequate several years ago, and most agencies are currently using AIDS or disabling HIV disease as the eligibility criterion for emergency services.

We are now in the process of moving toward using disabling HIV disease alone as a diagnosis of AIDS will no longer imply illness or disability. In the real world, in most of the country, a diagnosis means much more than a clinical status. It signals a need for more social services and is the baseline criterion for service eligibility.

Agencies barely able to keep their heads above water now will drown in the doubled caseloads and the growing

demand for their services. They will have to examine their current systems of eligibility and put together alternate methods of determining individual need, which will obviously take some doing that none of us have the time or the funding to do.

One last point on the implications for people with HIV. There is going to be a great demand for emotional support and psychological counseling for people who will be devastated by their sudden diagnosis. This includes people who will find out within two tests that first, they are HIV-positive, and then that they have AIDS, and people who have done everything right and taken care of themselves and now have AIDS no matter how good they feel or how well they are taking care of themselves.

I would hope that increased funding would be available so that we could responsible help people deal with their personal concerns around the definition's impact on their lives.

On the topic of funding, I want to touch on several points. The first is that we obviously, absolutely, need more Federal, State and local dollars dedicated to HIV services. That is no surprise to anyone here. Also, the

housing, mental health and substance abuse systems are also being overwhelmed by this epidemic.

The one good thing that I can see from this proposed revision is that it will increase the number of Americans living with AIDS. This will perhaps impress upon the funders, policymakers and the elusive general public out there the severity of the public health disaster of AIDS.

My concern that groups such as women and injection drug users will be undercounted once again in this definition is in part a concern that prevention campaigns and services targeted at them will remain as underfunded as they are now.

Numbers of AIDS cases governs Federal funding allocations to HIV epicenters. The care formulas make this very explicit, as Dr. Bowen referenced. And as we are facing a near doubling or perhaps more than doubling of the Title I cities in 1994, those new cities that will come in will desperately need those funds. But I also know that most of the Title I cities are barely getting by on the funds that Congress has appropriated this year, and that it goes against every principle of the Ryan White bill and the whole concept of disaster relief to cut funds to cities with growing disasters on their hands. Current funding levels must be

held harmless, and we all have the responsibility to lobby Congress to increase the appropriation levels to keep up with the need for services.

I support changing the definition to include more people with severe HIV disease. This will make AIDS look more like the disaster that we know it is, and I hope it will enable us to coerce Congress into giving us more funds for the services that we all know we need.

I think that the proposed change is far from ideal, however, as it will not capture people who are not accessing services, will not find many women or injection drug users, and will continue to undercount those who are undercounted now.

Until we can accurately measure the impact of the epidemic and, more importantly from my point of view, provide necessary medical and social services to all people with HIV, our efforts to fight this pandemic will continue to be seriously compromised.

Thank you.

CHAIRPERSON OSBORN: Thank you very much. That was a wonderfully concise statement, and I appreciate your input.

Ted, welcome.

DR. HOLLOWAY: I'd like to thank the Commission for coming to Waycross a while back. I'd like to kind of give you a follow-up on what has happened with us since you were there.

Your visit really galvanized our community and got a lot of political leaders to the meeting and to the table to discuss HIV/AIDS that hadn't come before, and we have been successful in maintaining that momentum and were lucky enough to be selected as one of three rural demonstration sites under Title III of Ryan White. So we now have the $250,000 per year Title III grant and also have $71,000 under Title II of Ryan White, so we finally have some HIV funding since you all were there.

About a year ago, we decided that--

MR. DALTON: Actually, may I say something to you about that same trip from the other direction. I don't know if you were here yesterday morning--

DR. HOLLOWAY: No.

MR. DALTON: --when we had a bit of a remembrance for Belinda Mason, and we saw her on videotape giving a couple of talks. In one of them, she described the importance to her of being in Waycross one fine spring when, as she put

it, her heart had grown cold, and she discovered spring not so much in the flora, but in the people, the doctors and nurses and other people, taking care of people with AIDS, with incredible dedication and without that $250,000 that you've just told us about. And in describing that visit, I think Belinda described all of our experience being in South Georgia.

One day the Commission sat around in a private setting and talked about the moments over the last two and a half years that have been most important and most marked in our memories, and for many of us it was the visit to South Georgia. So I just want to thank you.

DR. HOLLOWAY: Well, I certainly appreciate that, and I want you all to know how much it meant for you to be there because it really has helped us a lot. And individually I'd be glad to give you an update on the people that you met with HIV if you would like to ask me about it.

About a year ago we decided that the best way that we could halt the continued transmission in South Georgia was to make care available, especially when the recommendations came out about AZT at 500 and PCP prophylaxis at 200. We decided to make that available throughout all of our anonymous

test sites. So our procedure at that point became that at the post test counseling if someone were found to be positive, we would offer them a CD4 count. We would then get them into our--we've set up four wellness clinics that have nutritionists, mental health providers and social workers to work with people who are positive.

So we offered that, and it has been overwhelmingly accepted. People who have come in for anonymous testing then have to move into a confidential mode because they go into a continuing care type situation.

Over the last year, we've CD4-counted 94 people who were positive, and we have really seen the shift in the epidemic. Of those 94, 48 have been women and 46 have been men. So I think in the rural area, we really see kind of the future of our epidemic.

It has been extremely frustrating to us. As you know, we are a large rural area. We have no infectious disease specialists, we have no public hospitals, and we cover an area about the size of Massachusetts.

We recently had a male patient who had a T-cell count of about 120. On numerous occasions, he has had difficulty swallowing. He has been treated symptomatically

for candida esophagitis, but he was not scoped. He didn't have a definitive diagnosis. The doctor said it probably was that, but he didn't want to say it was presumptively that. That's a big deal with doctors as to what they put down. We could not get this patient onto Social Security. We couldn't get him any benefits. It is real difficult to get a PCP diagnosis. It is impossible in our area to get a definitive PCP diagnosis without sending somebody 180 miles to Augusta or 100 miles to Savannah, to a specialist.

So from my narrow perspective, we really feel that this simplification and expansion will greatly level the playing field. About 20 percent of the people we tested in the last year have had less than 200 T-cells when we first tested them. Seven of those were women. Only one of those women currently meets the AIDS diagnosis criteria. So there are six that this new definition would bring into the system. Of the 14 men that were less than 200, 10 currently meet the AIDS diagnosis, and four currently don't. And I think that reflects what has been discussed here today is that if you're male, you are more likely to have an opportunistic infection that will get you into the system.

So I really feel that, at least with our experience,

the change in definition will preferentially help females and also people without access to secondary and tertiary care.

Our clinicians are getting very used to using the T-cell counts. They are used clinically. I feel that by using this--and our patients also understand that at 200 they enter into kind of a different realm, because at that point we want to get them on PCP prophylaxis. So that in the context of a system that is trying to put care in place early on and follow people and keep them as well as possible, I feel that the change in definition will be extremely helpful.

In summary, I think that perfect is the enemy of good, and we're not going to get a perfect definition, but we will certainly get a better definition. I think that simplification will greatly enhance reporting in our area, and for us it will sort of level the playing field. The Title II Ryan White money was given out within Georgia based on our report of AIDS cases, and since we don't have a tertiary center and can't get presumptive diagnoses, we did not have the numbers that some other areas had, although we were following many, many more HIV-positive people than some other areas had. So we feel within the State it will level the playing field, and that had we been able to report the

cases we really had, we would have gotten almost double the amount of Title II money, the $70,000.

We feel that it clinically makes sense, and it will reinforce to clinicians at least in rural areas that are not familiar with AIDS the importance of CD4 counts as a clinical marker and will make sense to doctors and physicians.

We also think it will push our State, and it already has--the States are going to be competitive for numbers, for moneys, and so it will push our States into making CD4 counts available to all HIV-positives throughout the State. And certainly in Georgia we've seen that. We were one of the first places in the State, outside of the metro areas, to start routinely doing CD4 counts, but now almost every district health department in the State is doing that as a matter of routine. So I feel like it will do that because the money is allocated on a cost basis.

One concern about confidentiality, since we have some folks from HRSA here, the real breach that we're going to have with confidentiality is not going to be with the change of definition, but we're going to have a real problem with Title II report. That $71,000 is going to require me to report on each individual person that I do early intervention

on, on a myriad of different characteristics, and the only way we can do that--and these are HIV-positive people; these are not people with AIDS. So the extensive reporting required by Title II has me gravely concerned. We're going to have to set up a system to give unique identifiers to patients throughout my area so that we can come up with an unduplicated count. And I know that the intent of that was to find out what the money was going for, but I really have grave concern about confidentiality with that, not with the change of the definition.

Finally, obviously, the big thing is to get full funding for Ryan White. That is desperately needed, and those of us in rural areas who have been working with this epidemic with no funds have concern and feelings for what has happened in Atlanta and in epicenters, but they have had some base of services, and we have had none. So I really feel the full funding is vitally important in the Title II part of Ryan White.

I also have grave concern about Social Security decoupling from HIV. I feel public pressure should and will be brought to bear when people with the diagnosis of AIDS under the new definition cannot get care, and I think that in

the long run that changing this definition and adding more people being eligible will enhance the access to care and disability.

Thank you.

CHAIRPERSON OSBORN: Thanks very much, Ted.

I have to make the parenthetical comment, without begging any of these questions, that you're about the only person I know who defines his narrow vision as "as large as Massachusetts". And from our visit with you, I understand just what you mean, and we admire you for that narrow vision very much.

Ron, Welcome.

MR. JOHNSON: Thank you.

I would like to thank the members and staff of the National Commission for this opportunity to meet with and to address you on this critical issue.

I represent the Minority Task Force on AIDS, which is a multi-service, community-based AIDS service provider in New York City. The Minority Task Force was formed to respond to the impact that the HIV/AIDS epidemic was having on people and communities of color.

As the staff and members of this Commission are

aware, there is widespread, perhaps nearly universal agreement within the HIV/AIDS community that the current case definition of AIDS is inadequate. Under the current definition, as has been noted, there is systematic undercounting, especially of women and substance users, the majority of whom are people of color.

Although we are encouraged by the CDC's efforts to expand the current case definition to address the serious undercounting of populations most affected, we feel that the CDC's redefinition is not an adequate or even acceptable response to the problems that result from the current definition.

I would like to respond to the proposed revision of the case definition from the perspective of the projected impact and implications on the delivery of HIV-related care and services.

The proposed change in the CDC case definition of AIDS presents us with what I feel is a mixed bag of implications for care and services. By itself, the proposed revision would likely lead to a dramatic increase in the demand for HIV-related care and services. The CDC projects that of the one million people believed to be already

infected with HIV, 160,000 people who do not have an AIDS-defining illness now do have CD4 counts less than 200 and would therefore be diagnosed as having AIDS. All of these people would then become persons with AIDS.

In studies of women under HIV-related care, the CDC projects that the number of women defined as having AIDS could increase by 46 to 57 percent. There would also likely be--and probably this would hold up--a dramatic increase in the number of gay white men who would now be diagnosed as having AIDS and also therefore seeking services.

Ironically, since many of us have protested and urged a change in the CDC definition because it was too heavily skewed to gay white men, this proposed definition I think would have the ironic result of actually increase the number of gay white men who are diagnosed, while not addressing the serious undercounting of other populations.

Such increases in the demand for services would create serious caseload problems throughout the HIV/AIDS care and services delivery system. Most care and service providers, including community-based organizations, are already experiencing overwhelming increases in caseloads. At the Minority Task Force, the number of our case management

revision cannot be taken by itself. The new case definition would have to fit into existing realities that set and shape the HIV/AIDS epidemic here in the United States. Hence, the mixed bag of implications that I mentioned.

For example, for low-income people who represent the majority of our clients at the Minority Task Force and an increasingly large percentage of other CBOs and clients, there will in my opinion be virtually no impact. Most of the people who come into the HIV-related care system either at the Task Force or other CBOs are already sick, often well into an AIDS condition, even under the current 1987 definition. Of those clients who have clinical symptoms of illness but do not meet the 1987 case definition, we will continue to see them, and we will probably be introduced to them because, for example, at our agency we do not require an AIDS definition; we just require an HIV-positive diagnosis. So those people are already in our system, and I don't think there would be a likely impact by the new, revised definition.

As far as we are concerned, from a service delivery perspective, many of those people already have AIDS even if they don't meet the 1987 case definition.

Therefore, as I said, I don't think that the

proposed definition is going to have an appreciable impact on the number of people who would be coming into the services. As has been pointed out, the basic premise of the proposed definition requires that a person be in a health care delivery system, a primary care system. For many of our clients, they are not in that system, and the proposed definition therefore would not impact those people until they come to us with clearly clinical symptoms that would enable them to get medical care or, many times they have other social issues--housing, lack of housing, other issues for which they come into the system. So the proposed definition is not likely to increase that and is not likely to affect the already ongoing serious undercounting of substance users, women and other low-income people under the current definition.

I think, as I said, in summary, this gets into what David Hansell has already called the "Catch-22" of the proposed revision; you have to be in the health care delivery system to be included in the revised definition. You have to have regular access to health care. Large numbers of people of color, especially low-income individuals and families, do not have that regular access to primary health care. There

is no ongoing accessible mechanism by which their CD4 counts can be monitored. There is no adequate mechanism by which their HIV status will be diagnosed in the first place.

I would repeat the call that several people have made to the National commission to address the issue of extending the deadline. I would go a bit beyond that, given the fact that the deadline is next Monday, and I would hope that the National Commission would make a public call to both Secretary Sullivan and Dr. Roper to extend the deadline. The issues that have been addressed and undoubtedly will be addressed by other panelists are far too important for the implications of this disease and epidemic for the revised definition to be decided, or the comment period to be one month. It must be extended, and I'm hopeful that the National Commission would join us in calling for such an extension.

Thank you very much.

CHAIRPERSON OSBORN: Thank you.

Thank you all for very important testimony. We've been running about 15 minutes late, and I will assume that we still are and ask to get a chance to interact with you briefly before we take our break; and for those of you who

have come in late, we've been a little bit late along the morning, but we'll take time for discussion now since this is important.

Harlon?

MR. DALTON: Just a brief question for Ron and Dr. Holloway and for Ms. McGovern.

Ron, I heard what you said at the end, absolutely. I thought, though, that there was some inconsistency in what you said. That is, when you talked early on about the caseload increases and how organizations like yours didn't have the funding and weren't prepared to handle the increased caseload, later on, you said that there would be no impact on organizations like yours because you are already taking care of people just based upon HIV positivity. So there is some tension between those two points.

MR. JOHNSON: Yes, I admit that it may seem confusing. That first scenario, I said if that case definition were taken by itself, that is, all things being equal--

MR. DALTON: Oh, I see. But you don't take it by itself.

MR. JOHNSON: --there would be dramatic increases in caseload. But you can't take it by itself. All things

are not equal. You cannot discount the effects of racism, social injustice, and varying degrees of access to health care in this country. So given that reality, that's why I make the statement that the revision presents us a mixed bag and that the actual impact would probably be very negligible on the populations that are increasingly most affected by this epidemic.

MR. DALTON: Okay. Dr. Holloway, we were certainly struck that you, unlike some of your fellow folk further to the north, find considerable favor with the redefinition. It seems to me that in part it is because you in fact are doing early intervention, which is kind of nice, and apparently have access to a flow cytometer and the ability to pay for it. And I was struck that you said it's hard to get a PCP test, that you have to go to Augusta or some other city some miles removed, but apparently you are able to do T4 counts rather simply, and I was curious about how the latter. Is there flow cytometer nearby, or--

DR. HOLLOWAY: We're able to get our T4 counts done for about $60, and to get a PCP diagnosis you have to be hospitalized and be bronchoscoped, so it involves a surgeon, hospital fees, and it probably costs upwards of $1,000,

$1,500 to get that diagnosis. The same is true with really diagnosing esophageal candidiasis. You need to go to a physician who is going to do an endoscopy and look and diagnose the condition.

So the actual clinical diagnosis is much more difficult, and in our area people tend to treat more on probable diagnosis and, if they've got a pneumonia, go ahead and cover PCP as well as bacterial pneumonia rather than trying to determine exactly what it is because of the expense.

MR. DALTON: I see. Thank you.

DR. REYELT: Can I add one other point there? It's always easy to nail the blood sample in the patient--

MR. DALTON: That's a nice way to put it, yes.

And Ms. McGovern, the question with you has to do with you clearly were arguing in favor of, if we're going to change the definition, adding a set of additional symptoms, and that obviously is the contender or candidate that lots of folks are suggesting. But I was trying to understand how that would be helpful to women in particular. By the way, let me say that was a wonderful job of marshalling facts, and as a lawyer, I'm quite proud of you. But in any event--

CHAIRPERSON OSBORN: We have an ongoing discussion

about concise lawyers in this Commission; we celebrate them every time we get to see them.

VICE CHAIRMAN ROGERS: It's rare, but we celebrate.

MR. DALTON: But if you assume that the Social Security Administration would decouple entitlements from the AIDS definition, from any new AIDS definition--let's just assume for the moment that if you had symptoms, women-specific symptoms, that they would be decouple entitlements from the surveillance definition. What is your underlying idea about why women would be helped--because it would perform an educative function for the physicians? And why would there be better diagnoses of women?

MS. McGOVERN: Well, I think that it is two things. One is if the point of surveillance is an accurate count, then what I see with a lot of my clients is they present at an emergency room five years ago, and then they present three or four more times with these things like pulmonary TB, recurrent bacterial pneumonia. Nobody tests them for HIV, nobody does the T-cell count. So it's two things. If the perception of what is AIDS includes these very serious recurrent infections, then they will be tested, and a T-cell count will be done, and secondarily, I guess, it's the point

that the transmission effects and all the rest will be taken care of by an earlier diagnosis.

But I also want to make the point that this is AIDS. I am not confusing the issue of surveillance with the ancillary problems that the CDC definition has caused. I think that these major infections are AIDS and that because they are not considered AIDS, people aren't being tested earlier.

MR. DALTON: Are you saying that if AIDS is defined, the definition of AIDS includes things like PID and other women-specific symptoms, that that will then lead doctors to look for those symptoms, or when they see them to think of the possible connection?

MS. McGOVERN: Yes, when they see them they'll realize that they could be HIV, which is the major problem for a lot of poor people. They would have known two years ago that they had AIDS if the doctor had realized that pulmonary TB of septicemia six times in two years is probably HIV-related.

So it gives a more accurate count as well as saves lives, prevents transmission, because the other thing--transmission isn't really discussed that much--but a lot of

my clients didn't know they were infected, and this has grave--I deal with families coming in all the time, and this has grave repercussions, what is in that definition. But I also want to say again that I'm not talking about things that are minor symptoms; I'm talking about things that kill people that I'm sure are the things that those 10 percent die of.

MS. THOMAS: May I make a comment?

CHAIRPERSON OSBORN: Please.

MS. THOMAS: It works both ways. If the things are on the list, not only will doctors who find those symptoms in a woman think, we would hope, to test for HIV, but also a doctor will look at the HIV-positive woman standing in front of him and think to do a pelvic exam, for example, and think that the symptoms that she's showing up with are in fact HIV-related and treat them as such. So it works both ways.

CHAIRPERSON OSBORN: I think perhaps now is a good time for a break. When we come back we'll be talking about benefits and entitlements, and I think these themes will come through again.

[Break.]

CHAIRPERSON OSBORN: Excuse me for taking a little longer than we had planned, but the Commissioners have had a

chance to talk, and I think one thing is quite clear and unanimous among the voting Commissioners, and that is that this is a very important and complex topic--the overall theme of yesterday and today--that has a lot of potential to perturb if not well-planned for in an important time in the epidemic. So I have polled the Commissioners, and everyone is in full agreement that we should ask in a very succinct way--or, recommend in a very succinct way--that the comment period be extended substantially so that there can be interchange and further discussion of this sort with both provider communities and people who will be affected by change and so forth.

The witnesses have been wonderfully helpful to us in extending our awareness of the complexities of this issue, and we feel that we would like to recommend that others have that opportunity as well.

So I have, as I said, talked to all of the Commissioners, or David has, and that is something that we will do as soon as this morning's session is over. I thought you would like to know that sometimes things actually happen faster than you think they do, even in government work.

VICE CHAIRMAN ROGERS: June, I think this is clear

from what you said, but just to punctuate it, it will be transmitted today to the powers that be in terms of Dr. Sullivan's office, Dr. Mason and CDC, in terms of our recommendation.

CHAIRPERSON OSBORN: I want to thank the last panel for their patience, since we have been running behind, but we're delighted to have you with us.

We have two representatives from the Social Security Administration--Trish Butler, Associate Commissioner for Public Affairs, and Arlene Gahan, Deputy Associate Commissioner of the Office of Disability. And Dr. Christine Reyelt is Medical Director of the Comprehensive Care Center for AIDS, St. Joseph Hospital and Medical Center in New Jersey. Philip Fornaci is Staff Attorney with the Whitman Walker Clinic here in Washington. And Rozann Abato is Deputy Director of the Medicaid Bureau of the Health Care Financing Administration, standing in today for Elmer Smith, who was initially scheduled.

So thank you all for being with us and being patient, and we look forward to having you give us kind of an encapsulation of your thoughts, and then Commissioners are always rather lively with their questions.

In that order, if it is convenient.

MS. BUTLER: Thank you, Dr. Osborn.

With me, as Dr. Osborn said, is Arlene Gahan, the Deputy Associate Commissioner for Disability. Arlene is going to describe the step-by-step process for you on determining disability within our agency as it applies to law.

If you would keep in mind as Arlene does this that both the Supplemental Security Income Program disability benefits and the Social Security disability insurance benefits follow the same medical criteria, so that will apply across the board as she discusses this.

Then, I'd like to come back briefly to summarize for you the public awareness and outreach campaign that the Social Security Administration will soon launch around the country to help the public awareness and particularly people with AIDS and the organizations that service and care for people with AIDS in terms of our benefit programs.

I'll turn this over to Arlene, then.

MR. DALTON: Excuse me. Before you get started, I take it you are going to be describing the general process that you use for determining disability. Will you in doing that be discussing the SSA's proposed new approach to--

MS. GAHAN: In generic terms.

MR. DALTON: In generic terms. Obviously, one of the concerns that you heard expressed earlier today if you were hear, and if not, you will hear expressed, has to do with the ease of determining presumptive disability under the current definition, and whether under a different definition it will be similarly easy for people who are impaired to get a presumptive.

MS. GAHAN: Absolutely, I can address that.

MR. DALTON: Thank you.

MS. GAHAN: It is a pleasure to be here. I did miss most of the earlier session; I came in at the end. And my ears perk up every time I hear "Social Security". As you may or may not know, we administer the two largest disability programs in this country. Last year, we paid almost $40 billion in benefits to about 7 million beneficiaries and one million of their dependents. Each year we make decisions in about 2.5 million disability claims. It is a huge system that adjudicates these claims, and of course with that go rather detailed, lengthy and complicated Federal rules.

But I'd like to talk about the process because I think it is important that you understand the steps we go

through before we can understand anyone's criteria for AIDS or HIV and how it fits into the Social Security Administration's programs.

The two programs, as Trish alluded to, the first one is the Social Security Disability Insurance Program. We all earn coverage from that program when we pay our FICA taxes when we get paid, and those benefits are paid to disabled workers as well as their dependents. Beginning in January with the cost of living increase, Social Security disability beneficiaries on average will receive $662 for an individual.

Eligibility for SSI, the Supplemental Security Income Program is a needs-based program. It pays benefits to individuals as well as to aged couples, but it is disability, blindness and aged need program. The maximum Social Security benefit for an individual SSI beginning in January will be $422.

As Trish mentioned, the medical definition, the definition of disability for both programs is the same, and you will often hear people refer to the definition of disability being a strict one, and it is. The definition that is established in the statute is inability to do any

substantial gainful activity because you have a medically-determined impairment that is going to result in death or last at least 12 months. It is a strict definition. By "substantial gainful activity", to get a picture of what that means, for a non-blind individual, that's talking about $500 a month. It is not a lot of money. So if you can make $500 a month or more, you are not eligible for benefits under either of the Social Security disability programs.

Applications are taken in our 1,300 field offices around the country. At the time we take an application we gather information from the claimant on what their impairment is, the impact of the impairment on their ability to function, get all of their treating sources and vocational information--age, education, work experience, et cetera. Even though we take the applications in our 1,300 field offices, Social Security itself does not make the disability decisions. A State agency in each State called a "disability determination service" makes the disability decision for us; we fully fund their administrative costs; they develop the evidence.

They use a team approach which consists of a physician or a clinical psychologist and a disability examiner. A disability examiner goes through months of

training, and it is at least one year before they have the hang of it and are fully productive in adjudicating disability claims.

The DDS, the disability determination service, in the State, begins the process by going out to the treating source and getting medical evidence. In addition to the medical evidence, we always ask the treating source the impact of the impairment on the person's ability to function. What does it do to their ability to sit during an eight-hour day, to stand, to pay attention to directions, et cetera.

The evidence from the treating physician is our primary evidence. It is extremely important. It provides a longitudinal history of their impairment, and it is the most reliable.

If they do not have a treating source, we will send them for a consultative examination. If they do have a treating source, and we still don't get enough evidence to make the decision, we will also get a consultative examination. Our rules require that we give the treating source the first crack at that consultative examination. So we ask them if they are willing and able to do it. If not, then we will go to an independent source for a CE.

Now, we use a sequential process, and it is important that we understand that. It reflects the requirements in the statute, and it also is designed to ensure that we get some national uniformity using all these State agencies to make our decision. It is a five-step process. We call it the sequential evaluation process, and we go through each step in order. At all but the last step, the decision is either they are or they are not disabled, or you can't make a decision at that step and you go on.

The first one is are they engaging in substantial gainful activity. It is the most black and white, the easiest decision to make. You look at their earnings; if they are engaging in substantial gainful activity, they are denied; if not, they go on in the process.

The second step we call a "not severe" step, and it asks does their impairment have more than a minimal impact on their ability to function. If the answer is yes, it has more than a minimal impact, then we go on. If the answer is no, it does not have more than a minimal impact, we stop there, and the claimant is found not disabled.

Step three is where medical criteria come into play; and the only place in our whole rules where we rely on

any kind of medical findings, laboratory test results, et cetera. We call it the "listing" step. It is a list of common impairments with manifestations that are severe enough that if you manifest them, we say you cannot do any gainful activity, and you get paid benefits. It is designed to pay the most severely-impaired people. I.Q. scores are on the list; there are weight tables for obesity, cardiovascular. You can go through the gamut. It is divided by body system.

For HIV on the list are all of CDC's criteria plus more criteria. It is not limited to CDC's criteria. We are in the process of greatly expanding that list today, and it will be even more criteria, including a lot of the manifestations I have heard discussed here this morning.

When you get to the list, you take the results you have from the individual, you compare them to the list, and if they have them, that's called they "meet the list" , and we pay them. If they don't have what's on the list, however, because of common impairments, but they have something that is equally severe in a doctor's mind, we call that "equals the listing" and they are found disabled, and they "equal the listing".

In the HIV area as well as some other listings,

primarily the mental, we have some manifestations of HIV that alone you would not say if somebody had that, they could not do any gainful activity. So we have even coupled some less severe manifestations with some functional restrictions. So if they exhibit--anemia is on the list, weight loss, there are many others on the list--if they exhibit them and have a functional restriction resulting, the anemia limits their ability to undertake activities of daily living, they can be found a listing level.

If they don't meet or equal listing, no one is denied benefits. We go on, and we assess their residual functional capacity. It is a form that a doctor and a team can fill out together, and it goes through what they can still do despite their impairment. You are no longer tied by specific medical criteria. You are looking solely at their function. Then you use that functional assessment, and first you determine what we call Step 4--can they do their past work. Arlene was a secretary. Can she go back and be a secretary considering what she has? If the answer is yes, I am denied benefits. If the answer is no, then they go on and they say looking at Arlene's age, education and work experience and jobs that are available in the national economy,

can she do any other job. And if the answer is yes, I am denied benefits. If the answer is no, I am allowed benefits.

That's the process for going through and deciding a disability claim.

With regard to presumptive disability--

MR. DALTON: I'm sorry. The residual functional capacity, is that Step 4?

MS. GAHAN: You do that in between Step 3 and Step 4. It is a tool that you use when you move on to Steps 4 and 5.

Presumptive disability is a mechanism we have to enable us to pay claimants for SSI benefits, the needy claimants, right away. You pay them, but you still go through everything I have already explained to you in making a formal decision. Essentially, they can get six months of benefits if it is highly likely that they are going to be found disabled. And we make those decisions in two ways. One, they come in, and they follow the field office. Our field office employees are not trained disability adjudicators. So we have a list of what we call readily observable impairments, and you'll see things like double amputees on that list. So if they can see an impairment and pay somebody

right away, that's what's on the list.

We added AIDS to the list in the mid-Eighties because of the concern about needy people getting on right away and the medical benefits that come with that through HCFA. We have a situation today where about 54 percent of our AIDS claimants are receiving PD benefits when they walk in the door. That's not good enough.

That's one way to do it. In addition, when that claim goes to the disability determination service, the examiner and the physician looking at it can pay PD on any impairment, any time they think they are going to get paid. So they get one piece of information in, they don't have enough, but they can go ahead and make the PD payment.

Around 40 percent of our HIV claimants who are not defined as having AIDS get PD payments through that mechanism. That is still not good enough in our minds. So we undertook procedures to figure out how we could get PD to a greater proportion of both the AIDS and the HIV claimants, and what we are going to do is implement a new procedure that ensures that every time someone comes into a field office and alleges that they have HIV, that a contact is made with their treating source, and that contact can be by phone, it can be

by mail, and it will go quickly, and anyone who has HIV at listing level will be paid right away.

Still, they go on to the disability determination service, and they may have HIV that's not at listing level--listing level, we talk about the most severely impaired people--less than that, our disability determination service could continue to make additional presumptive disability payments while they are gathering any additional evidence that is necessary to make the formal disability decision.

So that's in a nutshell sort of where we are with that. Let me turn it back over to Trish to talk to you about some of the public affairs activities.

MS. BUTLER: By the first of the year, the Social Security Administration will be launching a national awareness and outreach campaign directed to people with HIV infection and organizations that provide care, counseling and services to people with HIV infection. Some of the initiatives that we are currently in the final stages of development or already have developed now are as follows.

We are working with the CDC and the National Clearinghouse for AIDS to be providing outreach materials on our disability benefits to some 15,000 organizations that

provide services to people with HIV infection. In addition to the new AIDS poster which we brought with us today and the outreach brochures that you find in your portfolios, we are also preparing radio and television public service announcements on the availability of disability benefits for people with AIDS and disabled because of HIV infection, and also print public service advertisements.

We are developing pilots right now in the Greater Baltimore Area that we hope we can replicate around the country, recruiting people who are HIV-positive to serve as representative payees for people with AIDS once they are no longer able to handle their own financial affairs.

We are also working to provide the medical community with more training materials and more information on the kinds of things that Arlene talked about, the medical evidence we need that can help expedite the processing of claims, particularly for people with AIDS.

We are working with AIDS advocate groups across the country to help disseminate our public information materials. We will also be undertaking an educational campaign utilizing our personal earnings and benefit estimate statements for people who have tested positive for HIV, and you have a sample

of that in your portfolios also.

We are encouraging people that as soon as they find out they are HIV-positive to send for a personal earnings and benefits statement to make sure that all of their earnings records are reported correctly, that there are no problems with their earnings records, so that in the event they have to file for disability benefits in the future there will not be a problem, and there won't be a time factor involved in correcting those wages statements.

We are also in the process now of standardizing a national AIDS in the workplace training program for all Social Security employees to ensure that every one of them fully understand what AIDS is and what AIDS is not, so every claimant who inquires about disability benefits under our programs because of HIV infection will be treated with the dignity, compassion, confidentiality and respect that they are entitled to receive.

That's our summary. Thank you.

CHAIRPERSON OSBORN: Thank you very much.

Let's proceed with the others, and then we can get a chance to discuss some more at the end.

Dr. Reyelt.

DR. REYELT: I was asked to speak as a practitioner. I work in St. Joseph's Hospital in Patterson, New Jersey, both with a small private practice of HIV patients, probably between 30 and 40 at any given time, and in the setting of a larger clinic where we usually have about 750 to 775 active patients, although registration is higher.

My response to the definition initially is that there are a lot of positives to be said for it. First of all, it does extend the numbers in fact of people who are affected by HIV disease rather than just qualifying by the defining AIDS definitions.

Secondly, it is clear and specific. It is a clinical lab tie-in procedure. You can check off the boxes neatly.

Third, it will probably help predict more needs services.

Fourth, if it relates to Social Security, perhaps we might be able to develop simpler check-off forms even for exchange of information both for their benefit and for our benefit and perhaps cut down on the amount of pages of Xerox that seem to go into medical records that get forwarded to Social Security.

The basic problem with the definition as I see it is that it is too clean, and the areas in which it is too clean, I think, are areas that have been mentioned, and that is women, particularly with PID and candida. I am very encouraged to see your information on Social Security. That is new.

I think I'd like to refer back to what Ms. McGovern mentioned, and that is the fact that sometimes gynecological records are not part of an i.d. clinic chart or a medical record. They are separate services. And again, I always consider a grandiose title to our program which is "comprehensive care", but that is at least our ideal, and it seems simpler than it is, is all I can say. It seems simpler than it is to get that information when you are even requesting it from another health care agency in your region.

Secondly, the other area that I see major problems with HIV is in the impact on courses of other diseases. One of them from a medical point of view is that of different forms of cancers. Cervical is well-known because of its relationship to women and the problem of women with AIDS. I have also seen rapidly progressing lung tumors, hepatomas, for example. It takes a longer time to get through a system

when T-cells are elevated, and people have these problems.

Another ongoing problem which I think is underestimated grossly is a rapid deterioration, a new disease or a reactivation of liver disease. This does not happen in everyone who has liver disease or a history of hepatitis. When it does, it is rapid deterioration, often outpacing the time it takes to get benefits for the individual.

Interestingly enough, in my practice proportionately I see this more in women. I don't know if it is a specific female problem or not. Again, the many bacterial infections, sinusitis, anemia, pulmonary tuberculosis at a higher level but at a much more disabling level.

So basically, to sum it up I would say that the areas that I see the problem with are with categories B1 and B2, where there are some symptoms, maybe high T-cells and maybe still an HIV relationship with that symptom.

So if you are looking for a measure, even from an epidemiological point of view, of the true morbidity and mortality and increase of health care cost for HIV infection, I'm not sure that T-cells alone grasp that. Again, I think it includes a lot, but I'm just concerned about the particular areas where it is exclusionary.

My experience is in a program where we do try to aim at earlier intervention. Part of the treatment and assistance program for the State of New Jersey, everyone who comes into our program who is HIV positive does in fact have T-cells. So from that point of view, it does not add to our costs.

What is interesting, reviewing the statistics for the last two years, which is all the statistics we have since the beginning of the program, one-third of the individuals on entry had less than 200 T-cells. Also, about 30 percent had AIDS from other diagnoses. However, those are not the same group. So it still suggests that we're not anywhere near where we should be in terms of early intervention, and that is in a State and in an institution where we try to use all forms of compensated care so that we don't necessarily charge people who really don't have anything to charge, and we try to go percentage-wise, or we bite the bill, to be honest with you. And even in that context, we're not reaching people early enough.

The other area where I see the definition as in fact a very positive thing, and an area where I see it in terms of both for epidemiological, clinical and possibly for

Social Security disability benefits, are in the fact of presumptive diagnoses. At this point in time, I hope to see less PCP, and at this point in time, I don't want to see my patients coming in with a P02 of 55 and an x-ray that is floored for PCP so I can report it as a presumptive PCP. I don't want to get to that point. Between prophylaxis and early diagnoses, I want to be able to get beyond that.

I don't want my patients to have lost 30 pounds from their esophageal candida by the time we get an endoscopy, or to have to wait three days for an upper g.i. and then culture candida from the throat. All of those are increased expenses, first of all to the individuals and their health, secondly to the system.

So some of the elements of this definition are real positives. I say that same with herpes simplex virus. We can make clinical diagnoses of prolonged herpes simplex virus; we don't always catch it on culture.

Wasting is another thing. I can't tell you the number of people who come in wasted. Why can't I prove that they are AIDS, or why can't I get them disability, perhaps. I have no documentation in any health care record previous to their coming to my clinic that they have lost 50 pounds.

Their mother may tell me, their spouse may tell me; their clothes may look baggy, but I can't prove it.

So that's the whole category of people--and some other examples I probably haven't thought of--that I see as very valuable, and I think it's going to help us all. I think this was what Dr. Holloway was referring to.

So although I think it's not perfect, I'd hate to see us beg the whole concept of the new definition, to be honest with you.

Now, one of the areas that I find problematic as a private practitioner and as a hospital-based physician interacting with private practitioners is that now we have a shift of reporting. Basically, since this is going to be laboratory, and I think we're going to deal with a lot more asymptomatic or minimally symptomatic people, the basis of reporting is going to be much more outpatient than inpatient. I think that is one of the problems. Doctors don't have to report it. There is a confidentiality issue. Okay, that's one. But if you want to report it or you want the information, people aren't going to be rushing to do it because it is more difficult. Most private physicians' offices really don't have a good mechanism for dealing with these things.

Even clinics that are well-organized and used to dealing with HIV infection don't do very much reporting because many of our patients come in, and their diagnosis is as an inpatient. So this is going to change our responsibilities as clinics as well, and I see that as a bit of a problem.

I see a real problem in educating the medical providers to their responsibilities in terms of reporting and in terms of referring people for case management, appropriate Social Security benefits. I'm glad to hear that that's going to be one of the target groups for your public campaign.

I do see a problem with confidentiality. New Jersey has recently--the law has been around for a while, but it is probably enacting a policy in which we will now have to report with identifiers HIV-positive individuals. This has not been the case to this point. There are States where that is still not true, and again giving people the magic AIDS diagnosis does put them in a different direction.

I also do think the implications of reading one day the word "AIDS"--"AIDS" is a psychologically loaded term for people. I fear that it is another disincentive for the private physician to deal with the relatively asymptomatic

HIV patient if they are going to have to explain a lot about these levels of care, and they have to explain reporting, they have to agree to reporting, and they are going to have to take a lot of time counseling individuals on what the meaning of T4 count is.

I do think it is predictive. It is not 100 percent predictive. I have people working with T-cell counts of under 40 for two and a half years; I can't explain why. Part of it is probably luck.

One of the other areas I see as problematic is reporting to private insurers diagnoses. Already with regard to T4 cells, a lot of my patients come in with a laboratory bill and ask which of these should I send in to my carrier, and I often try to get a T4 cell count done on a different bill so that they can send the other information in to their carrier without disclosure.

You also can use as a diagnosis, which I think is somewhat misleading but not technically incorrect, the chronic viral syndrome--you don't say which virus, that's all. I worry a little bit about some of the implications of now having a different label and even insurers requesting records. I do see that as an ongoing problem in private care.

I worry about a disincentive to physicians taking care of HIV patients who I do not find excessively willing to do so anyway. I find a disincentive to patients for early intervention the fear of being labelled, and I am a little concerned about how to handle that. And I do think the psychological issue of having the label "AIDS" attached to you as opposed to "HIV-positive"--which we have gone into songs and dances now for years, trying to encourage people for early intervention, that this does not mean this. It's a little bit of a problem--not insurmountable, and maybe not the last word, but part of it.

Now, with regard to some specific Social Security and benefits issues, I think whether Social Security extends the benefits to different groups, I am encouraged. I think the fact of the matter is they have to be funded. I think the fact of the matter is you need increased numbers in field offices and in State offices for the process to be rapid.

We have had very good luck with our field office. They have been extremely compassionate and kind for the most part. I have to say that because you hear so many negatives about things, and so I want to say that to you.

The central State office is not always as helpful.

Usually if you know an individual and they have worked with you, you have some help.

I do hope that the process could be streamlined if we use the definition such as this. It would still leave that whole category of indeterminate people more difficult, maybe prolonged.

One of the major problems with getting benefits for any patient is if someone is ill they are not always able to follow through with the information and material that is required. Some do not have family or friends who are willing to do that for them, and that remains an ongoing problem. I am encouraged to hear about the phone and mail thing; we could do some of that work from the hospital, for example, for an individual which before we could not.

The speed of the disease does not always match the speed of eligibility and funding, and that has been described before, but I can't say enough again.

Another problem I see is that with people who are gainfully employed who leave employment, Medicare often does not kick in for two years. In New Jersey, a single individual who is eligible for SSD is over the limit for Medicaid, so you have two years or 18 months of lack of coverage. I doubt

that my State is that unusual. I think New York is more the exception than we are, to be honest with you, where people are eligible for care.

You can say, well, people now can buy into their health care services from their last employer as kind of a guarantee. With the increase in cost of health care this is no longer feasible for most people who are now losing an income by going on disability. Also, if you are talking about a head of a household, a mother who is often a breadwinner and main parent, it may in fact disenfranchise the children from health care benefits as well, although the individual may not be.

The other area in terms of this without Medicaid is the cost of drugs for treatment, early intervention programs, such as in New Jersey, where we have the AIDS drug distribution program. It includes DDI and AZT, alpha interferon, pneumococcal vaccine--don't ask me where that came from--and Bactrim, but it doesn't include a lot of other things that we're now realizing keep people as functional as possible, and I see that again as another ongoing difficulty with extending definitions and perhaps having people leave the work force early.

Again, all you can say is that, yes, you can go on and on about AIDS, but in a sense it is a paradigm of the problems with the health care system and accessibility. I think it is good that we do this with AIDS, and I hope it doesn't stay only with HIV infection although that's what I spend most of my life doing, but that in fact it becomes a way of looking at the whole problem for the poor and disenfranchised in general.

Thank you.

CHAIRPERSON OSBORN: Thank you very much. That was very much appreciated.

Mr. Fornaci.

MR. FORNACI: Good afternoon. I'd like to thank the Commissioners and the staff for allowing me this opportunity to raise some issues with you.

My name is Philip Fornaci, and I am a staff attorney at the Whitman Walker Clinic, which is the primary AIDS service provider here in the District of Columbia. My primary duty is to assist people with HIV to secure all the public benefits to which they are entitled, as quickly as possible.

I am not clear on what issues I am to be addressing,

so I'll just address the ones that I would like to.

CHAIRPERSON OSBORN: That's what most people do even if they are clear.

MR. FORNACI: I've been noticing that.

[Laughter.]

MR. FORNACI: While the issue of the new CDC redefinition of AIDS is important for surveillance and similar purposes, people with HIV are far more concerned with the more basic issues--how can I qualify for public benefits.

While the CDC's new regulations merit the close scrutiny that they are currently receiving, it is regrettable that the impending Social Security regulations have not received similar review and criticism. It is the Social Security Administration, not the Centers for Disease Control, that will determine who gains access to disability benefits and to a large extent who will receive publicly funded medical care.

For those of you who have never been exposed to the Social Security Administration's sequential evaluation process, you have my condolences as you attempt to digest Ms. Gahan's and Ms. Butler's excellent presentation on this. Now imagine being seriously ill and trying to make the same

digestion. It is very difficult.

It is interesting also to note at this point that while the CDC has simplified its AIDS guidelines in order to spare medical professionals the supposedly burdensome process of actually identifying AIDS-defining conditions, the Social Security Administration has shown no such concern for people with HIV seeking to secure public benefits. Apparently the Social Security Administration believes that people with HIV are better-equipped to digest and apply difficult medical standards than are the medical professionals whom they rely upon for care.

When a person with HIV becomes too sick to continue working or to continue carrying out her normal life functions, she must face an amazingly complex maze of faceless bureaucracies upon whom she must rely in order to secure even a minimal income and some medical care. If she does not suffer from one of a handful of so-called AIDS-defining conditions, or if she cannot provide medical evidence that she suffers from such a condition, her chances of gaining approval for Social Security benefits without outside assistance are minimal. If she is denied for Social Security benefits, in most States she will also be denied Medicaid benefits,

leaving her with no income and no medical care. If she lives in one of the very few States that continue to provide income and some medical care for the disabled poor, she might qualify for local benefits which would provide an income surely under $300 per month and access to a rundown public hospital system. More likely, however, because her State probably uses the same definition as that used by the Social Security Administration, she will not qualify even for minimal State benefits.

The Social Security decision is crucial for all people with HIV and for all people with disabilities in general.

The course of HIV should not be a mystery to the Social Security Administration. After 130,000 deaths from AIDS, we know that in the process of this disease the immune system is slowly but inexorably destroyed. While many people with severe HIV-related conditions continue to live relatively normal lives for many years, most do not.

If an applicant is HIV-positive with significant immune suppression, the SSA inquiry need not proceed much further than that. Instead, the Administration requires that applicants show evidence of specific AIDS-defining conditions.

Because this list is necessarily limited it will exclude many conditions commonly suffered by people with AIDS, as has been discussed at length today.

If applicants do not suffer from one of these AIDS-defining conditions, they must alternatively show evidence of another set of HIV-related symptoms plus evidence of a functional impairment. The latter test is one that is little understood by most Social Security claims representatives and is often applied incorrectly by advocates for people with AIDS.

Instead of simplifying the process, early drafts of the new Social Security regulations indicate that the Administration is further complicating it. The complexity will require that all claimants get assistance with their applications from advocates, or face near certain denials of benefits.

Further complicating the scenario for Social Security applicants is the fact that Social Security employees receive almost no training on specific diseases or conditions. As a result, many Social Security offices rarely allow even presumptive claims for HIV. I know specifically of three offices in the District of Columbia that have not offered

more than five presumptive disability claims for HIV in the past year.

The Administration's new plan for presumptive benefits will still suffer from this lack of training. Employees don't know what they are looking for, and they don't know whom they are looking at.

If Social Security follows through with a highly complex system of disability determination for HIV cases as it looks like they will, the length of time from application to payment of benefits will increase even more significantly. Without comprehensive training for Social Security personnel so that they know when to process presumptive benefits under the new regulations, people with HIV will wait even longer than they currently do before they can receive benefits.

For most claimants, this means that they will have to wait not only for Social Security benefits, but for Medicaid benefits as well. Many will not live to receive these benefits.

At Whitman Walker Clinic, we assist several hundred people with HIV every year to secure public benefits, with the help of volunteer entitlement specialists and with extensive help from the private bar. Yet, even in a relative-

ly small city like Washington, D.C., we cannot hope to meet the current need for our services. The system for awarding disability benefits is so complex and unmanageable that few applicants can be successful in securing benefits if they apply on their own. Yet if the SSA moves forward with an even more complex set of regulations than the current guidelines, this situation will be even further exacerbated.

While those who are highly educated, who know how to gain access to community resources, and who receive regular medical care for HIV will encounter few roadblocks on the way to collecting their benefits, the poor, the uneducated and the dispossessed will find public benefits all but unattainable.

Thank you.

CHAIRPERSON OSBORN: Thanks very much.

Last but not least, Rozann Abato, Deputy Director of the Medical Bureau, Health Care Financing Administration.

MS. ABATO: Thank you.

I'd like to talk about the Medicaid program, eligibility for Medicaid, and some of the things that we are doing in Medicaid to serve people with HIV infection and persons living with AIDS.

Forty percent of all adult persons living with AIDS and over 90 percent of all children living with AIDS are served either by the Medicaid or Medicare programs. This includes person also living in the earlier stages of HIV infection.

In fiscal year 1992, we expect the Medicaid program alone will serve approximately 43,000 persons living with AIDS at a cost of $2.1 billion. That includes both State and Federal money, because as you know, Medicaid is a State/-Federal program.

The Medicare program in fiscal year 1992 expects to serve 4,300 persons, with estimated expenditures of about $280 million.

There are three primary ways that you can become eligible for the Medicaid program, and these are categorically eligible ways that are laid out in the statute. The first is if you are eligible for benefits under the AFDC program you are eligible for Medicaid. This primarily covers children and caretaker relatives, and clearly if there is a low-income family situation.

Secondly, States must cover pregnant women, infants and children up to nine years of age that are eligible under

various poverty-related tests. States must cover pregnant women and infants up to 133 percent of the Federal poverty level. Some States must cover up to 185 percent of the Federal poverty level because when the law changed, when 185 percent was an optional group, some States were covering at that level, and they became mandatory groups in States that were already covering up to that level. And it is still an option for other States to cover up to 185 percent of the Federal poverty level. And children, as I said, up to age nine have to be covered, and that is at 100 percent of the Federal poverty level.

These two groups, as well as the third group that I'm about to discuss, coverage is related to these categorical eligibility tests, not to the stage of HIV infection. So whether you have HIV infection or AIDS or not, you can become eligible for the Medicaid program.

The third one is the one that we've been discussing most during this panel discussion, and that is related to the SSA definition of disability. This covers, as you know, both children and adults. If the person meets the SSA definition of disability, they become eligible for Medicaid through the SSI program or through a related, medically needy program in

some States based on the basis of disability. And there are 36 States that have medically needy programs. Usually these are persons in the end stage of AIDS, but it can be at an earlier stage of infection depending on when the disability determination is made.

There is no Medicaid eligibility for individuals who do not meet these categories.

The principal avenue for Medicare eligibility is also to meet the SSA definition of disability and have sufficient quarters of coverage to receive Social Security disability insurance cash benefits. Both for Medicare and Medicaid, SSA's definition is the definition that we use under both these programs, and that is by law. We do not have an independent definition of disability.

HCFA, as I said, covers a lot of individuals under Medicare and Medicaid who have AIDS or HIV infection, and we take this very seriously because it is a very serious public health problem, as you all know. In every one of our regional offices we have an AIDS coordinator, and there are ten regional offices in HCFA. Primarily in the Medicaid program, the AIDS coordinators work directly with the States to encourage States to both educate and encourage States to

provide as many services for these individuals as possible.

I'd like to go over with you some of the things that we are doing to make health care services through the Medicaid program available for these individuals.

Sixteen States have special home and community-based waivers to support care for persons with HIV infection and AIDS outside the institutional settings. I think New Jersey was the first State that had an AIDS waiver approved, and they have been very successful. It gives a certain dignity to these individuals, and we are very supportive of States submitting waiver requests. We cannot tell a State that they have to do a waiver program, but we do encourage them to submit waiver programs, and we work hard with them to try to make those waiver programs approvable.

Over a dozen States have adopted enhanced reimbursement rates for services to persons living with AIDS, recognizing the heavy impact that this disease has on certain health care practitioners and facilities, primarily long-term care facilities.

Several States are using Medicaid State plan targeted case management services for persons with AIDS. In fact there are about six States that are doing this, and they

can provide services that are not necessarily health-related services, like educational services and other services, to try to help these individuals manage their care better.

Forty-three States have adopted the optional hospice benefit, and that is a benefit that has been very helpful to persons living with AIDS--and the key word is "optional". The hospice benefit is optional. States do not have to provide that service, but 43 States have opted to do that.

As you well know, the coverage of drugs was at one time a bigger problem than it is now in the Medicaid program because of the OBRA '90 legislation, so now States must cover prescription drugs that are manufactured by manufacturers--excuse the redundancy--that have a rebate agreement with the department, with the Secretary, so if a manufacturer has signed a rebate agreement, States must cover that manufacturer's drugs. This means that drugs such as DDI and Foscarnet are all available to Medicaid beneficiaries.

There are some other parts of the program that are related to eligibility kinds of things that offer services, or help make people eligible. There is the State option, as you know, to pay for cost-effective COBRA continuation

premiums for employer health insurance after termination of employment. This is in effect a new eligibility group, and it is a State option. I frankly don't know how many States have taken advantage of this option.

Then there is the qualified Medicare beneficiary program. This is where the Medicaid program will pay Medicare premiums and deductibles and cost-sharing for low-income persons--people below 100 percent of the Federal poverty level--who have Medicare eligibility. There is the qualified disabled working individuals benefit. This is where Medicaid will pay the Medicare Part A premiums for persons who have been found disabled but have been able to return to work. There is the so-called Section 1619 authority, where Medicaid eligibility will be continued for disabled persons formerly SSI-eligible, but who return to work. That eligibility has some limitations on it, but it is available.

And the last thing that HCFA is doing that I wanted to mention to you is that as you all know there is the congressionally-mandated demonstration study which focuses on the programmatic and health care status and the cost effects of extending Medicaid eligibility to persons in the early stages of HIV infection. I'm not sure when the results of

that demonstration will be available, but I'm sure you will be looking at that very closely, as will we.

Thank you.

CHAIRPERSON OSBORN: Thanks very much, Ms. Abato, and for standing in at the last minute, too. We really appreciate it.

These are very important topics that you've all helped us to understand the complexity of, or at least to appreciate the complexity of, and with some very clear presentations so we can begin to understand.

Harlon?

MR. DALTON: Ms. Gahan, actually, I have several questions for you, and I think I'll ask them at once. Having watched you work, I have no doubt you can keep them all in mind.

As I heard you testify, I got the impression that what you were telling us was that the Social Security Administration is about to issue a list different from the CDC list, one that is functionally focused rather than surveillance focused and that is, if anything, broader than the CDC's list in terms of the kinds of conditions short of currently CDC-defined AIDS that would qualify.

So I just wanted to check and see if that was indeed what you were trying to tell us.

Secondly, obviously, the question is what symptoms and signs and lab results will qualify for listing level, that is, will make the list. Another obvious question of concern to people in the room is which women-specific symptoms and signs will, together with an HIV diagnosis, put one at the listing level. How is this list being compiled, and whom are you getting the input from and listening to?

A related question, I suppose, is what procedures are being put into place to train people in field offices and at State disability offices to be able to administer the new regulations.

What is your timetable for putting these regulations into effect?

What is your best guess with respect to whether these changes that you are proposing to put into effect will result in more people or fewer people receiving a presumptive disability determination at the field office level, in other words, not getting bounced along to the State, but at the field office level?

Are more people going to get a PD, or fewer--which

I think is in may ways the bottom lie.

And given your understandable reliance on treating physicians as the source of information, how do you deal with the situation where a doctor like the ones that Dr. Holloway talked about says, "Listen, I'm going to treat this person as if he has PCP rather than going to the expense of mailing the body somewhere else," et cetera, so that you don't have an actual diagnosis of PCP or of some other sign or symptom, but you have a physician treating the person as if. How do you deal with that?

MS. GAHAN: I'll take them back in order. The SSA list is already broader than CDC's, and it will be made even broader than it already is. So you understood correctly.

Women and what specific symptoms will be added and specific women--I wish I could talk to you about all the specifics of this list today. I can tell you it includes a lot of the concerns I've heard in this room this morning. I can't talk to you about the list. I mean, we go through a regulatory clearance process. There are powers-that-be that have input into that. In developing the list, we not only worked with CDC, NIH, NIMH, leading researchers and clinicians around the country; we also took into consideration comments

we get from people like Theresa McGovern and legal aid lawyers and letters we get from the Whitman Walker Clinic, on suggestions on what to do as you expand your list. We have considered all of them extremely carefully. We have worked with pediatricians from Johns Hopkins. We look for children's specialists as well as adult specialists in the area.

Training. Training takes two shapes here. People have talked about our field office employees don't know a lot about AIDS and HIV and its manifestations, and they don't. We have tens of thousands of field office employees. The new procedures we are putting in place with respect to PD, which is their role in this process, to do more of that--and we anticipate that thousands more HIV claimants, thousands and thousands more, will get PD payments in a field office as a result of our new procedure.

We tried to design it so that they don't need to understand what PCP is in order to effect the new procedure. So if someone comes in and alleges, "I am HIV-positive," the procedure is triggered automatically. There is no guessing in their mind what to do next. The allegation must be there, of course. But once someone comes in, it is triggered what to do next.

Their training, we have written detailed procedures for them. We do videotapes, we do sessions that go out, and they give training in our field offices almost once a week in the mornings that will be used in that sort of session.

With regard to DDSs who make the disability decisions, certainly they will have detailed procedures on the new criteria and manifestations that are being added to the list.

With regard to the issue of test results, and do you really have PCP or don't you, it has always been a difficult area in Social Security--and let's separate it--first, to get PD. All the doctor has to say is Arlene has PCP, and PD is initiated. To get the final decision, it does get a little more complicated. The statute requires we have a medically-determined underlying impairment. It is in the law. It is a requirement, and that includes signs, symptoms and laboratory findings. I do not and cannot accept a diagnosis from a doctor that says Arlene has cancer without anything to back it up, any more than I can accept the diagnosis that Arlene has PCP without anything to back it in the long run.

Common sense has to come into play. Wasting

syndrome--I am a new treating physician, and I have no idea what Arlene weighed a year ago. We would take statements from relatives and friends and family just to say okay, yes, she did, and take statements such as that. But the criterion is there, and I know it's a tough nut, but we are hoping that using PD, and yes, the allegation is you've got six months of benefits while we, working with the treating physician or a consulting examiner, figure out unfortunately how we're going to get the evidence to establish conclusively that they do have something.

MR. DALTON: I think the only thing you left out was the timetable.

MS. GAHAN: Absolutely at the very latest by the end of this calendar year.

MR. DALTON: Thank you.

CHAIRPERSON OSBORN: Don Goldman.

MR. GOLDMAN: I'd like to ask just a technical question. What will the process be? Will the regulations be published in proposed form in the Federal Register, with a comment period prior to their--

MS. GAHAN: Sixty-day comment period.

MR. GOLDMAN: Do you plan to hold any hearings or

any forums of any kind?

MS. GAHAN: We publish all of our regulations with the 60-day comment period, and despite mailing them to thousands of people, we don't get a good response. I'm hoping and expect we'll get a much better response on the new HIV listing, and some of the decisions about what to do will depend on the written responses we get, but it may very well be that a public forum is necessary before going to the next step.

MR. GOLDMAN: Dr. Reyelt and Dr. Holloway, I'm just curious as to whether you think--and this is a question from a clinical perspective, and you're our clinicians--whether or not the exclusion of those in Category B2 in the definition is appropriate, as to whether or not from a clinical perspective, if you were going to set up a rational system, if you have somebody with a T4 count under 400 and that sequelae of conditions, whether or not it would make more sense in your judgment to add that to the list or not.

I don't know whether you've thought about it or not, and if either of you want to respond.

DR. REYELT: One of my problems is I'm not sure what is going to be considered symptomatic, and I think

that's where we get into the area where we do see a lot of people who are symptomatic, but maybe not all the symptoms are classically associated with HIV disease, or there is an article here or an article there, but it's not massive numbers of people. That's where the combination of disease, HIV plus another condition, can in fact make someone disabled.

Whether for surveillance purposes, they are AIDS, I don't know. From the point of view of significant impact on their health and longevity by being infected with the HIV virus, which I would say is a clinical issue, yes.

MR. GOLDMAN: Can you tell me whether or not the CD4 count is referred to or plays any role under any circumstances in the proposed SSA definition?

MS. GAHAN: Absolutely right now, you'll see a T4 count in your regulations; you'll see it in the context of a T4 count under 200 that results in a functional restriction. You're not going to see a change in the tie to the T4 count and functional restrictions. So that if you have, and it restricts your functioning, you are at listing level.

DR. HOLLOWAY: A couple of things that we were talking about--the thing on the weight has been a real problem with us. We had a woman who had lost about 100

pounds. We had family pictures of her. There were no clinical records to show that she had lost that much weight, and we could not document anywhere that anybody had recorded her weight, and we were totally unable to get her eligible up until her death.

The thing about PCP diagnosis, as you have mentioned, is just terrible, because if you wait until somebody comes in, you need to treat early rather than wait two or three days to get a bronchoscopy. Then you treat it, and if you did the bronchoscopy, the test might be negative because you'd already treated. So those are tremendous things.

The other thing that we have a problem with in a rural area with high unemployment is we have people who are substantially--they could do some work, but they can't come in and work an eight-hour day; when they get tired, and it varies day to day, they need to be able to take off and go home and have some variation there.

So it is hard for physicians to say--and a lot of physicians are prejudiced against people getting disability; they think a lot of people are out for getting disabled, so they won't let them get disability--so they say sure, he could work, but the thing is in Waycross, Georgia, he can't

find a job where he can work two hours one day, eight hours another day, as he feels. So it is hard to document that inability to do any substantial gainful work.

And then the real heartbreaker we have is somebody who is making $40 or $50 per month more than--they get Social Security, and they have something else, and they make just a little bit more than they could get on the State Medicaid program, so they would have been better-off if they didn't have any income. So that's a real problem that we see.

MR. DALTON: Dr. Reyelt?

DR. REYELT: Could I follow up on that and just say that what happens is sometimes you are almost in your head asking people to choose between a better income or better medical benefits, and depending on their particular situation, sometimes that in fact is the question that has to be asked.

The other thing is although--and I think I want to say that about Dr. Holloway--there is no public hospital in his area. In our State, there are very few public hospitals, and there are none in my area, so the private hospitals in fact--and the private hospitals particularly in the urban areas--bear the burden of taking care of HIV-positive people. So what happens in our State with regard to reimbursement,

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which is coming up again for a major problem, will again have a lot to do with what we are able to provide, and we can't diagnose, and we can't get people on the surveillance definition and/or the care track.

MR. DALTON: May I just ask a couple of follow-up questions from what Dr. Holloway said, and you can jump in, Ms. Gahan.

Two scenarios. One, you go to the treating physician, and the doctor says this person can work--whether it is because of the doctor's own judgment about what work means. Let's assume that the real world situation is that this person is sufficiently functionally impaired so that by the Social Security Administration's own definition this person would be out however much per quarter, per year, or whatever, to qualify. In that circumstance, if the doctor says this person can work, and the person says, "But I'm fatigued; I can only work so much," how does that get handled? That's one question.

The second question is if Dr. Holloway is my doctor, I go to him, he figures I have PCP and begins to treat me rather than sending me off to get a test; I then apply for Social Security; you call him, and he says, yes, I

think he's got PCP; I am not presumptively disabled, and I get money for six months, but it turns out that on follow-up tests I'm just fine because he is treating me. What happens then? Do I have to give back the money, or do I get kicked off in six months?

MS. GAHAN: With regard to the treating physician saying someone can work, we have a rule that says the opinion from a treating source is entitled to extra weight because of the treating source's relationship with their patient. However, the amount of extra weight depends on the documentation. In this case, if you say your patient can work, but the medical documentation you are giving us leads us to believe that he cannot work, we have rules for overruling the treating physician's opinion.

But there are lots of impairments where someone's persistence and pace at a task is interrupted more so than their ability to do a task, and one of the functional criteria in the HIV even at listing level is deficiencies in concentration, persistence and pace in doing a task.

Later on when you get to what I called residual functional capacity, you pass that step, you decide they aren't that severely impaired, so you're filling out this

form that takes 30, 40 minutes to fill out, you're filling out this form on the person, and you are looking at their ability to do job-related functions on a sustained basis--not one day a week or two days a week--on a sustained basis, so you have an ability to do an eight-hour job. So I may say on a good day, Arlene can do it, but on average, she cannot. That would come into play there.

These are all policies, these are all theories. We do 2.5 million claims a year. There are mistakes that are made, and it is unfortunate, and we keep hammering away to get the mistakes less and less and less often.

Hopefully, the public comments will help us make what we think is a much more superior system even more so over time.

MR. DALTON: And the PD--

MS. GAHAN: With regard to the PCP, you are not tested, you have treatment, it goes away. That's troublesome, and it's a problem for us administering it. You then go to have the PCP test, and you don't have it. Depending on what else you have and the impact on your function--the PCP goes away, and you're functioning okay--you would not be found disabled.

With regard to paying back PD benefits, you do not return PD benefits. If we pay you by mistake or an error, or later we don't have the test results, they are not paid back.

MR. DALTON: Thank you.

CHAIRPERSON OSBORN: Ms. McGovern, I put you off before, and I'm therefore kind of embarrassed to ask you to be brief, but we're half an hour over our public comment interval, and we'll need to do that and thank everybody, too.

MS. McGOVERN: Okay. I will be very brief.

I'm obviously in litigation with Social Security, so I can't directly talk to them, but I can talk to you about some of my concerns with a version of these new regulations that I've seen, and I will be very brief.

I have asked your staff to give you an analysis that I did of these new regulations. The most important point I want to make right now is that I was very happy to see that a lot of things had been added to a new listing, things like pneumonia, pulmonary tuberculosis. If you have them persistently, they are now named. However, they are also tied into a functional assessment test where a person has to meet two out of four functional tests.

I am very, very concerned for all the reasons that

I raised, for people who are already having problem, that they will continue to have problems with tying these things into a functional assessment. I think if you're going to leave PCP there, then persistent pneumonia or persistent pulmonary TB should be enough on medical criteria alone. The person should not have to further prove a functional restriction. That is or might be appropriate on lesser symptoms, but on the major infections there should be no functional; it should be medical criteria alone, and I'll leave it at that.

CHAIRPERSON OSBORN: Thank you very much.

If everybody wants to stay comfortable just for a minute, there have been what I will call one and a half requests for public comment. I have one person who signed up and then a little note without a name.

Let me ask Jean Emery from the Child Welfare League of America to make a brief statement, and normally we'd ask you to restrict that to a couple minutes, and we're glad to have you with us.

A VOICE: She has left for the day and has left a written statement with the Commission.

CHAIRPERSON OSBORN: Thank you.

And I have a note that someone from Beckten

Dickenson wanted to make a comment in the public comment period, but I don't have a name. If you could be quite brief, we'd appreciate it.

MR. MASHTRI: Yes. My name is Nagesh Mashtri [phonetic], and I run our Beckten-Dickenson immunocytometry system.

A question had come up about the technology, and I thought it would be pertinent to explain that three issues were raised. One was the precision reproducibility of the CD4 counting, number two, the cost involved, and number three, the ease of doing this.

I just want to inform this group that we have now released in clinical trials a system that answers all these three questions, namely, that it will be less than 50 percent of what it costs today; it will be a simple test, and therefore the reproducibility will not be as great as the cumulative errors that are entered, and finally, it is a very simple one-step method.

I just wanted to provide this technology information.

Thank you.

CHAIRPERSON OSBORN: Thank you very much.

In that case, I want to from my vantage point, and I think all of the Commissioners want to thank all of the witnesses for having really given us a sense of the complexity and the intensity with which you are approaching some challenging problems. We have learned lots, and as you gather, we've already reacted a little bit in suggesting that this is worthy of some pretty careful discussion because it impacts the lives of so many people.

So with that, the Commission is going to break for lunch, and we want to thank you all.

[At 1:00 p.m., the proceedings recessed, to reconvene at 2:40 p.m. this same day.]

AFTERNOON SESSION

[2:40 p.m.]

CHAIRPERSON OSBORN: Our numbers are going to dwindle some more, I think, because of departure times, so let's get started.

While we're getting ourselves organized here, let me apologize to our staff, of whom I hope you know how fond we are, for having been unable to all be together. We discussed that, and it's a technical problem. We don't feel it is appropriate to ask you to be paying for very fancy food

a lot, and at the same time, it is impossible to mobilize official funds. And because the Commission felt strongly about it, we decided that those of us who received a daily thing at official hearings would like to contribute part of our daily thing to make sure there was a pot for Commission staff who were able to join us--no need to feel you had to, but if you were able to--to join us when we got together for a meal or something like that. So we've talked about a way to at least get that launched, and we'll try and make sure that we don't end up so estranged. It was something that we regretted--we missed you--and we decided we wanted to be able to make sure that doesn't happen so totally again. So just so you know we missed you, I guess that's the message for now.

Roy has a better idea than I do of how to proceed, so I'll turn to him.

DR. WIDDUS: I was just thinking that the staff will be responsible for the care and feeding of the Commission and vice versa.

CHAIRPERSON OSBORN: Exactly. The staff does a nice job of care and feeding for the Commission, so it seems very appropriate.

DR. WIDDUS: Okay. The session this afternoon can be fairly brief, I think, and we will certainly be responsive to any individuals who want to raise questions outside this session.

Most of the discussion can take place around a memorandum that Commissioners should have, from myself, just updating you on the status of various activities. This deals with the distribution of "America Living with AIDS", the Executive Summary therefrom; commercial publication; the Puerto Rico report; the report on HIV in communities of color; HIV and transmission in health care settings; immigration and travel issues; the working group on religious communities, and the work plan.

I don't need to talk in detail on each of these topics. I'll mention one or two things and solicit your feedback, which can be in writing to us in the form of suggestions, for instance, for future distribution of the main report or the summary, which should be available shortly.

Tom has developed a listing of those groups and individuals to whom we have already distributed the comprehensive report, and you will note from that that the National AIDS Clearinghouse is undertaking an increasing proportion of

the burden of distributing the report. We are negotiating with them and a number of other agencies about the possibility of a second printing to cope with future demand. Any suggestions that Commission members have--

CHAIRPERSON OSBORN: I have a question about that. Does that mean we should still be directing people to inquire of the Commission when they want copies of the report, or should we be redirecting them now to National AIDS Clearinghouse?

MR. BRANDT: The Clearinghouse. We met with the Clearinghouse and talked this over specifically with them, and they are more than willing and anxious to be the primary distribution point for copies of the report.

CHAIRPERSON OSBORN: It would be helpful to me and perhaps to other Commissioners as they speak if you could give us a little set of cards or something--I hope it's not too much of a nuisance--but what I have been doing is taking my Commission card and saying, "Here, write to this address and you can get it." If I could keep doing that, it would certainly make my life more pleasant. And I don't mean giving that card, but I'm saying if you could just xerox off a bunch of them that we could have with us so that we can do

the same thing--"If you want a copy of the report--here, this is how you get it"--except that now it gives the instructions that get it off your back.

MR. BRANDT: Right now we have a distribution order form that we produce that we have out at the desk, and I can give you a copy of that for the here and now. It now has, instead of us, all the information Clearinghouse numbers on it, including an 800 number or an address, and all the ordering instructions that anyone can possibly use. And they are quite prompt.

DR. WIDDUS: If any Commission members wants us to send a copy with a personal cover note because it is an individual you are particularly familiar with, we'll happily do that, but the bulk of the requests should go to the Clearinghouse.

Okay. That distribution will continue as we think of other groups that it should go to. Groups that need to be aware of the report so that they may request a copy if they wish will be receiving the Executive Summary, which I think can be a document that can be a flier just to bring the Commission report's existence to the awareness of a number of other groups. Printing of that Executive Summary is underway.

Initially, we've ordered 25,000 copies, and we will be able to supply to Commission members a certain number if you wish to have something on hand to give people. It is a lot easier to carry that around than the full report if you're going to a meeting.

CHAIRPERSON OSBORN: I don't know if the Commissioners were aware--I had missed the useful point, and I'm delighted that was done--that rather than just exactly what is the first several pages, the recommendations are the fuller--that is, the recommendation with a little explanatory piece under each--as they appear at the back of the chapters, so that it is not just the xeroxing of the front of the book, and is therefore, I think, likely to be a particularly useful document to be able to hand to people because the recommendations themselves are a little telegraphic, and I thought that was a great idea, and I take no credit for it. I'm pleased that it was done that way.

DR. WIDDUS: We are continuing to explore the possibility of commercial publication of the report. The initial response from Harvard University Press was a polite turndown. There may be a very broad market for the book that we have not yet reached, and we'd like to get it into

commercial distribution channels. We'll explore the possibility with other university presses.

The Puerto Rico report, the first draft is finished. I've worked on the last draft, or the intermediate draft, with Patricia, who has been working exceptionally hard on this. If Commission members will bear with me, I've not had a chance to go through it carefully myself yet, so I would prefer to send things to you once I have made the judgment that at any particular stage something is ready to go out.

MR. PERNICK: Is this based on the hearings last year?

DR. WIDDUS: On the hearings and some other information gathering, including some assistance on the surveillance. I think it is now a report that addresses the national aspects of the way in which AIDS in Puerto Rico is managed. I believe that that can be mailed to you within the next day or two. I would just like to assure myself that we're not sending something which is garbled in the middle.

The release date for that is still, we hope, February, although the schedule is getting tight now. I think it is in fairly good shape. Your comments would be best if they got back to us by, say, Tuesday, December 17th.

The report on diseases in communities of color, you will read that June and Harlon have been actively engaged in sketching out some of the material for that and then fleshing that out. We are hoping to bring together in the very near future--in the next couple of weeks--four consultants who we have identified, who will write specific sections of the report on four communities, even albeit communities which are fairly diverse within the name--the African American community, the Native American, the Hispanic and the Asian American and Pacific Islander communities. We are bringing these consultants together so that the descriptive technical information that is written is of a consistent depth and format. They will also be asked to identify broader considerations that need to be included in a discussion chapter, and that will be done, we hope, sometime in January and early February. That, I think, is now proceeding quite well that we've identified those consultants.

The outcome of the meeting on HIV transmission in health care settings was intended to be two documents--a brief statement of principles and then a fuller report. The fuller report is in the process of being formulated, drafted, by three consultants, and they are working away fairly well.

The complication that has arisen in regard to issuing the draft statement of principles that was discussed at the last meeting is that the Centers for Disease Control have taken to heart a number of issues that were raised then and by other groups, particularly the difficulty of identifying and formulating into the recommendations the question of exposure-prone techniques or exposure-prone procedures.

CDC, I understand, is right in the middle of developing a new draft proposed set of recommendations, and I would propose that although Jeff Stryker has fed back to us a revision of the statement of principles regarding HIV transmission in health care settings, we postpone the issuing of this statement of principles until there has been an opportunity to review its content against the revised CDC guidelines.

CHAIRPERSON OSBORN: And that's undergoing active transmission even as we speak; right, Jim?

DR. MASON: Yes. Now, I had not seen--I don't know whether they were sent out in draft previously, or--

DR. WIDDUS: Those have only just arrived as a revision.

DR. MASON: Okay. There was something in here

about maybe they had been sent out. Let me look at these, and I'll get back in touch with you, Roy and June, in terms of where things stand.

DR. WIDDUS: Okay. The statement of principles is what we would hope to review in conjunction with the new CDC recommendations. Clearly, we don't want to make a statement of principles if something in the recommendations that it addresses has been changed radically.

I think the immigration and travel issue is fairly self-explanatory. Carlton, do you need to comment on that?

MR. LEE: No.

DR. WIDDUS: It seems that the immigration and travel issue may be revisited.

The report of the meeting of the working group on religious communities has been produced. I believe Larry has a copy of it. Once he has looked at the staff draft of that report, it will be finalized, sent to the other people who attended that hearing, and then distributed more widely to all Commission members, possibly with some suggestions or options for the way in which we might want to pursue that, which will possibly include not pursuing it in the light of the other work that the Commission is undertaking.

A last but one item is the work plan. There are attachments to this memorandum which summarize the input that we got from the Commission members last time, and I think that input is leading us to focus very much on major efforts in the implementation of existing recommendations and the question of what should be the longer-term continuing mechanism.

Some attention will also be paid to what was the second objective, which was sketching out the framework of the national plan, but I think the best we can do in that area would be quite a broad framework if we do much. We will feed back to you probably within the next two weeks a revised work plan, we hope with some rough costings of what different types of activities would take place so that you can see the prioritization process that we will have to go through, or we are going through now, in order to decide what can be done within the budget.

The final item that was distributed are some dates that appear to be dates upon which the maximum number of Commission members would be available. I think my comments on these dates would be that since people find it very useful to be able to plan their calendars in advance, these are

dates which you should hold as potential dates for Commission activities. I don't think we're yet in a position to identify whether these dates would be a full Commission hearing, a working group, and what topics would be dealt with on these dates, but I think if they are the dates which we know people have available for Commission activities, then we both plan much more effectively.

MR. DALTON: Are you saying these are the best dates available within these months, or at least the best sets of two concurrent dates, so that February 11th, for example, is the best we can do given people's calendars?

DR. WIDDUS: Yes.

MR. DALTON: I'm sorry. I couldn't tell whether that was an answer there.

DR. WIDDUS: I'm sorry. The answer is that to the extent that the calendars people had given us were still accurate at the time we were doing the review, these were the dates on which most people seemed to be available.

MR. DALTON: Because if we take Drs. Peterson and Mendez as one person, or at least covering one seat, that's barely more than half of all Commissioners.

DR. KONIGSBERG: These have got to be nailed down

right away; it just gets too sticky.

DR. WIDDUS: What you say is accurate. It's a reflection of the fact that people commit themselves a long time in advance.

CHAIRPERSON OSBORN: I've actually already got trouble on the 11th, but I'll have to cancel it.

DR. WIDDUS: I was going to add, if I'm entitled to one wish as a new Executive Director, that in the month of January the Commission, both for budgetary reasons and for other reasons, decide not to meet formally. The other reasons would be my request that we as staff have a month and a half that we can nail down some of the other activities that I yet have not had, because I haven't been present in Washington, sufficient time to feel they are comfortably underway, and we'll complete them within the year.

CHAIRPERSON OSBORN: Don?

MR. GOLDMAN: You're talking about cancelling the January meeting entirely.

DR. WIDDUS: Well, one hasn't been scheduled.

MR. GOLDMAN: Okay. My only concern has to do with Magic Johnson and some way of early beginning the interactions with him so he can be integrated within Commission activity,

and if the first time any of us meet with him is not until February, then that will be delayed somewhat, and that whole process will be delayed. That's a concern that I express.

DR. PETERSON: How about cancelling February instead of January?

DR. WIDDUS: The possibility exists that there are dates where groups of three or four Commissioners could get together outside these dates. These dates were sifted out of calendars with the idea of maximizing the attendance of everybody in the sort of traditional Commission format.

CHAIRPERSON OSBORN: Another possibility that I guess we could talk about briefly--I share a little bit of Don's concern, and I don't know how disruptive it would be, Roy, to schedule a one-day meeting in January which was in fact largely not ceremonial, but of the sort that some of us talked about informally, that the first time we meet with Magic Johnson, we can't exactly go ahead with business as usual because we are all used to interchange and interaction, so there needs to be a getting together at some point.

It is conceivable that we could take the second of those two January days, which looks like one of the better ones altogether, have a one-day meeting if Magic Johnson were

available, and then if indeed the pressures of both time and finances were such, it looks to me like February is particularly problematic, and we could jump that one and perhaps do small group things as you say--does that get in the way of your thinking about wanting to catch the staff's breath a little bit? If we did it that way, then there wouldn't be a sense of dropping everything entirely all the way into February, when he wasn't able to make the December meeting; also, a one-day meeting doesn't have to be quite as elaborate in terms of planning.

Larry?

MR. KESSLER: I was wondering if another approach wouldn't be to look at the work plan and approach the January/February meeting based on what's in the work plan, because that's the more logical planning way to do it. Is there something in that work plan that can be accomplished?

The problem with the budget is that even if we come together for one day in January, it costs almost as it does for two days.

CHAIRPERSON OSBORN: Depending on what kinds of witnesses and who we bring.

MR. KESSLER: I mean whatever expenses it takes; to

get an air flight for us round trip, it doesn't matter if it is one day or two days.

MR. GOLDMAN: But Larry, I think what June is saying is that, as I understand it, it turns out that the witnesses that we bring in end u costing more than the Commissioners do, so getting the Commissioners together for Commission business is a much less costly process.

MR. DALTON: I don't think we should be driven by the money since we haven't yet even costed out what we propose to do in the work plan.

CHAIRPERSON OSBORN: I wasn't proposing that we do nothing.

MR. DALTON: No, no. All I'm saying is I think this decision should be made on some basis other than trying to save money just yet. And what Larry has suggested sounds to me eminently rational. Why don't we look at the work plan and see what that suggests in terms of what we ought to be doing in January and February and whether that's something that ought to be done in a meeting or done without a meeting.

CHAIRPERSON OSBORN: I think that certainly is sensible, and I was rather assuming that would be a way to decide what to do. But the issue remains that we do at some

point have a new Commissioner joining us; that we have, as Roy has very gently said, a degree of stress on the staff that needs to be accommodated for. And the proposal I had put forward was not intended to finesse the work plan, but rather to find a piece of it that would submit itself to a fairly interesting one-day session, or an evening and the next day all day, in January and then have a gap in February when there is very extensive logistic work on the work plan and so forth, so that subsequent to that, it could be not downhill all the way, but a really good run at things starting in March.

Just looking at availability and some of the personal realities of this, it struck me that that would be a reasonable way to deploy ourselves while working out some of these thematic things.

Don?

MR. GOLDMAN: Forgetting about looking at the work plan for things to do, we still have to discuss the work plan itself, and certainly, if nothing else, if we had one day on the 14th to meet with Magic and finish up a discussion of the work plan and put it to bed in some more definitive way after you had done the draft that you had done, and cancel February,

that would give you six weeks from then to plan the hearing process that would begin in March. That would seem to me to be a very sensible, logical way of proceeding.

DR. WIDDUS: A meeting solely devoted to the work plan and other things would be useful. If one were looking for a topic which is in the work plan around which it would be feasible to hold a one-day meeting, I think there are two, but one needs to come before the other. The first one is--let me explain why--for two objectives. We need to start the process of thinking about that area with an evaluation of the future of the epidemic. Those are the need and the framework for a national plan, which is the second objective, and the need and the mechanism for a continuing monitoring.

If we had a half-day hearing and heard from a number of people on where they think the epidemic is going in the next 10 to 15, 20 years, that would be a reasonable lead-off for either of those activities and could also be accommodated as part of the work plan, and the rest of the meeting could be the work plan.

MR. DALTON: I just wanted to ask in terms of your somewhat cryptic comment about staff catching its breath, were you referring to the energy that goes into planning a

hearing, that that takes away from catching up with other work, or something different? That is, if we had a working session or a very truncated kind of session like the one you were just describing where we'd have half a dozen people talking about the future of the epidemic, rather than a larger hearing where we have to think about balancing witnesses and so on--is that what you wanted to say, or is it something else?

DR. WIDDUS: It;s more that I would have liked a block of time to distribute people amongst different parts of the work plan that we know are already high priority and get those activities firmly underway. I think if we have less than a full two-day meeting, some of those concerns diminish. Basically, we can accommodate a meeting in January, and particularly if it is on a fairly straightforward topic, not a simple topic, but one where we don't have to balance out enormous numbers of competing interests. We just have to identify the right people to come and talk to the Commission.

MR. KESSLER: The other thing that occurs to me is that if it is the first meeting that Magic is able to make, there will be a lot of media here, and so the topics we're covering will be of great interest as well, for some for the

first time, and in the future the epidemic might be something that is of interest to the media who are attending and watching Magic interact with us and the topic.

So rather than going with something that's dry and real technical, like Social Security regulations--or maybe we could get into the Medicaid--

MR. GOLDMAN: Magic hasn't been sworn in yet, has he?

DR. WIDDUS: No.

MR. GOLDMAN: Okay.

MR. BRANDT: This is really negative, but in regard to the hearing yesterday and today, for a couple of weeks, you know, Magic Johnson was on again, off again, on again, off again. He did that with us, he did it with AMFAR, and he did it with the Donald Trump affair; he has turned down Secretary Sullivan on some invitations to come to Washington. We don't know how reliable a participant he is going to be yet, and hopefully David will come across with some better indications.

I think the Commission needs to keep focused on doing the Commission work, and if he is there, maximize on it, great, we'll be excited and do a good job, but we will be

frustrating many of us who have to work with this on a day to day basis if we plan primarily around him and go on that day to day to day to day, up and down, we really will, and we don't know what the payoff is going to be yet.

CHAIRPERSON OSBORN: You're right, Tom, that's really negative.

MR. BRANDT: It is, but also, I've had more contact with his people--

MR. DALTON: I didn't think it was negative at all.

MR. BRANDT: --I've had more experience with his people than anyone here, and we've been very nice with them, and they've been very nice back to us, but the bottom line is--

MR. DALTON: June, what I hear him saying is that from the staff point of view, if you're having to plan around this and are being bounced around, that's very demoralizing, and that strikes me as an empirical observation, not negative, and if we can avoid that, I think we certainly ought to.

Now, a happy coincidence would be if we thought it would be useful to have a half-day hearing or whatever on the future of the HIV epidemic, and that were one that would work well if he were here, then great. But I don't see how that's

negative.

MR. BRANDT: But if we do that, make sure it's going to be hearings that are going to work with or without him. That's what I was saying--make sure it works with him or without him, that's all, because we already did it once in December, and if we do it again in January, and he's no-show--

DR. WIDDUS: I don't want to sound like I'm disagreeing with Tom--and he bears the brunt of this uncertainty in that--but I think the position we need to adopt is that the Commission, as it has always done, schedules its activities based upon the maximum participation of all Commission members. And we haven't up to this point changed any of the plans regarding what we've done, but Tom is right that it does create a certain amount of uncertainty as to if we've got to plan for a lot of media and so on.

CHAIRPERSON OSBORN: It argues, as I see it, very strongly for doing what we're talking about, which is a one-day meeting in January and skipping February. That gives a single day's commitment to follow through on. It sounds as if it lends itself well to some of the fundamental work that Roy feels is necessary to proceed. I think all of us will

find it an interesting topic if it is addressed by very capable people, and it would indeed highlight what we're trying to do in terms of overall awareness, with or without the extra media. But I would think given one day out of the next several, with the level of commitment that has been made, that it would be highly likely that he would attend.

MR. BRANDT: The media isn't the only aspect, but just for this current hearing, when we thought that he might be able to join us, we sort of did an "A" hearing and a "B" hearing. We would have had a different hearing if he had been here for at least part of it. So we sort of had to plan double and then hold off until the very last minute and decide which part we were going to implement. That is what really complicated things, and the media part would really be the lesser issue there.

So all I'm saying is if we plan something, make sure it's something that is going to work with him or without him.

DR. ALLEN: In January or possibly February, is there going to be any need or any desire to get the Commission together to discuss any of the reports that will be coming out, or is that all going to be handled through review of

drafts in the mail?

DR. WIDDUS: I think the bulk of it will be handled in draft through the mail. If it is convenient to get a final sign-off at a meeting, we may do that.

CHAIRPERSON OSBORN: It sounds like we've got reasonable comfort about having what I would guess would be the second of those two days in January, since more people are available--that is to say the 14th is a one-day session, with a theme that works to the longer game plan of the work plan--and probably not a meeting in February in order to accommodate the acceleration of work plan work; and then from that point on, the dates to be held as possible as written here; is that right?

DR. WIDDUS: Yes.

MR. DALTON: I'd only ask you, June, whether there is any possibility you could make it the 13th, because I at the moment can't quite figure out why I can't--if you can't, then the 14th is obviously better. You and I are the ones who can't make it on the 13th, and Diane can be there on the 13th, so if you and I could, then that would be everybody.

CHAIRPERSON OSBORN: It is one of the two meetings with the provost in the year, and I'm already in very serious

trouble with my job. It's not very negotiable. I've already turned down several committees because they conflicted with that.

MR. LEE: Has Diane Ahrens seen this list?

DR. WIDDUS: Her calendar was reviewed--

MR. DALTON: Let me put this question a different way. I asked before whether these were the days on which the most Commissioners were available. If a particular Commissioner, in this case Diane--but anybody--is systematically not able to make a number of meetings, that seems to me something that ought to be factored in, and I just don't know whether that was part of the mix.

DR. WIDDUS: I think, looking at the dates, it's a fact that most people schedule their routine commitments on dates other than Mondays and Tuesdays, but Diane has one that is scheduled routinely on Tuesday.

MR. DALTON: So in other words, if we did it on some other day, then other people would be systematically lopped off.

DR. WIDDUS: It seems so, yes.

CHAIRPERSON OSBORN: Carlton?

MR. LEE: Somebody could be bumped with another

systematic meeting they have at the time, so that Diane's not the one who is chosen, that's all, as sort of the person-- it's your fault you meet on Tuesday. I don't know if you can change it. I'm just saying I think Diane would be very upset.

MR. GOLDMAN: We're knocking out February, so--

CHAIRPERSON OSBORN: I guess there's one other question we could ask about January since we're knocking out February, and that is was this done as a two-day stretch, because if there were a different January single day, without the need to have two contiguous days, that might make it look a little different.

DR. WIDDUS: It was done looking for back-to-back days. So we could in fact do another review.

DR. PETERSON: Since this is the second week in December, I strongly suspect people's calendars for January are beginning to fill up.

MR. GOLDMAN: Yes. The answer is if you're going to do it you ought to do it this afternoon or tomorrow morning.

DR. WIDDUS: In response to Carlton's question, too, I think we should do for the later months a review to see if there are single days that we could hold a meeting one month

and not inconvenience Diane.

CHAIRPERSON OSBORN: My memory is that Diane has once or twice been with us on a Tuesday when it was special. I think for a single-day meeting, and I think for January, I quite agree--I'm already closed down, really, almost. But I think we can look at it for other times if that's what the hitch is, but it is an urgent thing in the sense that I had been holding off a number of people until after December 10th so that we could have this discussion, and so I've got all manner of folks who are planning to call me within the next two or three days to see whether or not I can now do something later in time. So we do need to resolve it, but I think it could be looked at--I remember doing that a little bit to make sure we didn't always end up on a Tuesday with Diane not being here.

DR. WIDDUS: That's it.

CHAIRPERSON OSBORN: That's it. Roy, you get to close the meeting.

DR. WIDDUS: The meeting is closed.

[Whereupon, at 3:20 p.m., the proceedings were concluded.]