TRANSCRIPT OF PROCEEDINGS

NATIONAL COMMISSION ON

ACQUIRED IMMUNE DEFICIENCY SYNDROME

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DEFINITIONS OF HIV DISEASE:

POLICY IMPLICATIONS

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NATIONAL COMMISSION

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DEFINITIONS OF HIV DISEASE:

POLICY IMPLICATIONS

Monday, December 9, 1991

9:07 a.m.

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AGENDA: (Continued)

Epidemiology and Surveillance

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P R O C E E D I N G S

CHAIRPERSON OSBORN: Good morning and welcome.

I think we should get started in a prompt way because we have an important and interesting set of activities today. For many of us, one of the most important that we will do as a Commission is now as we start by remembering Belinda.

The staff asked if I would start with comments, and I had an experience this week which is as good a way as any of starting off, I think. I was down in Miami earlier this week, giving what was the keynote address for the Agency for Health Care Policy Research and, as I commonly do now when I speak, I had the Commission report with me, and at the end of my talk I said that Belinda had been very important to us, that with some of her last strength she had contributed to it by helping us to pick out from her testimony the first time we met as a Commission some words that she particularly thought would be good to have in the Commission report, and that is, as you all know, at page 10 of the report.

I just told that little bit and then read them page 10 as the ending of my speech. It was one of these sort of high speakers tables, so that when we got done and people

came up, I sort of had to lean over to say hello to people. And a grey-haired man came up and took my hand, and I looked, and he was crying. So I held his hand and waited for him to catch his cool, and he didn't for a while, but he waggled his name tag at me, and it turned out it was Belinda's father.

I said, "Oh, Mr. Mason, I hope you didn't mind."

He said, "No. That was wonderful. I think Belinda would have liked it very much."

I had a much longer chance to talk to him the next day, and he told me that evening that he had called Steve and told him that that had happened and that he had been pleased, and Steve was, too.

So I feel good about that. I would probably never have dared to do that had I known he was in the audience, and yet it turned out that it was something wonderful from his vantage point. And we had quite a little talk about the wonderful kind of immortality Belinda had established in touching so many of us so deeply. I think that her impact on me is as great as anybody I have known, in ways that I continue to find more and more useful as we go on, and I think that's true of all of us.

As I told Mr. Mason the second time we talked, I

said, "I hope you realize what an enormously large family you have because of those of us who loved Belinda."

So with that as my set of comments, shall we proceed?

DR. WIDDUS: There is a videotape that will be shown.

[VIDEOTAPE SHOWN]

CHAIRPERSON OSBORN: We don't have any kind of set schedule here, but we felt that it would be appropriate for any and all of the Commissioners who wanted to have a chance to say something to do so, and I guess now would be a good time.

David, could I ask you to start?

VICE CHAIRMAN ROGERS: That was very powerful. I don't know whether I can or not, but I'll try. And my apologies for reading.

One couldn't spend ten minutes without Belinda without falling madly in love with her. She had a radiance, a luminous quality that lit up your soul. Yes, she was beautiful; yes, she glowed with intelligence; yes, she made those she touched feel distinct and special. But it was her irreverent, mischievous, gamine-like qualities that made her

most endearing to me.

And she was wise beyond her years in matters relative to the human condition. Perhaps it was her awareness of her own fragile mortality that gave her such insights, but they were everywhere apparent. She knew what was important and what was trivial. She knew what was genuine and what was take. She knew what was heartfelt and what was bombast. She could spot prejudice or intolerance or insincerity from a country mile.

I used her as a perceptive counselor, and she never let me down. And she loved playing the hillbilly hoyden. She could lay it on thick in a way which would disarm and charm the drawers off anyone within her radius in about 30 seconds.

Belinda had a way of phrasing her thoughts--and we've just heard it--which was unique and unforgettable. One remembered not only the thought, but the way it was phrased. She was eminently quotable--not always printable, but eminently quotable. I have a whole bagful of Belinda stories that I treasure and pull out and look at and laugh at very frequently.

What she did for people with AIDS will, alas,

probably never be fully recognized. She had an almost saint-like understanding of others' needs and fears and angers and suffering, and she became their spokesman and their advocate and their consoler. Despite her own illness--and it was a brutal, debilitating illness--she seemed to have an almost infinite capacity for love, and she dispensed love unsparingly, in huge quantities. She was a powerful therapist.

To say that I miss her enormously falls miles short of the mark. Despite out differences in age and background and culture, she was my dream girl--affectionate, humorous, wise, giving and very, very special. I am a different person because I knew her. She made the world a better place. I am glad I had the special privilege of being touched by her.

CHAIRPERSON OSBORN: Harlon?

MR. DALTON: Well, if Belinda were here she would say something funny now to sort of lighten the moment.

One of the things that I most remember sitting around a table like this next to Belinda is that she would appear not to be paying attention--she would be drifting, she would be doodling--there would be a witness there, pontificating, and suddenly Belinda would ask, "Do we have a bio? Do we have his written statement?" And I knew that she was

loading up for bear and that soon, somebody was going to be roadkill.

Belinda was certainly invested with heart, to use her old phrase, and her work with AIDS was because she had a calling. She described the ambivalence she had about her public life and the simple and satisfying life that she had with Steve Cardin, a rock of a man, and Polly Beth and Clayton, but she left that family home and took plane after plane, and sat at this table with us because she was truly called to, even at a tremendous cost to her body and to her simple, satisfying life.

What we saw in that last clip I think was perhaps the greatest loss occasioned by her death, which is the loss of someone with such a gift for words and such a love of words. When all is said and done, Belinda was a writer, a speaker and a writer of extraordinary talent, and as much as anything I think I will miss that as well as the fact that I never got to see her glide over those hurdles as a high school runner.

Belinda was supremely honest. In fact, if anything, she worried that she wasn't honest enough, that she prettied things up too much, that she never really told the truth in

all of its gritty reality. And yet for many of us, she took us about as close as we dared come to peering at the truth, and for that, I too shall miss her.

CHAIRPERSON OSBORN: Scott?

REV. ALLEN: I remember three stories. The first one, in Santa Fe we had a chance to be together at a conference in which she was very blunt, and the warmth truly shone through. Afterward, we went shopping, and she had a list of about 12 people back home that she wanted to buy gifts for. I had to follow her around to every store, hearing everything about every person on that list and why this was important to them and why this particular gift would go well, here, there and everywhere, and the excitement that she had of giving and, from one of my first contacts with her, the realization that it meant a lot to her to be a part of people's lives, and that was very much reflected as she became a spokesperson for people living with AIDS. She was a very tender and sacrificing person.

The second story is the elevator in Atlanta, as we were going down on Easter, as she mentioned in the tape, and her lamentation that she was not going to be with her family, and the magnitude of that sorrow. She knew the sacrifice

that she was making. She was going into rural Georgia, wandering the beautiful hills of Georgia, away from her family. As I watched her interact with folks, her attention was completely focused on the individual she was talking to, and she never lost sight of that; but there was also the secret sorrow that we discussed going down on the elevator, of not seeing Polly in the Easter egg hunt, not seeing Claytie in the excitement of the moment, and that kind of sacrifice that people don't realize.

And the last story was something that may be a little appropriate for today--the opportunity to meet the President. We sat in a room that night, talking about the historic nature of the moment, thinking of how the epidemic has moved through the lives of so many folks, and the need for Presidential leadership, and that we were very grateful the President was about to speak, that she was going to meet the President and so forth, and get that photo op. We were talking about the excitement of the time and the hoopla of that day.

We were sitting in the airport about to depart to our homes that evening, kicking back with our feet up, and I said, "Well, Belinda, what was it really like?" And she

looked and me and she said, "You know, Scott, like most things, it was smaller than life."

True life for Belinda was kicking back with her family. There was a time when the folks were trying to have a lunch with Barbara Bush and Belinda, and she said, "I would rather be at home, having grilled cheese sandwiches and having a picnic in the back yard than meeting with Mrs. Bush." That is true life, and that is something that she always brought, was the reality of what life was all about and the specialness of the moment, and that some things are necessary but are smaller than life. And Belinda truly did live that life, and I am very grateful to her.

It is a loss. It is a big loss. But as I sat in the meetings when she was so sick, and she couldn't come, there was always in the meeting a reflection of her, and continues to be so, because as David has said, she is very much a part of our lives and will always be so. And I think she would like it to be said once again that there are others; she is one, and she is one of many, and she made the reality of our task even more pressing as we go through and as we have gone through and as we do continue to go through this epidemic and try to do what we can to not lose sight of

the people who are hanging in the balance. I think that is something Belinda would want us to be constantly reminded of. She honored the PLWA community very much, and they were very blessed with having a representative such as she.

We just have to keep on, and I am just real sad.

CHAIRPERSON OSBORN: Before proceeding, Harlon's admonition that Belinda would want us to laugh, you just prompted a memory that I had actually lost from the time it happened until now, that David will share.

After we met with the President, we all ended up in "Guest Car No. 1" I think it was called. Belinda sat up in front, and David and I were in the back, and there was a uniformed and very proper-behaving driver. We were right behind the President's car and starting through this motorcade, going the wrong way through all the red lights in Washington, and while I was sort of looking around, I realized that Belinda had started in on the driver.

She looked down and she said, "Now, that looks like a very interesting car phone. Who do you suppose I'd talk to if I picked that up?"

And the driver looked sort of startled, and she worked him over wonderfully, and pretty soon he was relaxed,

talking with us and joking. And then I got into the spirit of it and asked if he ran red lights on his own time, because we really were going through all red lights.

But she had this extraordinary capability of taking a situation like that one and turning it into "plain folks" so fast you didn't know what had happened to you. I think that driver will probably never forget that ride to Arlington.

Diane?

MS. AHRENS: Occasionally someone touches your life, and you know that you won't feel that touch again as long as you live. Such was Belinda. Her genuineness, her intellectual honesty, her questions that were never really just questions, and her determined perseverance. But I think it was Belinda's more subjective qualities that touched me most--her smile, tinged with a bit of mischief; her soft Kentucky speech; her generous warmth toward me and toward all of you; and her down home, disarming nonpretention--I loved the disarming nonpretention.

I really only knew her slightly and for too brief a time, but to have been touched by Belinda is to know just a taste of heaven, just a taste of heaven.

CHAIRPERSON OSBORN: Eunice?

MS. DIAZ: I'd like to remember Belinda the very first day she was appointed to this Commission. It was a sunny California afternoon when the phone rang, and she introduced herself and said she had just been told that she would be on this Commission and asked me if I knew any of you.

I had known of David Rogers in my previous professional life, had heard of Larry Kessler and also of Don Des Jarlais, but the rest of you were unknown. She said, "Well, we share a lot in common. You know one more person than I do."

She talked about you, June. She had heard that you may in fact be our chair, and she had hope for a very warm relationship with all of us.

I called Belinda nearly every week of our knowing her as a Commission member. Many times, as happened to many of you, she was not able to come to the phone. Things that I remember she told me she treasured the most were calls and visits by various Commissioners, many of you here, and also the warmth and love shown particularly by one staff member, Carlton, meant a lot to her.

She would like to be remembered, as she told me many times, when we see that bright green color she loved so

much. I asked, "Why do you wear so much green? Why do you love green?" She said, "You really need to look back into this. It means hope."

Green has a special meaning for me now because Belinda loved it so much. She wore it well because she inspired that hope.

I also remember her because of the devotion and dedication she showed to the PWA family and the attention that she took in the times that she was ill to make sure that either Ron or Suzanne, who have both also died, were here at this table and the significance of that input into our deliberations.

But most of all I want to remember a speech that she gave in Denver when a coalition of organizations had both her and I as speakers on a weekend. We shared a room. We had many hours of talk together. But the speech she delivered that night has made a significant impact on my life, as I remember counsel that she gave to about 1,000 people, but she spoke to my heart personally. She told us that night to not forget in our arduous task of working on behalf of others and working in this cause to take time to smell the flowers as we go along. That was especially significant for me. She said

take time for your family, for yourself and for others.

She said, "This spring will mean something special as there will be flowers in my back yard and also those beautiful very small ripe tomatoes, and I will love going there and absolutely putting them in my mouth from fresh pickings."

As spring comes now, I will remember that, too, to take time to really smell those flowers, and with the freshness of that spring, look at that green now in a sense of the hope and legacy she left behind.

CHAIRPERSON OSBORN: At 10:00 we have to do other things, but there is a little time, and I know there are people who have joined with us this morning, and I don't know whether any of you would like to make comments. It would be wonderful if you wanted to, and we'll take other brief comments.

Michael is not looking up, so I'm going to tell a Michael story. Belinda took care of an enormous number of people, one of whom was Michael. It was some time after Belinda died that Michael sent me a fax one day saying, "Belinda is still taking care of me," and I forget what little present had arrived that day from one of Belinda's

missions to take care of all the people she was taking care of, but yet again something to remind Michael of the importance of his life with Belinda encircling him the way she has all of us, I think.

MS. FELDBLUM: I'm just going to tell a very brief story. My name is Chai Feldblum.

I listened to Belinda talk about her ambivalence about being put into the public and how she started in September of 1988. In that summer, the first Americans with Disabilities Act had just been introduced, and we had gotten an agreement that we could have someone with AIDS testify. We were going to have a panel with different disabilities, and one slot was for a person with AIDS.

There was a lot of discussion among those of us working on the bill because one the one hand many of us wanted a gay man with AIDS to testify because that is who is being affected most proportionately by the disease. On the other hand, we knew that politically maybe that wasn't the best thing to do. So there was really a tension, an angst there between what would politically make sense, that is, someone who didn't get AIDS through gay sexual activity or drugs. And we had heard--it must have been Tom Sheridan or

Michael Iskowitz or some of the people there who were trying to find witnesses--we had heard about this journalist form a rural community who sounded just right, "palatable", as Belinda said. We decided to with that. None of us knew Belinda. But we said fine, let's do that.

I remember writing testimony for this person, because that's what I often did in my job, was write testimony, because who knew what this person was going to come up with. And I think we tried to get her to fax us what she was going to say, and she said, "Fax you? I'm in Kentucky."

Then she appeared. She came in the night before the testimony. And Tom and I got the testimony--we wanted to get it, because we figured we'd have to rewrite it. And I'm reading it, and I said, "There is nothing to rewrite here. This is just somebody talking about who she is as a person with AIDS."

She was nervous about testifying. I think that may have been her first national hearing. She was great, and part of the reason she was so great was because what we were afraid of did not happen--she did not separate herself from the community of people with AIDS. She did not separate herself from the gay men with AIDS and from people who got

AIDS through i.v. drug use, et cetera. I think that was very special for many of us at that time and clearly she carried that through in the rest of her work.

VICE CHAIRMAN ROGERS: I was so heavy to start with, but let me extend one story of June's on this notable trip from the White House back to the hotel and the very stiff, up-tight sergeant that she was talking with. As I recall her first words when she got into the card, she fixed him with those wonderful eyes of hers and she said, "Sergeant, suppose I could drive this car?"

He said, "Oh, no, ma'am, no, no."

"Supposing I overpowered you?"

[Laughter.]

CHAIRPERSON OSBORN: B.J., please.

MR. STILES: There are so many stories about Belinda in relationship to the President that I guess I want to say at least three things. The first is, of all the Commissioners at the table, the one I have known the longest is David Rogers, and David, listening to you today reminds me of your eloquence as well as the clarity of your own convictions around inequality and civil rights. And I think you were the first academician I had ever known who, at the time

you were a professor at Vanderbilt University, joined many of us in front of Morrison's cafeteria, boycotting Morrison's because they refused to serve persons of a different color.

To those of you Commissioners who are leading our thinking about Belinda, I want to express my appreciation to you for your own heart and your own integrity in the way you as individuals as well as you as Commissioners deal with this epidemic, and a special thank you to David for interrupting a meeting I was attending in Paris in January of 1988, saying, "B.J., I know we have a really good program put together, and I think some important things might be said, but you know, I think we're missing something. I really think that the voice that would be the most important voice in this Nation, if the President and the media would listen to her, would be Belinda. What do you think?"

As you Commissioners know far better than I, when David Rogers says, "What do you think?" you learn to try to think the best you can, and you try to think the way David Rogers thinks.

I am impressed in our remembrances that we have not articulated the ways in which Belinda felt and dealt with her anger. I come to that because one other voice in this

epidemic whose words I first heard over a videotape is the voice of a woman named Barbara Angus, the mother of Steve Angus who is one of the subjects of the Los Altos Rotary Club video. In the documentary filming the Angus family just days before Steve's death, the mother looks at the family gathered in the family living room and says, "I get so upset and so preoccupied living with Steve's illness and living with all those other people we visit at the hospital, I find myself going to the grocery story, walking down the aisles, wanting to look at everyone and say, 'Somebody scream with me.'"

The screaming that Belinda did in her incredibly articulate and focused and loving way I think was one of those distinctive ways that helped most of the rest of us cope with our feelings of inadequacy and the enormous anger we feel because of the loss of this epidemic.

I would end only by reminding ourselves that though consensus is terribly critical in trying to form a wider wedge to cope with the HIV epidemic, sometimes jumping consensus and responding to that visionary lone voice is a way to move forward.

There are some of us who remember that as the rest of you occupy the Commission by virtue of your position or by

virtue of your election by the Congress or the House of Representatives, there are only two spots on the Commission that were left open for voices allegedly representing the public. And those of us who live and work in Washington in the HIV epidemic have grown accustomed to learning how to try to work together to put our resources behind a common point of view or a single nomination.

I well remember my first meeting with Belinda because at the time that she became visible she was not the nominee of the so-called unified AIDS community in Washington, D.C. I'm not sure that we had a nominee, but at least it was not Belinda. And in listening to her, I felt that whatever the views of others, that this was a human being whose voice would express what I thought we all needed to hear, and I said to my colleagues, "I think I want to be an advocate for getting Belinda considered as quickly and as favorably as possible."

And David, you describe her perfectly--you get within her orbit, and your mind changes very quickly. It did not take long before screeners at the White House learned that they had a voice that all of us would applaud and would support.

At the end of that first meeting with Belinda I said, "I guess I trust you so much because you remind me of the Southern writer for whom I have the greatest love and admiration."

She said, "And who is that?

I said, "Eudora Welty."

She said, "You have given me the greatest compliment you could ever give me."

CHAIRPERSON OSBORN: The quotation that we have in the Commission's comprehensive report, as I mentioned at the beginning, is something that Belinda helped work on and pick out from the testimony that began that videotape and is wonderful. I was a minority voice before she got a say; I was certainly more eager to have it happen her way once we had the chance to talk with her about it. But the quotation that I think will always have made the biggest difference to me, which resonates with what practically everybody else here has said, was again in that first set of hearings, when I didn't know Belinda and we were all getting to know her, and it was a bit formal and tense. We were in the Canon House Conference Room, sitting up in a high place, and as we began to discuss things, Belinda raised her hand and said, "Now,

there's something that I particularly want to say because I have so little time left." And then she looked around and the rest of us and she said, "Of course, that's true of all the rest of you, too; you're just not as aware of it as I am."

That was a wonderful help to me and continues to be.

I think if no one else wants to speak, what we might want to do is spend just a couple of minutes thinking quietly about this wonderful bit of heaven that we have known.

[Pause.]

CHAIRPERSON OSBORN: Thank you all. I told Mr. Mason, as I said, that he had a very large family. I think we all feel a bit the same family because of being united in the love of a wonderful woman.

Thank you.

The Commissioners are supposed to be at a bus at 10:00.

[At 10:00 a.m., the proceedings were recessed, to reconvene at 2:15 p.m.]

CHAIRPERSON OSBORN: I want to thank you for your patience. I'm sorry we're running a little late. As I think almost everybody knows, we had a very interesting morning at the Humphrey Building and met with the President and Secretary

Sullivan and his staff. I think it was a step forward that will be good.

This afternoon we want to get into the very important issues surrounding AIDS definitions and again in discussions tomorrow. It sounds arcane, and yet I think it is in fact a very central and very important topic.

Before I get started I want to comment, as I do not do nearly often enough, about what wonderful work the staff of the Commission does and how important it is in bringing together, in this case with relatively short notice, such a wonderful group of people to help us in our deliberations.

In addition to a general thank you to the staff, I'd like to say a farewell thank you to Joan Piemme who is not going to be on the staff anymore. I hope that's the only kind of farewell we have to make. She has been a very important source of work, and we wish her well.

Let me extend a very warm personal greeting to Carol Levine to start us off with an overview statement. Carol is Executive Director of The Orphan Project of the Fund for the City of New York and someone who many of us have seen as a leading thinker and an important source of inspiration in understanding the thorny ethical issues involved in this

epidemic.

Carol, welcome.

DR. LEVINE: Thank you very much. I'm very pleased to be here.

I have been asked to give an overview of some of the policy issues related to the CDC definition of AIDS, and I will try to do that as succinctly as I can.

I'd like to start if I may by going backward, not because my personal history is so important, but because I think it shows an evolution in our consideration of this issue, and I hope it will be useful to you.

I first started thinking about the CDC definition of AIDS at the behest of Dr. David Rogers, who was a distinguished member of the Citizens Commission on AIDS for New York City and northern New Jersey of which I was the Executive Director. As I recall, Dr. Rogers called up one day and said, "You know, a lot of people are talking about the CDC definition--it's not counting women, it's not counting this. Why don't you get a group of people together and start looking into it?"

Well, that led me down an almost two-year road. I think when I started hearing all of the problems and all of

the issues that seemed to relate to the CDC definition of AIDS, it seemed as thought, well, here are all the problems, and here must be the solution; just change the definition.

Well, in the immortal words of H.L. Mencken, for every human problem there is a solution that is neat, plausible and wrong. I now believe that my original conclusion was wrong.

One of the things that we found--and my colleague Gary Stein was the policy director of the Citizens Commission, who helped me immeasurably in this--we held two fairly large meetings of experts in the field, epidemiologists, public health people, advocates, clinicians, just to try to sort out what were the problems that were related to the CDC definition. What we found after two fairly extensive meetings was that everyone was talking about something else, and they each had their own perspective, their own agenda, and while each was justifiable in its framework, it did not fit together.

We could not at that point really come to any conclusion about it since everybody seemed to be talking about something else, so Gary and I decided to write a memo to everyone simply defining what we saw as the problem. That

memo turned into a 40-page paper with 77 references. And I'm sure we could go on forever.

So my first point is that it is an extremely complicated problem to sort out what the CDC definition is, ought to be, and what its implications are for so many other areas. It may see obvious, but it certainly was not the case when we started, nor do I think it is now.

The CDC's case definition is used by a number of individuals and groups, and I probably haven't listed them all--certainly, public health officials, researchers, clinicians, hospital administrators, disability specialists, insurance administrators, health economists, legislators, social workers, policymakers, and the media. It has clearly influenced the way the HIV epidemic is perceived and managed and funded.

It is not surprising, then, perhaps that the CDC definition and its proposed revision are currently the subject of intense scrutiny, certainly by this body and by others.

The case definition has transcended epidemiology to become a symbol for the inadequacies of the U.S. Government's response to the HIV epidemic and a particular symbol, I

think, for the failure to address the needs of HIV-infected women. I think it is very important to acknowledge the symbolic meaning of the definition while at the same time focusing on the definition itself and what it does, can do and cannot do.

Any changes in the definition will have repercussions for individuals, health care practitioners and institutions, State and Federal governments, and even the international community, which I know is not the purview of this group but still is something to take into account.

In this broad context I think it is important to first distinguish the primary purpose of the CDC's surveillance definition from the ancillary uses that it triggers in entitlements and benefits, in funding formulas, in clinical research, in medical care, and in calculations of the costs of health care and social services; and second, to try to offer some recommendations for action in areas for further study. I think "areas for further study" is kind of a catch-all phrase that we all use, but in this case I think it is clearly important to go beyond what the definition captures and even the proposed definition might capture to more fully understand the scope of this epidemic.

In my view there are two overarching questions: Is the CDC definition failing in its primary epidemiological purpose? Would the proposed revision take care of that or would it create new problems? And second, are the ancillary uses of this surveillance tool appropriate?

I think it is also important to recognize that the CDC definition has been changed before. If it is changed this time it may not be the last time. And each time the definition has been changed it has been on the basis of increasing knowledge. I think it is important as you are deliberating and hearing the experts on this aspect of it to sort out what the scientific basis, the epidemiological data, are for this proposed change.

What is probably most important for those who are advocating for reconsideration is not just the epidemiology but those ancillary uses that the CDC definition has triggered, and clearly that comes in the area of entitlements and benefits. And although the CDC's various case definitions over the years were developed primarily for surveillance activities, these definitions have become the diagnostic standard used by other Federal, State and local agencies to determine eligibility for entitlements and benefits.

This has had a significant impact, and it has been both positive and negative, and I think we hear more about the negative impact in those people who are excluded. It has also had a positive impact by assuming presumptive eligibility for those who had the CDC-defined AIDS.

The greatest impact in the public sector has been on the Federal entitlement programs administered by the Social Security Administration--and you will be hearing, I know, more about that--and that has been one of the most compelling areas for change in that numerous case studies and some data collection have shown that some people who are severely disabled by anyone's standards are not eligible for these benefits on the basis of the CDC-defined definition.

But beyond the SSA entitlements, a number of State and local programs also use the CDC definition or some modifications thereof. In New York, people with CDC-defined AIDS are automatically eligible for service at the Human Resource Administration's Division of AIDS Services, and people with severe HIV illness are also eligible but have a much harder time proving it.

I think it has been less examined that the CDC definition also has an impact on the private sector. This

has also, again, been both positive and negative in that some people have been able to get private insurance benefits because they were already employed with the CDC definition and some disability claims have been approved on that basis. As the private sector through the private insurance companies closes its doors to HIV-infected individuals and people with AIDS, broadening the definition of AIDS will, I think, inevitably mean that some people who might have been eligible under the other definitions will not be eligible because their conditions will have been seen as pre-existing conditions and therefore not covered.

So there are impacts on the private sector that are smaller in scope, perhaps, but for those individuals to whom they apply are certainly very, very meaningful. And I think you might take note of the recent decision by a Federal court in the Louisiana-Texas area that determined that a self-funded insured company was justified in deciding after an individual had filed a claim for AIDS treatment that it could limit its coverage to $5,000. I think as more and more companies become self-insured they will be able, if this ruling is upheld and expanded, to even after the fact cut their coverage, thus imposing a higher burden on the public

system.

Another area that the CDC definition has had a major impact in and that you will also hear about is in funding formulas. Federal funding formulas are mathematical equations that determine the allocation of resources. Based both on statistical considerations and political realities, they tend to favor the regions whose elected representatives have vigorously pushed for Federal aid for a particular purpose. Federal aid's grants to the States or cities follow a formula in which the CDC definition is the most salient feature. In the Ryan White Comprehensive AIDS Resources, the CARE Act of 1990, the CDC definition played an important part, and any revision, unless there is a subsequent legislative revision and additional funding, will mean that more cities will be eligible for money under the CARE Act, but if the pie is the same everyone will get less. So simply expanding the definition to make more AIDS cases without additional funding will not make any difference whatsoever.

Another area in which the definition plays a role is in research priorities. Up until now, much of the clinical research and probably the majority has been focused on AIDS itself, preventing the opportunistic infections and the viral

replication. There has been much lower priority placed on opportunistic infections themselves and on the spectrum of disease that is not yet AIDS.

Many advocates--and I have been among them--have been critical of research protocols that fail to include women and fail to include drug users and minorities. I personally don't believe that changing the CDC definition will do anything to rectify that situation since the primary reasons that these groups have not been included have not been their lack of a CDC-defined diagnosis of AIDS, but their lack of access to health care and, in the case of women, concerns about liability on the part of researchers, pharmaceutical companies and IRBs.

So there is a relationship, but it is not as clear what the change would do.

Another very important area is clinical care. One hears constantly about cases in which clinicians have failed to diagnose AIDS or even HIV infection among women and other groups. I think that the CDC definition plays a role in clinical care, but it doesn't drive clinical care nor probably should it, and a change, while influential, would not make the difference in those clinicians who, for whatever

reason, have not learned to recognize the signs of HIV infection and have not learned to counsel patients about their risk and about the advantages of early diagnosis and early intervention.

So it will take a lot more than changing the definition, I think, to bring the majority of clinicians into the epidemic, but the CDC definition does play a role certainly in defining who they must report to the public health departments and in their decisions about certifying that a person is disabled in terms of entitlements for benefits. It may have some impact on the latter and certainly on the former.

A final area. We don't know too much about the resource utilization that is not driven by the CDC definition. There is, surprisingly--and this is one of the things that my two meetings turned up--there is, surprisingly, a lot of data sources out there, a lot of different sources, perhaps not exactly comparable, but a lot of information about what kinds of resources people are using in terms of hospital care, in terms of other kinds of resources, before they become CDC-defined AIDS. And somehow that information has not been mined for all of the interesting and important directions it

could give us. So we need new studies, but we also have a lot of data that, with some assistance, could be culled for whatever it can tell us about who is getting sick, when, what do they need, and how can we better serve them.

As I mentioned, there is an impact on the international definition. There are, I believe, at least three definitions that are used internationally--the CDC definition, the Bangi [phonetic] definition for Africa, and a Caracas definition for South America, and other countries may have their own definitions. The CDC definition plays an important role particularly for developed countries but not so much for developing countries.

Let me conclude with what Gary Stein and I gave as our three basic recommendations, and these were recommendations that we developed before the proposed definition, and I think they are as relevant whether the definition is changed as proposed or not, or whether there is some other definition at a later time.

The three recommendations that we have were that surveillance should remain the primary function of the CDC definition of AIDS; revisions should be considered as a way of contributing to a more accurate understanding of the

prevalence, incidence, and manifestations of HIV disease in various populations. So we concluded that whatever else was going on, the primary function of the CDC definition is surveillance and should remain that.

The second recommendation was that the Department of Health and Human Services must assume responsibility for the secondary uses of the CDC definition under its direct control such as SSA-sponsored entitlement programs. We felt that HHS should ensure that all the Federal agencies that use the CDC definition work out consistent and appropriate uses.

Third, service needs should be separated from surveillance. People who are ill need help no matter how their illness is defined, and Federal, State and local agencies that provide or pay for services should construct eligibility requirements based on a realistic assessment of need.

Fourth, more studies are needed to determine the economic, social and medical impact of HIV-related diseases not defined as AIDS.

Those are fairly general recommendations, but I think they bear some relationship to all the specific details you will be hearing and that I found extremely confusing and

still do at some point, not being either a regulator, a clinician or an epidemiologist.

We are getting a better portrait of the epidemic. We have a lot of detail in some areas and some very sketchy information in other areas, and I think we need to work to use the CDC definition for its primary purpose and make sure that those ancillary uses of it are appropriate.

As I was doing my investigation into this subject, I spoke with Jim Chin of the World Health Organization, and he gave me what I thought was a very pithy statement. He said: "If you don't know where you are going, any road will take you there." I felt that the CDC definition is one marker on the road to effective HIV/AIDS policy, but it is not the destination.

Thank you.

CHAIRPERSON OSBORN: Thank you very much, Carol.

I think in the interest of time we'll move through the panel and have everybody stay around the table so we can all interchange. Let me now turn to, in this order: Ruth Berkelman, Chief of the Surveillance Branch for the Division of HIV/AIDS for CDC; Dr. Jack Dehovitz, Director, AIDS Prevention Center, SUNY Health Science Center at Brooklyn;

Dr. Don Des Jarlais, Director of Research, Beth Israel Medical Center in New York and our very own Commissioner; and Dr. Judith Cohen, Director of the Association for Women's AIDS Research and Education at the University of California at San Francisco.

If you would in order talk with us, and then we'll have an opportunity for broad discussion.

Thank you and welcome.

DR. BERKELMAN: I've got a handout that I'm passing out right now. I appreciate the opportunity to be here today. I agree with Carol; I think the AIDS surveillance is important. I think it has often served as the Nation's conscience in this epidemic. Almost everyone uses AIDS surveillance data in some way when describing the epidemic in the United States to tell people who is getting AIDS, how old they are, what racial or ethnic group they belong to, how they got infected, where cases are increasing most quickly and in what subgroups.

We use surveillance to look at the patterns of disease in a population over time and to assess the impact of that disease on illnesses and death.

Surveillance data tell us where we should target

our resources and also where we should target prevention efforts, both of which are critical to all of our efforts in fighting this disease.

For surveillance of any disease, we need to define the health event that will be used as the measure, and for AIDS we need to define the health event that is best to monitor this epidemic.

The measure should be as objective as possible and should be practical for use by clinicians treating HIV-infected patients. We know a lot more than we knew when the 1986 HIV classification system and the 1987 revision of the AIDS case definition were drafted. In particular, as shown on the first page of the handout, we know that the CD4 lymphocyte is the primary target cell for HIV infection and that studies have shown a strong association between the development of life threatening opportunistic illnesses and the absolute number or percentage of these CD4 lymphocytes.

As the number of CD4 lymphocytes decreases, the risk and the severity of opportunistic illnesses increases. In addition, as noted on the second page of the handout, measures of CD4 lymphocytes are currently used to guide clinical and therapeutic actions for HIV-infected men and

women in the United States. Anti-retroviral therapy is recommended for all infected individuals with a CD4 count less than 500, and prophylaxis against PCP should be considered for all persons with CD4 lymphocyte counts less than 200.

Because of these recommendations, CD4 lymphocyte counts have become an integral part of the medical management of HIV-infected persons.

On the third page of the handout is the proposed revision of the classification system for HIV-infected adolescents and adults. The classification system emphasizes the importance of CD4 lymphocyte testing in the clinical management of HIV-infected patients. The laboratory categories are consistent with guidelines for medical management of HIV-infected individuals.

What about the AIDS surveillance case definition? The case definition has been developed for the purpose of surveillance and used to track severe and life-threatening morbidity related to HIV infection. The case definition was last revised in 1987, and in the absence of an objective laboratory marker for HIV-induced immunodeficiency, we have relied on a list of conditions which are specific for or

highly predictive of HIV-induced immunodeficiency.

We have compelling scientific reasons to consider expansion of the AIDS case definition. We know a significant proportion of HIV-infected men and women whose health is substantially affected by this epidemic are not represented by AIDS statistics; that a broad spectrum of diseases including pneumonia, sepsis, meningitis, pulmonary tuberculosis, renal disease, cardiomyopathy, recurrent urinary tract infections, persistent vaginal candidiasis, Hodgkin's disease, cervical cancer and other cancers, many serious dermatologic and neurologic manifestations, are occurring in HIV-infected individuals, and these persons may not meet the AIDS case definition at the time they are receiving care for these conditions.

In addition, anti-retroviral therapy and PCP prophylaxis is delaying the onset of an AIDS-defining condition. These persons are literally backing up behind the AIDS case definition. We know that the number of HIV-infected persons needing intensive HIV medical care is increasing, and it is far higher than the number of cases that we show by using AIDS statistics.

Page 4 of the handout shows our proposal to expand

the AIDS case definition to include all HIV-infected men and women with CD4 counts less than 200 in addition to those who meet the 1987 AIDS case definition. This is everyone in the third row and in the third column. The objectives of this expansion are to simplify the reporting process, to be consistent with standards of medical care for HIV-infected persons, and most importantly, to more accurately estimate the number of persons with severe HIV-related immunodeficiency, those persons at most risk of developing serious opportunistic conditions, and all of whom are in need of intensive medical care.

Expanding the case definition to include all HIV-infected persons with severe immunodeficiency will also provide useful information on whether people are getting health care before they become ill with an AIDS indicator diagnosis. For example, if physicians from one locality are reporting people only after the develop an AIDS-defining condition like PCP, and they do not have CD4 counts, and you compare that with an area where they are getting CD4 counts and are coming in and being reported before they have PCP, then we'll have some more information on where to target resources for early intervention.

We also considered expanding the AIDS surveillance case definition by adding other clinical conditions, but I would like to share with you what we see as major problems with that approach.

First, the surveillance case definition for AIDS is the most complex disease surveillance case definition in the world. It has 23 conditions in it, each with its own set of guidelines. Its current complexity represents an obstacle to reporting, particularly as HIV care moves from an inpatient setting to an outpatient setting, and surveillance must rely on increasingly broad range of reporters.

Adding numerous conditions would increase the complexity of the case definition at a time when we have been working with the State health departments to find ways to simplify reporting.

We believe that simplifying the case definition consistent with the classification system and with the medical management of the individual person would facilitate reporting. Also, the conditions we have considered for inclusion are generally common in persons not HIV-infected, and in the HIV-infected person they may be coincidental to the HIV infection or they may be related to the immune

suppression. Use of a laboratory marker is a more specific and more objective measurement of the severity of immunodeficiency than the presence of the clinical conditions we have considered. Conditions such as bacterial pneumonia, sepsis, and pulmonary tuberculosis are likely to be associated not only with HIV disease but with poverty, with drug use, with access to care.

What do we expect the impact of the proposed change to be on the numbers of cases? On the fifth page of the handout are data on all men and women diagnosed with HIV infection and seen at selected medical facilities in nine cities around the country. Slightly more than half of these individuals were seen in public clinics or hospitals.

I want to take you through this. If you look at the last line you can see that we have 10,342 persons enrolled in this project, and of those, 3,240, or about one-third, already have an AIDS indicator disease. Of the remaining approximately 7,000, 1,670 have a CD4 count less than 200 but don't have an AIDS indicator condition.

If you look at this together, if you add the 1,600 to the 3,200, we are talking about a 52 percent increase in persons who would meet the AIDS case definition from these

sites. And that's the last column. This is also broken down by men and women. If we look at the women, we see that in the last column, the number of women would increase by 61 percent from these sites; the number of men by 51 percent. It is also stratified for you by exposure group. For men, for example, 55 percent increase for drug users, 52 percent for men who have sexual contact with other men.

I'll also just note that the increase--this is a very broad expansion--the increase in women is, for example, five times higher than the increase that we would have if we included cervical cancer, pelvic inflammatory disease and persistent vaginal candidiasis in the case definition at these sites.

The 61 percent of women is interesting. You may note if you look at these later or more carefully, women are getting picked up earlier in the course of disease at these sites than men. The average CD4 counts for men and women with an AIDS indicator condition are the same, but for those others seeking care, women have a higher CD4 count than the men, not significantly higher.

Again I want to emphasize that the major impact of the surveillance case definition is to recognize HIV-infected

men and women earlier in the clinical course of their disease, about a year and a half to two years earlier than they are now, and that these people will eventually generally develop an AIDS indicator condition.

The data on the sixth page of the handout--

VICE CHAIRMAN ROGERS: Excuse me, Dr. Berkelman.

DR. BERKELMAN: Yes.

VICE CHAIRMAN ROGERS: You made one statement that I wish you would clarify for me. If I heard you correctly, you said your CD4 counts would pick up five times more women than if you were using PID, vaginal candidiasis--explain for me what you were talking about there.

DR. BERKELMAN: In this spectrum of disease we are capturing information on all HIV-infected women, and we know the number with cervical cancer, the number with persistent vaginal candidiasis, and the number with pelvic inflammatory disease as recorded on their medical charts. And you'll see here 124 more women--this is the third column under "All Women"--have a CD4 count less than 200 but do not have an AIDS indicator condition. That number is about 20, 25 if you add all those other conditions together. So we'd have about 25 more women if we used those three conditions, whereas this

way we have 124 more women.

DR. WOLFE: Were gynecological conditions recorded at all those sites, or were gynecological examinations given at all those sites to all the women?

DR. BERKELMAN: These are HIV clinics, and I think Maxine Wolfe is making a very good point, that at some of these sites pelvic exams may not be routinely done; speculums may not be available, and women may not be getting diagnosed with these infections.

DR. WOLFE: So therefore you can't really say that your addition of women-specific symptoms would produce a different number compared to 200 T-cell counts because you don't know how many women absolutely were seen and how much information was gotten from them; it wasn't routinely achieved for each of those women.

DR. BERKELMAN: What I can say is that from these sites--and these include sites such as Grady Hospital, Charity Hospital, Thomas Street Clinic--that they would increase five-fold more than had we included that from these areas, from these clinics. But you are right in the sense that I cannot generalize to the rest of the United States as to what this means.

Okay. I want to turn to the sixth page. The data on this page indicate, if you look at the summary statement at the bottom, that 90 percent of women diagnosed with HIV infection at these sites meet the proposed AIDS case definition before death. Of over 1,000 HIV-infected women we followed in these nine cities, 58 have died. Of these, 49, or 85 percent, met the 1987--

MR. DALTON: Dr. Berkelman, excuse me. We all have the charts in front of us, and we can certainly read the numbers, but I want to talk about what it means. I gather that under the existing definition, 85 percent of women who died meet the definition, so that what is relevant here is that an additional 5 percent would meet the expanded definition.

DR. BERKELMAN: That's right.

MR. DALTON: That still leaves 10 percent of women who die with CD4 counts about 200; is that correct?

DR. BERKELMAN: That is correct.

MR. DALTON: Because one of the concerns about the expanded definition is that there are lots of women who are dying with CD4 counts above 200, and it seems to me that this chart bears that out. That is, of those women who do not

meet the current definition, two-thirds of them would die without meeting the expanded definition; is that correct?

DR. BERKELMAN: One thing that went out was that 65 percent of women died without meeting the case definition. Clearly, that was an overstatement. You are correct that 10 percent of HIV-infected women diagnosed with HIV infection still would not meet the AIDS case definition. But that is also why I have supplied a list of the causes of death for these women. You can see how varied they are, how frequently they are associated with alcohol and drug abuse, that these are not always clearly HIV-related deaths. And I think to capture all HIV-related deaths we need HIV infection reporting as the definition if you were going to capture all.

These are causes, as you can see, that do not readily go into one group or one particular condition. I also wanted you to note on this page that most of these women, including those who died, had a CD4 count, and only one did not, of those not meeting the case definition.

MR. DALTON: Let me ask you about that because that comes up again a couple charts later, where you suggest that between 85 and 90 percent of people in the Spectrum of Disease Project had CD4 counts. It is a little bit like Dr.

Wolfe's question--who are these people? Are you suggesting that these are typical of people with HIV, that between 85 and 90 percent of persons with HIV have CD4 counts, or simply that between 85 and 90 percent of the people in this particular study had CD4 counts? And what are we to make of that data?

DR. BERKELMAN: Well, let's go on to that last page, and we'll talk about it. This is the percentage of HIV-infected individuals with CD4 cell counts both in New York City outpatient HIV clinics and in over 50 clinics in the cities that you see below. As I mentioned, these do include Grady, Charity, and Thomas; they are some major urban hospitals seeing a large number of HIV patients. These are all of the patients in these clinical settings, so it is not a biased sample of them. The other thing to note--I think what this is suggesting to me is that if people get into basic care in this country, they are getting CD4 counts, and I think the issue in part is whether people are getting into basic care.

We see no difference in any of these sites, between a private clinic and a public clinic, as to whether a CD4 count is recorded on the medical record. Now, this does not

take care of those who never even get into these clinics, but if they don't get into the clinics and they don't get care, I agree with Carol Levine--they won't be counted, because surveillance systems are based on care systems, they are based on physician reporting and provider reporting. So women who are never diagnosed with HIV infection and women who never see a physician for HIV still would not get counted by any system.

MR. DALTON: I think the underlying question with respect to comparing the current definition with expanded definitions or with other options for expanded definition is whether in fact it is cheaper or easier for clinicians to put into a chart a defining condition, whether it is PID or whatever, or to arrange for there to be a CD4 count, pay for it, which would be a defining AIDS condition.

In other words, I guess I don't find this very helpful in making the judgment of whether an expanded definition to include CD4 counts would screen out people who lack the financial capacity or who are not geographically sufficiently located to get a CD4 count, rather than some other way of broadening the definition.

DR. BERKELMAN: I think what is important here is

that people don't get a CD4 count to get counted for surveillance. They can't get on AZT, they can't get on PCP prophylaxis today unless they have an AIDS indicator condition or they have a CD4 count. And since we are letting the CD4 count and the use by clinicians drive this proposal, we believe that this is the standard of care in the United States, that people should be getting AZT and should be offered PCP prophylaxis, and they really will not be receiving these therapies unless they have a CD4 count.

CHAIRPERSON OSBORN: Let me suggest that we proceed so that everybody's input is on the table, and then we can come back to these issues as we like.

DR. BERKELMAN: Can I end with one final statement?

CHAIRPERSON OSBORN: Please do.

DR. BERKELMAN: That is that when we change the surveillance case definition, the number of persons that we recognize with AIDS will go up. But the individuals are not new to the epidemic. Their needs will not change as a result of the case definition. What will change is that we'll be able to recognize their needs more easily.

Thank you.

CHAIRPERSON OSBORN: Thanks very much, Dr. Berkel-

man.

We will, I hope, get a chance for a broad discussion but I think it may be helpful to have several presentations on the table, and your foundation one is most welcome.

Dr. Dehovitz.

DR. DEHOVITZ: Thank you.

I have been asked to comment on the impact of the revised AIDS definition as proposed by the CDC. What I'd like to do today is specifically address issues concerning the impact of this new definition on the provision of services to those in the inner cities of our Nation.

Within the context of this discussion there are three important areas that I'd like to stress. These are the role of the definition itself--and to some extent I will be repeating what Carol has said, but it is so important it bears repeating--the impact of the revised definition on women, and finally, the obstacles to operationalizing the definition in our financially stressed public hospitals and community health centers.

I'd like to turn my attention first to the role of the definition. Earlier versions, as Carol said, of this definition were used to serve two processes--both surveillance

and service--even though it was designed for only one.

As we now know, these two processes are clearly not always overlapping. Patients who meet CDC criteria for AIDS may require no assistance or benefits, whereas other patients may require service well before they meet any surveillance definition. This will certainly remain true under the proposed definition, and the question really is what needs to occur to separate these two processes.

Carol mentioned one, that the Federal Government should be responsible specifically for social service agencies. Entitlement programs clearly do need to develop their own criteria for benefits, consistent with the current knowledge with regard to HIV infection. The Social Security Administration has clearly begun this process, and as many of you know and as Carol referred to, in New York we have been a consistent leader in this area. Determination of benefits, for example, for New York AIDS designated center programs, for the AIDS Drug Assistance Program, as well as other entitlement programs is considered independently of fulfillment of current CDC AIDS definition.

How are we going to ensure that our State and local entitlement programs understand what the role of the CDC

definition is? They clearly cannot take the easy out and simply adapt or adopt the definition as their own criteria for benefits. Rather, it is clear that the Federal Government needs to ensure that both Federal, State and local programs which provide entitlements for HIV-infected patients receive the information necessary to make the informed decisions so that eligibility for assistance can be determined in a rational manner. Only through this process can the discrepancy between the definitions for surveillance and service be corrected.

I now want to turn my attention to a brief overview of the current knowledge regarding the manifestations of HIV disease in women. My colleague Dr. Minkhoff, an obstetrician, and I have recently had the opportunity to review the literature, and I believe you have that review in front of you from the Journal of the American Medical Association.

To briefly summarize this, it appears that cervical dysplasia and cervical cancer pursue a more aggressive course in HIV-infected women. These women have a higher incidence of abnormal pap smears, will be more likely to have histologic evidence of cervical intra-epitheal neoplasia, and in those who do have cervical cancer, this cancer clearly proceeds

more rapidly. It also appears clear that more advanced disease is occurring more frequently in HIV-infected women.

What about the other gynecologic manifestations that were referred to here, specifically pelvic inflammatory disease and vaginal candidiasis? Both are clearly diagnosed more frequently in HIV-infected women and again, as with cervical cancer, appear to pursue a more aggressive course. As with cervical disease, both are also diagnosed frequently in the HIV-uninfected population.

Where does this leave us with regard to the impact of the revised definition on women? Clearly, that we have these three manifestations in women and perhaps others, which do appear more frequently in the setting of HIV infection.

However, none of the data available thus far define these manifestations as diseases which occur primarily in the significantly immunosuppressed woman, a standard which we have used for other opportunistic infections. Indeed, while these three manifestations are uniquely associated with HIV disease in women, they are not unique to HIV disease.

Thus, where does this leave us? These three conditions do not appear to be highly predictive of severe HIV-related immunosuppression. Nonetheless, given their

association with HIV infection, it is clear that their inclusion in Category B is a minimum standard for the surveillance definition. Hopefully this enhanced surveillance as well as, perhaps most critically, the linkage between HIV care and women's care within all HIV programs to occur in the setting of also additional natural history studies will further determine the incidence and the course of these manifestations in women.

I'd now like to deal with one last issue, and that is the issue that we briefly referred to here. That is, the practicalities of implementing this new definition in the outpatient care setting of our municipal hospitals and neighborhood family health centers.

Today most cases of AIDS are diagnosed in the hospital, reported by hospital epidemiologists or nurse epidemiologists within the hospital setting. Clearly, the setting for the reporting of AIDS under the new criteria will transfer to the outpatient setting, settings which at least in the inner city are highly stressed and in which we have staffs of individuals who are not used to reporting illnesses such as this. In addition we do have the concomitant problem of confidentiality and ensuring confidentiality.

In short, I am concerned that we will result in various undercounts as well as perhaps overcounts in certain settings because the sufficient facilities to provide for reporting are not going to be available. These undercounts are clearly going to be critical because in many studies, including my own, staffing patterns, OTPS funds, are dependent upon the number of cases which we report.

It is clear that there should be substantial assistance to these centers in order to ensure that they count their patients in both a rational and a means which will protect the confidentiality of all patients.

In summary, therefore, I have tried to raise issues regarding the role of the definition and the impact of the definition on women as well as the logistic implications of case counting in the inner city. Before we overstate the importance of this particular hearing, however, we should recognize that even a broadened definition as we have referred to will be an ineffective battering ram as we approach barriers to both service and care in the inner city. Patients will continue to have inadequate access to care, as we have talked about just within this brief meeting, and women in particular are often excluded from drug rehabilita-

tion, research protocols and therapies for HIV disease both because of their gender and their childbearing capacity. While changes in the case definition and criteria for entitlement programs are clearly important and paramount, we must not forget the broader social and economic barriers which occur right now in these settings.

Thank you.

CHAIRPERSON OSBORN: Thank you very much, Dr. Dehovitz.

Dr. Des Jarlais?

DR: DES JARLAIS: First, I'd like to say how glad I am to be able to attend this hearing.

[Laughter.]

CHAIRPERSON OSBORN: For those of you who don't know, Dr. Des Jarlais just survived the Pan Am situation, but barely.

DR. DES JARLAIS: I want to briefly review in some slides the potential impact of the new CDC definition on people who inject illicit drugs.

This first slide simply shows a history of the HIV epidemic among drug injectors in New York City. The virus was introduced somewhere around the mid-1970's. The first

evidence we actually have of women being infected was in 1977, when there were three heroin-addicted women who gave birth to children who later developed pediatric AIDS. We have historically collected blood samples going back to 1978, and there was the rapid spread of the virus among drug injectors from about 1978 through about 1983.

Trying to keep that curve in mind, the next slide shows deaths among narcotic users in New York City over roughly the same time period. You can see there is a massive increase in the number of deaths from 1978 through 1985, which is the last year shown on this slide. The top, dark orange bar in the graph shows deaths from AIDS, which were essentially zero back in 1978 and have increased dramatically. But you can also see the other colored bars show large-scale increases in deaths among drug injectors over this same time period, including the yellow, bacterial pneumonias, tuberculosis, endocarditis. There have been epidemic-level increases in deaths among drug injectors coincident with the HIV epidemic that are not captured by the CDC/AIDS surveillance definition.

The 1987 revision to that definition helped a little because many of these people, for example, with

tuberculosis could also be diagnosed as having wasting syndrome, but whether someone with tuberculosis and HIV-positive is also diagnosed as having wasting syndrome is a very chancy type of proposition, and is certainly not the type of thing that you can base a good surveillance system on.

I would also remind you that these are drug injectors who died. These are not drug injectors who later moved on to reach the CDC definition; these are drug injectors who died.

We have been doing current research on CD4 levels among drug injectors, and somewhere in the briefing book there should be a single page--in the last year and a half, we have tested somewhat less than 1,000 drug injectors in New York, recruited from people entering a detoxification program recruited through our street outreach programs, and recruited from people entering a methadone maintenance program. Slightly less than half of those drug injectors have been HIV-positive; 440 of them were HIV-positive. Of those who were HIV-positive 59, or 13 percent, had CD4 counts less than 200.

We then just recently--actually last week while I was away--did a match of those drug injectors who would be

classified as having AIDS under the proposed new definition with how many had been currently reported to the AIDS Case Registry in New York under the current definition, and we found only 15, or slightly less than 25 percent of those who would meet the new definition had been reported as having AIDS under the current definition. Now, clearly, some of that discrepancy is due to the fact that many of these people are not getting HIV treatment and that there are probably some of them with AIDS-defining conditions who have not been reported to the AIDS Registry. We do not think that that is a major proportion of them, however, because normally if you have an AIDS-defining condition you are usually pretty sick and you need to seek out care. So we believe that the vast majority of this potential undercounting is that these people would meet the new definition but they are not so desperately ill that they fight their way through to getting care in the very crowded health care setting of New York City.

So that in contrast to the findings that Ruth presented earlier about approximately a 50 percent increase in drug users with AIDS under the new definition, I think Ruth's study really applied to people who are already being seen in HIV clinics as opposed to drug users who are not being seen

in HIV clinics but who are coming in to drug abuse treatment programs or can be contacted to the street, that rather than a 50 percent increase we are really talking about potentially quadrupling the number of drug users who would be classified as having CDC AIDS under the new definition. That clearly hopefully would have great impact on providing services and funding, but we are really talking about a potential major revision in the statistics and hopefully, then, with a positive impact on both provision of services and attention to prevention efforts because currently a lot of prevention really is driven by people's sense of the epidemic coming from the surveillance definition cases.

So that I think particularly in terms of the i.v. drug users, the new definition would capture a lot of under-reporting that historically has happened and a new definition with even the minimalist type of case finding such as providing HIV testing and CD4 testing for people coming in to a drug abuse treatment program, would substantially increase the number of drug users with AIDS not 50 percent but perhaps on the order of quadrupling the number of drug injectors being diagnosed with AIDS.

VICE CHAIRMAN ROGERS: Don, all of your people who

were HIV-positive also had--

DR. DES JARLAIS: CD4 counts. The blood for both is collected at the same time. Actually, all of the HIV-negatives had CD4 counts done, too, because we simply collect blood at the same time and send it off to the lab. So there was nobody who was HIV tested whom we do not have a CD4 count on. But that's part of a research project.

MR. DALTON: Are you assuming that everybody with a CD4 count under 200 would in fact be reported? Are you assuming 100 percent reporting from physicians or whomever?

DR: DES JARLAIS: This is our research project so that we have the data. If you set up HIV testing and CD4 counts at, say, a drug abuse treatment program, you then could do the reporting right there.

MR. DALTON: I guess my question is in comparing the 59 people who would be covered by the expanded definition quite apart from their symptomology, and the 15 people who are currently in the AIDS Registry. The people who are currently in the Registry, we know they were reported. There may have been 20 people who in fact qualified under the current definition, and only 15 got reported. So I'm just trying to figure out what we're comparing to what here.

DR. DES JARLAIS: Okay. We're comparing the number who are currently reported with the number who would be reportable under the new definition, and there are two factors to that comparison. One is whether or not they would meet the current definition, and the other factor is whether they are getting access to good health care.

MR. DALTON: And the third is whether they in fact would be reported.

DR. DES JARLAIS: Yes, okay. I'm including that-- if they are getting good health care I think would include being reported if you meet the surveillance definition.

DR. WOLFE: Do you have statistics on what percentage of people in those programs are women?

DR. DES JARLAIS: Roughly 30 percent are women. We haven't done fully analyses of all of this data, but there does not appear to be major differences in terms of HIV seroprevalence or CD4 counts by gender.

DR. WOLFE: But they are less likely to get into treatment programs as far as I know.

DR. DES JARLAIS: Not these two particular types of programs. The programs where women have been traditionally discriminated against have tended to be the residential

programs. The detoxification program I know has no barriers toward admitting women.

DR. WOLFE: Even if they are pregnant?

DR. DES JARLAIS: Even if they are pregnant, yes. It is typically about a two- or three-day stay program. It is in-hospital. That hospital delivers thousands of babies each year. There would be no difficulty on that particular setting.

CHAIRPERSON OSBORN: Thanks very much, Don.

Dr. Cohen, welcome.

DR. COHEN: I would like to thank my fellow panelists for covering many of the issues I was concerned about, allowing me to concentrate my time on a couple of issues partly in support of what has already been said and adding perhaps something more of a non-New York perspective.

We also have a large cohort of women at risk which includes a subset of women who are infected with HIV who we have been following for anywhere from six months to five years now. The first thing we did when the proposed change in the definition was announced was to look at the proportion of women in our group who would qualify under the new definition for having AIDS. And these are women, you

understand, who are often identified early in their infection and have been followed, so they also are not typical of all women at risk. Still, our group would increase 83 percent essentially by adding less than 200 CD4 cells to the definition.

This is more pronounced among women who have problems with drugs, and I say that more generally than women who inject drugs because many of the women who have problems with drugs in our cohort have problems with, for example, crack cocaine and are not really able to find programs that address their drug dependency problems, so even if they wished to seek care for that problem, there is very little available for them in our part of the country, but I think more generally that is true.

So with Don I think I agree that there will be proportionately even larger increases in women and drug users who qualify under the new definition than in general, and that that will be particularly true of people who have not now achieved any success in obtaining primary care. Many of the women we are following have had virtually zero success in obtaining any primary care. They are poor women. They are women who have no access to insurance programs. Some of them

have problems with citizenship, if not among themselves, then in their families. Those who had insurance tend to lose it when a partner dies of AIDS. So that by and large their access to care is emergency rooms and, if they become pregnant, prenatal care programs with long waiting lists, three- to four-month waiting lists on the average.

To presume therefore that they would, because their CD4 cell count is less than 200, qualify for a variety of other things is to ignore just a huge range of access to care issues that I think are very important.

Further, I think if we were not out there as a research program, as Don is out there as a research program, most of these women would not have sought antibody testing, would not have been able to find out what a CD4 cell count was, much less what theirs was and what that meant. I think that is typical of a lot of women at very high risk in this country. And that is not a plea for more research but a plea for recognition that in the reality of things an awful lot of women who are at the highest risk really have no contact with this reporting system as it now exists or as it would exist under a revised case definition. They are simply not part of the picture.

We are spending a lot of effort trying to find out what women have before they come to the point of an AIDS diagnosis in terms of clinical conditions and again contrasting the ability we have to look at this and the ability most of these women have to be seen and diagnosed is, I think, a story worth spending a moment on.

As I think most of you already know, when the case definition changed in 1987, more women than men qualified for an AIDS diagnosis under the new definition, and much of this new case identification was in some of the more subtle and difficult-to-establish or chancy-to-establish diagnostic classifications--the neurological ones, the wasting. Without primary care, these are not the kind of things that physicians in emergency rooms are going to pay attention to or document.

I think the truest picture as much as I would like to be able to say something else is that I honestly don't know the answer to people who keep asking me what would be the case if we added a variety of women-specific conditions to the definition. We don't have any information. The reporting systems that might give us this frequently don't include any gynecological assessment of women. There are major AIDS care clinics that simply at best refer women for

gynecological evaluation elsewhere. If and when they show up is not the business of that clinic, and whether the data gets reported back to the clinic is not the business of that clinic. So an awful lot of that information is simply missing. And we are not improving that situation.

In one of my other hats, I sit on a community advisory board for one of the big national clinical trials programs. They are presently touting a huge new database which will be used to generate all kinds of numbers for planning and clinical trials and vaccine trials purposes. That database includes two questions specific to women, period, and they have at the moment no plans to add any more. If this continues, we never will know what is going on with women and gynecological conditions, and part of my concern even with a surveillance case definition that is designed to serve other purposes is that if you don't look, you don't see, and you don't have the numbers, and you don't generate the programs and the entitlements and the benefits and the recognition that this is a problem that more providers should be looking out for.

It is very hard to convince many ob-gyn practitioners that there is a problem they should be looking out

for because they say there is no data to support our concern. And yet we have a system that is designed not to give them that data. Whether it is there or not must remain an open question at this point.

Whether we intend it or not, the surveillance definition is used to have major influences on access to care, is used to generate suspicion levels in providers. My concern is that having made a change in the CD4 count that ignores many of these issues will improve the situation for those who are already in the counting and observational system and will do nothing to address the lack of observation, the lack of information and the obvious unmet needs of those who are not part of the counting system. And every time we make a change and agree to a change it gets that much harder to consider changing yet again the next time around. I truly have a lot of sympathy and recognition for the difficulty the CDC has every time they consider changing this definition, but I'm real worried about this one in that regard.

CHAIRPERSON OSBORN: Thank you, Judith.

Let's at this point have a discussion about the presentations thus far. Before that starts, so that we don't get any more disruptive than we have to, let me apologize in

advance. Dr. Allen, Dr. Rogers and I will have to leave at quarter of four to meet with Secretary Sullivan. We will try and get back if we can, although it is an important meeting, and we won't hurry it. And when we have to leave, I have asked Harlon Dalton if he would take over the chair so that we don't disrupt all of your schedules as well.

So with that said so you will excuse us if we make a quiet exit when we have to, I'd like to open it up for discussion among the Commissioners and the people at the table.

Don?

MR. GOLDMAN: Let me ask a question, and anyone who would like to answer it should feel free to.

If we were starting from scratch, and we did not have the historical baggage that we do have, my guess is that we would end up dealing with simply a CD4 count as a definitional point and not have any of the so-called opportunistic infections at all--or am I wrong? I just wonder if you were starting from scratch where would you begin in terms of a definition.

DR. COHEN: I would certainly include a CD4 count, but I would also like to see some sort of comparative measure

of function. I think a CD4 count alone does not define the severity of the conditions with which many people are living, some of which have been on lists at some time, some of which have not. So something, not necessarily our Konopsky [phonetic] score or something like that, should be part of the definition as well.

DR. DES JARLAIS: For surveillance purposes, where you need something as simple as you can make it because the more complicated it is the lower the quality of data, if we were starting right now, we probably would use a CD4 count of 200 or less, realizing not everybody is equivalent within that definition, but for surveillance purposes where you need a simple definition so that your counting process can be as error-free as possible, we probably would go with just the CD4 count.

DR. DEHOVITZ: We've got to separate the two issues of service and surveillance; I agree with Don that's exactly where we'd end up.

DR. BERKELMAN: I have been asked whether or not we would consider deleting the list of 23 conditions and going only with the CD4 count, and I think right now no. One of the reasons--even starting from scratch--is that we still

have people who have been alluded to here who do not get into the health care system until they are symptomatic, may have PCP and may never get a CD4 count today. That may not be true in three years, but today there still are those people out there.

The people in our study--I didn't mention this--but if you look at those who did not get a CD4 count at these clinics, they are more likely to have had AIDS. If they present with an AIDS indicator disease, there is less of a medical reason for having a CD4 count.

MR. GOLDMAN: The point I'm making is that there would be general agreement among the panel that a CD4 count would be an appropriate component of a surveillance directed and designed definition, and there might be some disagreement in addition to that over which opportunistic infections or opportunistic diseases might be appropriately added or not added.

CHAIRPERSON OSBORN: David, Diane, Harlon, Maxine.

VICE CHAIRMAN ROGERS: This is belaboring the obvious, but one, those were wonderful presentations, and I thank you. But we wouldn't be in all this contorted mess if we would simply as a nation say we've got people who are HIV-

positive, and that's what we ought to be talking about, would we? We have developed all these complex arguments because we are scared to death because we've got so damn many people who are infected that we won't deal with it adequately, so we do all these proxy kinds of measurements, of which there are bound to be enormous arguments. It's too bad we can't just roll up our sleeves and say we've got a million HIV-positive people, and they all need to be included in one way or another in the health system, and some are sick, and some are not.

MS: AHRENS: In the absence of a perfect world, our Commission spoke in our comprehensive report to the need for a national health care system that would provide access, but in the interim we also suggest some interim steps until we get there. I guess as I am listening to you I am thinking that governmental structures and governmental services change because they are forced to change. They are forced by pressures put upon them to modify. You crack the door, and then you push and cajole and do what you have to do to make that door open.

So barring some form of national health care system that would provide the kind of access that you're talking

about to the people who are in the system, if you don't support a change in the definition, do you think the status quo is somehow going to provide that access? How do we institute change? How do we push and shove and cajole to get the change if we don't take some steps, albeit incremental steps, to start the process?

Any of you can respond to that.

VICE CHAIRMAN ROGERS: Carol, I hope you'll respond to that, in part because I was puzzled by your recommendation that we not go with this when it is very imperfect but it seems to me, as Diane has suggested, it does add a lot more people to the care system.

I was, I thought, fairly careful in not giving my final reading on the proposed definition, and I'm very ambivalent. My concerns are on the one hand, I think it does count a lot more people, but it counts the same people earlier. It doesn't do anything to change the real problems of access.

I would be more comfortable with the new proposal if there were also some assurances or some statements or some understanding that counting a lot more people a lot earlier also presents a risk to them in terms of confidentiality, and

those are things that you will discuss tomorrow, but I don't think we can ignore that. That is clearly one of the concerns of people who do want the services.

I would be a lot more comfortable with it if I felt there was going to be funding and availability of CD4 counts, and here we have heard that they seem to be there, but that doesn't jibe with what I hear from the people on the front lines who are doing it every day and not in a research setting. In a funny way, the CD4 count has become the AIDS test that we said we didn't have all along. We've been saying no, no, it's not a test for AIDS. Well, now we have a test for AIDS, but then we have to make sure that we have all the things you're all going to hear about--laboratory control--as I understand, a fairly variable test. There are lots of concerns about that.

The main thing is will we be able to, beyond identifying these people and saying yes, they need care, where is the will to make that care? Now, these are not all things that the CDC can provide--some of them, I think they can--but those hesitations I have are, I think, real world things and can be addressed. This proposal doesn't solve everything.

So I do feel ambivalent about it, but I do think that we don't want to just take another step that will create more problems than the ones we already have and know what we're dealing with. That's my basic worry about this.

DR. DES JARLAIS: I think as part of our considerations we need to pay attention to the health care issues, but there is also an argument to be made for the pure epidemiology of trying to track the epidemic over time and space and subgroups. Certainly the health care issues are going to be tied into a definition of AIDS, but I think we have come to realize that the present definition of AIDS is not a very good way of measuring Acquired Immune Deficiency Syndrome, that having a list of opportunistic infections that you keep adding to becomes so complicated a process that the reporting starts to break down, and that to preserve decent epidemiology, we need a good definition of what Acquired Immune Deficiency Syndrome really is, and that if we wind up rejecting good epidemiological science because we don't think the care is going to be there, then we will get into a position where we have neither good epidemiology to know where the epidemic is going nor good care, either.

CHAIRPERSON OSBORN: Harlon Dalton, Maxine Wolfe,

and Dr. Konigsberg.

MR. DALTON: I have one question for Carol Levine and then one for Dr. Berkelman.

Carol, in your introductory remarks I was a little surprised that in mentioning the ancillary uses to which the definition is put, you didn't mention reporting, because it seems to me that in many ways is one of the big, lurking issues. David's notion is that maybe we should just have the courage to go all the way and say HIV positivity is the thing that we care about.

One of the answers to that is well, but there are some people, including some around this table, who are not in favor of reporting of all people who are HIV-positive. One of my concerns is that the new definition--you are telling us it is a million people, but I'm sure Dr. Berkelman would want a harder number than your or my guesstimate about that--one of my concerns about the new definition--and I have an open mind about all this stuff at the moment--has to do with whether or not it won't drive reporting in some direction that we haven't much thought about. For example, I am concerned that it may lead to laboratory reporting rather than health care provider reporting, and I'm not sure whether that's a good

thing; and I'm concerned that it may lead to HIV reporting across the board, and then you'd match it with the number 200 rather than AIDS reporting. So I just want to know if that's part of the--

MS. LEVINE: I guess I was including reporting under the general rubric of surveillance in the sense of you not only count, you report, you keep track, and you have a registry. So I was seeing that as one thing, rather than an ancillary use, in fact part of the primary use.

I am very concerned about the move--in fact, I see it as almost irresistible--toward required HIV reporting. It is now in half the States and was recently introduced in New Jersey although with a provision that people could still go to anonymous test sites.

I think we have to be very concerned about those issues, and certainly I have been for a long time. On the other hand, we are now at a stage where if people who can benefit from care can be in a system that will assure as much as is humanly possible their confidentiality once they are in that health care system, I think that there are countervailing arguments. I don't see that we're there yet. In fact, I see only the opposite, that we're going to make the list but we

haven't got the benefits to offer people on the other side.

I think this is sort of an interim step. This is reporting earlier and then it makes logical sense anyway if you take it out of the context of everything else that's going on in the world to institute HIV reporting. But I do not see the benefits of that outweighing the down side, which is keeping people underground for longer and longer and the clear potential for breaches of confidentiality for people who are identified earlier on and have more to lose because they are still at work, they are still out there in the community. It's not like identifying a person with AIDS who is in a terminal illness. These are many functioning people whose lives can be altered seriously by any breaches of confidentiality.

I don't feel that we are as a nation comfortable enough with HIV yet for me to feel that we can say we can go ahead. I in fact have been somewhat stunned by the concerns of mothers that I have been talking to about identifying a child in a public school system. Mothers will go to extraordinary lengths to avoid the identification of that child because they know that once one person knows in that school, everybody will know, and then everything will be a disaster.

This is ten years after we know about AIDS.

So when we are living in that kind of society, I think all of these things have to be weighed in very carefully. But I take them very seriously, and if I didn't specifically identify that concern it was a) because I put it under surveillance, and b) because I know you will hear about it tomorrow.

MR. DALTON: My question for Dr. Berkelman is short. What is the relationship between the proposed classification system and the proposed new case definition? I notice you've got this "B" category in the classification system which seems to include most of those symptoms that affect women but not men, but I gather the "B" category does not qualify one for an AIDS diagnosis under the expanded system. So what is the utility of the classification system in relationship to the definition?

DR. BERKELMAN: The classification system is to classify any HIV-infected person, and it really is for public health purposes and also for clinical purposes, and it does provide some prognostic value for them. It is a simple system. A clinic can use it. I know that some clinics already are using it to say how many patients they have at

different levels of immunodeficiency. They are actually finding the immunologic categories extremely useful to them.

Also, they have always wanted, I think, a category in which the physician's judgment could be used as to whether the symptoms are related to HIV or not, and that is the purpose of Category B. It does include pneumonia, sepsis, TB, any condition in which in the physician's judgment, they believe that this is HIV-related, or the management of that disease is affected by the HIV status.

CHAIRPERSON OSBORN: Dr. Widdus wanted to pursue that just a bit more.

DR. WIDDUS: Could I ask a specific question. Is it possible to compare the strength of the data that supports inclusion of Kaposi's sarcoma in the AIDS definition with the strength of the data that supports cervical carcinoma being in the "B" category?

DR. BERKELMAN: It is getting to be possible. Currently of the 1,000 women, we only have four cases of cervical cancer in those women. But when we look at more common diagnoses, we find that actually the 23 diagnoses do hold up in terms of their relationship to immune deficiency is much stronger than the conditions in Category B, than

pneumonia and sepsis, than any of the neurologic, dermatologic manifestations, including the women's conditions. It is about fourfold stronger.

DR. WIDDUS: Specifically, if the data stronger for Kaposi's sarcoma than it is for cervical carcinoma?

DR. BERKELMAN: It is currently, but that may also be affected by the low numbers that we have. Currently in the 1,000, if you look at women only--first of all, of the 23 conditions there is only one that is considered to some degree gender-specific, really, and that is Kaposi's sarcoma. The other 22 vary somewhat. You have some conditions that are more frequent in women, like esophageal candidiasis and wasting syndrome, than in men. The Kaposi's sarcoma, currently in this project of the close to 1,200 women, we have four cases of cervical cancer, four cases of Kaposi's sarcoma, and the other cancers are all two or fewer cases of cancer. But the cervical cancer--again, it's only four cases. Clearly, Kaposi's sarcoma is much more strongly related in men, in men who have sexual contact with other men.

CHAIRPERSON OSBORN: Dr. Wolfe and Dr. Konigsberg. Let me point out that while we started late, we are getting later, so that if we can be succinct.

DR. WOLFE: I just want to make a brief comment which may be dealt with in the next section. I am surprised to hear everyone have such faith in CD4 counts, frankly. The research shows that they are inaccurate, unreliable, that if you do them over again, they are likely to show an incorrect reading--

CHAIRPERSON OSBORN: Dr. Wolfe, maybe I will suggest that that come with the next presentation.

DR. WOLFE: Okay, but I just want to know if that has been taken into consideration in the presentation of how wonderful and scientific and objective an indicator they would be if we had to start all over again, because most agencies including research and vaccine testing are getting rid of them as an indicator. That's what was happening at the recent ACTG meeting--

CHAIRPERSON OSBORN: I really do think that might be something that would come up after we have had the presentation about the CD4 count, so that in the flow of things and if it is okay with you, we want to have the people who have been asked to present about that have a chance to have an initial presentation and then perhaps we could come back to that--if you don't mind.

DR. WOLFE: Okay.

CHAIRPERSON OSBORN: Dr. Konigsberg, and then let's move on to the next presentation.

DR. KONIGSBERG: I'll be brief. I want to agree with Don Des Jarlais' point about the need for the epidemiologic evidence on this in the absence of the services not being there. I think if we delay trying to in some way expand this definition for all the good reasons that it is needed because the services aren't there, we are going to be in a very circular argument that will lead to lack of identification of the need for the services, and to me that's just not the way to get on with it.

Harlon, I have to be a little predictable--you accused me one day of not being predictable, so lately I have been trying to be more predictable. It does raise the question about reporting of HIV-positives, although David, I did not hear you suggest that. If I was clear on what you were saying, you were trying to capture the spectrum of it in a different way. That's a subject on which I am somewhat ambivalent. Logic tells me if we really want a handle on incidence and prevalence, we've got to do something along those lines eventually, but I know all the reasons why that

isn't palatable and why it might be counterproductive. But I think that's a subject that the Commission ought not to be burying its head about, that we need to hear more about it.

I guess one of the next sessions we'll hear from the epidemiologists. I know what CSTE's position is on it.

MR. GOLDMAN: Aside from the factors that Charlie mentioned, and perhaps in response to what David said, is there a sound epidemiological basis for seeking to define severe HIV-related immunodeficiency as opposed to any HIV disease at all; and are we defining severe HIV-related immunodeficiency in an effort to avoid doing that kind of thing, or are we defining severe HIV-related immunodeficiency because that's the right thing to do from an epidemiological perspective to start with?

I guess I'll ask Dr. Berkelman first.

DR. BERKELMAN: Well, I hope it's the latter, clearly. What we have is some conditions, a long list of conditions that has gotten longer through the years, and there is a lot of disagreement as you keep adding to the list as to which of those have scientific consensus that it is a quote "HIV disease". I mean, do you call bacterial pneumonia in an alcoholic who has HIV infection and a normal CD4 count

an HIV disease? There is a lot of discussion about that.

MR. GOLDMAN: Well, why not just solve that problem and say just consider all HIV disease period, and we won't get into that? My question is is there a specific public health epidemiological rationale for seeking not merely to define HIV disease itself, but rather to define the severe form of that disease, which is apparently what your definition seeks to do.

DR. BERKELMAN: The reason is you need to track severe disease as opposed to just all disease, and even if there were HIV infection reporting, you would still need to track severe disease because there are many asymptomatic people who would not get tested, there are a lot of biases in the data that would come in. Whereas I agree with Don, once you really get sick, you get PCP, you will come in for care. You may be terminally ill, but you will seek care. So in that sense it is a much more representative--you know, getting close to death is a very equalizing factor.

MR. GOLDMAN: So that even if we had mandatory HIV reporting, you would still want a definition of severe HIV-related immunodeficiency for epidemiological surveillance, tracking, and health planning purposes.

DR. BERKELMAN: Yes, I believe we would.

MR. GOLDMAN: Okay.

VICE CHAIRMAN ROGERS: Is there any other disease in the world we do that with? That just makes absolutely no sense to me. If you've got HIV disease and get tuberculosis, you know you're going to go a hell of a lot faster, or if you've got cancer of the cervix. I find it bizarre to go through this--

DR. BERKELMAN: If you have a registry, then that's fine. If you can track people over time, you're not talking about two reports. But that's a registry. Cancer registries are a good example of that. But if you look at pulmonary tuberculosis when people's skin tests convert, CDC does not collect that information. They collect the clinical disease, the pulmonary disease. So tuberculosis in a sense is one example of that.

DR. MASON: Don, going back to your question and Dr. Berkelman's answer, if you don't have a system of identifying people at the time of infection or shortly after or in a fairly consistent time, then it doesn't matter whether you have a required reporting system in place. The determining factor is if they come in to be tested. And I

think we would all agree that mandatory testing or anything analogous to that is not the direction we want to go. What we want to do is encourage people to come in early and be tested, and to be able to have that information reported and not to have any adverse action taken against people either directly or indirectly because of the reporting system.

Dr. Berkelman's point from a disease tracking perspective is that you need to have a fairly uniform measure over time, and severity of disease so far in the epidemic has been it for AIDS.

CHAIRPERSON OSBORN: Let me again apologize for our disappearance and suggest, unless Harlon wants to do something different, that we move on to the next two presentations. There is a break coming after the next panel. We are really doing what we want to in these kinds of hearings and getting into the central point from a variety of directions, but I think both in the interest of time and some of the others who have come to talk with us, we should proceed.

Harlon, do you agree?

MR. DALTON: I agree.

CHAIRPERSON OSBORN: Excuse us.

MR. DALTON: The next panel is half an hour late,

so if people can manage to hold off for the break, it will go a lot better.

The two presenters on the next panel are Dr. J. Steven McDougal, who is Chief of the Immunology Branch of the CDC's HIV/AIDS Branch, and Dr. Stanley Inhorn, who is the Medical Director of the Wisconsin State Laboratory of Hygiene.

I don't know how long our staff has told you you each have, but as you can see, if you can keep it to about seven or eight minutes that will give us more time for questions.

Dr. McDougal?

DR. McDOUGAL: My task as I understand it is to briefly explain how this test is done and give some sense of the variation of the test and a brief overview of the factors involved in the implementation of large-scale testing.

The test is basically done by the use of flow cytometry technology. The technology itself is technically and electronically quite sophisticated, but the concept of the test itself is really very, very simple. The flow cytometer does a single cell analysis on multiple cells measuring three types of optical properties the main one of which is whether or not the cell has bound to fluorescent dye

that one has added to the cell population. For instance, in the case of lymphocytes up here there are, as you know, several populations. There are "T" and "B". Within the "T" is the CD4 population, CD8 population, and it is possible to derive fluorescent monoclonal antibody-based reagents that attach, identify and basically stain those cells.

In addition to lymphocytes within the whole blood population, though, there are other white cell populations as you know, and the other two optical measurements of the flow cytometry distinguish lymphocytes from non-lymphocytes. Those two other measurements are basically light scatter measurements which tell how big a cell is and how granular it is.

If I could just briefly move away from the microphone, in the next slide the data comes out in a dark spot with a single dot representing a single cell. It is generally done on two parameters with increasing size. In this parameter, these are the light scatter characteristics; increasing granularity in that direction. And based on size and granularity, one can distinguish within the white cell population what cells are small and nongranular, i.e. lymphocytes, which cells are granular and fairly big,

monocytes, and which cells are quite granular and medium-sized or granulocytes.

The machine electronically captures the lymphocyte gate, and within that lymphocyte gate it analyzes the fluorescent properties of those cells. For instance, it will measure, depending on the stain that is used--here is CD4 versus a pan T-cell [phonetic] marker. These are negative cells for CD3 and CD4; anything above here is positive for CD4. Anything in this quadrant is positive for CD3 and CD4. So basically this population here is the CD4 population within the lymphocyte gate. The machine simply adds up all the dots, divides the dots in this quadrant, that is, CD3, CD4 positive, by the entire lymphocyte gate and gives you a percent positive lymphocytes.

MR. DALTON: Could you go back to the microphone?

DR. McDOUGAL: Yes. The flow cytometry then gives you a single measurement of percent CD4 positive cells within the lymphocytes. To get an absolute CD4 count you need two other measurements. One is the total white cell count and a differential which tells you the percent of white cells that are lymphocytes.

So basically the absolute CD4 T-cell count is the

product of three separate measurements, each based on their own technology and each with their own inherent variation. So the absolute CD4 T-cell count will have to some extent an additional or amplified variation because it itself is based on three separate measurements.

The percent CD4 cell count done by flow cytometry is highly accurate within a lab as are the other two measurements. Both are currently widely done in an automated mode and have very consistent and fairly narrow variations.

There is also within HIV-infected people a fairly good concordance at the 200 CD4 cell level per milliliter between the number of CD4 cells and a concordant or corresponding percent CD4 cell level. In an analysis of over 6,000 HIV-infected people who had both determinations, a CD4 T-cell count of 200 corresponded to a percent CD4 count of 13 percent, that is, with an 85 percent concordance. That is, if a person is under 200 in the CD4 cell level or over 200 in the CD4 cell level, 85 percent of the time his percent will be over or under, respectively. Fifteen percent of the time there will be a discordance, that is, someone may have over 200 CD4 cells but less than 13 percent CD4 cells.

Variation I think is best viewed in terms of three

types of variation--the biologic or normal variation, disease-induced variation, and test variation. Biologic variation, the normal controls have a range of CD4 cells that range in most labs between 400 and 1,600, quite a large variation in normal populations. Within that broad range of biologic variation, there are several age, sex and race-specific differences that have been noted by some but not by all laboratories, and there is not a great consensus as to how age, race and sex result in much of a variation in the normal range.

I will say, however, that those labs that have reported a difference between sex, a difference in age, or a difference in race find that the differences are really quite small, on the order of 2 or 3 percent, compared to this and they waffle within this broad normal range that I defined as 400 to 1,600.

Now, the one exception to a substantive biologic variation is in the pediatric AIDS group. Little kids under two years old have substantially different normal ranges than do adults. But within the adult community, within the adult population, there are reports, for instance, that female CD4 percents are 2 or 3 percent higher in the mean than are males

and that there is a slight increase in CD4 cells with age, about one percent per decade. That slight increase per decade is not significantly different from a zero change with decade, and not all labs have been able to confirm the findings that some labs have.

In any event, the trends or variations in sex, age and race are very small compared to the large normal variation that one finds in normal populations.

Disease-induced variation, I don't think we need to talk about particularly; everyone knows that HIV-induced disease causes a progressive decline in absolute CD4 T-cell level.

But test variation is a very important factor in determining how useful this test is. Obviously, test variation has to be less than normal variation or less than disease-specific variation to be of any use clinically or in management of patients.

Generally, there is a lot of doublespeak in this field, but generally test variation is measured by replicate testing of the same sample many times and is expressed as a coefficient of variation. That is, the standard deviation of multiple determinations on the same sample divided by the

mean value gotten for that percentage.

There are three types of variation that labs generally rely on--intra-run variation, that is, the variation that one sees when the same samples are tested in the same run; inter-run variation, that is, within the same lab, the same samples run in multiple different runs; and the type of variation that I think you all should be most concerned with is how close are multiple different labs in terms of the determined value of CD4 cell counts when they all test the same sample.

There are several performance evaluation systems--CDC and CAP run several of them--that have determined the coefficient of variation of the same sample run by multiple different labs. The three components that make up absolute CD4 cell counts have been the subject of performance evaluation or proficiency surveys. The most recent CAP survey for automated determination of white cell count gave a coefficient of variation of 1.9 to 2.4 percent in the most widely used automated machinery in that survey.

I was surprised to find that none of the surveys do proficiency testing on percent lymphocytes, or haven't recently.

The CAP and the CDC performance surveys, picking samples that were in about the 13 percent range, there was a coefficient of variation of 8 to 12 percent in the determination of percent CD4 cells. And again, none of the performance evaluation systems have reported back or analyzed the product of those three upper measurements to give an estimate of the variation that we are to expect with absolute CD4 cell counts.

My estimation is that the variation in the bottom column has to be at least the additive sum of the three above it. The percent lymphs, we have no data on, but it also is an automated technology with an intra-lab variation that is very, very small and very, very tight, and I would be that it is no worse than 3 percent there. But again, it is all additive, and the absolute CD4 cell count would be expected to have a larger variation than any of the three components.

Now, a few notes about the implementation. The cost of reagents and machinery for a medium-volume lab is about $50. Add another $50 for personnel, which is a hard estimate to make. The test costs most lab about $100 to run. Labs are charging anywhere from $50 to $600, with most of them charging $100 to $150 for the test. It is currently estimated there are about 600 to 1,000 labs doing this test.

And of interest I thought was that most labs that are currently doing this test do a relatively low volume of testing, that is, less than 20 sample per week. So with respect to the equipment and facilities that are currently out there, there is the potential for a great expansion in running this test.

The CLIA regulations that are to go into effect hopefully next summer will affect this test. It will be technically considered Level 3, but the regulations for that will not come out until sometime later than the initial regulations.

There are two ongoing performance evaluation or proficiency testing programs, one run by CAP and one run by CDC, that will continue to go on. Each of them have about 300 to 400 labs participating. Many labs participate in both.

The facilities for training. Manufacturers all provide training and ongoing continuing education training for buyers of their equipment. There are currently two manufacturers or two flow cytometry instruments in use in the U.S., Beckton-Dickenson and Colter, and Ortho may re-enter the field quite soon.

CDC offers training, and a number of the profes-

sional cytology organizations offer ongoing workshops and continuing education programs at their annual meetings.

A number of groups have developed performance guidelines or recommendations for performance of this test, among which are the NCCLS; the Public Health Service is currently formulating regulations; ASTPHLD, ASHI. The ACTG has an internal document for their labs, as do the manufacturers.

So in a nutshell, that's basically all I have to say. I'm sorry I can't give you a better estimate of the expected variation of this test. That's the hard data that we have. I expect that in terms of absolute CD4 cell counts there will be a fair amount of variation, but my own feeling about that is if one lab gets, say, a value of 150 on a patient and another gets a value of 250, one would meet the criteria and the other wouldn't. Whichever of the two is wrong, if someone is misclassified as AIDS or misses the classification of AIDS, he still belongs in a cluster of patients that are descending in progression of the disease down the CD4 depletion pathway and are likely to go on to a clinical complication shortly, anyway.

MR. DALTON: Thank you, Dr. McDougal.

The next speaker is Dr. Stanley Inhorn. In addition to being Medical Director of the Wisconsin State Laboratory of Hygiene, you have some connection with the Association of State and Territorial Lab Directors, and you might tell us what that is, Dr. Inhorn.

DR. INHORN: Thank you.

The Association of State and Territorial Public Health Laboratory Directors has played a fairly significant role in improving testing to identify HIV disease. And since 1986, the Association has had annual consensus conferences, and another one is coming up in March of 1992. These conferences have promoted standardization of procedures and testing for the screening test, the ELISA test, and for the confirmatory Western Bloc and immunofluorescence assays.

At the last consensus conference there was a session devoted to flow cytometry to begin discussion of ways to improve and standardize this procedure.

One major strategy in the national response to the AIDS epidemic is early intervention to prevent transmission and to delay disease progression. So to determine the stage of HIV infection and changes in the patient's health status, various assays with prognostic value for staging disease

progression have been used alone or in combination.

For example, in my laboratory, the Wisconsin State Laboratory of Hygiene, we offer what we call a "monitor panel" which consists of flow cytometry for lymphocyte quantitation plus quantitation of beta-2 macroglobulin and P24 antigen, and other surrogate markers can be used to measure the function of a patient's immune status. This include immunoglobulin quantitation and neopterin.

Now, with the new CDC case definition of AIDS, reliance on tests to determine the CD4 lymphocyte number in a patient's blood becomes critical. So what are the issues and problems with placing reliance on a single laboratory determination to make a definitive medical diagnosis?

As we have heard, the enumeration of the total CD4 count depends on three separate laboratory procedures: the total white count, the differential and flow cytometry. And as has been pointed out by Steve, as is true for all quantitative laboratory tests, errors or inaccuracies from the collection of the specimen to its transport to the analysis to results validation to the final report and its interpretation by the clinician, things can go wrong all along the way.

There is both physiological and analytic variation,

and these are to be expected in any of the procedures. Therefore, when we have three procedures that we are dealing with, we do have, as was pointed out, the possibility of additive or compounded error to get the final CD4 count.

Now, the older procedures are the white counts and the differentials, and all the physicians know that these have been around for a long time, and for the most part today they are done by automation. But in so doing the laboratory must adhere to well-publicized guidelines such as standard H20T which was developed by the National Committee on Clinical Laboratory Standards, and for valid results, the preserved blood must be less than six hours old. A laboratory that does this type of testing for the purposes we're talking about today should maintain a documented coefficient of variation less than 5 percent for the white count, and the automated differential must also come up with similar reproducibility.

Flow cytometric analysis being a newer procedure has other problems. At present only eight of the State laboratories offer this procedure. We don't really know how many flows are out there in private clinical labs. In Wisconsin, I think there are about eight or nine operating in

hospitals and independent laboratories. They are used for research and for diagnostic purposes, including testing for leukemias, other blood and immunological disorders. In a large university or community hospital, all three of the procedures that have been mentioned will be performed within the clinical laboratory so that quality assurance can be more reasonably guaranteed. But when the HIV-positive individual is seem in a smaller hospital or in a clinic, the white counts and differentials may be on site, while preserved blood is sent to a reference lab. This means that in a laboratory such as my Wisconsin State Laboratory of Hygiene, which does perform flow cytometry, we must make calculations of absolute CD4 numbers based on white counts and differentials done without personal control or validation of test results.

Other issues relate to flow cytometry. These include specimen transport. At a meeting convened by CDC on November 4th and 5th of this year, it was agreed the immunophenotyping, the flow cytometry, could be performed on specimens as old as 48 hours, that is, those sent through the mail or by courier, if the proper anticoagulant is used. However, cold or hot temperatures or other problems may

destroy the integrity of the lymphocytes.

In addition to the proposed CDC cytometry guidelines, there are other guidelines as have been mentioned--the NCCLS, and there is a Canadian guideline, and the AIDS clinical trial group also have documents that give some instruments and guidelines for doing flow cytometry.

But flow cytometry is a very complex lab procedure that requires well-trained, skilled, dedicated operators, using properly-maintained equipment, operating in a quality laboratory environment. Our association recommends that all instrument operators receive in addition to the manufacturer's training additional courses or workshops offered by professional societies or universities. In some cases, in-house training at other experienced laboratories may be an acceptable alternative.

Before accepting specimens for diagnostic purposes for flow, each lab must have in place a comprehensive quality assurance protocol that includes standardization and quality control procedures. All cytometry labs should be enrolled and recognize proficiency testing programs such as the ones mentioned at CDC or the College of American Pathologists.

What, then, are some additional questions or

considerations relating to the expected increase in flow cytometry testing resulting from the new CDC case definition?

In my view, the basic question for the Nineties is whether physicians can rely on a single laboratory test to make a diagnosis as significant as AIDS. I believe that a single CD4 count of less than 200 should be validated by a second determination on a separate specimen, especially if there has been a sudden change in the CD4 count.

In most cases there will have been previous determinations on an individual patient so that the less than 200 count will occur after other tests have shown a decline in the CD4 count.

This brings up a related question: How frequently should immunophenotyping be performed? Is the currently recommended Public Health Service semi-annual scheme for adults reasonable or, as the CD4 level decreases to the 200-300 range, should tests be performed more often, or will physicians or patients themselves be inclined to ask for tests more frequently? If so, what is the capacity of American laboratories to handle an increased workload?

As you have heard, there is an estimation of anywhere from 500 to 1,000 machines in operation today in the

U.S., but most of them are doing a fairly small volume. Most are doing less than 1,000 cases or determinations a year, which is about 20 per week.

But there are regional problems in providing services. For example, in California, the most populous state with a large HIV burden, the public health laboratories there do not have flow capabilities.

As far as the cost for the increased testing, at our laboratory the cost of the analyzer depreciated over five years, reagents, technologist time, and overhead is about $15,000 per month or $240,000 per year, which is an expensive item in laboratory operation. Our charge for the flow panel is $170.

So these are some of the considerations I think we are facing in terms of trying to provide this service, and in placing reliance on this determination for indicating a disease definition.

Thank you.

MR. DALTON: Thank you.

Don?

MR. GOLDMAN: Just so that I understand, Dr. McDougal, in your chart you had an 8 to 12 percent--what was

the term that you used--

DR. McDOUGAL: Coefficient of variation.

MR. GOLDMAN: --coefficient of variation. Let's assume--forget about the 8 to 12 percent--let's assume it were 10 percent Would that mean in lay terms that a test result of 200 would in reality mean that it would really mean between 180 and 220?

DR. McDOUGAL: Yes. That would mean that if a number of labs were given a sample whose true value were 200, 200 plus or minus 10 percent is 180 to 220. Sixty-seven or so percent of the labs would fall within that range in their determination. Two standard deviations, which would be 160 to 240, 96.7 or something like that percent of the labs would come up with a determination that fell within that.

MR. GOLDMAN: How does that result compare or contrast to other kinds of tests used for diagnostic purposes? Is that a lousy test or a good test? I mean, what kind of value judgments or comparisons can we make in terms of other kinds of tests used for diagnostic purposes?

DR. INHORN: Let's think of another test where 200 is a magic number--your cholesterol. Five or ten years ago if you went in to have a cholesterol test, one day it might

be 200, the next day 240. People are very dissatisfied with this. So today in the U.S. we have a National Cholesterol Standardization Program which is working to bring down this coefficient of variation. So the laboratories that are in the program have to be able to perform within a very defined range.

So we've made some progress in that area, but we are really starting from scratch in terms of this determination, and we really don't know what to expect--

MR. GOLDMAN: But my question is in comparison to other tests, how does that 8 to 12 or 12 to 15 percent run--is that good, bad, indifferent?

DR. McDOUGAL: It is fairly good. The chemistries tend to be wonderful. This is probably within the range of enzyme tests. It's not terrible. It's definitely not terrible. [Laughter.] It could be better, and as Stan was mentioning, in other programs where the clinical community geared up to do widespread testing, the proficiency followed suit in labs producing that.

I fully expect the 8 to 12 percent number to improve in the future rather than get worse.

MR. GOLDMAN: Dr. Berkelman?

DR. BERKELMAN: I was just going to mention that Henry Holmberger [phonetic] with the College of American Pathology said that he would compare it favorably with most diagnostic tests, that is was as good or better, looking at tests for diabetes, hypertension, cholesterol, that it's within that range.

MR. GOLDMAN: Dr. Berkelman, is there any mechanism within the proposed CDC definition that would allow for anomalous results so that if a patient, let's say, had 800 CD4 cells in one day, and a lab result comes back and says he's got 3, and the physician says this patient is wonderful and fine, and that test result doesn't seem right to him, that the physician can override the test result?

DR. BERKELMAN: Yes, the physician can override the test result. It is the most accurate CD4 test that we're looking for, and we do rely on the physicians' judgment. If they say they don't believe the count, then we say fine. But it is written into the most accurate according to physicians.

DR. INHORN: Another point that I mentioned, too, is that these are not just single values coming out of thin air, that you are following patients over a period of time, and often their counts will remain at sort of a plateau, and

then they'll start to decline, so you are sort of watching them go down and you're just waiting until they reach a certain point.

MR. GOLDMAN: But as I read the CDC recommendations, it is the lowest test result which triggers the definition and not anything else--

DR. BERKELMAN: The lowest accurate.

MR. GOLDMAN: The lowest accurate, but without regard to why that might be, whether it be some of the environmental factors that Dr. McDougal mentioned that might cause the test result to be affected--

DR. BERKELMAN: That's not accurate, then.

MR. GOLDMAN: I mean, let's say I engage in some activity which causes the result to change. The result is still accurate. There may just be environmental factors that aren't related to my immune system that cause the result to change, or if I have a drink that might cause a change in the results. I assume there are certain chemical results and things I might eat, drink or do that might cause a change in the test result.

DR. BERKELMAN: Not big changes.

DR. McDOUGAL: Most of the biologic variations, as I

mentioned, all hover within that broad 400 to 1,600 range, the majority. There are oscillations within that broad range. An individual patient doesn't oscillate serially nearly that much. If someone is at 600, if they are normal they tend to stay around 600. And if you are on medication, like chemotherapy, of course, you may have variation, but most physical exertion and things like that should not shoot your count down below 200.

REV. ALLEN: What if there is an infection? Doesn't that raise the CD4?

DR. McDOUGAL: It depends on the--

REV. ALLEN: So you could be sick and not be able to qualify because you're too sick. I mean, if you have an infection and that raises it, then you wouldn't qualify--

MR. DALTON: Hang on, hang on for one second. As I understand, once you are at 200 then you qualify for the AIDS definition, assuming it is an accurate test, so that that is not a problem.

Dr. Des Jarlais, Dr. Wolfe and then Dr. Lemp.

DR. DES JARLAIS: Yes, this is not too much of a question, but I think the Commission ought to realize that most AIDS definition diagnosis and surveillance right now is

done on the basis of lab tests; that the 23 opportunistic infections are usually determined by a lab test, and it's not as if we're going from a gold standard to an imperfect lab test. And maybe Ruth might want to comment on it or the other two speakers about the quality of some of those lab tests where you've got multiple opportunistic infections usually based on a lab test versus the quality of the CD4 counts.

DR. BERKELMAN: I think you're exactly right, and I think they vary among the 23. I think the other point we all need to recognize is that this is the basis of patient care for AZT and for PCP prophylaxis, and we are using these, and I think it is important for surveillance, but it is particularly important that we are giving expensive and potentially toxic therapy to patients on the basis of these counts, and we need to do everything we can to make sure they are as reliable as possible, just like for cholesterol screening that is being done.

DR. WOLFE: In that regard, at a recent meeting of NIAID--first of all, in regard to what you said, Dr. Inhorn, research showed that in order to--

MR. DALTON: Excuse me. I'm sorry. I should have

said this before. We are already five minutes over this panel and before that we were half an hour over--I'm saying this in general--and out of respect for the final panel as well as everybody else in the room, for everybody if you can keep your questions short--this is not directed at you, Dr. Wolfe.

DR. WOLFE: Yes. I have written more about this, but the research definitely shows that you have to do two tests, separated in time, in order to even get close to accuracy. And that means twice someone is going to have to pay to get a T-cell test in addition to ever finding out they need one. So I just want to make that clear.

The other thing is that since 1987, more than 50 percent of the diagnoses have been presumptive, that is, without laboratory tests, in the CDC surveillance statistics. So in fact they have not been relying on that. And the variability that was presented at this recent conference for 200 T-cells at a very good laboratory--this is for research-quality data--was the 95 percent intervals, one standard deviation, were from 118 to 337; if you went to 250 T-cells it went from 149 to 421; 500 T-cells, it went from 297 to 841.

So we're not here talking about, as far as I can

see by the research that has been done, either something that is very reliable at this point or that is going to get that much more reliable soon. And in order to make it reliable, one has to do at least two tests at separate points in time from the latest research.

So I think we definitely have to keep that in mind if we're speaking about it as an indicator. And as far as using the data that exists for prophylaxis, none of that data was analyzed for women. And one of the papers that was also presented at this recent meeting was exactly about that and concluded that being repeatedly tested for CD4 over time increases the chance that a measurement will fall and be confirmed below 500 even if one's real underlying CD4 continually remains above 500, and it was particularly about using 500 T-cells as a marker for AZT.

So I think that before we figure out if we're ever going to use a T-cell level, what it's going to be, there is not enough research about its consistency and its reliability.

MR. DALTON: Do either of you want to comment on that?

DR. McDOUGAL: Yes, just two points. One is that whether or not two should be done or not is a point that is

important for clinical management, and as a clinician I would agree, I would like to see it done twice.

The surveillance definition, though, is the cart following the horse. I think any indictment or inappropriate use of the CD4 test should be directed toward clinical management, and the surveillance definition should follow suit. But I think your energies should be directed at criteria for clinical management and surveillance should follow suit.

The other--

DR. WOLFE: Could you explain what you mean by that?

DR. McDOUGAL: I think if you have a problem with the reliability of a single test, and you in your own head think you should do it twice, I think that your energy should be directed toward those that are clinically managing the patient rather than asking the CDC to come up from behind and impose that on clinicians.

DR. WOLFE: I don't think I'm asking that.

MR. DALTON: I take it your point is not very different from Dr. Berkelman's, which is that if we care about providing care, and if we're concerned about the unreliability of one test, then we ought to do two for care

purposes even more than for epidemiological. But you had a second point you wanted to make.

DR. McDOUGAL: No. I'll just stop there.

MR. DALTON: Okay. And did you want to comment, Dr. Inhorn?

DR. INHORN: Well, I don't think the results as bad as you've mentioned in that research study. The College of American Pathologists sent out unknown samples for proficiency testing, and the results, as Steve mentioned, were reasonable. So this is the ability of various laboratories to get the same result on the same sample. So I think the coefficients of variation are in a range that is less than 10 percent, and I think good laboratories should be able to achieve that with this determination.

MR. DALTON: Dr. Lemp?

DR. LEMP: First let me preface my comments by saying that I am supportive of the use of CD4 and this definition. Also I believe for practical purposes it is impossible to consider anything but one CD4 count less than 200 for the surveillance definition.

However, I am concerned that first of all there has been no presentation here on data on CD4 count, which is

available--certainly, I've been at enough meetings, and I have heard presentations from different research studies on that--and also that the estimates of the coefficient of variation seem to be a bit low from what I have heard. From cohort studies, both the Macks cohort study by Dr. Hoover--the data was presented by Dr. Hoover in Atlanta--the 95 percent confidence interval being 118 to 337 around a count of 200; and also, data that hasn't been discussed in other meetings includes some data by the State Viral Merketzial [phonetic] Laboratory, Dr. Haynes Shepherd, this is in Berkeley, California, data on the San Francisco Men's Health Study. There, the coefficient of variation within a subject was 21.4 percent, and coefficient of variation was over 20 percent. So there is a lot of concern that it is a lot higher than you are describing, and the ways you've tested samples by sending out blind specimens is not the same way as these studies that are looking at these individuals over time and the variations that occur in those individuals.

DR. McDOUGAL: It is a different kind of variation. It is measuring the biologic variation. There are no large proficiency programs for which the data that returns to the analyzer is the absolute CD4 cell count.

DR. LEMP: But the biologic variation is more important. I mean, that is certainly a critical factor, and real application of this is an important factor, certainly.

Another issue is that the second criterion of using less than 14 percent CD4 is another inclusion criterion for the definition, which we haven't even discussed as a backup inclusion. Again in this study, in California they differed in that they felt that 11 percent CD4 is actually approximate to the 200 CD4 count level and that 14 is perhaps a bit too high. Certainly, the 20 percent that is in some of the NIH protocols or whatever is certainly too high. But I'm concerned that the numbers we're talking about here are lower than what will actually be out there in practice--and not just from these research studies but also from talking to clinicians in the field, there is certainly a lot more variation around this test than we said. I'm not saying I'm not supportive of it; I just want us to realize what we're talking about with using this test.

MR. DALTON: Any other questions?

REV. ALLEN: In talking about the accuracy of the test, I'm talking about the biological variations, and what happens if they are on prophylactic, and their T-cells go up,

their CD4 count goes up? That's my concern.

MR. DALTON: Is your question what happens in terms of the AIDS definition, or in terms of--

REV. ALLEN: Perhaps. That is a part of it. What happens if CD4 increases due to medications, perhaps future medications or what happens now? What's going to happen--and I know we're not talking about the sociological setting and Social Security and all that--but it seems to bounce around in individuals that I know.

DR. BERKELMAN: I think there are several scenarios here. One is that if a person has an accurate count under 200 they would meet the AIDS case definition. If they come into therapy at, say, a count of 250, they are put on anti-retroviral therapy, and their count actually goes up instead of coming down six months later--like it might have been at 200 then--what we see, though, is that their count does not stay up very long with anti-retroviral therapy, and within a few months it does come back down.

So for surveillance purposes, you may be talking about briefly not meeting it--if they've just received anti-retroviral therapy, and they are just above 200, it may delay their getting to 200. But that's good, I hope.

MR. DALTON: Let's take a 10-minute break because we are getting quite behind.

[Short recess.]

MR. DALTON: Before we get started, I'd like to thank Drs. McDougal and Inhorn for their contributions in the last panel. I don't recall whether we ever thanked the first panel as well, but pardon our lapse in graciousness.

Dr. Roy Widdus has a couple of administrative announcements he wants to make.

DR. WIDDUS: The first is to in fact thank all of the witnesses for their flexibility and being willing to accommodate the changes that the Commission had to make today to go down to HHS.

The second is what I said at the close of the last session--if there are any individuals in the audience who desire to make a comment during the public comment period who had scheduled because of our previous timetable their comments for today, could they so indicate to me, or give a note to one of the Commission staff. Thank you.

MR. DALTON: Okay. The last panel is on epidemiology and surveillance. We have roughly an hour; it's ten minute of five now. We have four panelists, and rather than

introduce them twice, I will simply do it one time. Let's see--four people, one hour, and if you give us some time for questions, eight or nine minutes each should be about right.

Dr. George Lemp is Chief, HIV/AIDS Surveillance for the AIDS Office of the San Francisco Department of Public Health.

DR. LEMP: Members of the Commission, thank you for the opportunity to present comments today regarding the proposed expansion of the case definition of AIDS.

It is the position of the San Francisco Department of Public Health that inclusion of CD4 counts of less than 200 as an additional criterion for being considered an AIDS case is a reasonable step.

The current AIDS definition, which was last revised in 1987, is primarily based on the clinical syndromes commonly found and reported in HIV-immune suppressed gay men. The revised definition will no longer rely solely on clinical manifestations, but rather will characterize AIDS as a chronic disease, manifested by a progressive loss of CD4 cells and immune suppression.

This revision will better characterize the scope of the epidemic among women, injection drug users and gay and

bisexual men, and it should improve access to care for persons with HIV infection.

There are, however, several potential negative ramifications of this change which, if not addressed, would temper our support for the proposed revision.

First, I'll discuss the impact on AIDS case reporting and the AIDS caseload in San Francisco. We currently estimate that approximately 30,000 persons--

MR. DALTON: Dr. Lemp, if I may--I'm sorry--I realize that you are reading from your testimony. You will never do that in eight or nine minutes, but also we have it before us. And if we promise you that we will read it, can you essentially give us the highlights?

DR. LEMP: Okay. Let me just say, then--and some of these numbers that I was getting ready to tell you are important information--that there are 30,000 persons living with HIV infection in the city; that currently, 3,409 are living with AIDS at this point; that we estimate by April of 1992 that an additional 4,000 to 5,000 persons who have not yet progressed will progress to CD4 counts less than 200. Therefore, if we adopt this definition that the number of persons living with AIDS will more than double in San

Francisco, to 7,500 to 8,500 persons as of April 1st.

In addition, looking at it in another way, if we currently report 2,000 cases per year, we will need to collect about 4,000 to 5,000 cases in 1992 alone, which represents certainly more than a doubling of our current workload.

We have also started looking at information to substantiate these estimates. We have looked within one hospital in San Francisco, and to date we have 600 HIV-infected cases where their CD4 count is less than 200 currently, and certainly by April we'll probably have near 1,000 persons who will be reportable at that time, and that's one hospital in San Francisco.

Currently, this substantial increase in workload, as I mentioned, is a problem because we've only gotten support for a 22 percent increase in our surveillance staffing. We don't have the resources at the State or local level, and a lot of the increase in that support came from cutting funds of HIV seroprevalence surveys which were cut by approximately 4 percent nationally.

So to ensure the accurate reporting of cases, we feel that we need to have increased resources. In addition,

certainly it is a problem to cut the HIV sero surveys which are still critically needed to assess the scope of the epidemic and to make projections.

Let me say that I think I'm taking just as long paraphrasing this as I would reading it, so I'm going to go ahead and read it, and I'll just read it quickly if you don't mind.

MR. DALTON: But understand that I may well cut you off in about eight or nine minutes. I wasn't asking you to paraphrase it, but just give us the basic points that you want us to hear, because we're not going to remember 4,000, 8,000, the numbers, so much as your basic message.

DR. LEMP: Well, okay--

MR. DALTON: If that doesn't work for you, fine, then paraphrase or read; it's your choice.

DR. LEMP: Okay. We can go ahead and do that.

We have met with the clinicians and other persons in San Francisco, and currently there is a very mixed feeling about this definition. A lot of them are concerned. We have support in general, and there are some people who are not supportive and have said that they won't report cases under this new definition, but in general we have support. That

support will wane if there is a decoupling of the Social Security Administration with the CDC definition which is proposed, and that support will wane if the Health Resources and Services Administration does not increase Ryan White CARE funding commensurate with these numbers. Certainly, no clinician is going to be encouraged to report if we don't have any other services provided, so they will see this as no benefit to their patients. They are currently not very supportive of the paper work required to do this at the present time.

We do have enthusiastic support at this time to do reporting because of the fact that this is linked, but if you remove this link between the reporting and funding, then that support won't be there.

We have also been very concerned, as you can see if you read the text, that the HHS has not coordinated in any way between the various agencies the implementation of this entire definition. That has been a great problem for us in the field in that it has hampered our efforts to try to get support in the community because of a lack of information about what is being done at SSA or HRSA, and difficulty in responding to that concern in the community.

We recommend that CDC--and I think I want to mention this since not everyone has the text--that they fund in selected localities for the follow-up of persons with AIDS who meet only the 1992 case definition to assess what proportion of them will eventually meet the current definition of AIDS. This will help in assessing the impact of the definition on the trends of the epidemic.

We also suggest that this project also include follow-up for diseases that are not currently in the current definition, and those would include manifestations commonly found among women and injection drug users infected with HIV.

As you know, with the current AIDS diagnosis, presumptive eligibility for Medi-Cal, California's Medicaid, is possible. However, persons who are HIV-infected don't have that presumptive eligibility and need to document that they are disabled.

The decoupling of the SSA with the CDC definition is a problem in that we do believe it is a reasonable thing to decouple; however, we are concerned that the Social Security Administration does not currently have a user-friendly form for clinicians to report disability or to document it on. Therefore we would encourage them to develop

such a process so that physicians are not going to be confused and overwhelmed with this change that they are proposing.

In addition we think there need to be programs that SSA provides to educate physicians and help them become aware of the new criteria and train them in some manner to fill out the forms properly so they are not sending these forms back two or three times in each case.

Certainly, there are disadvantages to the individual with this change. Certainly, the loss of anonymity and the psychological trauma of being diagnosed with AIDS when you are still relatively healthy are problems. And we are concerned that some people may avoid CD4 tests and HIV testing, and therefore that will be a problem for their care.

The other issues will be mentioned tomorrow. Obviously, the threat of an early diagnosis will have implications for reporting, and certainly concerns about discrimination in the workplace and in housing.

Let me go briefly to our fiscal ramifications, both local, State and Federal. First of all, our model of care in San Francisco has been based on trying to meet the needs of terminally ill patients. So in San Francisco there has been

provision of a wide range of services to keep people in the community setting and avoid hospital stays, and we have been able to maintain our hospital length of stay at about 10 days even though the acuity of patients has been rising.

However, this model has been based on a process of sort of emergency aid services, and now as we move to a definition earlier we are going to have a definition which is of a chronic disease. And we have to change the services in San Francisco, then, to services that will be available in a longer period of time, and therefore we have to make a significant shift in the system, and we also have to now for the first time re-examine our criteria for eligibility for these services, particularly things like housing which are in demand.

Also, it is a problem for our early intervention program. The message out there is get early intervention so you don't get AIDS. Now we're saying you have AIDS, so now you should get early intervention to help improve your quality of life. So that changes quite a bit the message that we're trying to put out to people.

The next impact on the State will be in California, Medi-Cal. Certainly, increasing the number of people who are

eligible for Medi-Cal will put a great strain on the State of California's budget. Obviously, you are aware that the State of California has a huge deficit at this point, and this should further strain that budget. Certainly we are concerned about implications for reimbursement provided by the State and Federal program in that we think that some types of services may be excluded from coverage now, or the rates of reimbursement will continue to fall well below the actual cost. We are also concerned that this would affect the reimbursements that our hospitals are getting and certainly their inclination to even provide care or to even apply for or document some of the care that they are providing. Some will just simply provide some free care and not even bother with the system.

Finally, the Federal impact. Certainly, we have heard, and it will be discussed tomorrow, that the 16 Ryan White Title I cities will probably eventually rise to a number as high as 29 eligible cities, and without increase in base funding in Ryan White, that would mean that San Francisco would have the funds cut in half for San Francisco, basically. So we feel strongly that there needs to be an increase in the appropriations for care that are commensurate with the

increase in numbers.

The one benefit would be that the earlier diagnosis would bring people into Medicare because they would be alive long enough to qualify for Medicare. That would hopefully shift some of the State burden to the Federal Government.

Finally, I'll just say that although the original purpose of the CDC definition was to monitor the epidemic, the case definition has taken on a broader social and economic significance. Given this broad significance, it is not surprising there has been pressure on CDC to create a more inclusive definition. The 1992 definition will fulfill this goal by doubling the number of persons eligible for an AIDS diagnosis--this is doubling the number living. However, without Federal support to individuals and localities, the new definition may result in more reported cases but the same level of services. Rather than benefitting from the change, service providers will then be placed in the difficult situation of choosing which people with AIDS are the most needy.

I don't know if that was eight minutes.

MR. DALTON: No, and first of all it was unfair of me to try to make you change, but you were terrific. I found

myself writing very quickly a lot of information, and I thank you.

The next speaker is Dr. David Fleming, who can incorporate my time line, having had a little bit more notice. He is Deputy State Epidemiologist from the State of Oregon. I haven't read your complete bio--it says Council of State and Territorial Epidemiologists--I take it you are an officer in that organization?

DR. FLEMING: That's right. I am representing CSTE today.

MR. DALTON: Okay, thank you.

DR. FLEMING: In May of 1991 CSTE recommended changing the AIDS case definition to the proposal under consideration today. Today, in exactly nine minutes, I'd like to explain the rationale for that and also discuss some of the issues that we are going to be facing at the front lines in implementing that.

One of the fundamental requirements for containing any epidemic is to know the number of people who are affected and their characteristics. AIDS is no exception. Information gathered from AIDS surveillance about the AIDS epidemic is the foundation for public health prevention, education and

care efforts.

For any disease including AIDS, the usefulness of information collected by surveillance is determined by whether or not that information is complete and accurate. In disease surveillance, completeness of reporting is achieved by simplicity. Persons being asked to report AIDS should be able to quickly and easily identify whether an individual patient needs to be reported.

Completeness is also achieved by a certain redundancy. Multiple independent methods are needed to detect AIDS cases since no one method is going to be 100 percent effective. Accuracy is achieved by measuring the right indicator. What we are asking people to report should be representative of and specific for AIDS.

Now, like any surveillance case definition, the AIDS case definition governs both the completeness and the accuracy of information that we get. Well, how good is the present AIDS case definition? Quite frankly, as case definitions go, it is fairly awful. The present definition is not simple. Instead, as we have heard, it is the most complicated surveillance case definition in common use today, and has been unwieldy for clinicians and public health

providers alike.

The present definition does not allow for easy ways to find information about cases. Instead has required the development of unique resource-intensive methodology to assure completeness.

The present case definition does not measure underlying illness caused by HIV. Instead it relies on an indirect secondary manifestation of the disease or opportunistic conditions.

Now, despite these failings, AIDS surveillance information collected during the first ten years of the epidemic doesn't really have to be tossed into the dumpster because to date AIDS surveillance has produced reliable information because of the compliance of physician reporters, the availability of resources to conduct intensive surveillance, and a reasonable amount of public health creativity.

However, as the AIDS epidemic has evolved, the present AIDS case definition has become increasingly unable to serve its surveillance function, and unless a change is made the system will unravel.

With time, the number of AIDS cases has increased the reporting burden placed on health care providers. The

unwieldy definition has hastened the burnout of well-meaning but overworked physicians who are trying and ultimately neglecting to report a steadily increasing case load. The completeness of reporting is eroding in this country.

With time, the money and people available to conduct AIDS surveillance are being outstripped by the demand. To find the increasing number of cases that are going unreported today, most health departments have instituted alternative resource-intensive surveillance methods. Such methods include enlisting alternative reporting sources such as hospital-based infection control practitioners, reviewing enormous numbers of inpatient medical records, searching for AIDS diagnoses, and intensively examining other information sources such as pharmacy records and hospital and insurance data bases.

As the site of AIDS diagnosis has shifted from the hospital to the outpatient clinic, these overburdened alternative systems are becoming increasingly inefficient. With time, even assuming completeness, the picture of the AIDS epidemic generated by the current definition has become progressively less accurate. Antiviral and prophylactic antimicrobial therapies are becoming routine, and diseases

that are highly specific for AIDS, like pneumocystis, are being prevented.

At the same time, as we have heard, many people with significant HIV-induced morbidity from common diseases like pneumonia or pelvic inflammatory disease or sepsis are not included in the current definition.

So what is the solution? Well, one proposal has been to add additional illnesses and conditions to the present AIDS case definition. This proposal, while having some merit, would significantly diminish both the completeness and the accuracy of AIDS surveillance information. Increasing the complexity of the definition would reduce completeness by making an already unwieldy case definition unworkable. Confused and weary providers would report fewer rather than more cases.

Adding diseases that routinely occur in immuno-competent people would destroy the definition's specificity, further distorting our picture of who is truly affected by AIDS.

The proposal under consideration today is to broaden the AIDS case definition to include all persons who are HIV-infected and have CD4 counts less than 200. Using

CD4 counts for surveillance simplifies the case definition and thus eases reporting. Using a standard laboratory test to prompt reporting will decrease the need for other resource-intensive surveillance methods. The addition of an immunologic marker to the AIDS surveillance case definition increases accuracy by allowing all persons with severe HIV-related immunosuppression to be defined as having AIDS.

On good days, when I can see the new definition as a solution, implementing it doesn't seem that onerous. AIDS is already reportable in Oregon as it is in all States. The only action absolutely required to set the process in motion is to educate physicians and patients about the change and the reasons for it. Most States accomplished similar education with minimum fuss in 1987 when the definition was last changed. Now, many States including Oregon will choose to take full advantage of the simplicity of the new definition by also making CD4 counts less than 200 a laboratory reportable condition.

Laboratory reporting, in which laboratories report specified results to health departments, is an efficient, effective, longstanding way to assure accurate surveillance of diseases of public health importance. Laboratory reporting

is the standard of practice in most States for monitoring a wide range of diseases ranging from tuberculosis to syphilis to lead poisoning.

In Oregon, laboratories will report a physician and patient identifier to the health department when a CD4 test result is less than 200. As with other laboratory conditions, and importantly, physicians, not patients, will be contacted to determine whether the patient meets the criteria for case reporting.

Now, some physicians in Oregon send CD4 tests to laboratories using coded patient identifiers. That's fine. Laboratory reporting will not prevent this practice since the physician remains the one person responsible for submitting the completed AIDS case report. Laboratory CD4 reporting serves primarily as a prompt to alert both the health department and the physician that such a report may need to be filed.

The proposed case definition is not without its problems, and I'd like to briefly mention four. First, linking CD4 counts to an AIDS diagnosis could potentially discourage some HIV-infected patients from seeking CD4 testing. This concern is real, but providers I have asked in

Oregon believe this behavior will be uncommon. To assess that during the 18 months after the new definition is implemented, the Oregon Health Division will ask each provider submitting a case report whether patient concern about reporting delayed CD4 testing or therapy in that patient.

The second problem--surveillance programs will need additional resources to handle the increased caseload. On April 1st in most localities, the number of AIDS cases will increase by 50 to 100 percent. To date, only limited funding to meet this increased surveillance workload has been made available by CDC. States and cities can ill afford incomplete surveillance now that the Ryan White funding is determined by the number of cases they report. However, the bulk of the need for supplemental surveillance resources should be temporary. Although the new definition will identify people earlier in their illness, almost all the people meeting the new definition will eventually develop conditions that will also meet the present definition.

Over time, the number of newly-diagnosed AIDS cases will return to a level dictated by the epidemic and not the case definition. States that institute laboratory reporting

should accrue real savings by reducing the need for expensive alternative methods.

Third, the acute increase in case reporting will temporarily obscure our ability to analyze epidemic trends. This problem is not a big one. As I have mentioned, the disruption in case reporting caused by the change will be temporary. CDC has funded studies in several States including Oregon to evaluate differences in cases reported under the new and old definition. In the long term, case trends that are currently garbled because of the problems with the present definition will become more rather than less clear.

Finally and most importantly, the proposed AIDS surveillance case definition change has served to focus discussion on a number of other critical AIDS problems. One issue, for example, has been access to CD4 testing by infected persons. It is important to keep in mind that changing the surveillance definition has not suddenly created this need. In fact, meeting the AIDS surveillance definition is way down on the list of reasons that infected people need CD4 testing.

However, if the change can help to make this critical service more available, which it will, so much the

better. In a similar fashion, the case definition has served as a lightning rod for discussion of HIV-related disability, confidentiality and discrimination, and financing and provision of care to infected persons. Because surveillance is not an end, but a means, the problems that can be directly solved by changing or not changing the AIDS case definition are limited. However, by improving AIDS surveillance, the solutions to at least some of these problems become a little easier.

Thank you.

MR. DALTON: Thank you. You are making me look bad with Dr. Lemp since I know you were reading, but you came in on time. Thank you.

The next speaker is Dr. Maxine Wolfe, who I believe doesn't have written testimony so we don't have to play this game. She is a professor of psychology at the City University of New York Graduate School. The same time limits apply, Dr. Wolfe.

DR. WOLFE: All right. I will try to send you this tomorrow, but technical difficulties with my typewriter made it impossible to hand it out. I will try to keep it brief, but I will read some of it.

I want to support what you just said in terms of what is the important part of epidemiological research. I think the important part of epidemiological research is that information gathered can reduce the impact of a disease before its exact nature is understood. And the accurate information about symptoms and transmission routes is necessary first and foremost so that people themselves can take preventive measures to avoid infection, can determine if they might be infected and can seek appropriate care if it exists, and avoid further transmission.

Accurate information about symptoms and transmission routes is also important for health care providers, although they usually see people after they are already ill. However, if they know what symptoms to look for, they can be alert for signs of illness in people who may not know they are ill.

The Centers for Disease Control is the agency charged with doing appropriate epidemiological research, and with developing prevention and educational programs and setting standards of care based on that work. Yet the proposed definition of the CDC surveillance case definition does not reach, from my point of view, any of these goals.

Instead of developing a revised definition which

includes the clinical conditions manifested by women and injection drug users who have HIV disease, the CDC proposes the "simple addition of T-cell counts below 200". This measure, from my research, is unreliable, inaccurate, costly, and widely unavailable. It is not covered, as has been discussed, by anti-discrimination legislation or by legislation requiring anonymity or counseling. It is a back door to HIV mandatory reporting.

It substitutes a false sense of control for effective surveillance and epidemiology which could save lives. Let me give you some history about that.

It has become a truism to say that the AIDS epidemic is now spreading into communities which have been previously unaffected. This statement usually refers to women who are being, according to the CDC, infected through unprotected heterosexual activity primarily with men who are injection drug users or to injection drug users themselves. It would be more accurate, from my point of view, to say that the U.S. Government, including the Centers for Disease Control, have rendered these women invisible for ten years by looking for symptoms found in gay white men.

In 1982, Mazor et al., in an article published in

the Annals of Internal Medicine, reported opportunistic infections in five previously healthy women. That was 1982. The first CDC case surveillance definition was published that year, based on a small number of cases among gay white men. The conditions then considered to constitute an AIDS case were limited. This was before HIV was discovered and considered to be the cause of AIDS. Of the five women described in this paper, one was a non-injection drug using bisexual, one was a non-injection drug using heterosexual with a male partner who was an injection drug user, and the others were themselves heterosexual injection drug users. All had been diagnosed in 1981, the same time the first cases in gay men were noticed. One woman had had symptoms for 34 months before she got one of the identified opportunistic infections.

The paper describes all of the tests which were done but makes no mention of an internal pelvic examination or of gynecological laboratory tests either while the women were alive or at autopsy. It is reported, however, that one had cervical lymphadenopathy and one had bacterial pneumonia. The investigators in October 1982 urged physicians to be alert to the spread of the disease in women.

In 1985, after the discovery of HIV, the definition was changed to reflect that, and to add some new clinical conditions based on clinical experience. Although women with HIV existed, not one of the added opportunistic infections was women-specific. The change resulted in the reclassification of only one percent of existing cases.

In the same year, the U.S. Government through NIAID began a study of over 5,000 gay or bisexual men, most of them white and not i.v. drug users--a study which is still ongoing. It is called the Mack study. These men are seen every six months to assess their physical condition, the progression of their disease, and so on. This study showed a relationship between T-cell counts and being HIV-positive.

Yet in 1987 when the CDC changed its definition again, they only added clinical conditions and presumptive diagnosis based on existing clinical conditions. That is, if a person were known to be HIV-positive and showed known symptoms of certain illnesses, but tests could not be done because of their physical condition at the time, they could be diagnosed as having AIDS. These include esophageal candidiasis, CMV retinitis--some that you probably know about. This category, based totally on clinical observation,

has been responsible for more than half of the new AIDS cases since the 1987 revision.

In the current revision the CDC disregards T-cell counts for these and other existing conditions. That is, they stay as AIDS whether or not your T-cell counts are lower than 200.

Does this decision reflect recent data from the Mack study which indicates that at least 15 percent of gay or bisexual men with PCP--the most reported opportunistic infection--had T-cell counts of 250, or that 25 percent of these men with Kaposi's sarcoma had counts above 300, or that 50 percent of those with HIV dementia had counts over 200, and 25 percent were over 400?

This study has also shown that a clinical diagnosis of AIDS--that is, one using clinical conditions--was far more predictive of mortality than simply reaching a T-cell count of 200.

It is nine years since that first paper about those five women. In all of this time, the U.S. Government has never funded one comparable study of women. Nevertheless, research studies have been conducted despite governmental neglect and lack of adequate funding. These have shown

differences in the clinical conditions associated with HIV between women and men and between injection drug users and non injection drug users.

The Centers for Disease Control chooses to ignore this information even though it is of higher quality than the field data used for all of its previous definitions based on clinical conditions. Instead, to support its position it cites data from its own spectrum of disease study in which gynecological examinations were not required by participating sites, and even admits that the low percentage of gynecological infections found was probably due to that fact.

Yet, while admitting that these infections were "under-ascertained", they ignore accurate research and clinical experience which has found these conditions to be more prevalent and more severe and life-threatening in HIV-positive women.

The CDC further rationalizes its use of 200 T-cells and its disregard of the clinical conditions found in HIV-positive women by emphasizing research, as we have heard today, that with the addition of 200 T-cells, the percent of cases among women would increase considerably. From 46 to 57 percent of current female outpatients in certain sites would

now be included.

This argument is problematic to me in two ways. First of all, these women are already aware of their HIV status and are already being treated. This change does not therefore speak to major goal of epidemiology, that people who are not aware of their HIV status might recognize their symptoms or that health care providers might think HIV testing when women show these symptoms.

Secondly, the point is not simply to increase the number of AIDS cases in any way. It is to reflect the true scope of the epidemic in an accurate and useful way.

Furthermore, the CDC reached the decision to add 200 T-cells to its case surveillance definition without including in its meaning clinicians who regularly treat women who are HIV-infected; nor did they include HIV-infected women themselves or injection drug users in that decisionmaking process. In fact, as I understand it, this definition was developed as a compromise between those who favored mandatory HIV testing and those who did not, in the last minutes of a meeting. This is an irrational basis for decisionmaking which will affect hundreds of thousands of people for years to come. Thus the proposed change is the product of political

maneuvering and is not a product of scientific or clinical knowledge.

Until this definition was proposed--that is, for the last ten years--AIDS has been described as a "syndrome". It is not a single disease nor is it identified by a single marker. A "syndrome" is medically defined as a set of symptoms and diseases no matter how complicated that may be. The sex changes, and the basis for a diagnosis changes.

In addition, not everyone gets every symptom; and some symptoms are going to be unique to specific groups, for instance, because of anatomical differences. Women have vaginas, uteruses, fallopian tubes and ovaries. Men do not have these, and opportunistic infections of AIDS cannot affect them at these sites.

Some other differences which can and in fact do produce different symptoms and severity of symptoms in different people might be the mode of HIV transmission, age, endocrine differences, geographic location. For ten years we have used this kind of system, yet suddenly when it comes to the inclusion of women, specific symptoms become too cumbersome. I am almost finished.

After ten years and in the face of public testimony

from the American Medical Association, with continued pressure from numerous people, the CDC has finally admitted that HIV-positive women and injection drug users do get different symptoms than gay or bisexual men. However, it insists on keeping these conditions in the classification system and not shifting any of them to the definition.

The classification system is not used for national reporting. Equally important, the list of opportunistic infections contained in the monthly national surveillance reports and go out to individuals across the country will remain exactly the same. Thus the addition of cases to the classification system but not to the surveillance definition will not alert anyone to the possibility of their infection or their client's infection. It will only be known to those already treating people identified as having HIV. It won't serve as a basis for research which is focused on treatments for life-threatening, AIDS-defined opportunistic infections. It will not become a basis for education programs.

I want to say that the lack of integrity in even the classification system can be seen--please let me finish--as you go over--I do have points to make that have not been made, so just let me make them, please.

MR. DALTON: Let me just say the reason I'm doing this--and you could talk all afternoon--

DR. WOLFE: I know.

MR. DALTON: --but the Commission needs to arrive at some judgments about these things, and if Commissioners have questions, and we aren't able to ask them, that doesn't serve anyone's interest.

DR. WOLFE: Okay. I will try to do it quickly.

Even the classification system has changed over these months, with diseases jumping in and out, with pressure being brought to bear. The first one only had vulval/vaginal candidiasis, didn't have cervical carcinomas; then they got added; then PID got added, and HIV cardiopathy got taken out. This is irrational.

I also want to say that the CDC justifies the exclusion of these conditions by claiming that they are not as life-threatening and severe as those that are now in the CDC definition. They also claim that they are not HIV-specific while those in the current definition are. And while continuing to include previous AIDS-defining illnesses regardless of T-cell counts, it will only consider these new infections if they have a count less than 200. This system

is totally inconsistent and reflects a double standard.

Before AIDS was known, gay men had herpes simplex and CMV, which are included in the surveillance definition, and what made them become included in the definition is that with HIV they become severe and life-threatening. The same is true for cervical cancer, tuberculosis, or pelvic inflammatory diseases.

Before AIDS, KS was usually found only in men over 60--

MR. DALTON: Wait, Dr. Wolfe. Give me a second.

DR. WOLFE: Yes, I'm just going to finish--

MR. DALTON: Give me a second, please.

DR. WOLFE: Okay.

MR. DALTON: Everyone around this table knows about KS, understands that before AIDS it was only found in--

DR. WOLFE: I know, but--

MR. DALTON: --let me just finish--we have a quite thick briefing book that we are given on a number of issues, which I take it most of us have read or can read. I agree that most of what you've said you have been the first person to present on, but that's true of most everybody that we've heard from and I hope tomorrow as well. So I am asking you

please, out of respect for your fellow panelists and the Commissioners, to bring it to a close.

DR. WOLFE: I just have two more points to make, if you would. And the reason I mention KS is because Mitchell Mayman [phonetic] just reported the youngest case of cervical cancer ever reported in the medical literature, 16, in an HIV-positive woman. So the bases on which certain things have been included and other things have been excluded to me are not consistent and are not rational. And I think that people have to look at that.

I want to say that as far as I am concerned, the proposed revision has more to do with statistical consistency than anything else, and that is why the conditions that are already in there are kept in there despite the fact that there are gay men who, according to the Mack study, have KS with 400 T-cells, and yet all other conditions are considered not life-threatening and are excluded unless they have 200 T-cells.

I would argue that if we are going to revise this definition--and I think it should be revised--it should continue to be a clinical diagnosis, clinical conditions, as it has been--not 200 T-cells--and it should include the

clinical conditions that we know are occurring in women and injection drug users.

MR. DALTON: Our last speaker on this panel is Spencer Cox, who is a Public Affairs Associate for the Community Research Initiative on AIDS in New York City.

MR. COX: I was asked here today as a person with HIV disease to offer a quote-unquote personal perspective on the proposed change in the definition. My ability to generate such perspective being somewhat limited, I too am going to read.

A personal perspective usually means that one talks a lot about one's emotional reactions, and certainly in the context of AIDS and HIV infection, these emotional reactions can be severe.

Unfortunately, the uniformly progressive nature of HIV disease means ostensibly that all of us who are infected will at some point face life-threatening HIV-related diseases and, hopefully, an AIDS diagnosis.

Therefore, I'm concerned that my personal perspective on diagnosis not be allowed to obscure other more pressing issues which may make a difference in the length and quality of life for myself and other people with AIDS and HIV

infection. So I am going to focus in this testimony on some general considerations regarding the proposed change in the definition, and I'll return to the more personal aspects of diagnosis and disease in this context.

Congress has mandated that CDC collect information on the demographic characteristics of the population of people with AIDS and develop models demonstrating transmission patterns in the United States and internationally.

Traditionally, CDC has depended on State health departments to collect this data using diagnostic categories based on clinical symptoms. This has been widely criticized as excluding women and intravenous drug users. I would also add diseases which may be exacerbated by poverty and intravenous drug use.

Additionally, potentially fatal diseases such as tuberculosis often occur in patients without HIV infection. Their increased frequency and severity in patients with HIV is indicative of profound immunosuppression. Such diseases are sensitive but not specific to HIV disease and are generally not included in the current surveillance definition.

CDC has suggested adding depressed CD4 lymphocyte counts to its list of conditions which define AIDS. But

gross inequities in the availability of health care make it highly unlikely that the poor will receive this diagnostic test. Discrepancies in the rate of reported diagnoses based on CD4 lymphocyte counts are likely to bias CDC's data increasingly toward middle class white men. Because we expect the majority of new cases to occur in poor communities, such a bias is likely to render conclusions based on this data highly unreliable.

For patients without private insurance, these $100 to $200 tests are virtually unavailable. As a leading Harvard biostatistician told me, you want a surveillance definition to be affected as little as possible by personal decisions and access to health care. No parameter is perfect, but CD4 count may be the worst. It is completely dependent on personal and socioeconomic factors.

Conversely, a standardized AIDS diagnosis based on clinical symptoms can be consistently reported to CDC following emergency room treatment, a common mode of health care delivery in poor communities. Ironically, the proposed definitional change will place poor people with HIV disease in a triple bind. In order to pay for CD4 cell tests the patient has to qualify for Medicaid. In order to qualify for

Medicaid, the patient has to have an AIDS diagnosis. In order to get an AIDS diagnosis, the patient has to have a CD4 cell test. The proposed definitional change effectively implements another two-tiered system in which patients with private insurance are diagnosed earlier based on laboratory values, thus increasing their access to care and services, while uninsured patients are diagnosed later, when clinical symptoms appear, resulting in worse overall health, fewer services, and generally poor prognosis.

It would be unconscionable if the definitional change which the affected communities fought for in hopes of expanding the array of care and services offered to poor people with AIDS were used to widen the gap between the haves and the have-nots in the provision of these services.

CDC also suggests that the expanded AIDS surveillance case definition will promote optimal medical care--a clear acknowledgement that the CDC definition has ramifications far beyond AIDS surveillance. However, CDC does not provide health services, and our country is currently without a mechanism to provide such services equitably. CDC must therefore devise a surveillance system that will function despite the lack of health care in poor communities without

exacerbating that lack.

The proposed definition, even if it were to be adopted by governmental health and social service agencies, would provide an inadequate basis for assessing the need to initiate therapy. Optimal medical care in the context of AIDS entails initiation of therapy long before the collapse of the immune system. Currently, AZT is recommended for all patients with less than 500 CD4 cells. Therefore, in order to promote optimal medical care, it is necessary to recognize HIV infection as a spectrum disease with more aggressive treatment recommended for each succeeding stage of disease progression. That's a little bit more difficult to report.

It is necessary to clearly identify the functions of the CDC surveillance definition and to distinguish CDC's goals from those of other agencies, and other people have talked about this today.

The expanded definition does provide an additional argument for increasing the availability of CD4 cell tests. However, history suggests that we have no reason to expect a new surveillance definition to elicit an outpouring of services from an administration that has clearly placed AIDS and health care in general among its lowest of priorities.

Ultimately, the proposed definitional change will have a detrimental effect on CDC's ability to fulfill its congressionally-mandated AIDS surveillance tasks. By increasing the disproportion in diagnosis between high seroprevalence poor communities and lower seroprevalence middle and upper class communities, CDC will both inaccurately record the population of people with AIDS and will drastically reduce its ability to draw reliable conclusions about changes in absolute and comparative time trends and demographic subsets of the patient population.

CDC's definition is formulated for surveillance purposes, not for the purpose of identifying those who need social and health service benefits. However, CDC's inability to implement a reliable surveillance program is clearly a function of the American health care system's failure to adequately provide for the health needs of people with AIDS. This is hardly the only failing of the American health care system, but for people with AIDS, these failures are likely to be exaggerated because we are I believe twice as likely as the quote-unquote "general population" to rely on publicly funded health care.

Sadly, this administration has utterly failed to

address the current crisis in health service delivery. Until this country joins the rest of the industrialized world in recognizing health care as a basic human right, then our disease prevention programs will remain ineffective; our epidemiology will be shoddy; our health care delivery systems grossly unfair, and the health of all Americans will continue to suffer.

This brings me back to my personal perspective. I have a life-threatening disease, and my AIDS diagnosis will be traumatic. No alteration of the surveillance definition is going to change these facts. However, it will be enormously more traumatic if I receive an AIDS diagnosis because I did not have access to the medical care and services that would delay the diagnosis and keep me healthy longer.

CDC's epidemiology plays an important role in the allocation and delivery of these services, and I urge this Commission to recommend against their implementation of a surveillance definition that will needlessly sacrifice our ability to reliably track epidemiological trends and to rationally plan health services delivery.

I would like to add that I have spent some time now working in AIDS advocacy, and I am sick and tired of tinkering

around with the surveillance definition, siphoning off vital research funding, deregulating the pharmaceutical industry and squabbling with the parasitic insurance industry to ensure that a very few more people will have access to health care.

Therefore, I also urge this Commission to recognize the role of our collapsing health care system in the implementation of any surveillance program and to continue to advocate for equitable health care in the United States.

Thank you.

MR. DALTON: Thank you.

Questions? Don?

MR. GOLDMAN: It's really not a question, but there is another aspect and another facet of what you are talking about in terms of the impact that I think I would ask my colleagues on the Commission to consider and think about. And that is the implementation of any such change in definition.

One of the concerns that I have is that many people out there have been told that they are infected with HIV and that they have a long and productive life ahead of them, and after all they don't have AIDS. And we are going to be

taking people who may be in various stages of health, and all of a sudden on one overnight day, telling them that they have AIDS, which they may have previously been told was a death warrant and may have previously been told is a signal of their early demise.

I'm not sure whether or not in the process of doing this implementation we have done anything to prepare for the psychosocial implications of that change, or that I have seen anything that will be given and provided for, or treatment facilities, community-based organizations in other communities out there, regardless of how we end up doing changes, as those changes occur and the definition gets expanded, to prepare them for that kind of impact on people.

I think Belinda would have made us remember that above all of these technical and numerical things that we do, it is important that we consider the people and the impact on individuals and that that is an aspect of things that all during the presentations today, I have not heard anybody mention, and I felt that today it would be wrong if somebody didn't mention that, so I did.

MR. DALTON: Thank you. Actually, I believe Dr. Lemp in passing made reference to the psychological impact of

having an AIDS diagnosis. But I wanted to ask staff, Roy or Fran or whomever, if in fact anyone during tomorrow's testimony will be addressing these issues because I, too, had the same question as I looked over the speakers list for tomorrow.

DR. WOLFE: Could I say something about that? I think it is a mixed bag both ways. I have spoken to women with HIV who have incredible stories to tell about being extremely ill, going to doctors forever, and no one ever thinking that they could have HIV; so that they have been told that they are crazy, that they are depressed--I'm serious--

MR. DALTON: I'm just smiling because I understand the history behind that.

DR. WOLFE: Yes, that whole thing, and as strange as it sounds, their sense of relief when someone said, "You have AIDS."

On the other hand, I have also spoken to people who have felt the opposite way. I have spoken to gay male friends of mine who have less than 200 T-cells, who have never had what is considered symptomatic, who claim that if someone tomorrow made it 200 T-cells, they would freak out.

So I think there are different sides to that story, because it's not the same for everyone ten years into this epidemic.

MR. COX: I would also point out that whatever the reaction that an individual has to news of their HIV infection or their AIDS diagnosis, the psychosocial services to address that are simply, again, not in place. Yes, it would be nice if we could prepare everybody emotionally to hear that they have AIDS, but again I'm going to ask you what system we're going to use to do that.

MR. DALTON: Yes, Charlie?

DR. KONIGSBERG: A couple comments. I don't know whether there is anybody from staff, and June isn't here, who knows whether the Commission after two days of hearing plans to come up with a Commission consensus or position on the question of case definition expansion and communicate that to the CDC. There is time--I assume that it is still open for comment--is that right, Dr. Berkelman?

DR. BERKELMAN: Yes.

DR. KONIGSBERG: So I will kind of leave that as a question, Harlon, as to something we ought to consider.

The other thing I am having some trouble with, and

some people are confused maybe still, is about the difference between surveillance and what surveillance is for and the clinical aspects. I know it's not all that clean, but I don't think there is any doubt that there needs to be a lot more education with physicians as far as the symptomatology in women as it may be different from men, is different in some cases. But I think that is a somewhat different issue than this whole surveillance issue.

The Commission held long hearings on AIDS in women. I think it is a legitimate issue, and it needs to be continued, but we've got a whole separate issue in this country about primary care physicians--and I would include ob-gyns in that for the purposes of this discussion--and being alert to the early signs and symptoms of HIV disease. I think we're getting that in some cases a little bit mixed up with the whole surveillance question. We have had some very thoughtful testimony today, and I'm sure we'll have more tomorrow, about some of the ramifications of the expanded definition, and I think, Dr. Fleming, your testimony was just superb in trying to tease out all the different ramifications. So it should not be taken lightly, but it is a very clumsy--as a public health official, that is the clumsiest kind of thing I have

ever seen as far as a case definition, and I think something that would simplify it in the long run will be advantageous. But we need to attack the question of availability of care and the appropriateness of care out there as well, and not hold up the surveillance while those things are being worked on.

MR. DALTON: Before you answer, I just want to add to that--is it possible to decouple the use of a case definition for surveillance purposes from its use for care purposes in this epidemic? A lot of people have suggested that those are two different things, but can they as a practical matter be different?

MR. COX: I'm not sure how if the implementation of the surveillance definition is dependent on the health care system which has, as we all know, fallen to bits.

DR. KONIGSBERG: But that's true for every other disease. I mean, that was true historically for tuberculosis, and historically there were many physicians who had a lot of trouble trying to come up with appropriate diagnoses. I mean, some of us in public health have been down this road before. Admittedly, HIV and AIDS is more complex. That's why I made the comment. It's not quite that clean. But the

purposes to which public health puts surveillance to use is different than the physician in a clinical setting.

And while I've got the microphone, I guess I'm getting perplexed that I'm still hearing the question that CDC or the government's motivation with some of this relates to mandatory testing. I don't know. I continue to go to a lot of AIDS meetings and have for years, and I'll be damned if I'm hearing that anymore. I just don't hear it.

There is a continued discussion about mandatory reporting, and that needs to continue to be debated although the trends in the States are toward that, but mandatory testing is not a trend I am hearing. There may be a few isolated individuals in the so-called political sector who raise that specter, but not from the responsible public health community, whether it is Federal, State or local.

If anybody has some evidence to the contrary that is specific and concrete and documentable, I'd love to hear it.

MR. DALTON: Would you answer both questions? Your hand was up for the prior question as well, Dr. Wolfe, so go ahead.

DR. WOLFE: I want to try to say this in a way that

you will hear, and I have tried to say this professionally in my own field for the last 23 years, and I want to say it about medicine, and I want to say it about surveillance.

It always boggles my mind that when someone mentions women, people of color, or poor people, the issue becomes are we really talking about surveillance or are we talking about health care, as if the surveillance of white men is surveillance, and the surveillance of everybody else is health care.

I have never been able to get people to understand that a white male science is not an accurate science. It is whatever the purpose of surveillance, and in this case, we all know that it has many purposes, and I'm not talking about social services--I am talking about accurately reflecting a condition.

AIDS is not TB; it is not a single disease. Okay. And the law of parsimony that we have all been taught in graduate school, which is that the simplest explanation is the best, has not been proven real in the world. It has obscured most of the people who have been affected by most things in the world. And I think that somewhere we have to make a shift in that.

And I understand that there are difficulties in reporting. Everyone says that this is the most complicated definition that has ever been. It has been complicated for ten years, and as you said, you manage to get physician compliance and so on. Somewhere a government agency has to take the lead in saying that what is accurate must be done, and we must find a way to do it if it is going to include all of the people affected and indeed the accurate surveillance and epidemiology.

So I hope that people will hear that and not think women/social, men/real. That's what I constantly hear, and I don't think that makes any sense to me. To me, it is men and women/real.

MR. DALTON: Don?

DR. DES JARLAIS: This is a reflection of some of the testimony and not a question, but just a sense that this epidemic has generated a tremendous amount of anger, and the anger is certainly quite well-justified and that changing the case definition focuses that anger.

I am not at all confident that the new definition will resolve much of the anger. I am quite confident that keeping the current definition is probably going to generate

more and more anger, and I'm also I guess reasonably confident that coming up with a more complicated definition by adding more opportunistic infections is probably not going to address any of the root causes of the anger either. So that's sort of a reflection of hearing some of the testimony, that we've gone well beyond the issues of surveillance definition, and I think we've done it in a way to make us realize that whatever definition we have is not going to address the health care problems and the historical health care problems that have led to the current system.

MR. DALTON: I have a final question for Dr. Fleming. You spoke about lab reporting, and you suggested that should the new definition come on line it would probably press inexorably toward lab reporting in Oregon and other States, and you said that labs would report to health departments and to physicians, but not to patients. You also said the physician determines whether the patient meets reporting criteria. But one thing I don't understand is if the lab reports directly to the health department it seems like it's a little late for the physician to make a decision about whether this is really reportable once it is already reported.

I take it the physician could call the health department and say "Don't send this on to CDC; purge it from your files," but that strikes me as unlikely.

You also mentioned that lab work can be coded. That is, a physician or health care provider who sends blood to a lab for CD4 count could do that in a manner that is coded by patient. And I was glad to hear that, but I have certainly heard previously that the problem with T-cell counts is that it is not possible to do them--well, that still isn't anonymous; it is confidential--but it's not possible to do them in a way that preserves confidentiality. So I want you to address that.

DR. FLEMING: Sure. I think that part of your question may result from some misunderstanding about what laboratory reporting is and how that report is handled. With the CD4 count, for example, when the laboratory tested an individual and found a CD4 count less than 200, they would notify the health department that they had a CD4 test from an individual less than 200. The first and the only action that the health department would take with that result would be to call the physician who submitted the report and ask the physician does this person or does this person not meet the

AIDS case definition. If they do, would you please submit a case report on that.

At that point, if the physician says this person does not meet the AIDS case definition, nothing further is done with that case report; it is not kept by the health department, and it is not forwarded on to CDC. So laboratory reporting serves only as a prompt to the health department to serve to alert us that there may be a case out there, and we need to confirm whether or not that is true by directly contacting the physician.

MR. GOLDMAN: I have a question. Assuming the doctor neglects to send the case report back, am I correct in assuming that the next thing is that the health department would call the doctor back, and that the report would not in fact go to CDC until and unless the doctor in fact sent the form in?

DR. FLEMING: That's exactly correct because in fact we don't have the information on the case report form to send to CDC. That is relatively involved information about the patient. And the only thing we have is a patient and a CD4 count less than 200. So nothing will happen with that report other than that--

MR. DALTON: And the doctor's name.

DR. FLEMING: --excuse me--and the doctor's name, right.

DR. KONIGSBERG: Is that consistent with how you are generally handling other diseases such as hepatitis B or syphilis?

DR. FLEMING: That's exactly the way that other diseases are handled--thank you--in that the laboratory report serves only as a prompt, and the physician is the one who remains responsible for deciding whether or not to report a case.

DR. KONIGSBERG: Let me follow up because I think this is an important point, and because I think sometimes people are getting the idea that some kind of new inventions in surveillance are coming about here. So basically what happens with, let's say hepatitis B, if the laboratory gets hold of a positive, it is not reported to the CDC as a case of hepatitis B until there is that follow-up and that special form for case report. In other words, a laboratory finding from a laboratory in and of itself does not constitute a case report.

DR. FLEMING: Only a physician can report a case of

AIDS, and with laboratory reporting, that is still the case. Let me quickly address your issue about coded testing. Because the physician is the one that reports the case, if the physician chooses, they can on the laboratory slip that goes to the laboratory write down their physician's name and then some number that they know identifies their patient. The laboratory runs a test and reports the result back to the physician using that number. The laboratory reports to the health division, "We have Dr. 'X' who has a CD4 count in a Patient Code Number X-3." We call the doctor and say, "We got this case report. Does your Patient X-3 meet the AIDS case definition, and if so, would you submit a case report."

That's how that would work.

DR. LEMP: Let me comment on that. That's also true in San Francisco, and in fact a number of laboratories do not take names of patients from physicians. They basically just take the physician's name and information to call them back and a coded number.

So what we potentially could do is either having the laboratories report directly as a trigger, or what we're actually planning to do is to send staff into the laboratory so that they don't have to be bothered to even send them, and

we would then have to contact the physician and say "This is a number with your name attached; could you determine whether they are reportable under the definition?" And obviously, without knowing that they are HIV-infected, they are not reportable in and of themselves. So we would then get that information and then, working with them either right on the telephone or talking to them, if they confirmed it, they could report the case over the telephone to us at that moment, or they could report it themselves, or in San Francisco, since we have such active surveillance, most of the time we can report for that physician directly if they are a hospitalized patient through our active hospital efforts. But we would have to go through that process.

MR. GOLDMAN: Is what you are describing universal in all 50 States?

DR. KONIGSBERG: It's consistent with the public health practice in the half dozen States that I've been involved with, yes, that's pretty consistent.

MR. GOLDMAN: And from your organization's perspective, that would be the right way of--

DR. FLEMING: That's how laboratory reporting works in essentially all States.

MR. GOLDMAN: Okay.

DR. DES JARLAIS: It's important to remember that there are a significant number of people with essentially no CD4 cells who are HIV-negative but may be receiving chemotherapy for cancer or other things, so that you've got to base any reporting of AIDS, whatever the definition, on the physician making the diagnosis, not a lab test in isolation from that physician.

DR. LEMP: It would always be a two-step process; either a clinician or a medical chart would have to be examined. We'd have to either talk to the clinician or look at a medical chart to even confirm it.

DR. FLEMING: Let me just add that the advantage of this system is that it allows us to easily identify cases that may need reporting. Cases are not being reported because physicians are forgetting to do it, and this is just a way to prompt them to do it.

DR. KONIGSBERG: One other thing, too, Harlon. One of our favorite frustrations in public health has to do with the lackadaisical attitude that physicians have about reporting reportable diseases. Every State I've been in, the State epidemiologist swears up and down that it is the worst

in the country, when actually that's not the case; it is just worse for them because that's where they are.

I've seen one State where more punitive measures were used which I don't think are particularly helpful. There are a lot of reasons for that. One of the reasons from a practicing physician's standpoint is that a lot of times physicians in some States don't get any feedback. There are no reports put out. They don't know why. It is an educational process.

The truth is in AIDS the reporting has probably been better than any other disease that I'm aware of. It has not been perfect, but it has tended to be in a much better manner. But I think there needs to be a lot more education of physicians about reporting and disease.

Now, on the other hand, again from the physician's standpoint, there has been a lot of reporting of diseases that have minimal to no public health significance. I just left a State where we expended a great deal of effort getting physicians to report head lice, for God's sake. I mean, what are we going to do with that from an epidemiologic and any other standpoint. So we cleaned all that up. Influenza by name is another one that's kind of silly.

So there needs to be a modernization of it, but we've got to educate physicians on the importance of reporting, why it is important to have that information, and what their role is. And I think that's something that the State health officers, all 50 of us, need to be pushing, whether it is AIDS or hepatitis.

DR. WOLFE: Can I ask one question for clarification? So when you call the doctor, and they now file a case report, they do exactly what they've done before, and they use the same opportunistic infections that are now in the definition, and they list the presenting opportunistic infection along with the T-cell count as they now do, along with the AIDS diagnosis?

DR. FLEMING: They would use the same exact form as if they were reporting the case because the person had developed an AIDS-defining condition. There is no difference in the process.

DR. WOLFE: So you would never get any information about women-specific opportunistic infections because they're not on that list already.

DR. FLEMING: That's an issue that we have to deal with separately by either modifying the form or conducting

special studies. That's not a surveillance issue.

DR. LEMP: I would recommend that we do that--

DR. WOLFE: Wait, wait, wait.

MR. DALTON: That was a "Yes" to your question.

DR. WOLFE: That was a "Yes".

DR. LEMP: I am supporting your point in that I think the CD4 counts, implementing this, should be done, but I think that there needs to be specific deadlines, time lines, and we should be talking about adding in some fashion other manifestations either through sampled cities or through samples nationwide, or for all persons with CD4 less than 200 to add manifestations that are found in women or injection drug users and others that are not on the list, in addition to having CD4 count information. I think that until that information is available, the CDC is not going to make a decision based on a lack of information. There is not enough data right now as far as the sensitivity and specificity of those other manifestations for them to make that decision, and I think--

MR. DALTON: Or at least that's their position.

DR. LEMP: No, I don't think that the data is there. So I think that these types of studies need to be

discussed now, and proposed and funded so that they are ongoing so that people will know that that's going to happen. So if this B2 or B1 category--if people felt that eventually they would be moved into the C1 or C2 categories, they may feel that they are part of the process, that there is actually a plan, there is funding, and there is a program that is developed that will actually accomplish that. Right now there is no discussion of that, and there is no program to do such a movement. I think that would be some important compromise that would need to be considered.

MR. DALTON: Okay. Roy Widdus gets the last question or comment.

DR. WIDDUS: One quick question. Could the physicians meet their reporting requirements just by saying that the individual had less than 200 T-cells and not bothering with the rest of the form?

DR. FLEMING: No. The proposed definition would require that the individual also be HIV-infected, and we in addition would want to get a case report form on that person.

DR. WIDDUS: Which includes the description of the opportunistic infection. But if they are short of time, what's the likelihood they'll want to do it?

DR. FLEMING: We can facilitate that process.

MR. DALTON: I'd like to thank all four panelists, Drs. Lemp, Fleming, Wolfe, and we'll make you a doctor, Mr. Cox. Thank you.

I understand there are no people desirous of participating in public comment, so we'll meet again tomorrow morning at 9:00.

[Whereupon, at 6:00 p.m., the proceedings were adjourned, to reconvene Tuesday, December 10, 1991, at 9:00 a.m.]