THE PRESIDENTIAL COMMISSION on the HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC

HEARING ON Incidence and Prevalence

December 10 and 11, 1988

August 24, 1988

TO OUR READERS:

The Presidential Commission on the HIV Epidemic held over 45 days of hearings and site visits in preparation for our final report to the President submitted on June 27, 1988. On behalf of the Commission, we hope you will find the contents of this document as helpful in your endeavors as we found it valuable in ours. We wish to thank the hundreds of witnesses and special friends of the Commission who helped us successfully complete these hearings. Many people generously devoted their volunteer time in these efforts, particularly in setting up our site visits, and we want to fully acknowledge their work.

The staff of the Presidential Commission worked around the clock, seven days a week to prepare and coordinate the hearings and finally to edit the transcripts, all the while keeping up with our demanding schedule as well as their other work. In that regard, for this Hearing on Incidence and Prevalence, we would like to acknowledge the special work of Jackie Knox and Daniel Wartonick in putting together the hearing, and Jackie Knox in editing the transcript so it is readable.

For the really devoted reader, further background information on these hearings is available in the Commission files, as well as the briefing books given to all Commissioners before each hearing. These can be obtained from the National Archives and Records Administration, Washington, D.C. 20408.

One last note--We were only able to print these hearings due to the gracious and tremendous courtesies extended by Secretary Bowen's Executive Office, especially Dolores Klopfer and her staff, Reginald Andrews, Sandra Eubanks and Phyllis Noble.

Sincerely,

Polly L. Gault
Executive Director

Gloria B. Smith
Administrative Officer

PRESIDENTIAL COMMISSION ON THE HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC

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PRESIDENTIAL COMMISSION ON THE HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC

HEARING ON INCIDENCE AND PREVALENCE

Department of Health and Human Services
First Floor Auditorium
330 Independence Avenue, S.W.
Washington, D.C.

Thursday, December 10, 1987

COMMISSION MEMBERS PRESENT:

ADMIRAL JAMES D. WATKINS (RETIRED), CHAIRMAN

JOHN J. CREEDON

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POLLY L. GAULT, EXECUTIVE DIRECTOR

I-N-D-E-X

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

[9:10 a.m.]

OPENING

MS. GAULT: Good morning, ladies and gentlemen, members of the President's Commission. My name is Polly Gault, and I serve as the designated federal official. In that capacity, it is my privilege to declare this meeting open.

Chairman Watkins.

WELCOME

ADMIRAL WATKINS: Good morning. It's a pleasure to welcome our members, distinguished panelists and all of you in the audience who have joined us this morning for this meeting of the President's Commission on the HIV epidemic.

As many of you know, the Commission submitted its preliminary report to the President on December 2nd, and in that report we indicated that we would be proceeding expeditiously to address several issues we feel demand early attention.

The incidence and prevalence of HIV infection amongst Americans is one of our first priorities in this regard.

Today, under the leadership of two of our Commissioners, Mr. Richard DeVos and Mr. John Creedon, we have organized this public hearing to receive testimony from many individuals who are considered experts in the fields of epidemiology, biostatistics, public health and medicine.

In hope of coming to a better understanding of this disease and its future course, we have assembled five panels over a two-day period to focus on important issues such as the staging of the disease and the quality of the epidemiological data; the public health perspective in future trends; populations at risk; community-based organization perspective; and mathematical projections.

Determining the incidence and prevalence of HIV infection is critical for projecting the economic impact and developing a meaningful response to the epidemic.

Before I temporarily relinquish the chair this morning, I would like to set up operating procedures.

When the panelists have finished their testimony, Mr. John Creedon will lead off the questioning, and then other Commissioners, with me asking the last set of questions.

In this way, all Commissioners will get a chance to ask their questions within the time frame that has been allotted, and I will be able to close up each panel session.

So without objection from the Commissioners, we will use this procedure for today's and tomorrow's hearing.

At this time, I will defer to the chairman of the subgroup for finance and economics, Mr. DeVos.

MR. DeVOS: Thank you, Admiral. I also would like to welcome all of you here today as we prepare to get down to some of the hard numbers and the financial aspects that are attached to this challenge that we face.

We are going to try to get some numbers that carry us out to the year 2000 in order to have cost projections based on some realistic numbers.

I also owe you an apology, for I have engagements in New York today, and I will be going there; but I will be back here again late tonight.

It is a tribute to our staff people in the preparation of much of this data today. Carol Abrams, who did a lot of it, and Jackie Knox; Carol Abrams, who works with Mr. Creedon; and Jackie Knox of the Commission staff, have put together most of the material that you're going to be hearing about today. I want to commend them and thank them.

We've heard a lot in the past about the makeup of this Commission. From my personal viewpoint, it's an honor to be here and to be associated with people who are willing to give so much time and effort to this particular effort.

One of those is the man who is the chairman of this particular panel today and tomorrow, the president of the Metropolitan Life Insurance Company. We not only salute him, we thank him, and we wish him well in his hearing today.

Now, I turn it over to John Creedon.

John, it's all yours.

MR. CREEDON: Thank you, Rich, and thank you, Admiral.

It seems to me that today and tomorrow we will be examining a number of different issues.

First of all, we'd like to know as best we can how many people have the virus right now. We'd like to try to determine how many people will get the virus between now and the year 2000.

In connection with both of those questions, is an additional question; how reliable is the data that now exists? How reliable is the testing process?

How many who have the virus or will get the virus will get AIDS itself or some other disabling condition which will require medical care and how soon will they get AIDS or a disabling condition after the time they contract the virus?

Who are the vulnerable groups? What are the sizes of the vulnerable groups? Are they growing or diminishing? Are they likely to grow or diminish between now and the year 2000?

Will the disease spread, or is it spreading to the heterosexual community as well as to the vulnerable groups?

Reliability of the testing, reliability of the process that we're using to make estimates; these are the key questions.

I think we recognize that there are conflicting views on some of these questions, that the situation is necessarily fluid; that there may not be as much certainty as we would like; that it's complicated and that, to some extent, everything depends on a lot of different variables.

But this is a situation with which we are confronted, and in that atmosphere we have to try to develop as much good data as we can.

As the Admiral said, we have set up four different groups, two today, one in the morning and one in the afternoon and two tomorrow. The first one this morning will deal with the quality of the data that exists out there and the various stages of the disease among people who have the virus.

We have a number of panelists, and the first one is Dr. Fauci.

Dr. Fauci.

PANEL ONE

DATA BASE QUALITY/STAGING OF THE DISEASE

PRESENTATION BY DR. ANTHONY FAUCI

DR. FAUCI: Thank you, Mr. Creedon, Mr. Chairman, members of the Commission and ladies and gentlemen.

What I'd like to do this morning is to spend 10 minutes discussing in a broad outline the spectrum of infection with HIV, what the mechanisms are whereby a person can go from an

asymptomatic infection to developing symptoms and ultimately full-blown disease, and what the known data of the conversion from asymptomatic to full-blown disease is and what some of the projections are.

I'd like to start off by very briefly outlining the process that occurs when an individual is infected with the human immunodeficiency virus shown here on this slide in which the outer coating, the area which is designated gp 120, is actually the site of the virus which has a specific affinity for certain cells in the body, the most important of which is the human lymphocyte, which is responsible for protecting the body against invaders that are microorganisms as well as certain cancers.

I reviewed this with the Commission a few months ago, so I'll be very brief in this regard, but these lymphocytes, particularly T-lymphocytes, are responsible for what we call host defense mechanisms.

The virus, as I mentioned, on the right-hand side in a magnified form binds to a specific receptor on the T4 lymphocyte which we call the CD4 molecule. That molecule is predominantly expressed in a very large amount on T4 cells but also on monocytes and on certain cells of the central nervous system.

So monocyte macrophage lineage cells can also be infected and probably serve as an important reservoir for the virus.

The reason this T4 cell is so critical to the entire process of understanding the devastating effects of HIV is that the T4 lymphocyte is the cell that is literally responsible for the orchestration of virtually all aspects of the immune system.

This slide schematically diagrams arrows coming from the T4 lymphocyte to all of the known important immunological functions of a variety of cell types; therefore, the very interesting and somewhat diabolical situation of this virus is that by eliminating one specific cell type, it can in essence completely immobilize and destroy the immune system, leading to the devastating effects that we know as AIDS and AIDS-related conditions.

Now, it's also important to understand when you think in terms of infection versus symptoms versus disease is to understand that upon infection of the T4 lymphocyte on the top of the slide, two major events can occur:

Either the virus can immediately kill the cell, as shown on the left-hand side of the slide, by active replication leading to cell death and ultimately suppression of the immune system; or

As demonstrated on the right-hand side of the slide, the virus can exist in what we call a latent or a low-level chronic form. In this situation, there can be virtually no detectable immunological abnormalities, or there may be subtle, if not frank, immunological abnormalities that do not necessarily lead to full-blown disease or symptoms.

Nonetheless, in both those states, when the virus is latent or when the virus is fully expressed, an individual can pass the virus on to another individual by the well-established mechanisms of sexual contact, blood or blood products, or mother to child.

If you look at the progression of effect -- and this is important to understand the whole process -- and you measure total number of T4 cells as shown on this slide and you look at the progression from normal individuals on the left-hand side of the slide to healthy seronegative homosexual men to chronic lymphadenopathy, Kaposi's sarcoma and then all the way in the right-hand part of the slide, you see opportunistic infections.

In other words, it would be almost invariable that if an individual has his T4 or her T4 cells decreased below a critical number -- and that arbitrarily usually is about 100 to 200 per cubic millimeter -- sooner or later that individual is going to develop an opportunistic infection.

Interestingly, with Kaposi's sarcoma, you need not have such profound immunological suppression to see the onset of Kaposi's sarcoma.

Of great interest and importance is the fact that healthy homosexual men that we have followed at the clinic at the NIH who are seropositive -- namely, they're infected with the virus but they have absolutely no symptoms -- we plotted on the side on the vertical axis the total T4 cells and a certain immune response to a particular antigen on the horizontal axis.

As you can see, there are a number of individuals who are down around the 200, 300, 400 mark who are completely asymptomatic; yet, they are significantly immunosuppressed. That means that even though you're talking about large numbers of asymptomatic individuals, they may not, in fact, be perfectly well. We'll get into that in a moment.

This is the CDC classification scheme looking at various groups. The first group is acute infection. Some individuals, particularly the few health care workers who are infected with the virus, undergo an acute syndrome, usually mononucleosis-like syndrome, from which they recover, and then

after that they're essentially asymptomatic and then can go on to develop full-blown disease later.

Group 2 is asymptomatic infection.

Group 3 is persistent generalized lymphadenopathy.

Then Group 4, we get into what we call other types of disease.

The subgroup A is constitutional disease, or what we call R, and I'll get back to that in a moment.

Group B is neurological disease.

Subgroup C is secondary infectious diseases.

Subgroup D is secondary cancers.

Subgroup E are other conditions.

It's important to point out, as you'll probably hear from Dr. Redfield, that the Walter Reed classification breaks that down into even more subgroups, where you can actually look at subtle immunological changes before you even see any symptoms. That really becomes an important categorization to look at, as I'll explain on some of the subsequent slides.

This is a slide you've seen many times, the iceberg slide that Jim Curran and his colleagues have put together from the CDC.

If you talk about full-blown AIDS, that's the 47,000 plus that's going on in this country right now. There's a projection of about 150,000 individuals with symptomatic disease who do not have full-blown AIDS, and then there's the projection that there's a million to a million and a half individuals who are infected but asymptomatic.

Working from the bottom up, what do we mean by "asymptomatic?" Just that. They're infected with the virus. They have no symptoms. But an important statistic is now a known fact. If you plot the number of individuals who are asymptomatic who develop full-blown disease, about 20 to 30 percent of them within five years will develop disease. We know that. That's not a speculation. That's not a projection.

The important aspect is what is that curve going to do? In 20 or 30 years, is it going to be linear as the open dots that go up? In other words, there will be 80 or so percent of the individuals at the end of 20 years with disease, or will it plateau?

We don't know, but looking at the Walter Reed classification in which you measure immunological changes, even those individuals who are asymptomatic, a vast majority, 80 or 90 percent of them, over a period of a few years will develop some sort of immunological deterioration. That immunological deterioration doesn't necessarily mean disease, but it does indicate that there is a deleterious effect of the virus on these individuals even if they don't yet have disease, which makes one get concerned that a much larger percentage than 20 to 30 percent will ultimately develop disease.

MR. CREEDON: Will those people require medical care?

DR. FAUCI: Those people will not require medical care if they're asymptomatic with immunological abnormalities, but it is likely that if they progress in their immunological deterioration that they will ultimately require medical care, yes.

Now, then you move on to the next phase, which is symptomatic HIV infection without AIDS, what we call the AIDS-related complex. That's a complex characterized by fever, weight loss, diarrhea, fatigue, night sweats, you may or may not have lymphadenopathy and certain immunological abnormalities.

It is likely that a substantial portion of these individuals will go on to develop full-blown AIDS within a period of a couple of years, probably over 30 percent of these individuals.

MR. CREEDON: Again, those people will require medical care when they have that condition?

DR. FAUCI: Many people with ARC will, in fact, require medical care, because ARC can be a very serious condition even though it does not fulfill the criteria that we set up for full-blown AIDS. There are individuals who have ARC who are seriously ill and require medical care.

MR. CREEDON: In trying to determine what the needs are going to be for caring for people who have the virus, at what point do they need medical care? Are they likely to need medical care of some kind?

DR. FAUCI: Yes. With ARC, they are likely --

MR. CREEDON: Pre-ARC, maybe or maybe not?

DR. FAUCI: Maybe not, right.

Now, this is the standard number that you've seen many times. As of just last week, there are approximately 47,000 cases. The breakdown among the different groups and subgroups is essentially the same. You'll probably be hearing more of that from other speakers.

Moving on very quickly, the typical infections in patients with AIDS, this is a list of them. We need not go through them. You've heard about them, one of the most important of which is obviously pneumocystis carinii pneumonia, which affects about 60 percent of individuals who have full-blown AIDS.

But let me give you some examples of the devastating effects of some of these opportunistic infections. This is a normal retina looked through an ophthalmoscope. This is what you would see if you look into a normal eye.

This is one of -- oops, we don't have it. We missed that, I'm sorry, but there was a destruction of the retina by cytolmegalovirus

This is an esophogram, which should be a very smooth channel of dye coming down, and you can see it's ragged at the edges. That's an individual with candida esophagitis.

This is a normal chest X-ray in one of my patients who developed a full-blown pneumocystis carinii pneumonia; as you can see here, devastating effects and one of the highest causes of mortality in full-blown AIDS.

This is a series of CT scans of the brain, and if you concentrate on the upper left and the lower right, you'll see a dark white area on the righthand side there. That's toxoplasma gondii, an important cause of central nervous system disease.

Even more importantly has been the realization over the past year or two that HIV can actually infect the human brain. These are multinucleated giant cells from the brain of an individual who died with AIDS and cephalopathy, and the dark grains that you see scattered around the cells are a probe looking for HIV. So HIV is actually present in these cells.

Individuals who develop HIV in the brain can have anything from an asymptomatic infection, and we know now in our studies at the NIH and at Hopkins and elsewhere that about 50 percent of individuals who might even be asymptomatic, can grow the virus from the central nervous system.

They might not have any central nervous system symptoms, but individuals with AIDS, if you study them, for example individuals with Kaposi's sarcoma or individuals with

opportunistic infection, when you do a lumbar puncture, 50 percent of them will have virus grown from the central nervous system.

Other abnormalities include cognitive and psychiatric abnormalities, frank dementia, meningoencephalitis or localized or diffused neurological abnormalities.

This is a classic example of tutanious Kaposi's sarcoma in one of our patients, and as I mentioned, the immunological abnormalities that you have when you have Kaposi's sarcoma are usually not as profound as those that you have when you have opportunistic infection.

Finally, a recent article in the New England Journal of Medicine, looking at thousands of patients from New York City, the one year following diagnosis survival was 49 percent, whereas five years following diagnosis it was 15 percent, with individuals with Kaposi's having better survival than those who present with opportunistic infection.

If you look at the data compiled by the CDC in fatality rates throughout the entire epidemic, you see here it's 57 percent. It has remained relatively constant.

But if you look at individuals who have been infected and who had the disease in 1981 and 1982, between 80 and 90 percent of those individuals are dead today.

So, finally, in summary, HIV infection can exist in a number of forms. It is important to distinguish the difference between asymptomatic infection, who have a 20 to 30 percent chance in five years of developing disease; symptomatic infection, who probably will need care, who have a greater than that percentage of going on to full-blown AIDS; and individuals who have full-blown AIDS which now constitute the sum total of approximately 47,000 people in the United States up to this point.

MR. CREEDON: Dr. Fauci, you said that 20 to 30 percent will develop AIDS within five years.

DR. FAUCI: Right.

MR. CREEDON: What about the others?

DR. FAUCI: Again, what I showed on the slide is that at this point, we can not precisely predict whether, in a linear fashion, you have 40 percent in 15 years, 50 percent at 20 years, 60 percent -- we don't know that. But if you look at the immunological deterioration, and you find -- and this you'll probably hear more from Dr. Redfield -- that over a period of

years, most of those individuals will have immunological deterioration, which suggests that if they are not treated over a period of time, they may go on to develop full-blown AIDS.

MR. CREEDON: Penny, do you have some questions?

MS. PULLEN: Not at the moment.

MR. CREEDON: Ms. Gebbie?

MS. GEBBIE: No.

MR. CREEDON: Any questions from the other end? Yes, Dr. Crenshaw?

DR. CRENSHAW: Of the different classification systems of HIV infection that I'm familiar with, the four point one that you mentioned, Walter Reed which is six phase and AMA which is seven, can you comment on the relative value of each and which you think should -- which you would recommend become the adopted standard?

DR. FAUCI: Well, it's very difficult to say that one should be adopted standard. What has happened unfortunately, they have all become so complex that if you look at it, it becomes almost very difficult to read, of all of the different infections that constitute one subgroup versus the other.

We use the CDC classification of the various groups and subgroups. But I think that the Walter Reed classification has merit in that it gives us insight into the immunological deterioration that you would not pick up on the other. So I use really a combination of both of those.

DR. WALSH: Tony, on the HTLV-I, are the tests that we're using today sensitive? Will they pick that up as well?

DR. FAUCI: For HTLV-I?

DR. WALSH: Yes.

DR. FAUCI: The adult T-cell leukemia one. The test that we use, we are not universally screening the HTLV-I at this time, but the tests that are available are sensitive tests and do pick it up.

DR. WALSH: And has that been identified with AIDS at all, or is it primarily just leukemia?

DR. FAUCI: Well, there are individuals who are doubly infected with HIV causing AIDS and HTLV-I either causing or not causing a secondary lymphoma. But there is not AIDS caused by

HTLV-I. You can have both infections, but there are no reported cases of someone who has AIDS, and the only thing they have is HTLV-I.

DR. WALSH: Okay. Thank you.

DR. SERVAAS: Dr. Fauci, do you think it's important that we start testing for HTLV-I?

DR. FAUCI: I think that it should be given serious consideration, given the fact that now with the individuals -- for example, the leukemics who have received multiple blood transfusions, it's starting to show up that there is a proportion of those individuals, small but nonetheless it's a significant proportion, would have antibodies to HTLV-I, which would indicate that in massive blood transfusions, there's a chance, a very small chance, but there is a chance of getting HTLV-I. So it would be appropriate to at least examine that issue of whether or not, in fact, that is being addressed at this time.

DR. WALSH: Tony, is there any credibility to the fact that reexamination of some of the blood that they had from the days of Hiroshima showed HTLV-I positive?

DR. FAUCI: Well, I wouldn't be surprised. If you look at the fact that HTLV-I has existed in Japan probably for a very long period of time. It was only recently recognized by the Japanese investigators and by Gallo and his colleagues within the last couple of decades. But, in fact, if you look at it, it is very likely an ancestral virus that was in the population for a long period of time. I wouldn't be surprised at all if you went back to sera in Japan and you found antibodies to that virus a very long time ago.

DR. WALSH: Thank you.

DR. SERVAAS: Does it have a 20-year average latency period, the HTLV-I?

DR. FAUCI: HTLV-I can have an extraordinarily long latency period. In fact, if you look at the populations in the endemic area, there is a significant proportion of individuals who are infected with the virus, who are asymptomatic, and a small percentage of them may go on to develop lymphoma and leukemia later on.

MR. CREEDON: Dr. Primm?

DR. PRIMM: Dr. Fauci, a friend of mine, who is in New Orleans, Louisiana, submitted a number of blood samples to the National Institutes of Health from a drug treatment program, Mr. Vernon Shorty, and indicated to me that out of 250 samples from

his addicted population, about 50 of those samples were positive for HIV -- well, HTLV-I. None were positive for HTLV-III, but about 50 were positive for HTLV-I.

My question is, since the population has shown no incidence and prevalence of leukemia whatsoever, nor is there any problem of leukemia in the New Orleans area, particularly in the Desire housing project where these samples were taken from -- that drug treatment program, how do you explain that kind of seropositivity for an antibody in that population without any disease whatsoever?

DR. FAUCI: Yes. If, in fact -- I haven't seen that data, Dr. Primm, but if, in fact, the data is correct, that there is X percentage of individuals in an IV drug-abusing population who are positive for HTLV-I with no disease, that's not entirely surprising, because if you look at the Japanese population, the conversion for antibody positivity to full-blown disease is a very, very small percentage. In other words, there are many, many, many more individuals in Japan who are antibody positive than have disease. In fact, you can, in some endemic areas, up to 10 percent of the population is positive, but the incidence of disease is very low.

It's not like AIDS, where already after five years you know that 20 to 30 percent are going to develop disease. When you're talking about HTLV-I and T-cell leukemia, a very small fraction will develop disease.

DR. WALSH: Is it a sufficient fraction, Tony, so that it's knocked out on blood products?

DR. FAUCI: Excuse me?

DR. WALSH: The HTLV-I. Is the significance of the positivity such that they would not use it in blood products, if there's positivity on the testing?

DR. FAUCI: Oh, I would be certain that if, in fact, there was a broad universal screening of blood in the United States for HTLV-I, and a unit was found to be positive, it would be eliminated in exactly the same way as HIV-positive is eliminated, because it's a blood-borne and sexually transmitted disease.

MR. CREEDON: Dr. Fauci, are there any other recommendations that you have for the Commission, either in the specific areas that we've discussed or otherwise?

DR. FAUCI: No. I think I've essentially made the points that I wanted to make about the differences in the group,

and I think an appreciation of those differences is very important in formulating recommendations and policies about them.

MS. PULLEN: In terms of the opportunistic infections that an AIDS patient is subject to or an HIV-positive person as they progress in the disease is subject to, could you define specifically what opportunistic infection is, and would you indicate whether any of the infections that are common in these persons goes beyond the definition of opportunistic infection to a more transmissible infection?

DR. FAUCI: Right. An opportunistic infection, by definition, is an infection which a person, normal person in the sense of normal host defenses, would not be expected to get, and only when the person's defense mechanisms are severely impaired, either iatrogenically through chemotherapy, through a cancer or through a virus like HIV, that the body's defenses are so dismantled that the particular microorganism, which under most circumstances would be harmless, seizes the opportunity to then invade the body. Hence, we use the terminology opportunistic infection.

The opportunistic infections that are very common in patients with HIV are usually the kind that are endogenous to them, not the kind that you would consider highly transmissible from one to the other.

In certain populations in the United States, tuberculosis is one of those opportunistic infections, particularly in individuals in the poorer socio-economic areas where you would find higher incidence of tuberculosis. It's a common opportunistic infection in African AIDS and a common opportunistic infection in AIDS in Haiti. That is one that's communicable from one to the other.

But pneumocystis carinii pneumonia, M-avium. CMV is probably reactivation of CMV they already have. Toxoplasmosis is probably reactivation of infection they already have. Herpes is probably reactivation. So more of it is infection that's part of the normal environment of the body.

DR. SERVAAS: Dr. Fauci, could you tell us how difficult it is to treat AIDS patients who have tuberculosis? Is the medication as effective?

DR. FAUCI: Well, whenever you have a situation in which the body's defenses are significantly suppressed, there will always be less of an effective response to standard chemotherapy. For example, part of the defense against tuberculosis would be your own body's immune system plus therapy, like Isoniazid and Rifampin and Ethambutol. If you take away the body's defenses and just give the person the drug, that person

would have a much more difficult time clearing an opportunistic infection such as tuberculosis.

MR. CREEDON: Dr. Primm?

DR. PRIMM: Yes. Dr. Fauci, you know, in Harlem, for example, we rank number two in the Western world for the incidence of tuberculosis in the population there.

I think that people in Harlem are far more susceptible to the HIV virus than would normally be, because of the high incidence of tuberculosis, only second to Haiti, which is the poorest country in the Western Hemisphere, and, you know the incidence of tuberculosis in Harlem.

Yet very little is reported about this, and I like the fact that you have offered to the Commission what you just offered, and I think we need to look at the incidence and prevalence of tuberculosis in Harlem. A lot of our patients die, by the way, from tuberculosis before they are even diagnosed to have, or be positive for the human immunodeficiency virus antibody.

So the point I'm trying to make is that ought to be made public, and physicians ought to know about it, and I'm going to particularly ask Dr. Axelrod about that this afternoon. If you would comment on that a little bit more, I would appreciate it.

DR. FAUCI: Sure.

DR. PRIMM: I want to apologize, too, for not having been here a little earlier. Our plane was late from New York this morning. You might have already commented on that. But as you know, how much I appreciate very much your offerings to this field.

DR. FAUCI: Dr. Primm, I think what's important is not necessarily that if you have a high incidence of tuberculosis in an area, that would predispose you to developing HIV if you come into contact. I think it's important that, as in Harlem, if you have a high baseline prevalence of tuberculosis, individuals who are infected with HIV will very likely develop tuberculosis as an opportunistic infection before another individual in a different area, which did not have that basic high prevalence.

And I think it's very important to address the issue of tuberculosis. In fact, paradoxically enough, tuberculosis research has been really kind of a sleeping area over the past several years, and there's been an emergence of interest now. I know at the NIH in our own Institute we've set several new initiatives to do some more basic research in tuberculosis for

that very reason, that in populations such as in Harlem or in the South Bronx or in areas of Miami where you have high incidence of tuberculosis, that is becoming a very important problem.

So I agree with you completely that is something that should be addressed as an important issue in the whole picture of AIDS.

MR. CREEDON: Dr. Fauci, are you going to be able to remain with us for the rest of the morning or not?

DR. FAUCI: Until the end of the morning, yes. I'll be here for the morning but not for the afternoon.

MR. CREEDON: That will be great. Okay. Jim, did you want to --

ADMIRAL WATKINS: I just have one question, Dr. Fauci. The Centers for Disease Control have just broadened their definition of the ARC/AIDS relationship, and they've included now in AIDS chronic progressive weight loss and dementia. And the question is, are we seeing a migration out of the gray zone of ARC; between asymptomatic and, you might say, full-blown AIDS being redefined, and if so, what is the impact of that on the prevalence and incidence database?

DR. FAUCI: Well, just this past report from the CDC, which probably Dr. Curran would be better to address, but there has been an increase by a small percentage of the cases. In a sense we did a jump. We're at now between 47 and 48,000, and we took a jump over a week of an extra 1500 or 1800 cases out of the total. That's all the difference was.

So what it is, is that some things that were not called AIDS, particularly some of the neurological abnormalities that are now falling into AIDS, have increased the numbers of AIDS on the transition week or month or what have you, and I think you're going to then start seeing it just leveling off.

ADMIRAL WATKINS: But do you see the potential for more migration from ARC to AIDS in other areas, because it seems to me that is germane to entitlements, for example, for certain AIDS patients? So what is really happening there, and how much more attention is being given to that "ARC to AIDS" transition as being more AIDS than ARC, if you will?

DR. FAUCI: I think that's something that's still in the process of being looked at, because we're constantly trying to redefine and finetune the definitions. These are, as you know, empiric definitions, but it was clear that some of the things that were not called AIDS before have not been reclassified as AIDS, and perhaps some of the more serious ARC.

As you can see in the subgroup now, they've listed it as constitutional disease and then infections and neoplasms. So constitutional disease, which is essentially ARC, is now in the subgroup that includes the other AIDS categories.

DR. CRENSHAW: Dr. Fauci, in relation to the Admiral's question, you indicated that, if I understood you correctly, approximately 50 percent of asymptomatic HIV-positive individuals had a virus that could be cultured from the brain; is that right?

DR. FAUCI: No, I didn't say it's asymptomatic. I said approximately 50 percent of people with AIDS, who have no central nervous system symptoms, when you routinely do a lumbar puncture, you can find virus in the central nervous system. But they have AIDS; they're not asymptomatic carriers.

DR. CRENSHAW: I understand that virus-positive cultures are quite common in those that are otherwise asymptomatic and that the CNS can be one of the presenting symptoms of the disease.

What I'm wondering is, if you culture virus out of someone who is otherwise asymptomatic, may have fine motor coordination problems or something subtle neurologically, are they automatically classified as AIDS, or at what level of symptomatology of CNS involvement is the AIDS diagnosis made, or is culturing the virus sufficient? If they find virus in the spinal fluid, does that make someone qualify for AIDS?

DR. FAUCI: No, no. The answer to that is, the neurological classification is neurological symptoms, neuropsychiatric abnormalities of the categories that I listed on the slide. The actual culturing of the virus out of a variety of body fluids itself does not constitute the diagnosis of AIDS. There has to be involvement in a clinical pathological way, such as symptoms.

Now if there are subtle cognitive changes that could be listed as dementia, that person would be considered to have AIDS then.

MR. CREEDON: Just one more question, Ms. Gebbie, and then we'll move on.

MS. GEBBIE: You made mention briefly of the most recent CDC report that just was issued. For purposes of making projections toward the end of the century, is that a document you would use for making those projections, and if not, what critique would you make of it?

DR. FAUCI: Which CDC report are you referring to?

MS. GEBBIE: The one that was just issued last week or so that gives projections, recritiques the incidence and prevalence data and the possibility of projecting for the end of the century.

DR. FAUCI: Yes, I would use the CDC material definitely.

MS. GEBBIE: Thank you.

MR. CREEDON: Thank you very much, Dr. Fauci. Our next witness is Dr. Donald Francis from the California State Health Department. Dr. Francis?

PRESENTATION BY DR. DONALD FRANCIS

DR. FRANCIS: Thank you, Mr. Creedon, Mr. Chairman, and Commission members. It should be pointed out that I am assigned to the Department of Health Services in California from the Centers for Disease Control in Atlanta, however.

First, I would like to thank you for allowing me to testify before this important Commission. Second, I want to make it clear that the testimony I give here is my opinion, and does not necessarily represent the opinions of either the Centers for Disease Control in Atlanta, or the Department of Health Services in California.

And, last, I would like to express my admiration for the Committee in their preliminary report. The recognitions of the need for more societal commitment was refreshing, but the statement that too much time has elapsed, and too many people have become afflicted while questions remain unanswered was really spectacular. The call for collective dedication was truly magnificent.

Since I am sure that many in the next two days here will fill many of the details of AIDS prevention, including prevalence, incidence estimates, et cetera, I -- as a young, but well-bruised veteran of serious epidemics -- would like, if I may, give some insights into the broader issues.

The overall gist of what I will say is that, one, we really know a great deal about HIV, its transmission, and how to prevent it. Two, we in public health want and should move ahead with a scientifically-based aggressive prevention program.

And three, there are some obstacles that inhibit us moving ahead in such programs. I think the most useful is that most of these obstacles really are relatively readily removable.

First, let me outline, in brief, what we know about HIV. HIV, from Tony's -- and I'm sure from George Rutherford's and other information you will see today, Bob Redfield's -- it is clearly one of the most virulent viruses that infects humans.

Any virus that is going to kill over ten percent would worry us in public health. Even one that would kill over one percent would be of major concern, actually. When you start getting up to 20, 30, 40, 50 percent, it becomes an issue of health care planning in a big way.

But, in terms of public health, they are all very severe percentages in terms of death, and need appropriate reaction.

Two. This virus has a long and silent incubation period, during which time infected persons remain infectious to others. And last, it is transmitted exclusively through sexual intercourse -- both heterosexual and homosexual; through sharing of blood, especially during intravenous drug use; and from infected mothers to their babies.

The first two of these, linked with the high mortality and the silent infection, make this an especially difficult agent to deal with, in terms of public health. It has got considerable opportunity for spread.

The combination of high virulence, long silent incubation period, and sexual transmission make this virus a major concern for those who have watched similar epidemics before.

Indeed, evidence to date indicates that the virus has already extensively invaded the United States. Regardless -- I think this important -- regardless of what estimate it takes, we have a major tragedy on our hands.

The good news is that we, as a society and as individuals in a society, have it in our power to stop transmission of this virus. Preliminary evidence from both the homosexual male community and intravenous drug using community suggests strongly, I think, that well designed intervention programs can effectively reduce the transmission of HIV.

I want to repeat that. Well designed, aggressive intervention programs can effectively reduce the transmission of HIV and, as a result, eventually reduce the cases of AIDS.

Given this information, a broad consensus has been reached in the public health sector. Reports from a wide variety of individuals and groups, such as the Surgeon General, the National Academy of Sciences, the Association of State Health

Officers, the Conference of State and Territorial Epidemiologists, et cetera, have basically all agreed on the approaches that are necessary.

There is a very broad consensus on what needs to be done. Yet, despite the major problem and the consensus on what needs to be done, there is -- at best -- only a skeleton of AIDS prevention programs actually in the field.

Why is this? I see several obstacles to fielding a successful AIDS prevention program. First is the perception, from the public and public health workers, and from much of the society, asking does anyone really care?

Using your own words, it appears that instead of having a solid prevention program based on modern science, we have a program that is fragmented and sometimes confused by, quote, "prejudice and fear."

Second is the confusion centering around the question of whether AIDS prevention should be a police action of the government against the people, or a cooperative effort of the people with their government.

The consequences of these obstacles have been the absence of necessary resources and effective leadership, slow delivery of basic prevention, and an absence of the usual positive American We-Can-Do-It approach.

We can, and should, rebuild this can-do spirit. Use modern science to generate policy. Let me repeat that. Use our modern science to generate policy. Supply the resources, and quickly mount an effective, aggressive prevention program.

I think we, in the public health sector of this society, at all levels can do it. Indeed, from my experience at local, state and federal levels, everyone wants to do it. I am confident that, given the spirit, the leadership, and the resources, we can launch an AIDS prevention program which could severely inhibit further extension of this virus into the American public.

It is now six and a half years since the discovery of AIDS. It is time to act maturely, ignore all the peripheral distractions, and mount an effective AIDS prevention program.

Regarding some of the issues that you, Mr. Creedon, asked for early on in the introduction, the estimate of prevalence in this society: the test is extremely good, extremely accurate, extremely sensitive, extremely useful.

Sampling techniques are available, and we could go out and actually sample individuals. What the problem is, again leads these national attitudes regarding the leadership, the protection of the individuals, and the help that you will provide these individuals, should they be found to be infected.

I think you just have to turn it around and think about yourself being an infected individual in a household, or at least in a risk group in the household, and this individual knocks on your door from the government to do a test on you.

If the spirit in this country, by the highest authorities, is that this is our people's problem, a world's people problem, and we as societies are going to work together to do this, and we need to know the prevalence of infection, if someone knocks on your door, stick up your arm and get bled, we will counsel you, we will take care of you, and we sure won't throw you in quarantine or lose your insurance, or whatever it may be, if you participate in this thing. If you don't have that, you can imagine what the reaction is going to be.

We have clearly seen it in our California prevalence information, that the more restricted the environment, the less confidential the testing, the lower prevalence of infection we find. It is only logical.

Questions of a heterosexual epidemic constantly come up, and end up throwing great confusion on us in public health. We have tried to make relatively straightforward recommendations towards heterosexual transmission. The quote "absence of the heterosexual epidemic" is only a matter of what your expectations were regarding heterosexual transmission of this virus.

There is a huge epidemic amongst homosexual men, on top of what I consider a really very significant epidemic in the heterosexual community. But no doubt 500 or 1,000 cases, or however we want to count it, is diminished by 47,000 cases of others in the epidemic.

All we need to do is pull away and say, take away those cases and say, are we concerned about having all these infected heterosexual people, and look at the data that is available on heterosexual transmission. And clearly we have a problem. It is a matter of expectations, not of scientific data.

You asked about medical care regarding seropositive individuals. I think every seropositive individual is going to require medical care. Again, turn it around to yourselves on the panel.

If you were infected with a virus that Dr. Fauci says has a 25 percent, 30 percent chance of killing you in three or

four years, and Dr. Rutherford is going to tell you 40 percent in seven years would you want to be all by yourself and not get medical care?

If the doctors tell you that early intervention now could help keep you out of the hospital, prolong your life as a productive and healthy individual, would you not want to get into a medical system to care for you?

Yet, we as a society tend to isolate these people. If they come in they get discriminated against by their doctors, by their health care system, by their neighbors. We need to provide that kind of protection so that individuals can come forth and get into medical care systems.

I say that not as a physician, but I put on my public health hat and say that I want these people coming in who are serologically positive so we can help work with them to modify their behavior, because they are the source of infection for the next generation of cases.

All of this requires a true spirit of cooperation with these individuals. Some say, why do you want to cooperate with individuals as a public health individual, when you -- and I -- have used quarantine, been thrown in quarantine for infectious diseases?

I say I use quarantine for diseases that are transmitted in nonconsensual settings, where an individual is at risk in this society from, let's say, walking down the street or coming to a meeting like this, or whatever.

But if two individuals are undertaking mutual, consensual activities, that either one of them could prevent, then it is our job to give them the information, the motivation, and the skills, to make that individual decision, work together with them, so that no more transmission exists. This is a very important determination between consensual versus non-consensual, in terms of government intervention.

Thank you.

MR. CREEDON: Thank you, Dr. Francis.

Ms. Pullen, any questions?

MS. PULLEN: No.

MR. CREEDON: Ms. Gebbie?

MS. GEBBIE: One of the major purposes in my line of this discussion is to get straight what incidence and prevalence

rates we could use to make subsequent calculations, so I want to pin you down a little bit in that area.

Based on current numbers, and what you said, you would indicate that if, indeed, a million people are currently infected we need to plan in illness treatment costs for that whole batch of people.

My first question is, are you comfortable using that kind of number as a currently infected population? Or do you have some reason to say we should adjust that upward or downward?

DR. FRANCIS: Two things. I am confident with the numbers as they exist now, with wide confidence, because of the way they are derived, obviously. We can refine those, and CDC is in the process of attempting to do that, as Jim Curran will get into.

The problem I have is these are perfectly fine projection numbers, considering where we are and where we need to go to. If we were planning for health care of these individuals and were moving ahead today, and we are thinking, well, are we going to get overwhelmed tomorrow, and we need to find out just exactly how much that adjustment would be, then I would say, gee, let's get together and it should be our major priority to refine that number.

We are so far from using this quick and dirty data that we have now, in terms of our progression. If I want to know exact numbers, if I knew that we would societally adjust and appropriately tune our system.

But I think what you are doing is having a six-cylinder car that is running alright on four cylinders, and you are saying, well, gee, maybe we should put two more spark plugs in this when, in reality, the car is up on blocks.

MS. GEBBIE: I am not taking issue with that planning. I am trying to pin down -- again, I will do this consistently all morning -- whether those numbers are good.

The other piece I think I have heard you say is that, for purposes of looking ahead toward the end of the century, whether we can use some kind of straight line progression in the number of people who are infected; just assume it is going to keep growing at the present rate, or whether we could assume that we will somehow drop that rate off, is dependent upon the degree to which we launch programs, educational programs, deal with the societal attitude.

DR. FRANCIS: Clearly.

MS. GEBBIE: Absent that, are the current projections ones that you would live with?

DR. FRANCIS: The difficulty we have, as Tony pointed out, is that we have only limited years of follow up of individuals of a recently reported outbreak into this country, obviously. So the oldest data you will see from the United States comes from San Francisco, and George Rutherford, I am sure, is going to present that.

From then on it is all guess. You will hear data from both George and from Bob Redfield that, as Tony pointed out, the rest of these folks don't look so good, immunologically.

But Tony could have made 17 different more lines on that curve. Is it going to level out at 40 percent, or level out at 50 percent, or 60 percent. That is a clearly important variable in terms of, ultimately, the number of cases that are going to come out from these infected people.

MS. GEBBIE: I am more interested in the conversion from non-infection to infection.

DR. FRANCIS: Sorry.

MS. GEBBIE: That question, I think, is very good for dealing with illness treatment costs --

DR. FRANCIS: Let's say hospitals. Right.

MS. GEBBIE: In the relative short term. The major question is, can we hold the total number of infected people at the current million, or -- as some have projected -- two million, or somewhere, or are we just going to lead that on.

DR. FRANCIS: No. Since the major number of infected people in the United States right now are Gay men, and the remarkable change in incidence of infection -- starting at 20 percent peak down to -- everyone is reporting, really, in the United States, and outside, and cohorts infected.

Infection rates, formerly 20 percent, now down to one percent a year. That is a remarkable change, and that clearly is due to behavior change. So you will not see this continued enlargement of the largest segment.

The question now comes, especially from the IV drug-using community, the poor, inner-city primarily Black and Hispanic communities, of the rates of infection that are clearly increasing at remarkable rates, and can we stop that.

Therefore, now we have this big bolus of homosexual men. Are we then going to have a big bolus of IV drug users and their sexual partners? That is a very challenging public health problem.

But I think we can have a major effect. Whether you can turn that around to one percent in three years, like the Gay community did, I am not sure.

MR. CREEDON: Dr. Primm?

DR. PRIMM: Dr. Francis, on the one hand you talk about this big bolus of homosexual men who are infected; and, on the other, you say that there is a possibility that there is a similar bolus on the side of intravenous drug users, particularly among Black and Hispanics.

But you don't say for sure. What does it take to convince someone in your position that it surely is out there? Because, from my perspective on a daily basis, from testing people in my program -- who, in one clinic, may have 72 percent seropositivity for the antibody; another program in another part of the city, maybe in Harlem, they might have a 60 percent -- I know that that bolus is there.

We need people like you to say that, rather than to say perhaps there is a bolus there. When, indeed, good data should certainly signify that there is a bolus already there.

DR. FRANCIS: I agree. I am sorry if I implied that there was not a bolus already there. The question that I had the unknown on was, can we drop the very high transmission rates we are seeing in those groups now to, let's say, the 10 percent seroconversion that we see a year in those groups now down to one or less percent next year?

I think that was the question that Ms. Gebbie asked--can we inculcate that behavior change in these individuals? I, not being a behavioralist, as an infectious disease epidemiologist, am really getting more and more impressed with the truly hard data of the soft data people in terms of behavioral change.

Programs tailored to the appropriate socio-ethnic groups, with all of the language, et cetera, that might be offensive to some people -- but those behavioralists, if they do that, and tailor those programs, can really have remarkable effects in large populations, including IV drug users.

These are people who can understand the risks of this infection. It is a tremendous motivator. If we can assist them in that process of -- as the behavioralists say -- information,

which is the education part; motivation, which is saying how dangerous this is and this will ruin your day if you get infected; and the skill-building, in terms of how they, as individuals, part of the society norms, and as individuals, can actually develop the skills to do whatever is necessary to modify their behavior, add in protective IV drug use, sexual barriers, et cetera, et cetera.

That process is remarkably effective. I continue to be impressed, even with programs that, by-and-large, the behavioralists say are not using all the wisdom that we have gained from seat belts, cardiac disease studies, et cetera, et cetera.

We have not really, I don't think, applied our big guns in behavioral medicine yet to this disease.

DR. PRIMM: As you know very well, I have been a proponent of that all along, at the risk of being called a black racist myself. I would like very much for those of you who are in positions, who know the data and so forth, to begin to orchestrate that, so I will not be alone when the forces come for me.

[Laughter.]

DR. PRIMM: The other thing that I would like to comment on that I think is really important is co-factor behavior. We have talked about that among Commission members, and when we talk about progression of infection on to full- blown AIDS, I am thinking very strongly that a number of my patients in my treatment program go on to full-blown AIDS because they do not control their co-factor behavior.

I wonder what you feel that plays in further development of opportunistic infections, and even other less than opportunistic infections that can, when combined with a weakened immune response, go on to cause death -- and not be diagnosed as an opportunistic infection, particularly among intravenous drug users, i.e., subacute bacterial endocarditis, glomerulonephritis, and diseases of that nature.

DR. FRANCIS: I would like to give two answers to that. One using my clinician's hat, and the other using my public health hat. We know in the laboratory that this virus, if you infect lymphocytes, let's say, in the laboratory, the major target in the immune system that, if those lymphocytes are not stimulated with some sort of equivalent of a foreign antigen, they will take in the virus, and the virus will not kill these lymphocytes. They will carry on.

But if you stimulate those lymphocytes with the equivalent of drugs, or foreign infectious agents, they will multiply. The virus likes that when the cell multiplies, and, ultimately, you will eliminate that population of cells.

I think it is very logical, in terms of clinical recommendations for individuals who are infected with this virus, to prolong their health hopefully that they not expose themselves to multiple different antigens, continue to have multiple sexual partners, continue to shoot drugs, et cetera, et cetera.

Both for exposing themselves to diseases, and to stimulating their lymphocytes. However, as a public health person who wants to motivate people in a very logical sense, the data that I see on progression of disease in infected individuals, whether that individual is infected by homosexual sex, heterosexual sex, blood factor receipt, blood transfusion, et cetera, that curve that Tony put out there, these different groups controlled from time of infection are just different spots up above or below that line.

It gives me so much concern to say that, regardless of co-factors that may affect this a few percentage points either way. This is such a dangerous viral infection that you just can't take a chance of getting infected with it.

That message is delivered towards the uninfected individual you want to maintain ininfected, versus the clinical prescription for the infected person that you would like to remain as healthy as long as you can.

I think it is an important differential that we don't say, well, go ahead and get infected with this virus, and carrot juice and good thoughts will keep you from getting AIDS.

MR. CREEDON: Dr. Crenshaw?

DR. CRENSHAW: A comment that I frequently hear that is used as an argument against the perception that there has been a major slow down in the homosexual community is the following, and I would like you to respond to them, to help clarify this.

One is that in our major cities, depending on what statistics you believe, 50 to 70 percent of the homosexual population is infected, and the slow down is more a reflection of the saturation rates than a genuine slow down.

In some cities, such as New York, there is still a prevailing view among many of the homosexuals as they have become more sophisticated about AIDS, to avoid knowing, and not getting tested.

Some recent figures that I read were that the number of sexual partners -- although it wasn't mentioned within what sphere of time -- in San Francisco, for the Gay community, had been reduced from 10 to 4.6. In a population where over 50 percent is saturated, if condoms and really effective prevention measures are not consistently used, then you have a greater than 50 percent chance of becoming infected if you have more than one partner.

In San Diego, we have five bathhouses open and functioning, two of which began business this last year.

In addition, the one other argument that comes to mind is that the rates of gonorrhea and other sexually transmitted diseases have gone down. People contradict that by saying that those are treatable diseases; and, since people are coming in to be checked more often, it is getting eliminated.

They can still transmit AIDS, but they are not passing gonorrhea. I would like some reassurance. Can you address some of those points for me?

DR. FRANCIS: I think, Dr. Crenshaw, that your comment -- let me start with the most significant concern you had, and that is that bathhouses are opening, instead of being closed. If bathhouses are continuing to -- our health education method should, through the free market processes, eliminate bathhouses -- at least those where there is at-risk sexual activity going on -- as a profitable entity in the free market system.

It concerns me that if that exists, and you know the rates of disease in San Diego are considerable, that maybe that is a place where you need to target your additional efforts, no doubt.

Let's deal first with the issue of the high prevalence of infection, because that is a very important point, in terms of looking at the potential effect of a prevention program.

Let's say the gay men in San Francisco, where probability samples have shown that 50 percent of the population is infected, I really was not terribly optimistic of getting the rates of infection down to one percent a year, because there you really have to control your activity.

It is not like when there is one out of 100, or one of out 1,000 people infected, where you make a mistake and you can get away with it. There you don't make many mistakes. Indeed, you do get infected.

We, as a cooperative association of the epidemiologic groups in northern California, have actually all the groups,

cohorts of men that are being followed, and examined every single seroconverter. That is, every person who, in recent 12 months, got infected with the virus.

Indeed, they all had some violation of the practices that are recommended. Very frequently due to people who have made a commitment, have clearly changed their behavior, and then have, so to speak, gotten off the wagon, and ended up getting infected with remarkably few sexual encounters. So that is true.

The saturation effect let me deal with that. In a place like San Francisco, 50 percent of the population of Gay men remains susceptible. Thank goodness. So there is plenty of substrata for this virus to continue to chew on.

We have seen from, let's say, our hepatitis-B studies in the gay community, where we were looking for susceptible people, actually set up the cohorts that George Rutherford put forth, that 70, 80 percent of the population coming into the door of a sexually transmitted disease clinic were infected.

We were looking for people who were susceptible to get into hepatitis-B vaccine trials. We would cull out only the uninfected individuals, and then follow them. The rates of infection were still 20 percent infection a year.

It is not like these are different people. They are clearly still at risk.

Sure, there is some saturation effect. But from our experience with this virus, if they went ahead and opened up the bathhouses again and continued to have unprotected sex in San Francisco, you could get a lot more than 50 percent of the people infected, I guarantee, with this virus.

DR. CRENSHAW: I think your point is well taken, particularly given that San Diego has the number two attack rate in the nation.

DR. FRANCIS: Let me deal with the last point, though. That is that everything goes together. The gonorrhea rates you can see going down; the telephone surveys of their self-reported behavior go down; and the infection of HIV go down.

It all fits very nicely, scientifically.

DR. CRENSHAW: Is hepatitis-B also going down?

DR. FRANCIS: Yes, in the Gay community. Sure.

MR. CREEDON: Dr. Walsh?

DR. WALSH: You commented on the accuracy of the test and so on. Also, one of the things that still concerns me is that I keep hearing projections, estimates, and the like, of the incidence of disease and so on. You tell us that the percentage in the homosexual community, no new cases has dramatically --

DR. FRANCIS: New infections.

DR. WALSH: Of new infections has dramatically dropped. This brings me to that very sticky wicket about testing. In the homosexual community in San Francisco, is it correct to assume that a large majority have already submitted to voluntary testing?

DR. FRANCIS: At least the telephone surveys estimate that somewhere in the neighborhood -- George, correct me if I am wrong -- that somewhere between 25 and 40 percent of the men have been tested.

DR. WALSH: On that basis? This is the basis of your projection? The second thing that concerns me about the optimism is that I rarely believe what I read in the newspapers, but if one is to believe the article that I think was in the New York Times a couple of weeks ago, about 40 percent of the homosexual males are still engaging in rectal, sexual habits without any protection.

Isn't this a rather remarkable optimism, or a remarkably optimistic statistic, if the habits are still continuing in that community?

DR. FRANCIS: I didn't make it clear about where this one percent figure comes from.

DR. WALSH: That is what I would like -- that is what I am after.

DR. FRANCIS: These are not random surveys of people. These are very extensive groups of Gay men that have entered in studies for years and are being followed, asked about their sexual activity, and bled periodically and tested as research programs.

The question that you asked is a vital one, though. Are these men that come into these studies immediately biased by the fact that they are in the studies, and therefore you get this group of concerned individuals?

I think there is some truth to that. You have to say that one percent is probably the optimistic figure, but realize that the rates of infection in these men was 10, 20 percent

seroconversion a year, so that at least these men as representative are models that behavior can be changed.

But saying that in all of the Gay communities that are not involved, that have not been tested, that is it one percent seroconversion a year--I think that would be optimistic.

DR. WALSH: That is why I am trying to understand. On the basis of education and prevention programs, are we seeing -- other than those control groups, in effect -- any increase in voluntary testing among the high risk groups? In your experience?

DR. FRANCIS: There is a lot of confusion. The sticky issue of testing is not the sticky issue of testing. Testing is an inherent part of our society; it is there; it will be here forever. And people want to be tested, by and large.

There are some individuals that cannot deal with that, but it is clear as early intervention programs come, and some benefit comes out of testing, that everyone is going to come forth to be tested, unless there is severe risk to come forth to be tested.

I am a great proponent of serologic testing, as many others are in the Gay community, outside the Gay community. But the reality is, you just can't do that. When you get the news of being infected with this virus, it is a very, very heavy bit of information.

You need help with it. You need assistance with it. That process alone, in many studies, shows that you can improve behavior and it is very beneficial for the society.

But if the society puts restraints and controls and disincentives on that, then the balance goes the other way. That's all. What we hear now is that we have to get out there and test everybody, and throw them into jail.

It only takes two people in the country to do that, to throw my program off in the field for three weeks.

DR. WALSH: No one is interested in going out and testing everybody and throwing them in jail.

DR. FRANCIS: No, but two people say that, and the newspaper picks it up, and off we go.

DR. WALSH: No, we are not. No one is interested in that. What I am trying to get at is the purpose of this

meeting--to see how accurate a projection of incidence we can get.

I am trying to find out from those of you who are in the trenches how much you really believe your own statistics. You have already qualified one of your reports, very factually and very honestly. And I am glad to hear that.

But what I am trying to find out is what can we do about the projection of incidence, so that we can do the planning that you are talking about? And we can recommend the planning for care that you are talking about?

This is one of the real problems with which we are faced. As our preliminary report indicated, we are vitally interested in helping to plan, particularly in the area of care and prevention.

But I am trying to find out what numbers, as I say, we can believe. I think that CDC is to be commended, for example, on what absolutely is limited data to my mind, and skimpy data -- that their projections have been so blessed accurate. This encourages me.

But as a physician and a scientist, I also understand that you both have indicated a lot of it is now guesswork. Yet we have to make a recommendation on what is anticipated, and how to get better data? That is what I am after.

DR. FRANCIS: How do you get better guesses? I mean, they are all guesses.

DR. WALSH: That is right.

DR. FRANCIS: If you had to design a better program, the one percent seroconversion that I told you about is actually not a CDC study, but is an NIH-sponsored study at the University of California by Warren Winkelstein.

They went in and randomly selected houses in San Francisco and knocked on the doors, and had people stick their arms out, and got remarkable cooperation at that time. You are not going to get any better data than that.

Now you are going to ask me, are those people different because they volunteered? I am going to say, well, probably. But can you design a better study? That costs a million dollars already, and I don't think you are going to get better data than that.

But I think you will have to say, yes, there might have been some artifact in that study, that one percent may be a

little higher than the actual seroconversion. But if you look at randomized telephone surveys in the same area of self-reported behavior and compare those to the people who are in the study, there is remarkable overlap.

So I think for those data, they are the best you are going to have. Now, is that true in Detroit? Is that true around the world? You would have to guess.

DR. WALSH: No, San Francisco is way ahead.

MR. CREEDON: I think we are going to have to move on here.

DR. SERVAAS: Dr. Francis, I wanted to tell you that I am very impressed with the work you have done. In JAMA, in July, you reported that in Alameda County, one's chances of coming in contact with a woman who is infected may approach one in 200.

These weren't -- Alameda County wasn't high risk. You also mention in that report that this was preliminary. I am asking you if you have done more work on that? The other question is part of this question. These women in Alameda County aren't prostitutes, to a large extent I don't suppose; but just by chance in that same JAMA it also mentions that there are women who use other than vaginal sex.

Is that a very important factor in the spread of AIDS in the heterosexual community? Is that something in prevention that we have been neglecting? There are more of those individual women than all the homosexual population together, according to this letter we see in JAMA.

DR. FRANCIS: These are women whose serum was submitted to the County Health Department for premarital syphilis and rubella screening. We scrambled the identifiers on these individuals, and have no other information on them, other than their age and sex and race.

We do not know their behavior, whether or not they are prostitutes. All we can say is that, in women applying during that period of time, approximately one of 200 -- with quite large confidence limits, mind you -- were seropositive at that time.

I don't know if they are prostitutes, I don't know if they are IV drug users. I am presuming they are just exposed to that high risk somewhere, but the infection was clearly there.

Regarding the article on anal intercourse, I put on two hats. One is my scientific investigator hat, and one is my public health hat, again. The scientific investigation would

show that putting the virus on rectal mucosa of both men and women is really quite an effective way to transmit the virus.

But I would also say we know from several laboratory studies, or at least laboratory observations, that putting the virus on the female vaginal tract, or cervix most likely, is also an extremely effective way of getting the virus into an individual.

If you had to rank those, you would probably rank them in terms of anal intercourse, vaginal intercourse, and then receptive vaginal intercourse, and insertive vaginal intercourse next down the line.

But we don't have data to be able to tell you totally if one is one-and-a-half times, two times more effective than the other. So, in public health, my comment is that when you put penises into various orifices of the body in sexual relationships that are unprotected, you have a major risk of transmitting the virus.

I think the only hedge on that is oral sex, and we don't know the answer to that, to be honest. It is clearly much less than vaginal or anal sex. But I have this terrible fear that if you say, well, I don't practice anal intercourse -- which at least the data shows is remarkably common amongst heterosexuals -- then I am not at risk.

That is a very dangerous thing. Clearly unprotected vaginal intercourse -- did I say anal intercourse -- that anal intercourse, if I don't do anal intercourse then I am not at risk of HIV infection. That would be a dangerous thing to get out there.

If you are having vaginal intercourse or anal intercourse with whatever sexual combination you are doing, then you are at risk of HIV if there is infection in that population.

Did I totally confuse you now?

DR. SERVAAS: I just wondered how much more dangerous the former is than the latter?

MR. CREEDON: Mr. Watkins?

ADMIRAL WATKINS: Dr. Francis, let me close out the questioning of you in a couple of ways. You opened up your statement this morning in an area that we are not focusing on today, but one which is extremely vital to the Commission. We have hearings planned in a little over two months that we are now preparing for.

It is going to be one of the most extensive that we hold, because we know it is so important. You said that well designed intervention programs which can substantially reduce HIV infection are essentially in hand by a group of experts who have designed these, and I assume have tested them and demonstrated them.

I would like to have a report from you, if you could possibly give it to us now, in the very near time frame, of exactly what you mean, what you have tested, how you have measured it. It is going to be important for us to lay groundwork for those hearings that could be very meaningful.

We may want to talk to you again about that. If you could provide us with a follow up on your opening statement in more specific terms by letter, we would like that very much.

But I would like not to focus on that right now, because it is prevalence and incidence that we are talking about today, primarily, and I would like to keep the focus on that.

DR. FRANCIS: I have a reprint that I will give you now that I think will be useful.

ADMIRAL WATKINS: Have you had a chance to read the latest CDC report to the Domestic Policy Council in the White House that was aired here a week or so ago about the family of surveys, and so forth?

DR. FRANCIS: I have it and have not read it.

ADMIRAL WATKINS: Are you familiar enough with it to know whether you are satisfied that the progression from family of surveys to a national seroprevalence survey by household is as expeditious and as efficient as it could be from your experience in doing proper sampling, assuming you can find mechanisms to eliminate the obstacles?

I am asking you to assume we can eliminate those obstacles, can it be done faster? In other words, 1990 is when the report would come out on the national household seroprevalence survey, as laid out by CDC.

Do you think it is necessary to wait that long? Or are there other techniques that could be used to get us closer to the real world, rather than relying on the mathematical models that we are now using?

DR. FRANCIS: I frankly have not sat down and worked through it all enough to be able to answer that question. I think Jim Curran probably could deal with it. The major problem that I see is not fielding the survey. The major problem that I

see is your assumption. You don't want to spend the money for a large survey without that assumption.

ADMIRAL WATKINS: The next question -- the last question -- that I have is that the incidence reflecting the new cases of infection can obviously change with effective intervention as you mentioned.

How is this very important measurement going to be monitored on a continuing basis? And this measure of incidence is really one of the only ways, it seems to me, we can know if our interventions are working. We need to have that.

How organized is that now? Does it need an institutional process that is cleaner than it is today?

DR. FRANCIS: That is a question that we have been dealing with a lot now, because as we get these family of surveys, while we have plenty of prevalence information, you have good surveillance on good cases, but what is your actual incidence of disease?

The studies that I mentioned are a million dollar a piece studies. Then everyone says, well, how good are they? They are people in studies.

There are several ways around it. One, I think you need to spend money for incidence studies of large cohorts, despite them being very expensive. But then when you start thinking about these cohorts and low incidence groups where you need thousands and thousands of individuals, they get even more expensive.

It is clearly going to be limited to the number of those that you can really put out there. But there are other surrogates that I think are important to watch. Behavior surveys of individual, self-reported behavior are remarkably effective.

It always amazes me what people will say over the telephone. But you can do relatively inexpensive surveys. Unfortunately, we don't know the real validity of them. But at least they parallel, let's say, in the Gay community what we see on the people in the actual prospective studies.

I think those are useful. I think looking at things like sexually transmitted disease, increasing the surveillance of sexually transmitted diseases like gonorrhea and syphilis, to see if these surrogates also go down, to corroborate your behavioral and your few incidence studies that you have in a few cities around the country.

And then to continue to monitor that will be part of our society as groups come in, like the military data that you will hear from Bob Redfield. I am sure you will see more and more prenatal data coming through, as more and more babies are monitored. You will see the prevalence of infection. Mothers coming to clinics. You will have an idea if that prevalence is actually -- it won't drop, because these women will be there for quite a while. But at least it won't go up.

And to continue to do prevalence surveys. Now, the difficulty with prevalence surveys, which is that prevalence is just a cut in one period of time -- you get different people Tuesday than you do on Wednesday. To actually say that you have an incidence from those is difficult.

But I think we have to design inexpensive programs, because they have to be very, very broad. You are not going to be able to spend a million dollars in every city in the United States to get a group under an incidence study.

It is a very good question, and we are dealing with it, and seeing if there are inexpensive ways to monitor that by surrogate methods.

ADMIRAL WATKINS: Do you have any data now on your surrogate techniques already imported that show that there is correlation between the data you are now tracking from actual measurements against that behavioral survey?

DR. FRANCIS: I think all the surveys that have been done -- be they behavioral, incidence of sexually transmitted diseases, or HIV incidence -- indeed do track very, very well.

ADMIRAL WATKINS: Can you give us any specific data along those lines?

DR. FRANCIS: Sure. I think they are referenced in the manuscript that I will give you.

ADMIRAL WATKINS: The military experience has been the same. We said we did not have a drug abuse problem in the Navy. The behavioral survey said we had a 55 percent, or 60 percent rate.

When we actually had the urinalysis examinations, it was 58 percent. So clearly there is other data, from other behavioral surveys. I don't just mean it on this one particular infectious disease. But there may be other data from other kinds of problems that we have had, behavioral correlation that may give enough strength to the proposition that maybe that is a way to go in the near term.

Maybe that kind of a survey is something that we could have sooner, and give us a better feel for where we really are, relative to the modeling that is now used. Put those two together to see how close we may be. What do you think about that?

DR. FRANCIS: I agree. Actually the State of California has launched that program through a private telephone survey company in San Francisco. It would be very worthwhile for you folks to talk to, to get a prevalence of behaviors, instead of prevalence of infection, across California; and then be able to link that up through the family studies survey to show the prevalence of infection by behavior, and then see if you can make some sort of guesstimate projection that way.

ADMIRAL WATKINS: Thank you very much.

MR. CREEDON: Thank you very much, Dr. Francis. You mention the fact that a million dollars is a lot of money for a survey, but in relation to what we are talking about here, it is not. We are talking about medical care of $8 billion to $16 billion by the year 1991. It seems to me that the Commission, at least, has to consider what additional types of surveys need to be taken in order to get a better fix on exactly the nature and extent of the problem.

PRESENTATION BY DR. STEVEN L. SIVAK
NEW YORK MEDICAL COLLEGE

DR. SIVAK: Mr. Creedon, Committee members, ladies and gentlemen, I have been asked to speak about the work that I and Dr. Gary Wormser, also from the New York Medical College, have done in trying to estimate the prevalence of HIV infection in this country. I will read my written report.

Since widespread testing for human immunodeficiency virus infection is not performed in large groups of Americans at different risks for HIV infection and since those cohorts which have been tested may not accurately represent the groups to which they belong, it is impossible to determine precise figures for the prevalence of HIV infection in the United States.

This matter is compounded by the fact that HIV infection, except in the form of acquired immunodeficiency syndrome or AIDS, is not a reportable condition. Furthermore, obtaining exact figures as to the total population of risk group members is difficult. Determination of prevalence must therefore at this time be considered an estimate based upon inferences from potentially biased data.

Using the numbers of the known cases of AIDS based upon surveillance data collected by the Centers for Disease Control,

as well as reported data regarding prevalence of HIV infection in several risk groups, we believe that one can estimate, and I underscore that word, the prevalence of HIV infection in the general U.S. population as well as in identified subgroups.

The critical assumption in our calculations is that the ratio of the number of living patients with AIDS to the number of individuals infected with HIV is constant within different groups. We believe that this assumption is reasonable and has been used by others in attempting to estimate the prevalence.

Since the epidemic of HIV infection in this country is probably in a dynamic state, we chose to use the ratio employing the number of currently living patients as opposed to the total number of patients with AIDS since this may give an even more accurate cross section approximation of information relevant at this particular point in time.

In 1985, we demonstrated, using the best available information regarding the prevalence of HIV infection in two well studied groups, as well as the surveillance data from the CDC, that for every intravenous drug abuser or hemophiliac alive with AIDS, at that time there were approximately 300 IV drug abusers and 300 hemophiliacs infected with the virus. We applied this 1 to 300 ratio to each of the then identified risk groups and obtained a total estimate of approximately 1.7 million Americans infected with HIV of which about 64,000 individuals were at no known risk.

Using census data for adults in the United States and subtracting approximate numbers of known high risk group members, we estimated a prevalence of HIV infection for U.S. adults at no known risk to be 45 per 100,000. At that same time, the United States Red Cross reported that the prevalence of HIV infection among blood donors at presumably no known risk for HIV infection was 38 per 100,000. We felt that since the ratios of those alive with AIDS to those infected in two well studied groups were similar and that the estimated U.S. adult prevalence of those at no known risk was similar to that actually seen, our assumptions and data were reasonably accurate, and these results were reported in November, 1985.

Other estimates for that same period of time of the prevalence of HIV infection ranged from 500,000 to over 2 million. We recently re-examined the data in a similar fashion. We again determined the estimated prevalence of HIV infection in high risk groups where data was available in an attempt to obtain the current ratio of those alive with AIDS to those infected. It is clear that this figure is subject to change over time due to many potential factors.

As those at high risk modify their risky behavior, the prevalence of infection in that group is likely to change. As more infected individuals develop AIDS and insofar as the survival currently may be different than it was in the past, this aspect of the ratio may change as well. Change in the definition of AIDS may also have led to a change in this ratio.

In one well studied cohort of homosexual men, the reported ratio of those with AIDS to those infected changed from 1 to 825 to 1 to 28 over a four year period. Another study revealed in 1985 that the ratio of those with AIDS to those infected with the virus was 1 to 30. This group of homosexual men attended a sexually transmitted disease clinic and may not have been representative of all homosexual men because of a potential bias towards individuals with early manifestations of AIDS.

At this time, we chose to determine the ratio in question in well studied populations of New York City. Here, reasonably accurate figures for prevalence of HIV infection exist and estimates of the total numbers of members of high risk populations are available.

It is estimated that in New York City, there are up to 700,000 homosexual men of whom approximately 50 percent or 350,000 are infected with HIV. We obtained data from the New York City Department of Health AIDS Surveillance Update of October 28, 1987, which reports the cumulative cases of AIDS in New York City by risk group.

According to this report, 43 percent of all patients with AIDS since the epidemic began remain alive. Because survival data for each risk group was not available at the time of this report, we assumed that this figure applies to all risk groups. Since there are an estimated 3,021 homosexual men in New York City alive with AIDS, then it follows that for every homosexual man in New York City alive with AIDS, there are approximately 115 homosexual men in New York City infected with HIV.

It is also estimated that there are approximately 200,000 intravenous drug abusers in New York City of which an estimated 65 percent or 130,000 are infected with HIV. It is further estimated that there are approximately 1,500 + New York City IV drug abusers alive with AIDS, and hence, for each New York City intravenous drug abuser alive with AIDS, there are approximately 85 New York City IV drug abusers infected with the virus.

If then an average ratio of 1 to 100 of those alive with AIDS to those infected is applied to all risk groups, one may obtain a current estimation of the prevalence of infection.

Although we have assumed for the purpose of calculation that the ratio is the same for all groups, this obviously need not be the case. For example, the ratio for those who receive blood or blood products is probably lower since heat treatment of factors along with the screening of donated blood has resulted in a decline in the HIV infection in this group.

In fact, our calculation of the ratio in hemophiliacs is 1 to 57. The ratio of those at no known risk or heterosexual partners of high risk group members may be higher since the epidemic of HIV infection in these groups is probably not as old as in other risk groups. The ratio appears to tend to decline as the epidemic ages since there would be more cases of AIDS, hopefully prolonged survival of those infected and hopefully a decrease in incidence of infection.

If one applies the ratio to New York City cases of AIDS at no known risk, one can estimate the prevalence of HIV infection in this group. Since there are approximately 34 New York City adults at no known risk for HIV infection with AIDS based upon the data from the New York City Health Department, we estimate that approximately 3,400 New Yorkers at no known risk are infected. The U.S. Census reports that there are 5,306,000 plus adults living in New York City. By subtracting estimated numbers of high risk group members, one can estimate that there are approximately 4,161,000 New York City individuals at no known risk for HIV. This translates into a prevalence of 80 per 100,000. The actual prevalence of HIV infection in blood donors in New York City is 90 per 100,000. The similarity here again appears to support the accuracy of the calculations and assumptions that we have made.

If the ratio of 1 to 100 of those alive with AIDS to those infected with HIV is applied to the U.S. population, then the new approximation for adults infected in the United States is just short of 2 million. This represents an overall increase of 11 percent from the data that we calculated in 1985 and is probably consistent with the reported incidence of infection in high risk group members of 2 to 20 percent of the remaining uninfected population per year. There also appears to be approximately 25,000 children infected with the virus if the ratio holds true in this group.

I don't know if the members of the Committee have received a copy of my report, but if you have, I will draw your attention to the table on the second to last page, just a couple of comments. We compare the data for 1985 and November, 1987 in tabular form. It appears, if our assumptions are accurate, again, that may be a big "if," that there are currently 1,467,100 homosexual men in the United States infected; 307,400 intravenous drug abusers in the United States infected. This

makes up the bulk of the 1,953,000 adults infected in the United States.

Again, from Census data, we know that there are approximately 191 million adult Americans and this translates to a prevalence overall, including all groups, to 1 percent, 1 percent of Americans, if these figures are accurate, are infected with HIV.

In summary, the ratio of cases of AIDS to those infected with HIV appears to have change from 1 to 300 to 1 to 100 from 1985 to 1987. It does appear, however, to remain relatively constant in two high risk groups in which reasonably accurate figures concerning the prevalence of HIV infection in the total population exists.

The total number of Americans infected is estimated to be just less than 2 million and has increased by 11 percent since 1985. More accurate estimations of the prevalence of HIV infection could be made if more data concerning HIV infection in other groups was available.

This perhaps could be accomplished through the reporting to local Public Health Departments individuals who are infected with HIV in addition to those who have developed AIDS.

We recognize, however, that this is a controversial issue and must include protection for the rights of those infected. If such safeguards are not enacted, high risk individuals and others may refrain from being tested, thus potentially increasing the risk of transmission to other individuals.

We also feel that aggressive attempts to educate the American public about HIV infection would be an effective means to decrease the incidence and prevalence of the infection. Thank you.

MR. CREEDON: Thank you. Any questions for Dr. Sivak?

DR. WALSH: No, I think his paper is very clear.

MR. CREEDON: Dr. Primm?

DR. PRIMM: I would like to reserve my questioning until Dr. Redfield talks about the military study, because then I can compare the two and ask Dr. Sivak really what population groups he is talking about. I think the prevalence is quite different. It might be higher in certain groups, particularly blacks and hispanics.

DR. SIVAK: Certainly, but if I could address perhaps what I think is a question. When we state that the ratio is similar among groups, by no means does that imply that the prevalence among groups is similar. In fact, it is rather dissimilar. There are a couple of infectious diseases which do appear to maintain a constant ratio among various subgroups, of those with clinical disease to those with sub-clinical disease.

The classical example would be St. Louis encephalitis, where the ratio appears to remain constant at 1 to 200. Of course, in different groups, there is a higher prevalence of infection. It is sort of a back door way to get back at the prevalence, since as mentioned by the previous speakers and also the opening remarks of my comments, we really don't know the answers. We are using data that is extrapolated from potentially biased information.

The prevalence is greatly different in different groups, but we think, we postulate or assume that the ratio of those with clinical AIDS to those without any clinical disease but infected remains constant.

DR. PRIMM: Unless those technical definitions are given, I think your studies could be misleading to laity, and that is my concern, that you must do it in the manner in which you just explained it to me, when you recognize that was indeed going to be probably my question.

I think it is an excellent piece of work but it must be put into the proper context by proper definition. It is not a criticism as much as to say that to be clearly understood by people not involved with the technical language that you use, it must be done a little more simply.

DR. WALSH: I just have one question. Did I understand you to say that AIDS is not reportable in New York?

DR. SIVAK: No. AIDS is reportable. The presence of HIV infection is not. I suggested that perhaps if that were, we would have better data.

DR. PRIMM: Nor is the antibody status reportable. Infection is not reportable nor is the antibody.

MR. CREEDON: Any other questions?

[No response.]

MR. CREEDON: I had a discussion this morning with some of our actuaries about their using a similar technique to arrive at estimates. I found it quite interesting. I think it

is kind of indirect compared with getting direct information about the people who have the virus.

What about the heterosexual aspect of it? Did you reach any conclusions about that in the work you did?

DR. SIVAK: In terms of this particular ratio?

MR. CREEDON: Yes.

DR. SIVAK: We did not study that group. There is simply not very good data in those populations at least that I could find, to try to compare the ratio in those populations. Most of the data on prevalence of infection comes from the classical high risk group members, homosexual, bisexual men, intravenous drug abusers, hemophiliacs.

Furthermore, it is very difficult to get the denominator in many of these populations. Even if one knew the prevalence, it is very difficult to find out how many individuals are in a particular subgroup. For the group that you mentioned, it is very hard to know that answer.

MS. GEBBIE: Looking toward the future, because one of our tasks is to try to figure out what incidence rate, prevalence rate will apply toward the end of this century for program planning, based on the study you have done so far and what you have seen here, would you continue to use the ratio you have identified of infected persons to ill persons for a figure for the year 2000 or would you make some shift?

DR. SIVAK: Clearly not. I think as the epidemic progresses and insofar as the pathogenicity of the virus appears to increase the longer one is infected, in other words, the longer one is infected, it appears as though the more likely one would develop clinical disease.

This ratio may change dramatically with time. I mentioned the one study which was actually reported by Dr. Curran a couple of years ago, in which the ratio changed from 1 to 825 to 1 to 26 over a four year period. Clearly, this ratio may not be applicable even tomorrow, let alone the year 2000. I think it would have to be looked at, if better data wasn't available by then, and hopefully it will be. That ratio will have to be recalculated.

MS. GEBBIE: It certainly can be recalculated every time we get new data but given today and in an attempt to write a report that predicts at that level, what number would you apply?

DR. SIVAK: We haven't even thought about what the ratio might be in the future. We have less information that

would enable us to determine that. We barely have enough information to develop the current ratio, let alone the future ratio. I really can't answer that question, except to state I would not be surprised if it was vastly different in the future than it is today.

MR. CREEDON: Penny?

MS. PULLEN: Do you think it would be helpful if the CDC collected the HIV infection reports in places where it is reportable rather than just case surveillance?

DR. SIVAK: I think that would be helpful to this type of endeavor. Again, I must stress that is a rather controversial area, as you know. If that information becomes a part of the public record and those individuals who are infected aren't protected, then --

MS. PULLEN: I am not talking about identified reports. I am talking about incidence reports; statistical incidence reports.

DR. SIVAK: Yes, I think it would be helpful to have that information.

MS. PULLEN: Thank you.

MR. CREEDON: Do you have any comment, Dr. Sivak, on other studies that have been done that have suggested a lower level of prevalence of the virus?

DR. SIVAK: In some of the reports on the prevalence of the virus, they are merely stated and a lot of the data used in calculations isn't made available to the reader. I really can't comment. Dr. Rees, in an issue of Science, used a mathematical model to project total number of infected individuals based upon the mean latency period between the time of infection and the time of AIDS development, based on people who had received blood. That appeared to be a study that was based on reasonably good mathematical models. That prevalence was actually higher. In 1985, he projected 2.5 million infected at that time. I can't comment on the other studies. I'm not familiar enough with how they derive their figures.

MR. CREEDON: Thank you.

ADMIRAL WATKINS: Let me finish up the questioning, Dr. Sivak. Was your data among those considered by the Centers for Disease Control in their latest analysis of a variety of inputs, which ranged all the way from .45 million up to 2.3 million infections but clearly the density was nominally in the 1 to 1.5, I think it was .95 to 1.4 in the curves they showed in their

data. If it were not, do you have any idea what the fundamental differences are in approach that perhaps in principle we could deal with?

The numbers are considerably different than the weighted centroid of what the CDC have projected. What is the difference?

DR. SIVAK: I don't know if they used the data we had reported in the past. If you are speaking of the recent report from CDC that was mentioned this morning, I have not yet seen it.

ADMIRAL WATKINS: Would you be willing to do that analysis and let us know what fundamental differences in approach are causing the very significant difference in the projection of the numbers infected?

DR. SIVAK: Certainly.

ADMIRAL WATKINS: We have to come to grips in making any recommendations with what is wheat and chaff on some of these projections. If we can't get better data, at least the data we do have, we need to be able to verify it, whether we are right in the middle or whether we have that kind of 25 percent differential in the upper limit.

DR. SIVAK: I would be happy to do that. I'm not sure that 1.5 and 1.9 million, in terms of the scope of this illness is that significantly different when one considers the methods that by design had to be purely inferential and little hard data was available to determine these numbers. I would be happy to look at that.

ADMIRAL WATKINS: The range of costs and some of the health care facility projections will affect it significantly because of what we are dealing with here. It is significant, I think.

MR. CREEDON: Especially if you look to the lower end.

DR. SIVAK: Economically, yes. Statistically significant, I'm not sure.

ADMIRAL WATKINS: Have you tried to engage in any kind of surrogate survey concept, behavioral surveys, for example, along the lines that Dr. Francis talked about, to see whether or not your model tracks reasonably well with behavioral surveys?

DR. SIVAK: No; we have not.

ADMIRAL WATKINS: Is there any intention to do that in the future?

DR. SIVAK: We have not thought of it but it is something to be considered.

ADMIRAL WATKINS: Do you think it may have merit to do that?

DR. SIVAK: Yes.

ADMIRAL WATKINS: Thank you.

MR. CREEDON: Dr. George Rutherford from the San Francisco Department of Public Health.

PRESENTATION BY DR. GEORGE RUTHERFORD
SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

DR. RUTHERFORD: Mr. Chairman, Mr. Creedon, members of the Commission, ladies and gentlemen, thank you for asking me to address you today on the subject of the prevalence and incidence of human immunodeficiency virus infection and the rate of progression from HIV to AIDS.

Today, I'll be discussing data from the San Francisco city clinic cohort study, prospective epidemiologic study of AIDS and HIV infection among San Francisco gay and bisexual men conducted by the San Francisco Department of Public Health and the Centers for Disease Control.

I'd first like to describe how we've gathered the data that I'll be discussing. The 6709 gay men who participate in the study were originally recruited between 1978 and 1980 from the San Francisco City Clinic, our municipal sexually transmitted disease clinic, for studies of the epidemiology of hepatitis B, an important sexually transmitted disease of gay and bisexual men.

359 participants who had never been infected with hepatitis B were subsequently enrolled in a trial of hepatitis B vaccine. Blood samples were drawn from each participant every six months, and unused blood was frozen. Later as we reenrolled these men in AIDS studies, we were able, with their permission, to defrost their frozen blood and test it for HIV antibodies, thus establishing when an individual became infected. By aggregating these data, we're able to establish the prevalence and incidence of HIV infection and also the risk of developing AIDS as a function of the duration of HIV infection in this study population.

This slide shows the prevalence -- that is, the cumulative proportion of study participants infected with HIV -- by year from 1978 to 1986. In 1978, the prevalence was 1

percent. By 1982, it had risen to 43 percent. Since 1982, however, the prevalence has risen only slightly with the 1986 prevalence being 46 percent.

Data from the other two large cohort studies of gay and bisexual men in San Francisco, conducted by Professors Warren Winkelstein of the University of California-Berkeley and Andrew Moss of the University of California-San Francisco, have found similar prevalences, thus leading us to estimate the overall prevalence of HIV infection among gay and bisexual men in San Francisco to be approximately 50 percent.

Another way of examining the spread of HIV infection in this cohort is by calculating the annual incidence of HIV infection -- that is, the proportion of study participants newly infected with HIV per year. This slide shows the annual incidence of HIV infection expressed as the percentage of previously uninfected men who seroconverted or who became newly infected during each year from 1978 to 1986. As you can see, the percentage of men becoming newly infected rose rapidly from 1 percent in 1978 to 21 percent in 1982. In 1983, however, this percentage fell dramatically to 2 percent and has remained very low ever since, with only 0.8 percent of previously uninfected men becoming infected in 1986 and none in 1987 to date.

Data from Professors Winkelstein's and Moss' cohort study show similar dramatic changes. Together, these studies indicate that the incidence of HIV infection among gay and bisexual men in San Francisco who participated in these studies increased rapidly until about 1982 or 1983 and subsequently fell abruptly and has remained low ever since. And parenthetically, I might add that this virtual cessation of HIV transmission predated HIV antibody testing programs by two years.

How representative are these study participants of all gay and bisexual men in San Francisco, a concern that you quite rightly have voiced? Or put another way, can these findings be extrapolated to the entire San Francisco gay male population?

In short, we feel that our study participants are quite representative of gay and bisexual men living in San Francisco at the times the studies were begun. Professor Winkelstein's study population, for instance, as Dr. Francis has point out, was recruited by a random house-to-house survey. Reproduceability of the finding of declining incidence in all three studies, moreover, is very compelling and strongly suggests that this same decline has occurred in the gay community at large. Furthermore, these changes in HIV incidence can be corroborated by changes in the incidence of other sexually transmitted diseases in San Francisco in gay and bisexual men.

For instance, the incidence of rectal gonorrhea in men diagnosed at San Francisco City Clinic between 1978 and 1985 fell from almost 1500 cases per quarter in 1980 to 100 cases per quarter in 1986, a decrease of 93 percent. During the most recent quarter, there were fewer than 30 cases. These data thus corroborate the changes in HIV incidence seen in the three cohort studies and clearly support the conclusion that HIV infection has decreased markedly among gay and bisexual men in San Francisco.

In summary, we have observed a marked decrease in the incidence of HIV infection among gay and bisexual men in San Francisco, with very low levels of new infection since 1983. This decrease has been accompanied by a similar dramatic decrease in high-risk sexual practices within the gay community, which I have presented in written testimony and which appears to have causally contributed to the decline in HIV infection. But what part of behavioral change can be attributed to fear and what part to health education is less clear, although I think it is quite certain that health education helped to channel gay men's desires to reduce their risk of AIDS into safer sexual behaviors. I would now like to turn to the question of what is the risk of developing AIDS once a person is infected with HIV.

MR. CREEDON: May I ask a question, Dr. Rutherford?

DR. RUTHERFORD: Please do.

MR. CREEDON: Going back to your prior slide, was the gay community in San Francisco sufficiently aware of the danger in 1981 and '82 to have changed their behavior, so as to produce the results in '83?

DR. RUTHERFORD: Yes. Actually I have brought the slide of rectal gonorrhea changes, but it won't fit into this newfangled carrousel. Actually the rates of gonorrhea started to fall in late 1981. It actually predated --

MR. CREEDON: So it related to that. In other words, it was the rectal gonorrhea that maybe caused a change in behavior rather than AIDS?

DR. RUTHERFORD: Oh, no, I don't think so. Gonorrhea was widely viewed as a treatable disease that was just, you know, sort of like getting -- I don't want to be overly flip -- it was like getting parking tickets. I mean, it was just sort of the lifestyle that you'd have to go and get treated.

MR. CREEDON: But my question is, was the gay community sufficiently aware in 1981 and '82 of the danger of AIDS to have changed their behavior dramatically, so as to produce the change in '83 and '4?

DR. RUTHERFORD: Yes. Our survey data from 1983 suggests that there was widespread knowledge -- the change occurred between 1982 and 1983. But there was widespread understanding and knowledge of AIDS and a lot of theories about what caused AIDS and how one contracted it.

DR. PRIMM: Dr. Rutherford, this N is 359?

DR. RUTHERFORD: That's correct.

DR. PRIMM: Thank you.

DR. CRENSHAW: And one other point. The dramatic change that you see there, can you give us, for our understanding, I think one of the most important things? What has been the breakdown of behaviors, and what in particular -- how many of those who are not getting infected are having more than one partner, regardless of what safe sex measures they're using?

DR. RUTHERFORD: In the written testimony, I've presented data collected in 1978 and 1984 and 1985, which spans this period. In 1978, the mean number of sexual partners -- I'm sorry -- the median number of sexual -- non-steady sexual partners in the four months preceding the interview and the blood collection was 16, and in 1981 it was 1.

Dr. Doll from the Centers for Disease Control has developed a product called an exposure product, which is basically -- you get by multiplying the numbers of sexual partners times the percentage of time they practice a certain sexual behavior, so if you have 10 sexual partners and you practice insertive anal intercourse 50 percent of the time, your exposure product is 5. That data is in the written testimony as well. That's decreased about, oh, 95 percent during this same time period. As to whether we have year-by-year information from this cohort, no, we don't. We have year-by-year blood samples from this cohort.

DR. CRENSHAW: But basically if I understand you, what you're saying is, I think, really important, and that is that numbers of -- in order to achieve these results, the number of partners haven't been remaining at a multiple partner level, but it's really approximating 1; is that correct?

DR. RUTHERFORD: I'm not inferring that causally. I'm saying what we've observed is that both the numbers of partners have declined, and the specific types of sexually activities have changed as well.

MR. CREEDON: Thank you very much.

DR. RUTHERFORD: Now I thought I would turn to the question of what is the risk of developing AIDS once a person is infected with HIV. This question has not only important clinical ramifications for the individual patient with HIV infection, but also can provide us with a framework for more exact forecasting future numbers of AIDS cases.

Among a 20 percent random sample of all San Francisco City Clinic cohort participants, there are 63 men for whom we know the approximate date of HIV infection and have detailed medical records. On average, these men have been followed for 76 months, since HIV seroconversion. These 63 men, 19 or 30 percent have developed AIDS with a mean interval of 55 months between seroconversion and diagnosis of AIDS. 13 or 21 percent have developed AIDS-related conditions, including oral candidiasis or hairy leukoplakia, weight loss, fever, diarrhea, and 17 or 27 percent have developed persistent generalized lymphadenopathy without other signs or symptoms of HIV infection. Only 14 or 22 percent of this group have remained asymptomatic.

114 men from the vaccine trial who were seropositive on entry into the cohort or who seroconverted within a known 24-month period during the study were included in a Kaplan-Meier survival analysis of the cumulative proportion of men who will develop AIDS by duration of infection. From analysis of these men, we estimate that 11 percent of HIV-infected men in this cohort will develop AIDS within 48 months of infection, 15 percent will develop AIDS within 60 months, 22 percent within 72 months, 28 percent within 84 months, and 35 percent within 86 months with a 95 percent confidence interval of 16 to 54 percent.

Stated another way, we estimate that the average annual incidence of AIDS in this cohort will be less than 1 percent per year during the first two years following HIV infection, 5 percent per year during the next three years, and 7 percent per year during the next 26 months, which is as far out as this cohort goes at the present time.

Two questions need to be addressed. First, can these progression estimates be applied to other HIV-infected gay and bisexual men, and second, can these estimates be applied to non-gay or bisexual populations infected with HIV?

With regard to the generalizability of the study group to other gay and bisexual men, all the men in this study were recruited from a sexually transmitted disease clinic, and repeated venereal infections or reexposure to HIV are important cofactors in the progression of HIV infection to AIDS. These men may be at higher risk for disease.

However, these men were seronegative for hepatitis B virus when they were recruited in the vaccine trial, and therefore probably had less cumulative exposure to other venereal diseases than the other men in the cohort. If venereal diseases are a cofactor, then one would expect a prognosis of vaccine trial participants to be better than that of the remainder of the cohort.

However, analysis of a random sample of the entire cohort showed virtually the same time progression to AIDS as vaccine trial participants. Additionally, other epidemiologic studies of gay and bisexual men in New York City, Washington, D.C., and Denmark have shown similar rates of progression, although none of these studies have followed their patients for as long as this study.

With regard to the question of how these data compare to similar studies in other risk groups, the rates of progression following infection with HIV have been estimated amongst recipients of HIV-infected blood and blood products. Data from both transfusion recipients and hemophiliacs demonstrate very similar rates of progression with 7 percent of transfusion recipients developing AIDS after between 10 to 63 months of HIV infection and 13 percent of hemophiliacs developing AIDS after 60 months of infection.

In summary, our data suggests that 35 percent of gay and bisexual men with HIV infection will develop AIDS within 84 months following HIV infection -- I'm sorry -- 86 months following HIV infection. They also suggest that over a similar time course, the majority of HIV-infected men who have not developed frank AIDS will develop other signs and symptoms of HIV infection. Furthermore, our findings are consistent with those from other studies of the natural history of HIV infection among gay and bisexual men, transfusion recipients, and hemophiliacs. Again, thank you for the opportunity to speak with you this morning.

MR. CREEDON: Penny?

MS. PULLEN: No questions.

MR. CREEDON: Ms. Gebbie?

MS. GEBBIE: If you were going to use more information to try and estimate or predict the seroconversion rate in the currently uninfected gay population of the United States at large over the next few years, would you use the figures from early in San Francisco with a seroconversion rate of 10 and 20 percent a year or the current figures of 1 and 2 percent a year and why?

DR. RUTHERFORD: I don't think anyone can possibly answer that question. You have to realize that there are three large cohort studies in San Francisco that have been carefully measuring this for several years. The multicenter collaborative studies which are conducted in -- and Dr. Fauci can correct me -- I think it's Pittsburgh, Los Angeles, Baltimore, and Chicago -- have been gathering similar data since 1984. Outside of those cities, I don't think anyone has a real handle on what the true incidence of HIV infection is among gay men.

I think that it would make sense to say that the epidemic in San Francisco probably started about a year after the epidemic in New York, and the epidemic in other large gay metropolitan urban communities started somewhat later than San Francisco. But as to putting an exact handle on it, I don't think anyone can really do that accurately.

MS. GEBBIE: I know it isn't specific. We're trying to make calculations. If you can't -- if you're not willing to make a guess of which of your numbers you would use to apply nationally, would you comment then on your view of using the current CDC report, the most recently released one, as being a good estimate to use, or where would you turn to get good estimates that we can use for the end of the century calculations that we need to make?

DR. RUTHERFORD: Well, I think that I agree with you, that it's important to make these estimates. I think the estimates have to be made with the best data available, and if there's not good data available, which there is not, then I think that data has to be generated de novo, and Dr. Francis spoke earlier about the need for recruiting and doing these kinds of cohort studies in other cities and flinch somewhat at the price tag. I'm less of a flincher these days.

And I think that you really basically, to make accurate estimates, you know, you'll be faced with questions. Do we need to open up -- do we need to build $300 million hospitals in Houston, for instance? And I think one of the -- my recommendation would be to generate these data de novo if they don't exist, rather than try to extrapolate.

MR. CREEDON: Do you have any comment on that, Dr. Fauci?

DR. FAUCI: I agree. I think perhaps the slant of your question, if I'm not mistaken, was if you're going to -- could he use the data from early on in '82, '83 about the yearly incidence of new infection, could we use that in other parts of the country? Were you asking that?

MS. GEBBIE: That was the import of my question, yes.

DR. FAUCI: Again, we don't have the answer to that, but I would think given the current state of knowledge of the dangers of certain types of risk behavior among the male homosexual population throughout the country, I would think it would not be unreasonable to presume that people in Chicago and Houston and Miami and Baltimore are as aware of the problems of risk behavior, male homosexuals, such that I think the yearly incidence of new infection in those communities you could extrapolate from your early data. Would you agree?

DR. RUTHERFORD: With some caution, yes, you could extrapolate it. I would also point out -- and I'm sorry the slide doesn't fit -- that there's a fairly tight correlation between cases of rectal gonorrhea in men and this observed incidence, and that's something that's available right now. It's collected nationally. Those data are available, and we've used those data quite a bit in our planning efforts. And if you want to look for an easy way to do it, that's a much easier way than trying to take these data and extrapolate them.

MS. GEBBIE: I'm well aware there's not a simple, easy way. I'm just trying to push to look at what ways different people would do it as a basis.

MR. CREEDON: Dr. Fauci and Dr. Rutherford, would you comment on Dr. Sivak's approach? Did you follow his presentation?

DR. FAUCI: I think that the data from Dr. Sivak's presentation is reasonable and sound. If you look at it, it does not differ significantly from the kinds of projections that have -- in fact, it's more confirmatory of the type of projections.

MR. CREEDON: Well, there is a difference, as Chairman Watkins pointed out. There's a significant difference really between the most recent CDC range -- well, it depends on what you call significant, but it looks significant to us. Dr. Rutherford, do you --

DR. RUTHERFORD: I'm sorry. I didn't hear the entire presentation. But hearing the discussion of the methods, it seemed a perfectly reasonable way to generate the data. I also took great comfort in the fact that Dr. Sivak used the no identified risk data from New York where the analysis of cases and the assigning of cases to risk groups is probably the best in the country.

MR. CREEDON: Dr. Primm?

DR. PRIMM: Dr. Rutherford, you continue to refer to the slide with GC that won't fit. I mean, you can take the carrousel off and put it in there. I'd like to see it.

DR. RUTHERFORD: Sure. It's in the written testimony.

DR. PRIMM: I'm sure other Commissioners would like to see it, too. But I have another question for you. Since your figures have indicated very encouraging results for intervention strategies for one population group at risk, and that's your homosexuals, I think certainly San Francisco and other parts of the country have a unique opportunity now to -- certainly, as you know, I was just out there recently, and one of the big complaints that I had from meeting with 30 people out there was indeed that they didn't have the same kind of thrust for the intravenous drug-using population as you have had for the gay population in San Francisco.

DR. RUTHERFORD: Yes.

DR. PRIMM: And as a result, I wonder what the incidence and patterns in IV drug users are in your city -- I mean, what is the incidence when you compare the two groups? I've heard that it's very low, and that we could even keep it low in San Francisco, even keep it low in Houston and Los Angeles, by employing some of the same things that your cohort group employed.

DR. RUTHERFORD: Yes. That's correct. The incidence of HIV infection among heterosexual intravenous drug users is approximately 3 percent per year in San Francisco, but that's based on -- I'm sorry -- this is the gonorrhea slide, and you can see that the slide starts to take place -- the peak is in - - the highest peak is in '80, and there starts to be a downward plan that becomes markedly exacerbated between '82 and '83, and I think it parallels that other data fairly dramatically.

I'm sorry. Getting back to your question, we think that the overall prevalence of infection among heterosexual intravenous drug users in San Francisco is approximately 15 percent and that the incidence of new infection is approximately 3 percent per year. We're not seeing, as measured in primarily clinic-based studies, we're not seeing this rapid acceleration of disease, of infection among intravenous drug users. And it would be my guess that should our control programs not be as successful as they were among gay men, that HIV infection among heterosexual intravenous drug users, their sexual partners, and their children will become an endemic disease principally of the black and Latino, to a lesser extent the American Indian, community in San Francisco.

DR. PRIMM: It's three times higher now in intravenous drug users, as you admit right now.

DR. RUTHERFORD: That's absolutely correct.

DR. PRIMM: So it would seem to me that there ought to be such a concentration on that population in San Francisco at the moment, which does not exist. I mean, I heard people talk to me from Contra Costa County and from all over San Francisco in drug treatment programs. Dr. Whittaker was at that meeting, as you probably know, and I was shocked that we don't have the same kind of thrust, and I think that it's because that group does not have the political clout that the gay community has in San Francisco, and indeed that if they did, and if there was a greater voice in San Francisco, that there would be greater concentration in terms of setting up programs of intervention for that group as well as the other.

DR. RUTHERFORD: I strongly disagree with you. To start with, the San Francisco that I'm speaking for is the City and County of San Francisco and not Contra Costa County and Alameda County and the other counties in the Bay Area.

There are -- probably more money is being spent now for prevention and treatment of intravenous drug users than there is for prevention services for gay and bisexual men. There's been a major revamping of the programs that's gone on in the last 12 months with the new clinic, for instance, that's being opened in the Tenderloin area of San Francisco, which is roughly equivalent to the Lower East Side, and I think we've made a major commitment.

We have not recruited cohort studies, the cohort kinds of studies that we have recruited in the gay population, and have based our estimates principally on in-treatment clinic populations, which is indeed a shortfall.

But in terms of the prevention efforts, I think that they are there. San Francisco, for instance, pioneered the use of bleach, dispensing bleach and teaching people how to clean their needles with bleach between sharers.

So I think we have made that commitment, and obviously we could always use more money to open up more treatment slots, and that is, in fact, the real shortfall of our programs, that we need several hundred more treatment slots, which I think is true if you multiply it -- you know, add an extra zero to it, which is also true in New York.

MR. CREEDON: Dr. Fauci, you wanted to comment?

DR. FAUCI: Yes. I have a general comment in response to what Dr. Primm said, and that is I think that many people on the outside really do not appreciate the fact that what is required for change in behavior among IV drug abusers is certainly much different than among the homosexuals, because the

responsiveness of the male homosexual population to education has been outstanding and really a model in behavioral change.

When you are dealing with IV drug abusers, there is a misperception sometimes. This has nothing to do with San Francisco, I agree with Dr. Rutherford that the San Francisco system has actually done quite well from both areas, both IV drug abusers and male homosexuals.

In a system where you are dealing with IV drug abusers, there is sometimes a misperception that the same sort of educational campaigns that would have a significant impact on male homosexuals would also have a similar impact on IV drug abusers, failing to appreciate that IV drug abuse is a medical disease that needs to be treated and the way that you can get to the IV drug abusers is to have intensive treatment programs as well as education programs. Education alone is not going to do it.

I agree with you, Dr. Primm, that we really need to have nationwide much more intensive efforts at the IV drug abusing population that is more than just education. Education to a person who has a medical disease is not going to cure the medical disease. That is what IV drug abuse is.

DR. PRIMM: Dr. Rutherford, perhaps you could supply for the Committee some follow-up statistics on when monies were put into an intravenous drug user community and what was the results of the infusion of those dollars.

I know Haight-Ashbury certainly has done a lot in passing out bleach in small bottles. I have certainly heard about it, two and a half years ago, long before it was done on the East Coast.

I'm not doing a comparison or being critical as much as I see a need for greater concentration in those areas. I know the program in Bay View. I know Ron Kletter's program. I know Al Comparo's program. I just had a meeting at the Cadillac Hotel with Leroy Luper, who was constantly working with intravenous drug users.

What I am talking about is what people have actually said to me that I have on tape. I'm quite surprised that you should say today that there is great concentration and good results and so forth, when indeed there is a difference of opinion among other people who are working with intravenous drug users.

DR. RUTHERFORD: I am equally surprised you said it.

MR. CREEDON: Dr. Crenshaw?

DR. CRENSHAW: Based on your cohort study and whatever other knowledge you can draw on in San Francisco, how many, what percentage of individuals, gay men, acquired the infection as teenagers, number one. Secondly, what percentage of the men you work with or what do you estimate from your current knowledge is the percentage of any degree of bisexual or heterosexual activity among homosexual men?

DR. RUTHERFORD: In terms of what percentage of men acquired the infection as teenagers, all these study cohorts basically used a bottom age cutoff of around 25. We really can't answer that question. That was one of the points, and I'm glad you raised it. I said that we feel these data are representative of the types of men who would have been enrolled in these studies. We really don't have data on younger men. I think that is a need as well.

I think nationally, if you look at people who are 20 to 24 years old with AIDS, the large majority of them presumably who acquired the infection during adolescence and adolescents themselves. The large majority of those people, certainly in excess of 70 percent, and I'm not sure of the exact numbers, are gay or bisexual men. I think adolescents are at risk, gay adolescents are at risk of the HIV infection.

They may more properly fit the Freudian term, bisexual, and they may be supporting themselves as gay prostitutes, for instance, but nonetheless, that is the predominant mode of acquisition of the virus among people who are between the ages of 13 and 24.

DR. CRENSHAW: Which is the predominant mode?

DR. RUTHERFORD: They are classified as homosexual or bisexual. I am talking about AIDS patients now. That's the only thing I can infer from.

In terms of how many gay men are bisexual, I think the real question is how many are bisexual in a period of time of the epidemic rather than historically. Is that correct?

DR. CRENSHAW: Yes. I also mean specifically. I don't mean bisexual necessarily, equal numbers of each partner, but any heterosexual activity regardless of how infrequent.

DR. RUTHERFORD: In our studies, it is between 10 and 15 percent, depending on how you cut the cohort into different sample sizes. I am talking about the people who are enrolled in these cohort studies now, the three cohort studies. It is

between 10 and 15 percent, within the period of time the questions are asked, which is usually in the last -- basically since the beginning of the epidemic.

MR. CREEDON: Dr. Walsh?

DR. WALSH: Has the behavioral change in the homosexual community been as good in other cities as in San Francisco or is San Francisco unusual?

DR. RUTHERFORD: San Francisco is certainly unusual, I'm sure. I really can't answer the question. I don't have firsthand knowledge of a lot of other cities. What I can tell you is there are declining rates of rectal gonorrhea in men who were first reported in New York City in 1983 or 1984, and have also been reported from Seattle.

I think Dr. Fauci's thought that these sorts of changes are being seen in other large urban gay communities is probably true.

DR. WALSH: Have they been as dramatic?

DR. RUTHERFORD: There is not data to support it.

DR. WALSH: Dr. Fauci, do you know? Has the behavioral change in the gay community been as dramatic in other cities?

DR. FAUCI: It is very difficult to say that. We do know that if you look at sexually transmitted disease clinics in other cities, for example, in Denver, where it has remarkably decreased with rectal gonorrhea, 80 to 90 percent, you wouldn't consider Denver as one of the major cities in this country with AIDS and yet there is clearly objective data showing a decrease in that kind of activity.

DR. WALSH: Denver has had a lot of things like contact tracing and everything else, which has also played a role.

DR. FAUCI: Possibly.

DR. PRIMM: I have one more question for Dr. Rutherford. You spoke with pride about the use of the Clorox being handed out in shooting galleries or wherever people congregate to shoot drugs. I wonder how much emphasis is placed on the stopping of the use of drugs period and intravenous drugs period, wherever they are handed out.

DR. RUTHERFORD: Yes, I'm glad you asked the question. Certainly, our take on it is in terms of overall AIDS prevention strategy, as Dr. Fauci says, that intravenous drug addiction is a

medical disease and needs to be medically treated and the only true way to stop it is to stop addiction. We place our primary emphasis on the treatment of intravenous drug use. Unfortunately, the majority of our treatment slots are funded by the federal government and they have been fairly fixed over time and in fact are being reduced.

We are faced with the decisions, should we cut down on the number of detoxification slots to open more methadone maintenance slots, to try to trade the more expensive means of treatment for the less expensive, more expeditious means of keeping people from sticking needles in their arms. That's a problem.

In terms of the bleach, that is obviously a second level of advice. Our advice is if you use intravenous drugs, stop using intravenous drugs. If you can't stop using intravenous drugs, don't share needles. If you can't stop sharing needles, at least do this.

DR. PRIMM: I think there should be some emphasis also on primary care in those already existing treatment centers, where you have a greater contact with health care givers and those people receiving. Like Dr. Fauci has indicated, this is a disease and unless we begin to look at it as such and not only expand our treatment efforts within the center itself by greater contact with the patient, more sophisticated care for that patient population, than is now being witnessed anywhere in the United States, I think that could happen in San Francisco. San Francisco is such a magnificent model, there is no question in my mind that it could be demonstrated right there. The drug treatment programs are intact, maybe one needs to put more emphasis in that area, along with just saying stop using drugs and greater concentration. That in itself will give the addict the feeling that indeed they are cared about within the population. I think you would see quite a behavioral change.

DR. RUTHERFORD: I agree. I thank you for your comments. We are always lobbying the Alcohol, Drug Abuse and Mental Health Administration for demonstration project monies to open up new treatment services and to expand existing treatment services. They have been disinclined to provide those sort of funds in the past. I think that is a recommendation that would be very worthwhile.

DR. PRIMM: AIDS is a window of opportunity.

DR. RUTHERFORD: I agree.

MR. CREEDON: I would like to move on, if we can. Could you hold your questions and come back if we have time?

ADMIRAL WATKINS: I would like to close. First I want to make sure that what we saw on the screen, on the rectal gonorrhea cases, is your Figure 3 in your report.

DR. RUTHERFORD: Yes.

ADMIRAL WATKINS: I would like to ask Dr. Francis, if this data on rectal gonorrhea has a close correlation, which is almost remarkable from what Dr. Rutherford is saying, why isn't that among the surrogates, perhaps a family of surrogates that would give us even more accurate data than we talked about in behavioral surveys, where now we have indication of a more direct correlation. I would like to ask your opinion on that.

DR. FRANCIS: I agree.

ADMIRAL WATKINS: You are the advisor to Centers for Disease Control. What have you done to talk to Centers for Disease Control with this data being reported as an infectious disease, to do more studies and gather more data to confirm that correlation and perhaps with the largest segment nationally being in this category, this may be a very near term opportunity for us. What has Centers for Disease Control done about this kind of correlation?

DR. FRANCIS: I am Centers for Disease Control advisor to the state, not the state's advisor to Centers for Disease Control.

ADMIRAL WATKINS: I understand.

[Laughter.]

DR. FRANCIS: At least the State of California's recommendations is increasing their watch on the rates of gonorrhea so we can monitor them. Unfortunately, it is interesting that some areas do not separate rectal and non-rectal so you have to start that program up. That is not a difficult thing to get in place.

ADMIRAL WATKINS: Is that already one of your programs at Centers for Disease Control, to take this on, to take a harder look at this data or perhaps even other data, maybe other kinds of infectious diseases that have some sort of correlation with the HIV infection process.

DR. FRANCIS: Clearly, as you say, this is one of the pieces and the family of surrogates I think is a good way to put it.

ADMIRAL WATKINS: Should the Commission try to dig deeper into a family of surrogates as a more near term, closer prevalence and perhaps even incidence projection model?

DR. FRANCIS: Surely. I would keep behavioral in there also.

ADMIRAL WATKINS: Absolutely. When I say the family, I mean it would include a variety of things where we have technical correlation, like this, as opposed to behavioral. It seems to me that has some merit to it.

DR. FRANCIS: With really very small resources, you have a huge amount of data.

ADMIRAL WATKINS: Another question, the participants in your cohort study, Dr. Rutherford, probably received some intensive education in that particular cohort and are involved in their own medical care process.

I'm not saying it is the best case but I know when you have a closed community like that, that you are intensively looking at, there tends to be a bias to say that is a special group. What I am saying now is do you have any kind of indication from those not in cohort studies, what the incidence in the non-cohort study might represent as opposed to something more confined and more closely controlled?

DR. RUTHERFORD: You are describing the phenomenon of cohort bias, which is clearly operative in these cohort studies. Just to reassure you, on this cohort study to start with, the AIDS follow-up study started in 1984. Prior to 1984, this had been a Hepatitis B vaccine trial with emphasis on basically the vaccine mediated prevention of Hepatitis B and basically these people came in every six months and had blood drawn and little else.

I think the cohort bias you are worried about clearly is in effect after 1984 and later, but were not in effect when this decline occurred.

The question about generalizing it to people outside of cohort studies, I think the gonorrhea data, after all, HIV infection is a sexually transmitted disease and you look at another sexually transmitted disease which does not confer immunity, so you can become infected multiple times, that is clearly supporting data and again, there are behavioral data which support the notion of changing sexual practices in the gay community.

ADMIRAL WATKINS: Thank you.

MR. CREEDON: Dr. Robert Redfield of Walter Reed Medical Center.

PRESENTATION BY DR. ROBERT REDFIELD
WALTER REED ARMY INSTITUTE OF RESEARCH

DR. REDFIELD: I appreciate the opportunity to share my experience of the AIDS epidemic with this Committee. The views that I present are my own and do not purport to reflect the position of the Department of the Army or the Department of Defense.

My perspective on the AIDS epidemic is the product of the opportunity that I have had to practice medicine in the military hospital in the early years of the AIDS epidemic. As a physician, scientist and military medical officer concerned with public health, I was placed in an unique position to integrate these disciplines to comprehend the magnitude of the problem that the AIDS virus is causing and will continue to cause our nation.

First recognized in 1981, AIDS was a new and mysterious syndrome. Today, AIDS is no longer a mystery. It is an infectious disease caused by a retrovirus. Within three short years, science has identified the etiology, elucidated the pathogenic mechanisms of how this virus causes disease, defined the methods of transmission, and developed accurate diagnostic tests for HIV infection.

Yet, despite these unprecedented advances by scientists and the Public Health Service, the AIDS epidemic has escalated from a medical curiosity to an isolated public health problem, to what in my opinion is a worldwide crisis of potential catastrophic proportion requiring an urgent coordinated response. Yet, the magnitude of the problem remains a subject of controversy, definable yet undefined, resolvable yet unresolved.

Why? Unfortunately, the original case definition of AIDS identified only the late clinical stages of the disease and thereby underrepresenting the magnitude of problems from the very beginning. The clinical spectrum of HIV infection, if you look at the first handout, really ranges from acute retroviral syndrome, as Dr. Fauci said, to chronic lymphadenopathy, to subclinical damage of the T cell system and finally, the systemic evidence of T cell dysfunction, as manifested by an opportunistic infection.

This spectrum of disease can be reduced to six stages of infection which are provided in the second handout, which really, for practical purposes, represent advancing stages of immunological dysfunction, caused by this virus. Although early studies reported progression rates of asymptomatic seropositive to AIDS of only 5 to 10 percent, the natural history of the AIDS

virus has been clarified. Today, multiple cohort studies demonstrate progression rates in excess of 30 percent.

Our own cohort study, which is outlined in the third handout, demonstrates that actually greater than 75 percent of all the patients in any stage followed for greater than 18 months demonstrated progressive immunological disease as accessed by this pathogenic framework staging system.

For example, patients that were evaluated for greater than 18 months that were Walter Reed Stage 2's, 10 percent developed AIDS, what we would refer to as Stage 6 disease. If the individual began at Walter Reed Stage 3, it was 29 percent. If the individual began when he first was evaluated at Walter Reed Stage 4, it was 71 percent and if the individual presented with what we refer to as Walter Reed Stage 5 in the follow-up period, 100 percent developed AIDS as defined by an opportunistic infection.

If one was to look at it in terms of death, followed for 18 to 42 months, if you started out at Walter Reed Stage 2, 5 percent of the individuals died in the follow-up period. If started out at Walter Reed Stage 3, 14 percent died in the follow-up period. If they started out at Walter Reed Stage 4, 57 percent and Walter Reed Stage 5, 87 percent.

If you refer to that graph, you can see that despite what stage you started at, over 90 percent of the 62 patients that were entered in that cohort in 1984 in fact developed progressive immunological disease as assessed by this staging system.

My conclusion for one of your first questions, from the available data to date, is that in the absence of a scientific solution, HIV infection is a progressive infectious disease in a majority and possibly all individuals that are infected with the virus, characterized by progressive immunological dysfunction which may require 5, 10 or even more years from the time of infection to the time of death.

In addressing the accuracy of our information to date, another problem is that our understanding of the epidemiology of AIDS was originally incomplete, which contributed to the underestimation of the problem. Today, scientific investigations have unequivocally documented the following modes of transmission--sexual, both heterosexual and homosexual; parenteral and perinatal.

Sexual transmission is and will remain the major mode of transmission of this virus. It is critically important to recognize that the sexual transmission of HIV is not dependent upon a risk behavior. For the HIV virus to be transmitted from

one human being to another, all that is required is that one human being is infected with the virus and the other human being isn't and they communicate by a method efficient for transmission.

Despite this scientific understanding, some still focus AIDS as a high risk group disease. I would argue that we all recognize today that homosexuality does not cause AIDS and heterosexuality does not protect it. Today, there is only one common risk group for HIV infection and that is a human being that has been sexually, parenterally or perinatally exposed to the virus.

I think that is the message we must communicate.

Despite our knowledge, some still underestimate the ultimate importance of heterosexual transmission and I will take a minute just to make a comment.

Individuals speculate that HIV will be unique among sexually transmitted diseases, rather than assume that the laws of nature as they have been described, will continue until definitely proven otherwise. Worldwide heterosexual transmission is the major mode of transmission of this virus, yet some individuals hope that the United States somehow will be unique. Unfortunately, I believe that in the absence of a scientific solution over the next decade, the heterosexual transmission of this virus will become the major mode of transmission in our country. We have to recognize it for what it is, because we have an opportunity to make a major impact on that process.

Today, the AIDS cases represent an historical account of the magnitude of the epidemic actually in the late 1970's, but fail to give us any understanding of what the problem is today. If one continues to focus on AIDS as the magnitude of our problem, we will recognize the magnitude of today's problem in 1997, and I know you are all aware of that.

Likewise, we appreciate now that the epidemiology of AIDS today is really a historical reflection of the epidemiology of human to human transmission of this virus a decade ago, probably five years before we even knew this virus existed, yet fails to inform us about the epidemiology of viral transmission today.

I think it is critical that we change our focus from AIDS and the problem in the 1970's toward the virus and the problem today. We should embrace the scientific advances that were made by the Public Health Service from 1981 to 1984.

Serological testing gives us that opportunity to define today's problem today rather than debate the issue. I believe we

should define the problem and redefine it again in the following year and the following year. The logic that elects to confront the problem undefined when definable should not be embraced by our society.

What do we know about the extent of HIV infection today? It is with pride as a military physician that I reflect on the approach that the leadership of the Department of Defense has executed in response to the AIDS epidemic. HIV infection has been confronted by the military as an important medical, public health and military problem that it is. The Department of Defense policy has been guided by science coupled with important medical and public health issues.

It is also with pride as a military researcher that I reflect on the foresight exhibited by the leadership of the Department of Defense in developing a system to collect this operational data and provide that to our nation as it is an estimate of the extent of HIV infection in our nation's young sexually active people.

One of the programs I am going to comment on, and I will comment on two of them today, is the civilian applicant screening program. All civilians applying for the Armed Forces undergo a medical examination which includes, with other medical testing, screening for the AIDS virus as part of their medical evaluation for fitness for duty. It should be noted that the test results are available within 24 hours for those individuals negative by the ELISA screening, and 72 hours for those requiring confirmatory testing, despite where the serum is obtained throughout the United States.

Some have criticized that the HIV testing is too expensive. It should be noted in rebuttal that the DoD program, including confirmatory tests, costs less than $5.00 per individual tested. Some speculate that serological testing in low prevalence populations would generate prohibitive numbers of false positives and in rebuttal, as reported by Colonel Burke in his recent congressional testimony, the scientifically documented false positive occurrence following the DoD algorithm was less than 1 in 100,000 in our program.

In addition, it should be noted that the DOD has provided test linked education to over 4 million individuals to date, without precipitating a social crisis, so that large scale timely, accurate, inexpensive HIV screening can be done. It is done every day by both the American Red Cross and the Department of Defense.

Between October 1985 and if you look at the first table there on civilian applicants, the numbers are there, between October 1985 and September 1987, over 1.2 million civilian

applicants for military service were tested for the presence of HIV antibody. The overall prevalence of HIV was 1.5 per 1,000.

In light of the demonstrated efficient sexual transmission of HIV, the fact that 1.5 per 1,000 of Americans who desire to serve their country are already infected with the AIDS virus, I perceive as a national tragedy.

The prevalence for infection among males was 1.6 per 1,000 and among females, .7 per 1,000, for a male/female ratio of 2.4 to 1. This is in sharp contrast to the male/female ratio of the cases of AIDS reported to the Centers for Disease Control.

The prevalence increases linearly with age, as you see the numbers, 17 year olds, .16 per 1,000. By the time an individual is 20, .98 per 1,000; 22, 2.17 per 1,000; 24, 3.25 per 1,000. For individuals 26 and over, it was almost half a percent, 4.4 per 1,000.

It is of interest that among the 17 and 20 year olds, the male/female ratio was actually 1.6 to 1. Race and ethnic groups also had different prevalences, such that in the Caucasian population, the overall prevalence was about .75 per 1,000 and in the Black population, it was about 3.8 per 1,000.

Prevalence rates also differed by geographic location. I gave you a mountain map there, which is really just plotting the lowest confidence intervals by county throughout the United States. One can see that in the United States, at least in 1986, this was a relatively geographically restricted epidemic.

New York State led with about 4.2 per 1,000 of the young men and women from the Empire State that wanted to join the Service were infected with the virus followed by Maryland and New Jersey. Certain metropolitan areas, like New York City, Newark, San Francisco and Washington, D.C. all included counties where the prevalence rate was greater than 1 percent for both male and female applicants, with a male/female ratio actually approaching 1 to 1.

For example, in Manhattan, the male prevalence was 2 percent and the female prevalence was 1.7 percent.

As you moved into these metropolitan areas, no longer was sex or race a predictor of whether or not you were infected, the most important predictor was whether you were 18 or 25.

Analysis of overall temporal trends of the military applicant program by birth year cohorts, by Dr. Bundage, unfortunately also documented a substantial increase in HIV infection among our civilian applicants from birth year cohorts

between 1962 and 1969, i.e., those individuals really basically between the ages of 17 and 25 years of age.

For example, male applicants between the age of 18 and 20 had a 30 percent greater likelihood of being HIV infected over an one year period. This was true for both white and black applicants. The estimated doubling times of the HIV in young men born between 1962 and 1969 throughout the United States is less than three years.

These data demonstrate that a substantial proportion of America's youth are already infected with the AIDS virus and unfortunately continue to be ignorant of their ability to transmit this virus to others.

Another source of information that we can get a glimpse of what the epidemic is today is a result of the U.S. Army's HIV program. Preliminary analysis by Major Kelly at WRAIR demonstrated the overall prevalence of HIV infection among male soldiers currently in the U.S. Army is 1 in 500 and among female soldiers currently in the U.S. Army, is approximately 1 in 1,000. Again, the male/female ratio is 2 to 1.

Age is the most important variable with prevalence rates ranging from .4 per 1,000 for those under 20 to basically 3 per 1,000 for those 30 to 34. Again, analysis by race and ethnic group show that caucasians were infected on the order of 1.1 per 1,000; blacks, 2.6 per 1,000; and hispanics, 2.5 per 1,000.

If one was to do a by variance analysis, by race and sex, the prevalence rates range from .4 per 1,000 for caucasian women to approximately 4.7 per 1,000 for black males.

I think it is notable that currently the prevalence of infection among black and hispanic women in the United States Army on active duty is greater than that of caucasian males, 1.6 per 1,000 versus 1.1 per 1,000.

Also to interest to me is the fact that in 1983 and 1984, as a physician at Walter Reed, I had the opportunity to understand this epidemic largely because of the patient population I cared for. Half of the patients I cared for with symptomatic disease back then were, in fact, married men and women. I was forced to confront the grim reality of this epidemic and the impact it would have on the American family eventually back then.

Although many critics challenged our findings on heterosexual transmission, few acknowledge the uniqueness of the Walter Reed patients in 1984. That is, of the patients we cared for with AIDS, 50 percent were married men and women and actually 20 percent were female.

As a result of our HIV program, it comes as no surprise to us that over 40 percent of the soldiers currently on active duty infected with the AIDS virus are in fact married men and women.

The philosophy behind the HIV program simply put is that we believe that knowledge of HIV infection is better than ignorance of HIV infection. Each member of the U.S. Army is provided several and very important opportunities based on what I consider to be an important medical agenda. That is the opportunity if infected to receive medical care based on all the medical knowledge available in 1987. I think all patients should expect that same right -- The opportunity to face the future without blinders based on full knowledge of their body and the illnesses it has; the opportunity to no longer unknowingly transmit this deadly virus to another human being; and again, the opportunity at least to have the right to be informed, if they have been unknowingly exposed to this deadly virus.

The HIV screening programs were responsible for providing this knowledge 70 percent of the time, less than 3 percent of the total infections identified in the Army were established because of voluntary self referral testing. Actually, about 26 percent were established because a doctor put it in his clinical diagnosis at some stage. Therefore, greater than 70 percent of all HIV-infected individuals in the United States Army only became aware of this and then therefore benefitted from that knowledge as a consequence of one of the military screening programs.

The Department of Defense has a firm grasp on the extent of HIV infection in the Department of Defense. The U.S. Army also has in place procedures that will not only ensure earlier accurate medical diagnosis of HIV infection in its members but also to define the dynamics of the epidemic within the Army over time. Guess work will not be required.

Preliminary analysis of direct measurements of the incidence within the United States Army, a population where all the members are provided specific test linked education is in excess of 1 in 2,000. I believe that the data provided by the U.S. military provides America with its best guess, but it is still a guess. However, because of our selection biases, it should be recognized that the military data is likely to underestimate the HIV infection rates in the "general population" of young sexually active Americans.

What is the magnitude of HIV infection in America today? That was one of the questions posed to me. What will it be next year? How will it change? Is our current policy effective? How will we know?

In closing, I say that never before in the history of the human race has society been given the opportunity to have all the scientific knowledge at its disposal than at the time of the emergence of a new infectious disease. We have been given that rare and treasured opportunity and it is our responsibility not to waste it. In the year 2000, neither you nor I will be held accountable for whether or not an AIDS vaccine is developed or curative therapy discovered, these scientific advancements will come with time. No one knows when.

However, we will be accountable to Americans in the 21st Century, our children and theirs, for our utilization and implementation of the knowledge that was available to us in 1987. No matter how excellent the alibis for why we do not have a firm grasp on the magnitude of HIV infection in 1987 in our nation, we can obtain this crucial information. I believe it is crucial. We must define the extent of HIV infection, because if we continue to mount our national response to meet the challenge of AIDS in 1987 based on the cases of AIDS in 1987, we are doomed to failure. Our national policy should be based on the knowledge of the extent of HIV infection in our nation today and not limited to guesses, models or opinions.

We must ensure that we don't lose the war against AIDS just because we underestimated the enemy, or having committed all the necessary resources, apply them to the wrong front. The only way that I know to ensure the generations of the 21st Century, my children, our children, and beyond, that we confronted this virus to the best of our ability, is to first be sure that we accurately define the problem. This is the only way we can optimize our national response, providing all the resources when they are needed, where they are needed. Some people say it can't be done. I don't accept that.

I believe that with presidential leadership, we can assess what the extent of HIV infection is in our country today and we don't need to wait until 1990. This virus will steal the lives from more young Americans over the next decade than those who gave their lives to defend our country in the last four wars. We can hope for an early scientific breakthrough from Dr. Fauci and others, but unfortunately, the AIDS epidemic of the late 1990's has already occurred. However, the epidemic of the 21st Century is preventable. We have at our disposal all the tools we need to eliminate ignorant transmission of this virus today. Yet to date, we have failed to take charge and accept our responsibility to challenge this virus with the vigor and courage and the commitment that has made our nation so great.

We only need to use our knowledge to recognize our compassion, to exploit our ingenuity, to demonstrate our courage, and then to persevere. To paraphrase Teddy Roosevelt, "At best,

we will know the triumph of high achievement measured in the reduction of human suffering, or at worst with failure, know we failed while daring greatly." It is important that we recognize the problem for what it is so we can begin to develop a solution for a better tomorrow. I think we need to define the problem and remove the uncertainty. I think we should change the debate from is there a problem, where it is, how great is it, to now that we know the problem, what can we do.

In closing again, I think it is important to reflect on what I said before, more Americans will die over the next 10 years from this virus than lost their lives in the last four wars. Beyond that, the losses will probably be greater. You have to ask, what is an appropriate response to the reality of such a preventable loss of American life? I think we must recognize it as what it is, no matter how excellent the alibi's for why we have done so little to limit the impact this virus will have on our nation. We have all the tools to do it.

The epidemic of the 21st Century is preventable, yet we have been slow to take charge as I said. Public health is a responsibility of government, the cooperation to maintain public health is the responsibility of each citizen in that government. Any infectious disease knowledge of the infection is paramount to its control. Routine test linked education, I believe, to be the cornerstone of our medical national response. I would hope that soon every sexually active American will be given the same opportunities and provided the same rights as provided to those members of the Armed Forces. Vigorous leadership coupled with accurate education, classical public health measures will limit the spread of this deadly virus in our nation. First, we as a nation must define and recognize the problem as it is. We must have the courage to develop effective national policies and the resolution to mobilize the resources necessary to combat and defeat the enemy. Again, the epidemic of the 21st Century can be prevented and I firmly believe we can do it.

I thank you for the opportunity to share my point of view and I would just tell you there is an extensive amount of data available in the Department of Defense, far more than I could present to you in this short time and probably I am not the appropriate person to present it. We know exactly what it is in the civilian applicant pool and we have investigators following that. We know what it is in the Army and we have investigators following that. The Navy knows what it is and they have investigators following that. The Air Force knows what it is and they have investigators there. The National Guard data is coming in now. We are getting basically what the prevalence is in the National Guard by state. All the Army Reserves now are also being evaluated and all that is available, too.

I would encourage you basically just to make formal requests through the Department of Defense to really get access to all the data that is available. I don't even have access to all of it. There is an extensive amount of information that is available. Thank you very much.

MR. CREEDON: Thank you, Dr. Redfield. I think everyone on the Commission would agree with the fact that there is a problem. We certainly recognize there is a problem. We think the appointment of the Commission itself is a manifestation of the recognition of the problem by the President and others. I guess the important thing is having recognized the problem, what do we do about it. Do I understand correctly -- you feel there should be widespread testing outside of the military? Is that one of the suggestions you would make?

DR. REDFIELD: I think the critical thing you are trying to address today is what is the extent of HIV infection in the United States. You would like to have that information today. I sort of reflect the old idea, and you are a businessman, if you could have as accurate information as possible, you would like to have that information. I argue that I think we have asked the wrong question. We have assumed that we can't get the information. That has basically been the debate, not that we don't need the information. Everyone agrees we need the information but we have moved to modeling and guessing and what our best guess is.

The recent reports to the President suggest that we will have a family of studies that will estimate the prevalence and incidence of HIV infection in our country and the answer will be available in the year 1990. My position is that I really think that if we are going to have an adequate national response to this disease, not spend more money than we need, but not spend less money than we need, not put our resources in the wrong areas, the best way to ensure that we don't do that is to actually define the problem and know it, and I believe we can do that. Again, the first question is can we get it. You have asked how. I think there are several methods. One is, and I think it is really just a matter of time, that the medical community will begin to promote the medical agenda, and in fact, the practice of medicine will be such that many of these studies of routine sampling in VD clinics and drug rehabilitation clinics in different cities will be the practice of medicine, so we will have that operational data. Right now, we don't have it so we can design a family of studies. Eventually, I think it will become the practice of medicine, most doctors will recognize that they have the responsibility to accurately diagnose their patients.

MR. CREEDON: Eventually might be beyond 1990.

DR. REDFIELD: Again, that is where we come to the sample of studies. I would make the argument that you have two approaches. One is to basically do a sample of what I call high prevalent/low prevalent groups, i.e., those individuals who come into VD clinics, very similar to what the Centers for Disease Control designed as their family studies, VD clinics, drug rehabilitation clinics, hospital admissions. Those are individuals in the "general population," that would be likely to be the upper boundaries of the epidemic. Then you could also sample in different counties individuals who have physical exams, prenatal visits, football exams, and those could be the low prevalence boundaries.

Where we have the debate is I think the President could have this answer in six months, not in two and a half years. The other way one could do it is even probably more scientific, as you may argue that is a selective approach. I think if the President of the United States said he doesn't know if he needs to send a platoon to Butte, Montana and call up the Guard in New York or vice versa. Some people say we have a big problem. Some people would say we have a small problem. Some people say the problem is just here, some people say the problem is everywhere. I need to know to make the decision.

I am sure if he wanted to, and if he told the American people he needed their help to decide how much we need to put towards this virus and we did do a national survey and we did it by a non-government agency and we convinced people on both sides, and some people argue that people infected won't come forward, I think if the President of the United States said, listen, this is how we are going to decide how much money we are putting into this, if you are called on by an non- government agency to donate blood, totally anonymously so we can get a handle on it, do your part as an American and help us understand what our defense strategy for this virus will be.

I don't think the gay community won't come forward. I think anybody who thinks they are infected would come forward. I bet you if that was done, you would know right now what the prevalence of HIV infection is in the United States, and we could get some very talented epidemiologists to put the sample size together, and you would know that answer in 1988.

I think that is crucial and doable and I think one of the debates has been that it is not doable. I can tell you that if the President of the United States put it that way, listen, I have a problem, I don't know how much to put into it, I don't want to take away from these other important programs, but I don't want to undercut this epidemic either, because I realize the opportunity we have to confront this epidemic. As Dr. Primm said, it is a window of opportunity that is closing.

I think the American people would come forth, all the American people. Then you would not ask us to guess what we think the epidemic is today, you wouldn't be forced to guess. You would actually know. That's my position.

MR. CREEDON: How do the other panel members feel about that?

DR. RUTHERFORD: I agree with Dr. Redfield on this score. I think that a national serosurvey, a random household serosurvey is the only way to answer the question. I point out that in Mexico such a survey is going on now. They have enrolled 50,000 patients in six months and have 22,000 to go. Even next door, it is doable.

DR. PRIMM: Those people who have come forward in Mexico, are those people who have had high risk behavior?

DR. RUTHERFORD: No, it is a random household basis survey.

DR. PRIMM: Strictly voluntary?

DR. RUTHERFORD: Voluntary.

DR. PRIMM: You don't think they would be influenced by past behavior?

DR. RUTHERFORD: I can't answer the question directly. I am just saying that as an example of a nation that has gone on to try to establish these sorts of numbers, that is the kinds of numbers they are dealing with. Those are the sorts of timeframes they are dealing with.

MR. CREEDON: Dr. Sivak?

DR. SIVAK: I would agree also that if the proper studies were developed, to avoid the great potential for selection bias, this would really be the only effective way of determining the extent of the infection in the United States, rather than us sitting up here guessing with various models, you would have firm information as to what the extent of the disease is and prevalence of infection.

MR. CREEDON: Dr. Francis?

DR. FRANCIS: I agree. I think if the President took the leadership and if this was done in a very positive way--that this is a community problem of the entire American community, if not the world, and we are going to help, we are not going to jeopardize you, we are not going to do all the negative aspects that have gotten more air than the positive aspects about moving

ahead--this would be a critical move and would lead ultimately to the leadership that we need to have a positive American type spirit in the entire AIDS prevention program, including serologic surveillance.

ADMIRAL WATKINS: By that same token, Dr. Francis, we have just had a report from the Centers for Disease Control, who seemed to think they couldn't get there from here for a variety of reasons. You are connecting that.

What is the problem between what you are all saying here and what the Centers for Disease Control has just reported, that they can't really do this until 1990? Is it bureaucratic? Are there manpower obstacles in there? Is that what we are talking about? Are we talking about attitudinal changes necessary in the country to build the confidence that we can have the anonymity and the concern for the human rights, the civil rights aspect and protection of confidentiality, without discrimination.

I am trying to come to grips with this. We are hearing the words here and they all sound wonderful but the top outfit in the nation comes forward and says, there is no way we can get there from here until 1990 and we have to go through this evolutionary process going through 30 pilot cities, we have to have the updating of the family of surveys, and we want to run three pilots just before we run our seroprevalence survey nationally. We are confused now. What are you talking about?

DR. FRANCIS: The way I view it, if you went out there today, whether it was a government program or non-government program, government funded, private program, went out and asked people to stick their arms out, we have very strong data in California to show you are going to get a major bias toward low estimate of prevalence for people who are known high risk not volunteering for the program.

You need that leadership. That is true, if you did it today, if we just took the millions of dollars it would take to go out there and do that today, you would waste your money. There is no doubt in my mind, because the spirit is not there that this is something we are going to do for ourselves and as a community of Americans moving forward, instead of a community of Americans divided. Clearly, there are an awful lot of attitudes from wherever it comes at high levels, but it gets an awful lot of publicity that this is a divided country and we are not going to move ahead together.

ADMIRAL WATKINS: Why would CDC make that recommendation? Are they already factoring in their judgment that the American people would not respond to that leadership? Why didn't their recommendation say, Mr. President, with your

leadership, we could do this faster? It didn't say that. I don't really understand where CDC stands on this. If they are already biasing their own report to the President by not taking this into consideration, then it seems to me they have thrown a variable in there that we don't understand. You have a whole new variable thrown into their equation that I don't understand.

DR. FRANCIS: I would defer that to Jim Curran later. Sorry, Jim.

MR. CREEDON: Dr. Fauci, could we hear from you on this question?

DR. FAUCI: I agree completely that we need the kind of data discussed just now by various members of the panel. I might add that what we also need if we are going to tell the President that this is the kind of thing we need--I think we also need a strong move towards what we don't have legislation to protect not only confidentiality but the rights of individuals who turn out to be positive, because what Dr. Francis said, if in fact you can guarantee in statute, that an individual will not be discriminated against, if in fact that person turns out to be positive, and you would offer counseling, then you would have the coming forth of individuals who would volunteer to take part in these mass screenings.

If you don't have that kind of protection, people are not going to come forward. I think all you have to do is look at the amount of discrimination against the male homosexual population in this country and IV drug abusers. You are going to see the same thing, individuals afraid to lose their jobs, afraid to get thrown out of school, afraid to lose their health insurance. If you can guarantee that won't occur, I think you can do it in six months. We need a law.

DR. WALSH: You are not going to guarantee that by legislation. Legislation doesn't guarantee attitudes. I think the point that the Admiral makes is a sound one to this extent, that you have the example of the military giving us a rather sobering report, while here we are getting publicly displayed reports that rectal gonorrhea is down, so let's run a flag up, everything is fine. That's misleading when one then hears what Dr. Redfield tells us.

Were they misled by the fact that a certain high risk group in a certain city has less rectal gonorrhea, yet we read from Dade County or wherever it may be, that there is a 35 percent increase in sexually transmitted disease. Obviously, our education program isn't working either.

I think what we are getting at is maybe the word "mandatory" is a horrible word. I think what they do in the

military is what I call "conditional testing." In other words, if you want to get into the Army, one of the conditions is you have to take a test and you make a free choice if you want to get in the Army.

Why not, if you are going to buy life insurance, if we want to buy life insurance, the condition is we take a conditional test, not a mandatory test. We can buy life insurance if we are willing to do it. Instead, we get legislation that is so heaped on this emotional latitude of discrimination and so on, that we are going to protect the few and jeopardize the many. Somewhere along the line, I think CDC does have a real opportunity to create a proper climate for the President and the legislators to do exactly what you want them to do. I think that is what the Admiral is talking about.

MR. CREEDON: I thought Dr. Redfield's proposal was this be completely anonymous.

DR. FAUCI: If it is completely anonymous, then what you are going to have to have is the cooperation of people wanting to get involved in a completely anonymous study. If you can convince them that in fact they can trust that, then I would be absolutely in favor of doing that study right now.

DR. WALSH: That's the answer.

DR. REDFIELD: If I could just clarify the position. I think it is important about what you are trying to study. What I think the President of the United States needs to understand in how to mobilize the resources of this country, he needs to know basically what the prevalence of HIV infection is in our country by age, sex, race and geographic location. It doesn't need to be a scientific study about the behavioral characteristics of Americans.

What the President of the United States needs to know now is simply what is the extent of HIV infection in age, race, sex, geographic location and probably geographic location is going to be of far greater importance than sex or race. I think by doing an anonymous survey by a civilian, non-governmental, private sector group, that we have talented people that could put together a random sample of this country which we sell. If you don't come forward, we are going to underestimate this problem. I think that many people that say the government is not responding to the AIDS epidemic will have to deal with that in their own minds.

MR. CREEDON: Dr. Curran is here from CDC. Would you like to make a comment?

DR. CURRAN:: I want to comment a little bit on the process by which Dr. Mason and the rest of CDC and the National Center for Health Statistics came to our conclusion that pilot studies would be needed. It was not done based on our presumption of the power of the presidency in influencing Americans to participate in the survey. It was rather based upon data that came from a pilot study of the health interview survey in which some 50,000 Americans that were randomly selected are being asked specifically now whether they would participate in such a survey. The preliminary data is that only 67 percent of them said they would do so on an anonymous basis.

This fundamental problem is not the ability to bleed Americans. There are probably going to be 20 million Americans bled this year, many of whom will be in the military, many of whom will be blood donors, many of whom will be in family surveys, many of whom will be tested in doctors' offices.

The question is how can we take that data and tell you what the age, race and sex specific prevalence of the virus is. The problem is that when you look at the populations that are bled, you come up with different answers.

If you take the military applicant data and you extrapolate it to the general population of the United States, you come out with a number something like 300,000. All of us on this panel would acknowledge that is far too low, because we don't know what the extent of deferral from applying to military service is. That is after doing 700,000 tests a year. The number of tests done doesn't give you the answer.

If you take American blood donors, 20 million tests a year, and you extrapolate that to the American population, you come up with a number of 90,000 infected Americans. We know that is wrong.

If you take hospitals and Job Corp applicants, we come up with a number of something like 700,000. We think that is closer. We don't even think that is right for a number of reasons. Active intravenous drug abusers, for example, can't get into the Job Corp.

The problem is you do need to know who isn't participating in your survey and what their risk factors are compared to who is participating in your survey and what the risk factors are. We shouldn't confuse the use of testing for prevention purposes, for insurance purposes, for health care purposes, with the need for an absolutely fundamentally good scientific survey.

A survey could be done very quickly. We could go out and test 1 million Americans. I think it would be garbage. The

reason I think it would be garbage is we have had three major consultation groups in of people who do these surveys and they tell us there is too many uncertainties to know whether what we got at the end was accurate or not.

What we want to do is get good information and do it as quickly as possible. We don't want to do it as quickly as possible and then find out whether it is any good.

MR. CREEDON: I think to some extent we will be exploring this subject a little bit further after lunch.

DR. CURRAN:: I suspected you would. My tongue was nearly bit in half.

[Laughter.]

DR. REDFIELD: My only point is not for us to waste American dollars, but I still think the ability of this President to generate an understanding that we are all in this battle together and that we need to define the extent of the problem and he needs to ask for the help of the American people, if he only gets help from 99.999 percent of the American people or even less, I think you will have a better understanding of the AIDS epidemic.

ADMIRAL WATKINS: Let me close out by saying, Dr. Redfield, that one, I can assure you the President is on your wave length. Back in May, he asked for this. In October, he was shocked to find out we couldn't get the information on recommendations from his best advisors for a couple of years. He doesn't like it either. He wants to move and he is waiting for guidance from somebody to say, this is the package, this is the strategy we have to get that data, and this is what has to be done and here are the obstacles to doing that.

That is why we picked it up as the first element in our near-term interim report that we plan for February, so that we can get through these hearings which are absolutely critical to carry out the rest of our charter which cannot be done in many cases for health care facility planning, for financial planning across the board, that we are chartered to do, until we get this information.

That is why we are working on this issue today. We need to take what your recommendations are and what the general consensus is and try to find the practical strategy to execute that so we don't have the individuals that we talk to on the street, and we have been out and I can tell you that many of those people will not participate on the statement that we can guarantee you anonymity at this point in time. The credibility isn't there yet.

How do we build that credibility is extremely important. That is the strategy we are looking for, not the rhetoric alone that gets to the bottom line before you can transition and get the American people to believe that they can have an anonymous test that isn't going to affect their jobs, isn't going to affect their health care, the discriminatory things that frankly people with AIDS tell us about in spades.

We can't sit here and say we can do these things and have these people come forward. Then we will find out the survey was inaccurate and that isn't going to help us either. How do we get from here to there is the reason we are holding these hearings. Those are the kinds of things we need to talk about. I would like to close it out now, because we are really behind schedule.

MR. CREEDON: I would like to ask Dr. Vogt from the Vermont Department of Health to proceed.

PRESENTATION BY DR. RICHARD VOGT

DR. VOGT: Mr. Chairman, Commissioners, thank you for the opportunity for testifying before you today. I have been asked to provide you information about the accuracy of HIV antibody testing in both high and low prevalence populations. To review, there are two testing procedures used to attempt to identify persons infected with the AIDS virus. The first procedure is the ELISA test, which measures human immunodeficiency virus antibody levels in serum. The ELISA test was originally designed to be as sensitive as possible to pick up all those persons who may have antibodies to the virus so that there blood could be removed from the blood donor pool.

As a result, this test creates a significant pool of individuals who may not have the antibody but test positive anyway. Therefore, it is recommended that the blood sample be reanalyzed with the ELISA technique to determine if the sample is repeatedly positive. If a sample is repeatedly positive through two analyses, the level of suspicion is raised that this may be a positive test.

If the blood sample is repeatedly positive on ELISA, the blood sample is subjected to another test, the Western blot method. This is a very laborious and costly procedure which identifies specific particles of the HIV antibody in a person's blood, as is shown in the next slide. Each band shows a reaction to the antibody to the specific components of the HIV virus. Researchers currently feel that positive tests of both the ELISA and Western blot should be considered as probable laboratory evidence for infection with the virus. However, as we shall shortly see, the accuracy of that determination depends on

who was tested. If the test is considered positive by the testing laboratory, the person submitting the sample would be notified of a positive test result, and the person is counseled in the likelihood for exposure to the virus. Turning to the accuracy of the HIV tests, all laboratory tests need to be evaluated for their accuracy and are usually measured against the comparison called a gold standard. When the ELISA test was originally licensed, they were evaluated against patients who have AIDS and evaluated against the Western blot test.

Most determinations about accuracy of HIV antibody tests are made by comparing ELISA with Western blot procedures. Test comparisons with the recovery of the virus, the true evidence of infection, are technically difficult and usually do not enter into the discussion about test accuracy. One of the dilemmas that confuses all discussions about HIV test accuracy concerns the disagreement within the scientific community about what constitutes positive Western blot tests. The next slide shows the different criteria for test positivity by different scientific groups using this test around the country. As you can see, the bottom shows the Red Cross, DuPont, ASTHO, NIH, and the others are reference for what may be considered positive for HIV.

Laboratories also use different preparations for conducting their Western blot procedures. It is no wonder that there has been a great deal of discussion about the accuracy of HIV antibody testing when we have disagreement over the criteria for the positive Western blot test. Most statements about accuracy of laboratory tests are made in terms of two determinations: sensitivity and specificity, as shown on the next slide. The gold standard is listed at the top of the 2 by 2 square, and the test result is listed on the lefthand side. The numbers of the tests for each category will be placed in the respective cells.

The published sensitivities -- that is, C/A+C -- or the chance of correctly identifying a positive test in those who have AIDS, the specificities, D/B+D, or the chance of correctly identifying a negative test in those who do not have AIDS, of the ELISA test look fairly good. The range of published ELISA sensitivities is 93.4 percent to 100 percent, and the range of specificity ranges from 99.2 percent to 99.8 percent. There were similar agreements when comparing the ELISA test with the Western blot analysis.

When considering whether a medical test is meaningful in high or low prevalence populations, you need to turn to two different measures of accuracy, as depicted on the next slide. The comparison cells are the same as those used for sensitivity and specificity determinations, but different equations are used to determine a more important measure, predictive values. Predictive values answer the following questions. What is the

chance that a person with a positive test is truly infected with the virus? That is A/A+B on the slide. Likewise, what is the chance that a person with a negative test is truly free from the virus, D/C+D on the slide?

These are very important questions to be answered when a patient wants to know the meaning of his test result. Whereas sensitivities and specificities remain relatively constant with both low and high prevalence populations, predictive values are widely different, depending on the characteristics of the population screened.

This stands to reason, because if you screen a population that has no chance of being infected or inflicted with a disease, all the positives generated from a test will be false positives, since no laboratory tests or series of tests are perfectly accurate.

For example, you could test 1,000 men to see if they were pregnant. The laboratory tests will identify a few that will be test positive, even though there is no possibility that the positive results will be accurate. In this situation, we would refrain from testing an inappropriate population such as men, so we would fail to generate erroneous information. We need to consider the test accuracy with the combined procedures of both the ELISA and Western blot tests. Sequential testing will tend to further limit the number of false positive tests but will not eliminate them. The number of false positive tests for both ELISA and Western blot will still escalate when you screen populations without much infection.

This is an exaggeration of testing errors that occurs with any laboratory tests or sequences of test which tends to be magnified in populations that are sparingly infected.

The next slide helps to describe the value of the combined ELISA and Western blot analyses when they are used to screen different groups. The likelihood of combined correctly positive tests is depicted on the vertical axis. The horizontal axis is the estimated infection rate in different populations. Populations with a greater likelihood of infection will tend to be further to the right on the horizontal axis.

Two assumptions for the sensitivities and specificities of the two tests are given in the legend. The exact values do not have that much importance; however, the curves that they generate help demonstrate the principle that the value of combined positive test results will deteriorate if they are used to screen low risk populations such as those seeking marriage licenses or routinely seeking medical care.

Looking at this situation in another way by using data in an article published by Meyer in the New England Journal of Medicine, the overall best estimate of the false positive rate for the combined tests, the ELISA, first ELISA, second ELISA and confirmatory Western blot is estimated to be one per 20,000 samples in that article. The article also states that seroprevalence of a low prevalence population, such as female blood donors, is also approximately one per 20,0000.

That means that for every 20,000 tests run, there will be a total of one false positive test and one true positive test. Therefore, half of all positive tests will be inaccurate when one screens this population; that is, the positive predictive value of the test is 50 percent.

Sequential testing presents another dilemma that often fails to be addressed when HIV testing is discussed. Persons may be ELISA test positive but Western blot test negative. It is difficult to sort out whether the patient is infected, and the result is frequently considered indeterminate. The likelihood of an indeterminate result increases dramatically when populations who are unlikely to be infected are screened.

Using strict criteria for Western blot positivity has the appeal of minimizing the number of false positive results; however, this will increase the number of indeterminate test results as well. One can see that one runs the real risk of generating inaccurate seroprevalence data when low risk populations are screened. Even more importantly, one also runs the risk of labeling someone positive who is not really positive if widespread screening of low risk populations are undertaken.

The tests as developed are extremely useful when used to screen appropriate populations; most notably, those persons who are engaging in high risk behaviors such as intravenous drug users and persons who are having unprotected sex with multiple different sexual partners.

But the tests can and will fail when applied to incorrect populations. Tests have to be close to 100 percent sensitive and 100 percent specific to be applicable for all groups. The ELISA and Western blot tests are not that accurate for universal applicability.

Thank you.

MR. CREEDON: This is a very important discussion and one which I, at least, have some difficulty with. If you test a million people in a vulnerable group and a nonvulnerable group, will the number of false positives be the same?

DR. VOGT: When you say "vulnerable" and "nonvulnerable", I'm sorry, I don't understand.

MR. CREEDON: Well, high risk.

DR. VOGT: High risk groups? The number of false positives, no, they will not be.

MR. CREEDON: The number of false positives will be different?

DR. VOGT: That is correct. The number of false positives will be far greater in your low prevalence population.

MR. CREEDON: Why is that?

DR. VOGT: It's a function of the testing scheme. What you do, if we could go back to -- if you could turn the slide back on -- The estimates of high risk -- if you could put people in the high risk category in the right-hand side of this particular graph and low risk people on the lefthand side, you can see the likelihood of coming up with an accurate positive test dropping dramatically. The predictive value of the positive test can also be equated with --

MR. CREEDON: I guess I don't understand why. I understand what you're saying, but I don't understand why.

DR. VOGT: It's because you're generating so many individuals and you have so few positive tests that you're going to identify that the possibilities of having a laboratory error increase dramatically.

MR. CREEDON: Why?

DR. VOGT: It is the situation -- if I may explain, it's the same situation of testing 1,000 men for pregnancy. You will have perhaps one, two or three individuals who will -- they are at no risk for infection or affliction with the disease. They will have one or two perhaps that will test positive under those circumstances. Under those circumstances, 100 percent of those individuals will be test positive and false positives.

DR. CRENSHAW: So what about women? How many false positives for pregnancy? I think that's the point that you're getting at.

DR. VOGT: In women, it's going to be a lot lower. You're going to have a situation there where you're not going to have the false positivity rates that we're talking about. We're talking about -- I'm not an expert in pregnancy exams, but I use that as an example. I would say that we're talking, depending

upon what stage of pregnancy you're in, in the vicinity of zero to 5 percent tops.

DR. SERVAAS: Under that theory, could we ask Dr. Redfield to explain in actual practice how he didn't have the false positives? How is it that the Minnesota Blood Bank doesn't have the false positives?

DR. REDFIELD: Again, it depends when you're dealing with this in terms of how you set your criteria in terms of your philosophy. The Department of Defense's philosophy is that specificity of this test will be maintained.

If you want to say in your philosophy that you want to maintain sensitivity at the expense of specificity, then I think I could probably come up with data consistent with what was presented.

The Department of Defense, in applying this test in low prevalence populations, has developed an algorithm that maintains specificity.

DR. WALSH: What is the difference between specificity and sensitivity, please?

DR. REDFIELD: Basically, specificity -- sensitivity is the ability in population -- Don's the epidemiologist. I'm the clinician. If he wants to describe it, but it's the ability in a general population to tell those individuals who are infected that they are infected. Specificity is the inability in a population to tell those individuals who aren't infected that they aren't infected, and you look at the accuracy of that.

So that, for example, when we use sensitivity -- if we wanted to say, okay, we wanted to make sure we picked up every single person that was infected even if we knew we had some false positives, we could set criteria that was more sensitive at the expense of specificity. Or we could set criteria that is extremely specific, recognizing the tradeoff is we lose a little bit in sensitivity. As we've decided to go in to provide test-linked education to low prevalence populations, we've said that the critical thing to do is to maintain specificity at all costs.

MR. CREEDON: Suppose we were going to test two groups of a million people each, and we said we want to maintain specificity? Would you get a different result in a high risk group and a low risk group, given that criteria?

DR. REDFIELD: I personally don't think you would, but, you know, again, I don't want to put myself off as an epidemiologist. We have tested 6 million people. We have

assessed our false positive rate in the low prevalence populations. We're not guessing what it is. We've done it.

Again, I've told you that I will provide the testimony of Colonel Burke that he provided before the Congress of the United States. It was one in 135,000 when we basically assessed it in our first assessment. We assessed exactly what it is. Rather than debate what we think it may be, let's go out and measure it. I do agree, though, without careful quality control and criteria to maintain specificity, we could have a real serious problem on our hands, and I don't think we disagree. That's a fact of the case, and we need to get the specificity into the program before we really expand outside.

ADMIRAL WATKINS: But, Dr. Redfield, you said earlier that if we just got some leadership on this thing and got it going and we calmed people about anonymity, we could get all the data we need. Now we're saying that we're possibly not ready because of the false positive problem that we may have, that we don't have the quality control out there, and that we have to say part of the strategy to get ready to do the very thing you want to do may well have to be a reappraisal of where we are on the quality analysis of the testing we'd be doing.

So you see, what I'm saying is we need to get out of the rhetoric phase and into the specificity in this context of what steps do you have to do to get to the point where we're not going to shock a lot of people.

DR. REDFIELD: Can I respond? Can I respond, because I did have a response, and I didn't get an opportunity to do it. I will provide you an outline of a program that really went to the family of studies as is proposed in the document that went to the President. The only difference was the time course for providing the answer was six months as opposed to two and a half years.

I would like to just comment. From the time the Deputy Secretary of Defense Taft decided that the civilian applicants of the service would be tested for the AIDS virus, it was six and a half weeks. He actually said it would start October 1st. We all said it was impossible because the cost of the test was too expensive. We couldn't quality control it, and logistically it was going to be a nightmare.

All I know is on October 15th we did get a two-week extension. By November we had tested the first 50,000 samples. Within the next month, we were at a quarter of a million samples a month that were being tested basically with a 24 hour turnaround turn at less than $5 with an accuracy rate of 1 in 135,000.

So I agree, we need to do that. Where I debate it, I don't think it's going to take six months. I think with leadership it could come in place in six weeks to eight weeks to 12 weeks, and that's where I think the difference is.

MR. CREEDON: Dr. Sivak.

DR. SIVAK: I would just like to make a comment. Included with my written statement was an article that Dr. Wormser and I wrote about the predictive value of the test. In there is a very in-depth explanation of Bay's Theorem, which is a mathematical theorem to which all this information comes from.

Basically, the specificity does not change from group to group. What happens is the proportion of individuals that truly have the problem to begin with.

Considering the pregnant situation, 1,000 men who are not pregnant obviously, if the specificity of the test was 95, 5 percent of those 1,000 men would be identified erroneously as being pregnant, or 50.

Women who subject themselves to tests for pregnancy, let's assume that 70 percent are, in fact, pregnant. We know that by the gold standard of the crying baby nine months later. Hence, there are only 300 out of that group of 1,000 who are not pregnant. Five percent of 300 is 15.

So in two different groups with a different probability of having the condition being sought to begin with, the specificity doesn't change. The predictive value changes.

MR. CREEDON: That was the main point I was trying to make. That's true.

DR. VOGT: Thank you for clarifying that.

MR. CREEDON: You said it better than I.

DR. FRANCIS: Again, to move away from the theoretical aspects, none of us are laboratorians where we deal with them day in and day out.

This is not a pregnancy test. The ability of these refined tests using modern biochemical techniques to differentiate between antibody negative and antibody positive is absolutely phenomenal.

Now, you use a combination of tests, whatever combination specific labs use, when you pool the data together and they share their hard specimens, I think it's the consensus, as I understand it from the laboratory people -- and I certainly

find it from the person who has to refer to the problem specimen individually, if we're dealing with the individual -- that we've got this refined now where, as Mike Ascher at the State Health Department in California would say, the sensitivity and specificity of this test have at this point exceeded our clerical mistakes in the testing procedure.

I think that military experiences in those laboratories that have done large numbers of specimens who have to really work at it, because many of them at this point have to tell the individual -- that's what Bob was talking about, making sure that a positive is a positive -- they have to tell the individual the result, so then you really have to know this because it's a very important piece of information.

It's still an issue that you have to keep in mind, but that is not the issue in my mind regarding either a treatment prevention program or a serologic survey. If you get the right laboratory doing these, we can tell you what's positive and what's negative.

DR. VOGT: I think the key question is if you get the right laboratory doing it. Right now, we don't have that capability.

The other issue, too, that is often skirted in this is that what do you do if you're going to set up your very strict criteria for your positivity, what do you do with the ELISA individuals who are positive and the Western blots who are negative?

We really don't know what to do with that population.

DR. FRANCIS: We do in the laboratory. You add another test to it, and you figure out your algorithm, and you can find out who's positive and who's negative.

MR. CREEDON: This is very helpful. I guess what we want to tell the Commission is that they're taking their own lunchtime if they ask questions now.

[Laughter.]

DR. WALSH: I want to ask just one question.

First of all, you know, there are multiple laboratory tests that we do in medicine. I gather from what you say, this is among the most accurate of all that we do in medicine.

If we applied your reasoning, we would abandon all laboratory testing in general physical examinations. I mean, why not?

Secondly, I would like a comment on the false negative, because I think that's more important than the false positive if we're going to combat this disease.

What is the incidence of the false negative? Isn't it relatively the same?

DR. VOGT: Did somebody work this out? I have worked this out using one of the JAM articles using viral recovery in terms of --

DR. FRANCIS: You can't use that. The sensitivity is too low.

MR. CREEDON: Dr. Sivak.

DR. SIVAK: Based upon a mathematical model again, sensitivity and specificity does not change according to the group that you're testing. What simply changes is the proportion of the individuals in the group that are likely to be infected before you test them.

Just as the predictive value of a positive test, in other words, the likelihood that a positive test is truly positive, goes up amid high risk individuals, the likelihood that a negative test represents a true negative goes down in high risk individuals.

In fact, in some high risk group members, the predictive value of a negative test may be as low as 90 percent. That means that 10 percent of individuals who are high risk who are infected may be infected, but yet their test would be negative.

If you test a low risk population, the predictive value of a negative test, the likelihood that an individual who tests negative is truly negative, is 99.999 percent. It's highly accurate when the prevalence of the disease or the pretest probability of the infection is low.

When you have prevalences as high as 70 percent, say, in a test that's only 95 percent sensitive, in that population specifically the predictive value of a negative test may be as low as 90 percent, indicating that up to 10 percent of individuals who test negative in that group are really positive, and those negatives are false negatives.

DR. WALSH: Dr. Redfield.

DR. REDFIELD: Just to follow up, because what you see based on that logic is that as the seroprevalence of the

infection goes up, the power that serological testing for HIV has given us to basically allow people to know if they're infected or not will begin to go down.

Again, one of my points that I try to make over and over again is that the way we have approached this in the old days is we define sort of a risk group. The risk group here, if you're antibody positive for the AIDS virus, the person at risk for being "seronegative" uremic is the individual who has had sexual exposure to somebody who is basically infected with the virus.

So I still make the point that serological testing for the AIDS virus coupled with public health follow-up basically is one of the mechanisms that we have until there is a scientific solution to identify the seronegative uremic and to have some handle on this "false negative."

MR. CREEDON: Ms. Pullen, Penny.

MS. PULLEN: First, I'd like to ask Dr. Redfield whether he can be with us this afternoon while Dr. Curran is testifying.

DR. REDFIELD: Unfortunately, I would love to hear Dr. Curran's testimony, but we are having a program review today by the Public Health Service, and I have to be back there.

[Laughter.]

MR. CREEDON: Each of the panelists is certainly welcome to stay this afternoon because we will be involved in related matters.

MS. PULLEN: I have another question, please.

Dr. Redfield, would you please provide us with a county-by-county breakdown throughout the United States of the infections that you have found in your testing of this low prevalence population?

DR. REDFIELD: I will make the request of the Department of Defense to provide that to you and give you the updated data. I'm sure that they will provide that, and I will provide that to you.

DR. SERVAAS: Dr. Redfield, you said that it was $4, and you had two ELISAs and two Western blots in the Army and the Department of Defense.

Now, Damon Laboratories, I believe, a commercial laboratory, did this for that low cost when Dr. Vogt said it was very expensive.

My question is this. If they are no longer doing Department of Defense tests, isn't this perfectly good organization available to do the surveys for that price if we did enough of them? They are accurate, and we hear that in Minnesota they have a good lab and in Iowa they have a good lab.

Could you tell us how many good labs are there available if we wanted to do these surveys?

DR. REDFIELD: Again, I think that Admiral Watkins has sort of jumped out at me there if we're not ready.

The point is I think that most laboratories could be quality controlled to the level of the Department of Defense laboratory within about six weeks of some effort.

It's something I think, when someone said let's do it, it could be done.

The Damon Labs, please don't tell me they're not doing some of our testing. We have multiple programs they're still involved in.

But I think a number of labs could do it if you got the standards the Department of Defense has developed. They work, they're doable.

I think the other point, in follow-up, about the real problem, when you're testing a quarter of a million samples a month of more, it's not that the test is having any problems. I agree with Don Francis. This is the best test that we've ever had in Madison. It's the fact that our technicians or our clerks make a mistake.

That's why the Department of Defense requires, before someone's told that they are infected with the AIDS virus, to have two separate samples drawn on two separate occasions. When the first one is positive, they're not told they're infected with the AIDS virus. They're told they have an abnormal blood test, and we do a quarter of a million samples a month and we may have made a mistake, and we now need to do another test. That test is done, and the results are usually back within 72 hours.

So I think the technology is there. Again, at a federal level, I think there has to be some oversight on the quality control.

MR. CREEDON: Dr. Primm.

DR. PRIMM: I just wanted to ask Dr. Redfield a question, since he won't be back here this afternoon, at the expense of starving a little longer.

That is, isn't your testing of military recruits a bit biased in this sense -- they have to have a certain education standard, they can't be intravenous drug users, they can't be homosexual or bisexual?

Isn't it also so that this is sort of creaming that whole group when they come in to you initially? Isn't it also true that if you look at the progressive age and seroprevalence or seropositivity among that group, that if you looked at ethnic groups, blacks and Hispanics, that it would be far different and far greater in terms of what you have listed here on the demographic characteristics?

DR. REDFIELD: My answer to your question is yes, it's a biased group. In addition to all the other exclusions, you have to actually have a high school diploma. That's why I think relying on the military data basically probably underestimates the epidemic in certain areas.

DR. PRIMM: That high school diploma has to be a diploma, not a GED?

DR. REDFIELD: My understanding now is it's a diploma, but, again, I don't set the program. It used to be an equivalency, but it's a diploma. We would have to check on that and get back to you. But I agree with you. It's a biased group, and I think we underestimate the epidemic.

MR. CREEDON: Admiral Watkins.

ADMIRAL WATKINS: We are going to recess the morning hearings now. We want to thank each one of you for coming. I think it's been an extremely worthwhile exchange for us. As Mr. Creedon indicated, we'd love to have any of you back this afternoon, and when the level of intensity gets high and you want to stand up, much like one of our esteemed candidates for the presidency did the other night and as Dr. Curran did earlier, we would hope you would stand up. You're also asked to be continuing witnesses by exchange of correspondence with us. We've asked you for certain information. We want to have the dialogue between now and the time our report come out.

Remember, we're trying to get to the President with some recommendations about prevalence, seroprevalence surveys in the country, between now and February, so you have an opportunity here to give us, a strategy that would take us through the very obstacles you just mentioned. Dr. Redfield's comments are the

first time I heard it would take six weeks to straighten out laboratories so we can feel that the false positive rate would be within bounds.

You see, that's an element that we need to hear about. So maybe if you have a plan that would get to the six-month seroprevalence survey in the country, let's have the plan, because we would like to review that.

So, please, we'd like you to continue the dialogue with us, and thank you very much for appearing today.

[Whereupon, at 12:55 p.m., the hearing recessed, to reconvene at 1:45 p.m. this same day.]

AFTERNOON SESSION

[1:45 p.m.]

MR. CREEDON: I would like to call the meeting to order, if we may. All the Commissioners are here except Ms. Gebbie. We started the session this morning talking very generally about some of the questions we are trying to get at through these series of hearings today and tomorrow; really pretty basic questions such as how many people have the virus now? How many do we think will have it between now and the year 2000? How reliable is the data on which the estimates are made with respect to the incidence of the virus? How reliable is the data on the estimates of the way the disease is likely to spread? How many who have the virus will develop some form of AIDS or other kind of medical condition requiring medical care and attention? Who are the vulnerable groups, the at-risk groups, and are those groups growing or diminishing in size? To what extent has the virus spread to the heterosexual community other than partners of IV drug users? What are the stages of the disease and the time periods between when the virus is incurred and the various stages take place? Are we doing enough as a society to find out about the virus? Do we need to do tests other than those that have been done or are being contemplated? Recognizing that there are conflicts and differences of opinion and that the situation is fluid and complicated and so forth, what about testing? Is testing reliable? Should we test large portions of the population that have not been tested and so forth?

These are the kinds of questions that the Commission is trying to form a judgment on, and we very much appreciate each of you being here and helping us out. I think this morning, while there are necessarily overlaps and conflicts between and among the different categories this morning, we've tried to focus more on the data base quality and the staging of the disease, and I guess the people with us this afternoon are public health specialists. But we recognize that this is not tightly compartmentalized, and is overlap, as Dr. Curran recognized this morning, between at least two other groups. So if we may, Dr. Curran, we'd like to start with you. The process will be to have each person giving testimony speak for such time as he or she would like, and then we'll have some questions from the Commission.

PANEL TWO
PUBLIC HEALTH PERSPECTIVE/FUTURE TRENDS
PRESENTATION BY DR. JAMES CURRAN

DR. CURRAN: Thanks, John, Mr. Chairman, Commission members. It's my privilege to be here today. You could tell I could hardly wait to speak and came early. I'd like to

congratulate you on your preliminary report, and what I've seen in the press about it and a lot of the language that gives confidence to all of us that you've got your priorities in good shape. I'd like to thank you for making incidence and prevalence of infection a priority and congratulate you for making intravenous drug abuse a priority, I'm sure over the strong objections of Dr. Primm. I'm going to say one sentence about that, and that's all, and that is that intravenous drug abuse is at the very root of our epidemic in heterosexual men, women and children in this country. The concern, if we have one, about the heterosexual population has to begin with intravenous drug abuse. You've got the priority straight, as far as I'm concerned.

What I'd like to do in a few minutes here, since I know that all of you have the President's report and virtually no one else in the world does, is provide you with a few charts that I've organized in a way to go through rather quickly; say a few words in preparation of looking at these reports; and answer three things that came up this morning that I wanted to mention that won't be answered by going through the reports. First of all, I think there's some confusion in all of the discussions -- many of the discussions that I've been involved with in the last few years about AIDS. Because of the amount of concern about the problem, which is appropriate, people are always looking at half empty glasses and half full glasses, and it is very difficult to say something is half full and half empty. So you usually end up with a lot of people telling you it's empty and a lot of other people telling you it's full. That's going to happen and I'm sure it's happened already; but what is being done, what is not being done, and what do we know and what don't we know about the extent of the problem in the United States? I would like to say that I think we know quite a bit about it already and that we're on the right track to learning what we need to know.

The second thing is the issue of what are the key questions. Let me just reemphasize them from what you've said. The key question is not only how many Americans are currently infected with the AIDS virus, how many of them will progress to AIDS, but how many Americans will become infected with the AIDS virus. That is something that is a very, very difficult thing to know. It's a little bit like projecting the economy for the year 2000. It's going to depend upon the behavior of Americans, among other things, over the next 15 years. The fundamental thing that is going to determine how many people get AIDS after the year 2000 will be how effective we as a society are in preventing the virus infection between now and then. I think the incidence question and how effective are current programs and evaluation of behavior changes are really what really gnaws at all of us in terms of what we need to know. No modeler who is honest or no epidemiologist who is honest is going to say the glass is all full in terms of what we know. It's very, very empty in terms of what we know about behavior change, our ability to create

behavior change, our ability to deal with things like heroin abuse in our society, et cetera, et cetera.

We do know, I think, fairly well, how many Americans are currently infected, and we will be on track to learning an awful lot more through the surveys that are proposed and under way in many communities throughout the country. The last thing is that I'd like to stress -- well, first of all, let me run through a couple of quickies. The TB situation in New York City is very important, and I wanted to alert you that this week in the MMWR there will be a report from New York City on tuberculosis and AIDS in that city. It will be coming out tomorrow. Actually, it comes out today. Tuberculosis is up 35 percent in New York City over the last two years, and this is the first year in the history of my life when there has been an increase -- last year was the first year there was an increase in tuberculosis nationally. Almost all of that increase can be attributed to HIV infection in Florida and New York where the biggest TB increases have occurred. So that is a very important problem that Dr. Primm brought out, and there's a report on that in the MMWR this week. The next thing is that the report that many of you have referred to will also be published next week in the MMWR and will be available to virtually everybody then. We are scheduling the Christmas breaks to try to get it out, but that will reach 100,000 health professionals and others. The second to last thing was the issue of the case definition. You are faced with many different classification systems for infection. AIDS surveillance is aimed at reporting as honestly and accurately as possible the severe morbidity and mortality due to HIV infection. That is something which is much more easy to get at because it results in hospitalization, it results in death, you can validate that with death certificates and things like that.

The word "ARC" has never been defined by anybody. It means something different to everybody, and no honest classification system even contains it. So when you even ask the question does this contain ARC, no one can answer because no one knows what ARC is. ARC means AIDS-related conditions. Severe ARC is included in the new case definition that CDC puts out; that is, the severe weight loss, wasting syndrome and someone who has evidence of infection with the virus. Our attempt with the consultants that we had in was to capture everything that results in death or severe hospitalization morbidity that can be attributed to AIDS. How well did we do that? Well, the main breakdowns are the places where the medical system breaks down or reporting breaks down. It's not a function of case definition. The case definition is pretty good in capturing that. The problem is people like drug addicts who die in the streets of unexplained pneumonia. In New York City, a recent report from

Dr. Stoneburner saying that mortality was up in inner city drug abusers who didn't go to the doctor who couldn't have been diagnosed with AIDS to begin with.

The second problem is the fatigue in reporting. The same health departments and the same doctors that we've got putting everybody on AZT and taking care of them and being concerned about their social and medical welfare are the same ones that are reporting. Now we're going to be asking those same people to do our serosurveys. We're right in our priorities, but we can't expect surveillance of AIDS and reporting of AIDS to be as good as it has been in the first six years. This year, we're starting to see longer reporting lags and less adequate reporting, and we have ways, we hope, to deal with that. The last thing is the question of test reliability. That has to be broken down into two things: the test itself and how well it's performed. I think Dr. Vogt and others gave very good examples. Dr. Sivak gave a very good example of how good the test can perform when it's done by very good laboratories, and most of the tests had been performed by very good laboratories. When you consider there have been 40 million blood donations tested in the United States, six million military people, millions of people in the private and public sector and relatively few problems about the test itself when it actually gets back to the patient, then things must be done well in those good laboratories. However, not all laboratories are good, and not all batches of the tests have the same reliability. It's important to continue to evaluate laboratory performance. CDC has a laboratory performance evaluation program, and we now have 750 laboratories in the program. All of the laboratories that are involved in public testing and counseling can be involved in this and are encouraged to be involved in this program at the CDC.

In addition, all the laboratories involved in this family of surveys will be involved in this. The answer to this at the back end is Dr. Walsh's answer. It's up to the doctor. That's one of the key problems we have in prevention and control of AIDS in the United States. We have a test. We test somebody and, unlike the military where everybody is guaranteed a doctor because they have guaranteed medical care, when you test somebody in another circumstance, there may not be a doctor to be the final bottom line. This is not something that the laboratory should decide. It's like a positive VDRL. There are a lot of positive VDRLs for syphilis. When you have one, you don't go to the laboratory or get a letter and say should I commit suicide or shouldn't I and have somebody go back to the lab and tell you. You go back to your doctor, and your doctor helps evaluate whether you might be infected, whether auxiliary tests are needed, whether testing is to be repeated. A lot of drug abusers and others don't have such doctors. So, ultimately, there needs to be a doctor for all the positives and probably for a lot of the negatives. That's a fundamental problem in our lack of

distribution of adequate available medical care for the people who are infected with the virus.

Now, let me get to what I was going to say, and that was to go over is the issue of several epidemics. One of the things that's very confusing to try to talk about is that we are obviously looking at several epidemics when we're talking about AIDS. There's the epidemic of AIDS, which looks like the numbers of reported cases in your first chart. We know that that's not the epidemic of HIV infection. The easiest way to conceptualize this is to think about hemophiliacs. You can change the scale a little bit, but we know that hemophiliacs are essentially not being infected with the AIDS virus at all anymore. There might be a case report here and there, but essentially there is no epidemic of HIV infection in hemophiliacs. But the curve of AIDS looks like this, so we know that in hemophiliacs, this tells us absolutely nothing. If the United States epidemic of HIV were like hemophiliacs, then you wouldn't have any kind of prevention message. All you'd have to worry about is treatment and health care and things like that, caring for the families and transmission to sex partners. So we know that we're not measuring the epidemic of HIV infection when we look at AIDS. That doesn't mean that it's not useful. It's extremely important to look at from the point of view of health care. It's extremely important to look at and compare to what we know about incidence and prevalence of HIV to see if there are any big surprises. If there aren't big surprises, then that can be reassuring in a sense, but it is a different epidemic.

The second epidemic is the epidemic -- the differences in epidemics are differences by risk groups. What is the epidemic of HIV infection in homosexual men? What is the epidemic of HIV infection in San Francisco homosexual men versus Chicago homosexual men and homosexual men with a graduate degree and homosexual men who have no high school education and black and Hispanic homosexual men and white homosexual men, 40 year olds, 18 year olds? What is the epidemic in intravenous drug abusers? What is the epidemic in sexual partners in heterosexual men and women?

Finally, there are going to be differences in geographic areas, different epidemics by city and by state. The ratios that Dr. Sivak talked about were derived from New York City primarily for New York State, but they're obviously going to be somewhat different in different communities where the infection came later and AIDS has not caught up as much. That's analogous to saying that the changes that he describes over time are differences throughout the country geographically. You could say that the epidemic in the midwest started a few years later than the epidemics on the coast, for example, to be simplistic about it. With that, let me run very, very quickly through these charts that were meant to accompany the report. I think they are

part of the report but some of them aren't. The first refers to sources of information of data on AIDS cases and HIV infection for the report. I'd like to point out that as much published and unpublished information as could be found was put into the report, and the information was not largely CDC information. It was collected by CDC, the Alcohol and Drug Abuse Administration, NIH and by state and local health departments. Most of the information was not published and was shared very generously by the people who did it. In addition to national reporting of AIDS cases, there are surveys and studies in high risk and general population groups. They will include STD clinics, drug treatment centers, hemophilia treatment centers and a variety of sources of information down the line there.

The next graph is an epidemic curve of reported AIDS cases. To date, there are now 48,200 cases of AIDS reported; approximately 20,000 cases in the past 12 months alone. Now, of that 48,250 cases, about 2,200 fit the revised case definition of AIDS. That doesn't mean that the 2,200 were all diagnosed since September 1, however, because many of these are backlog cases which had been reported to CDC previously and which had driven us to change the case definition to begin with. But we are keeping very good track whether cases fit the old case definition or the new case definition so that we can tell that.

The next graph is the so-called coolfont curve, in which yellow represents the numbers of cases projected based upon projections from previously reported cases. From that, it was estimated that there would be 270,000 cases diagnosed and ultimately reported through 1991. You can see by the black dots that the black dots are still within the 68 percent confidence bounds. They are about 5 percent lower than would have been predicted in the past 16 months but still pretty close.

The next graph is curves of males and females with AIDS Now, the female curve is made larger so that you can display it, but basically 92 percent of cases are still reported in men, and you can see from this that in both groups, the 20 to 50 age group is most often affected. But if you look down you can see that the women are about five years younger on average than men. That has several implications. One, I think, relates to the fertility of the women. Since they are quite a bit younger, that puts them smack in the middle of a very fertile age group for having HIV-infected infants.

The next graph is a pie chart of the race specific percentages of the U.S. population in the 1980 census as well as the race specific percentages of AIDS patients through November 2nd. You can see basically about a two and a half-fold increase in the crude percent for blacks over the population estimate and about twice as many two and a half-fold also in the Hispanic population. I will discuss this briefly later. The next graph

is the Venn diagram by transmission category of AIDS cases through the first 44,000. I think there's a few things remarkable about this, having shown this Venn diagram now for about six and a half years. I can say that it hasn't changed very much over the six and a half year period. Most of the patients with AIDS have been homosexual and bisexual men who are not intravenous drug abusers; the intravenous drug abusers have remained a very steady one-sixth in the heterosexual intravenous drug abusers and about 10 percent of the homosexual and bisexual men have such a history.

Another way to look at the issue of heterosexual AIDS is to remind ourselves that everybody who isn't homosexual or bisexual is heterosexual. That means that 27 percent of the cases are heterosexual men and women. You can see that in the heterosexual men and women group, the vast majority are intravenous drug abusers. That should tell you about where the heterosexual epidemic is now and where you should look for it to go first and why we're seeing such high rates of infection in pregnant women in cities where intravenous drug abuse AIDS has been a problem. It is not at all surprising to me to see 1 to 4 percent prevalence rates among pregnant women in cities like New York City, Baltimore, Atlanta, and people shouldn't be surprised about that. Nor is it surprising to see high rates in minority military applicants from those same cities where there is an enormous problem of AIDS in intravenous drug abusers.

The next one is a state map of AIDS cases. I'd like for you to look at the next two at the same time. I want to apologize for having different denominators. I did that mostly to confuse you. The AIDS case map is the cumulative numbers of AIDS cases per million population. The second map is the prevalence of HIV antibody in civilian applicants for military service in the United States. The Department of Defense has worked very closely, has been very, very generous and worked very closely with CDC in providing up-to-date information on the prevalence in military recruit applicants. You can see by these maps that the states that have the high rates of AIDS also have high rates in military recruit applicants. There's no surprises from these maps. Generally, if you were to make this per million population, the national average is about 200 per million for AIDS, and it's about 1,500 per million for military recruit applicants, about seven times higher.

Military recruits, as Dr. Redfield says, represent an absolute bottom line low estimate of the number of infected Americans. So we can put military recruits as the absolute bottom line estimate of infected Americans at around 350,000. It's got to be higher than that, and I could make the point that it's got to be higher than 2.5 times that high. It cannot be lower because these people are self-deferred from even attempting to get into the military to begin with. But basically, you can

look at the ratio by state, by city, by county and not only get the number of HIV antibody positives by age, race and sex for a county but also the numbers of cumulative AIDS cases by age, race and sex by the county. The key point that we make in a collaboration between state health departments and the Department of Defense and an outside contractor will be to determine what risk factors the military recruit applicants have. This is really not adequately known yet. It's irresponsible, in my view, to conclude that they all acquired it through heterosexual contact, or most of them did. It's also irresponsible to conclude that none of them did or that we know. We simply do not know. That is a very high priority for determining. There have been selected studies, but nothing on a national basis yet. That's sitting around OMB now waiting for clearance.

The HIV prevalence among Red Cross blood donors is the next chart, and this shows the difference between the rates in all donors and the rates in first time donors. You can see that the rates in all donors have steadily declined from about 4 per 10,000 or .04 percent down to what is now about .015 percent. This has been largely by the cleansing of the donor population; repeat, donor population. The first time through you get all the positives out, and you tell them not to donate again, and then as all people who donate blood know, they keep your name and they get a hold of you, and they keep getting a hold of the negatives over and over. So 80 percent of the donors on a given basis are repeat donors. One would expect them to have a much lower rate after they've been screened a couple times. You can see that that's encouragingly getting lower. The first time donors are a better estimate of what's going on in donor deferral and what's going on in the other population. You can see that bounces around a little bit, probably related to changes in donor recruitment for employment purposes and summertime when it goes up for hepatitis and other things when everybody takes their vacation and they have to go elsewhere to get blood because the companies don't have as many donors, things like that. It's not totally known, but these rates are very, very low, at any rate.

The next two surveys, I want to mention very quickly. This is the numbers of surveys and studies from which CDC was able to obtain data on antibody prevalence in homosexual and bisexual men. This represents some 25,000 or 30,000 homosexual and bisexual men and shows a range with most in the 20 to 50 percent level. It's important not to just average those surveys out and say that's the average of the country de facto. But in homosexual and bisexual men, that's less of a problem because there's not that much difference in the country. But in intravenous drug abusers, there's a big difference, and the next chart I want to point out is misleading. The largest number of surveys in intravenous drug abusers would suggest that the prevalence in 33 surveys is between zero and 4 percent, and there's very few in the 30 percent and above category. Now,

don't be misled to think that most intravenous drug abusers aren't infected, because the first cities to do the surveys and the first cities to recognize the problem were cities like New York City, Washington, D.C., Baltimore and New Jersey and San Juan, Puerto Rico, where probably 75 percent of the heroin abusers in the country live. They did their surveys. Everybody said, hey, we better find out what's going on in our population in 1986 and 1987, and the cities where there's a much lower rate of infection came in later. So if you were to weight these by the numbers of drug abusers that each survey represents, you'd find a much higher rate of infection in intravenous drug abusers. I think cities that have a 5 percent prevalence in IV drug abusers have an opportunity, but they shouldn't be all self-congratulatory and say, well, we only have a 3 or 4 percent infection rate per year. Ask Dr. Primm and others in New York City what the hell they're going to do when it's 50 percent and try to prevent it. When you have 3 to 5 percent, you have an opportunity, but it's going to take a real concerted effort to deal with it.

The next chart is a comparison of what the intravenous drug abuse problem largely means to blacks and Hispanics. You can see that looking at the epidemic of AIDS cases and the epidemic of HIV infection, there would appear to be a difference in the relative risk for intravenous drug abusers. Let me explain that in those tested, in those populations tested for HIV, you can see that blacks and Hispanics are 3 to 12 times more likely to be infected with HIV. With AIDS, it is as high as 25-fold for children of IV drug abusers, sex partners of IV drug abusers or for heterosexual IV drug abusers themselves. That's factored in by multiplying the difference in prevalence among, say, black IV drug abusers compared to white IV drug abusers and simply the number of IV drug abusers in the black community and the white community. I guess what I'm saying is that IV drug abuse itself as a societal problem is a disproportionately black and Hispanic problem, and the rates of infection are also higher in those groups. You multiply them together, and you have a very serious problem in black and Hispanic minorities. The next graph is pretty but also confusing. It's got a lot of purple bars around the United States.

To summarize this, this summarizes the prevalence in homosexual men, IV drug abusers and hemophiliacs around the country. It shows that the hemophiliacs are all about the same everywhere, and that's because they all became infected the same way, through national distribution of contaminated products for about a five-year period from the late '70s to early 1980s. So one would expect them to have about the same rates throughout the country. Homosexual men, there's about a two-fold difference from about 20 percent to maybe two and a half or 50 percent around the country; not as big a difference as there is in IV drug abusers where there's a massive difference, but the East

Coast cities and San Juan, Puerto Rico, have very, very high rates of intravenous drug abuse positivity, high prevalence rates. The western cities like New Orleans and others, again, have very low rates now. But that's not likely to be true forever.

The next chart is a summary, a very quick summary, of the HIV prevalence in high risk and general population groups. Now, the prevalence in the general population group should not be confused to saying that we know how those people got it. When you interview first-time blood donors, for example, who represent the .04 percent, you find that about 85 to 90 percent are homosexual men, intravenous drug abusers or sex partners of one of the above. So that even that low prevalence rate does not necessarily represent random unexplained spread.

The next graph is another somewhat confusing curve of what we know about HIV incidence. Now, again, the number of people becoming infected with the AIDS virus is one of the most difficult things for any of us in public health or epidemiology to determine. I call it the epidemiologic equivalent of finding a safe and effective vaccine. I do that on purpose because it's almost impossible to know on a national basis. People don't have symptoms. All they do is sero convert. They don't go to doctors, and you sort of have to be there to watch their antibodies come up on an individual basis. We can get that from the cohort studies. From the large cohort studies in homosexual men, there's evidence that in those cohorts who are being followed and who are not necessarily typical of other homosexual men, there's been some consistent declines that have been measured. On the one hand, you can say the cohorts are not typical. I think the pattern is encouraging that they all show declines. On the other hand, you can say the so-called Hawthorne effect is what we want. That's the kind of attention we want our prevention programs to give. We want people to be in cohorts, followed and counseled to change their behavior. So even if it is atypical, let's do more of it. It doesn't have to be a million dollar study. You don't have to draw blood every week, but you could do the same kind of tender loving care that gets people to have this kind of infection rate. Now, it's still not down to very low. Three percent, on average, is not low enough. If I had a 3 percent chance of getting AIDS virus infection this year, I'd think that was terrible. So I don't think anybody in the gay community or anybody here ought to say that's good enough; nor is it representative of all the subepidemics that I talked about, black and Hispanic minority, homosexual men, young homosexual men, people who haven't decided whether they're homosexual yet, et cetera.

The next table represents a smattering of the so-called surrogate information, and this is primary and secondary syphilis rates in homosexual men from 1980 to 1987 in six cities

in the United States. It shows, comfortingly somewhat, that syphilis rates are down in homosexual men in all of the cities. I used to run the program in Columbus, Ohio about 15 years ago, and we had lots of syphilis in homosexual men. There was one case in 1987. So people working in the field are speaking empirically. They're saying, hey, wait a minute. I was involved in a Hepatitis-B vaccine trial in San Francisco also, and in doing that, I went out to the San Francisco Health Department VD Clinic, which had the very highest rates of Hepatitis B in the entire industrialized world in homosexual men. Seventy-five percent were infected. The thing was conducted in the VD clinic there, and they had 400, 450 patients a day. You couldn't get in the place. They had to move to a much larger building. I was out there about three months ago, and there's nobody there. The clinic is almost empty. People are not getting VD in these communities.

You can say is this an education campaign? Does it result from simply being absolutely scared to death and watching all your friends die? But many people in the homosexual community have changed their behavior. It's been replicated throughout the industrialized world. Everybody hasn't. I'm concerned particularly about adolescents and about minorities, homosexual and bisexual men, and I'm also concerned that 3 to 4 percent a year is not low enough. But the glass is at least half empty in this regard.

The next three tables represent the estimate of infected Americans done in two ways. The first table was the Coolfont estimate, which takes arguably bad data about the size of the population groups. No one has any idea how many homosexual men there are in the United States, but that isn't the only important question. The question is how many are homosexual and are acting out in their homosexual behavior with someone else who might be infected. That's the true denominator. But these were the best estimates in June of 1986 of the experts that were assembled, and that's where we came out with the one million to one and a half million estimate. This has been scrutinized in a variety of different ways. Using the same method, taking the best prevalence estimates from the 300 or so surveys that are summarized in the report, you come out with a number that's about the same in 1987. What that means is, on the second chart, that 1.5 million was too high in June of 1986. It doesn't mean that a million was too high in June of 1986, but we believe that 1.5 million was too high in June of 1986.

The last chart, I'll just explain -- you can sort of ignore the numbers except to notice that they go from 276,000 to 1.5 million. This represents the ability of modeling to tell us the number of infected Americans. There are now something like 60 to 65 scientists throughout the industrialized world again who are actively involved in scientific modeling of HIV. They will

do that no matter how definitive our numbers are, and they will continue to help talk about spread and things like this. These three models, these three curves, the logistic curve, the log logistic and the exponential curve, all fit reported case data very, very well. They're all compatible with what's happening with AIDS. In predicting the number of infected Americans using these three models which all fit, you can see the range goes from 276,000 to 1,650,000. The major reason for that is that virtually nobody gets AIDS in the first two years or three years, so none of these models can tell you who's been infected since '84 or '85. In fact, isn't that the question we really want to know most? Who's getting infected now?

So the models may be able to help you, and it might be somewhat reassuring that they come out 1 million to 1.5 million when you use the best estimates, but they're only telling you the point prevalence, and you know that they're telling you nothing about how many people have become infected, which is a very important point. The last table is the comprehensive HIV surveillance plan that CDC is conducting with the nation's state and local health departments. These will be concentrated in 30 standard metropolitan statistical areas. Lest you think that this is a small 30-city survey, let me remind you that these 30 SMSAs have about 80 million people living in them, and they account for about 85 percent of the reported AIDS cases in the United States. So there's a lot of places we aren't sampling, but the top 20 cities in the country have about three-quarters of the cases. So we're getting a lot of the places where the problem currently is. The intention is to blanket these cities with a large variety of surveys which will allow the people concerned about public health in those cities and in those states to develop their programs and conduct them.

The last thing I'd like to say about these serosurveys is they do far more than come up with a number. They get people to take the problem seriously. Atlanta, Georgia, at a hospital in Atlanta, Georgia, people had a couple cases of pediatric AIDS. The director of OB/GYN there did a very bold thing. She decided she would offer routine testing and counseling in her prenatal population. A lot of people for a variety of reasons are afraid to test pregnant women and tell them their results because they're afraid of trying to deal with the positives. They don't know what to do. Well, this director of OB/GYN found that 1 percent of the pregnant women were positive. It only had three or four cases of perinatal AIDS. Now all of a sudden she knew that 75 women would be delivering babies who were positive that year in her hospital. It forced a lot of things to happen--education of the doctors and nurses in her hospital to protect themselves from infection; consultations with the family planning clinic to say, hey, why didn't we stop them from getting pregnant or give them advice and do some testing in your clinic before they reached our clinic. So these surveys which will result in

testing of 1.6 million very high risk people, a lot of whom don't have any idea that they're at risk or aren't infected, is going to drive a lot of public health action, and it's going to drive a lot of positives into the health care system. There's going to be a lot of people here who need doctors, who need medical care, who need hospice care, and a lot of these people are going to need drug treatment. So these surveys are going to do more than just tell us where the problem is. They're going to lay it in our lap.

Finally, the last page is propaganda. This is a chronology of major events specifically focused on those that the Public Health Service has been involved in over the last six years, beginning with the first cases that have been reported, the discovery of the virus and a few other things. Thanks. We probably don't have any time for questions.

[Laughter.]

MR. CREEDON: In the discussion this morning with the panel that was here, Dr. Redfield from Walter Reed seemed to think that the best way to find out how many people have the virus would be to do, I guess, a nationwide survey. What is your reaction to that in relation to what CDC is proposing as outlined here?

DR. CURRAN: It's partly a question of terminology. We are doing a nationwide survey. I consider doing 30 surveys and 30 SMSAs a nationwide survey.

MR. CREEDON: I assumed that they knew --

DR. CURRAN: There will be a national random probability sample household survey. That is also being undertaken beginning with the request for contract in the next week to go to an outside contractor, a nongovernmental contractor, to look at the feasibility of that. In my view, what will happen with the national probability sample is two things. One is that we will find that there will be some nonparticipation, and we hope with the pilot studies to find out whether the nonparticipants are more likely to be infected than the participants. If we can do that and proceed with the study, then we will have a decision to make about how much money we want to spend on it. If we want to do a study of, say, 50 to 100,000 Americans and if we got even a 100 percent participation and everybody was infected, and let's say the true number of infected Americans is one million, the confidence intervals around that million would be about three-quarters of a million to 1.5 million. So you can see the problem we get into. If you want to narrow that range from a million to 1.5 million to, say, 1,200,000 plus or minus 50,000, you're going to have to test about 300,000, 500,000, a million people in the United States at

the cost of perhaps $500 each. Now, if you're going to test that many people --

MR. CREEDON: Why? Dr. Redfield said it was costing them $5.

DR. CURRAN: It costs them $5 for the laboratory part, but he's already hired the doctors and nurses and interviewers and the people --

MR. CREEDON: Maybe we could get the Army to do it for us.

[Laughter.]

DR. CURRAN: They don't have a good reputation in the gay community. But you're right, though. Maybe we could discharge the people in the survey into the Army for medical care would be a way to do it. I think the Army program is very useful from telling us how many infected Americans there are, but it's a low number. Now, the Job Corp applicant data would give you numbers that are about 2.5 times as high as the Army. They do not exclude homosexual men from the Job Corp. They are slanted toward minority people, but even when you adjust that for the United States population, you come up with a rate of about 2.5 times as high as the military.

We already have information down to the census track level on age, race, sex data on a quarterly basis from all American Red Cross blood donors, U.S. civilian military recruit applicants, Job Corp applicants. We have information from about 20 million tests a year by census track, and we can track that over time to see what happens to it as well as track the prevalence in each of these surveys over time. Now, the problem is in some areas, the prevalence goes down. The prevalence of HIV infection can't go down because the only way out is death. You can't -- increases in prevalence like Dr. Redfield was talking about, you can say, well, the 20 year olds have a higher prevalence than the 19 year olds, so you subtract 19 from 20 and you get a one-year rate. That sounds okay for one year, but when you think about that over a 10-year period, you're saying that a 29 year old who applies to the military has the same characteristics as a 19 year old. We know that's not true. Someone who is 29 is quite different from somebody who is 19. So it has to be made up of yearly differences that are cumulated over a 10-year period. So there are problems with indirect interpretation of incidence by doing those kinds of subtractions.

Another problem is that when you look at the military recruit data over two and a quarter years, there's actually been some decline. Now, how do you explain a decline in prevalence in

the United States? It doesn't make any sense. The only thing you can explain from that is that they have been more effective in deferring people from applying to the military. The people who are in risk groups, for example, have caught on and don't apply, and they tell their friends. They go back to their communities and say go get tested first before you apply or things like that. That would be my first explanation. The answer is we don't know why the prevalence is starting to go down or staying flat. So it's important not to overinterpret data just on the incidence, too. That probably was fairly confusing.

MR. CREEDON: I think not, but it does raise a question as to the reliability of the data.

DR. CURRAN: The reliability of the prevalence data?

MR. CREEDON: Yes.

DR. CURRAN: The total number of infected people?

MR. CREEDON: Right. Which, from our standpoint, it seems to me we have to try to find a reliable figure.

DR. CURRAN: The best that can be done is a range of estimates of the total number of infected Americans that cannot be below three-quarters of a million and is very, very unlikely to be higher than one and three-quarter million.

MR. CREEDON: One of the witnesses this morning, a doctor from New York He said it was a little bit higher.

MR. CREEDON: He seemed to come in at 2 million. I suspect we may have at least one witness this afternoon who would come in with a much lower figure. I don't know. It's kind of frustrating.

DR. CURRAN: It's very hard.

MR. CREEDON: The range is so big, and the consequences of the range being so big is that you can't get a handle on the cause.

DR. CURRAN: I think it's very hard to get lower than a national probability sample would give you. I think if we did a national household survey now, we'd come out with a fairly low estimate. That's the purpose of the pilot studies, to see how low that would be, because we know that many people in risk groups would not participate from the surveys that have been done. How can we increase the participation rate by people in risk groups? Can we or do we need to test people separately?

Are the homeless more likely to be positive than the people who live in households? Things like this.

MR. CREEDON: Well, one of the suggestions of Dr. Redfield was that the Commission urge the President to get on television and say this is important, that in order to get a handle on --

DR. CURRAN: I think any presidential -- see, I think that the focus on our household survey to provide an answer is if the question is how many infected Americans are there and you want to know that within a range smaller than a million to a million and a half, which I think is adequately defended in the CDC report, and you're not that interested in incidence, how many are becoming infected, which is the next question --

MR. CREEDON: I think we are interested.

DR. CURRAN: But I'm saying that if that is of secondary importance than the number, than a household survey, in order to do that, would have to be extraordinarily large as well as being accurate. There are major concerns about its accuracy because of participation rates. There's a large number of Americans who wouldn't let you draw their blood no matter who you were. They don't want their blood drawn. They don't want their fingers stuck. So you have to ask the question are people who give you their blood and people who don't give you their blood more or less likely to be infected. How do you find that out unless you get their blood, for example? You can say you don't need to have risk factor information, but if you have risk factor information on blood donors and military recruits and you know most of them who are positive turn out to be homosexual men and intravenous drug abusers, you do a national survey that's anonymous and you find out that the number is fairly low and you don't have any risk factors, is that doing a service to the American public by saying we have all these infected people out there who don't acknowledge any risk factors? Whether they acknowledge them and whether they have them is two different matters. I don't think any president could get a homosexual man to acknowledge these risk factors. It's too big a risk. It's not worth it. You might lose your job. It's too tough.

A lot of people don't want to know if they're positive. These things all apply to surveys as well, but I think we know how many Americans are infected within a small enough range, and we know how many people are currently hospitalized, and we're continuing to keep track of how many people are hospitalized. It's time to get down to the business of how effective we are in preventing infection and figuring out ways to measure how many people are becoming infected with the AIDS virus and to do that at the local level where the prevention programs need to occur.

MR. CREEDON: Cory?

DR. SERVAAS: Jim, could you tell us, the OB/GYN in Atlanta, did she have any problem in getting the pregnant women to have their blood drawn? Do we know how many refused?

DR. CURRAN: A very small number.

DR. SERVAAS: We used that information and referred these women to doctors?

DR. CURRAN: They come in for their prenatal care, they have a very good high risk prenatal testing program at that hospital. They offer all kind of STD tests, chlamydia, gonorrhea, syphilis. They just offer this as another test. Many of the women who were positive were intravenous drug abusers. Many were not but lived in the same communities.

DR. SERVAAS: Do you have any problem throwing away the positive serum and not notifying the people -- do you have problems with this?

DR. CURRAN: I have a lot of problems with knowing the results from someone's test and not telling them. There has been some confusion about blinded testing and non-blinded testing. Blinded testing refers to getting serum that are obtained for some other purpose for which there is no identifier. You couldn't tell the person if you knew the result because you don't know the person's name, you don't know whose it is. These surveys are often done for a couple of reasons. One is the survey can't be done any other way. Many of the surveys that have been done, that have been blinded, simply would not have been done because of all the barriers to getting testing done with people.

The original survey, I believe, in the emergency room, that Dr. Baker was involved in, was a blinded survey, where they took excess blood drawn from patients coming in. That survey was another example of a survey which really drove medical care and drove the emergency room physicians to deal with the problem. Had they had to go through an institutional review board and get permission from each emergency room patient with a trauma, who came in comatose from an accident, to draw their blood, the survey never would have been done. People never would have realized that a high percentage of people coming into the Hopkins' emergency room were positive and nobody would have begun to deal with the problem. Once you find out the results, that tells you there is a problem you have to deal with. I'm the first one to argue that you ought to go back to that same

emergency room, that same OB clinic and start doing something about it, testing, counseling and family planning referral, sex partner referral and other things.

Dr. Baker can tell you whether they are doing that now. That is not easy, even after you find out. It is the first step in many cases. A lot of times the blood is drawn for other purposes, like a VDRL. Blood may be drawn for PKU filter paper testing as in Massachusetts, where excess blood is available, you can find out which hospitals have higher rates of infection in their pregnant women and then you can go in and target those hospitals for active programs to prevent perinatal AIDS and prevent sexual transmission. That may be the first step. Once you know a person's name, you have to tell them.

MS. PULLEN: Are you familiar with the CDC sponsored study that is about to take place in Illinois prisons on the rate of transmission in the prison? Do you know how that study is designed?

DR. CURRAN: Generally; yes.

MS. PULLEN: I have been told that the blood that is drawn initially is preserved for testing later, when the second blood sample is drawn and tested. Could you tell me why the blood isn't being tested when it is first drawn?

DR. CURRAN: CDC is involved in a number of surveys in prisons. We are working with the Bureau of Prisons and federal prisons to look at the prevalence rate in prisons. About two years ago, there was a great deal of concern, there began to be a great deal of concern about HIV infection in prisons. All of the prison consultants, medical consultants and legal consultants, got together and shared and devised their policies. Dr. Axelrod may want to discuss this more in the New York State Prison. CDC took I think a fairly aggressive approach about what ought to be done. We made an argument that what is good for the civilian population is good for the prison population. The prison officials felt there were additional problems in terms of staffing prisons, in terms of isolation of inmates and other things and they said the question they wanted us to help them answer was what is the incidence of infection in prisons, how many people become infected in prisons, and that the only way that could be done would be to draw blood on entry and exit from the prison, counsel people on exit, not test the blood until exit.

The survey was designed. It has taken about a year to get approval by the various IRBs and others to get this done, but it has finally been funded in Illinois. This next year we will be doing a survey with the National Institute of Justice of the prevalence of HIV infection in at least 10 or 12 state prisons.

I still personally believe that prisons and jails represent -- I mentioned to Dr. Primm before -- there are probably more intravenous drug abusers in prison or jail than there are in treatment programs. Isn't that a sad statement if it is true? Somebody ought to find out if that is true. Isn't that something? We are trying to prevent an epidemic and there are more people in jail and prison who are intravenous drug abusers than we have in treatment programs. If we have all of them now and most of them are going to get out in two years, why don't we do something about it in the next two years? They are there. What an outreach program -- prison. We have them. You can't find them on the street. You have them in prison and jail. All you have to do is test them and put them in a treatment program, give them testing and counseling and a good doctor.

MS. PULLEN: Amen.

DR. CURRAN: The reason the prisons don't want to do it is because they don't know what to do with them.

MS. PULLEN: If you don't find out who is seropositive, you don't do anything with them either.

DR. CURRAN: That's right. The prisons that have done that, like the Georgia Prison, has tested their prisoners. Generally the prisons that have been most active in testing prisoners are those that had the fewer cases of AIDS. The prisons that have very large rates in IV drug abusers are those prisons on the East Coast, whose states I won't mention, but Dr. Axelrod is sitting next to me, and I believe they are afraid to test the prisoners because they wouldn't know what to do with the tens of thousands of them that are positive.

MS. PULLEN: So is Illinois.

DR. CURRAN: Georgia has tested people because they have only had a handful of AIDS cases and they found about 150 so they have got a prison for HIV positives. They have filled up one, now they are going to go to another one and they are talking about building one. Rather than treatment programs, we will have prisons for IV drug users.

MS. PULLEN: Let me ask you one other question about the Illinois prison survey. It was my understanding that something like the first 3,000 inmates that were taken in after the survey was set up were to have their blood drawn initially and then again in a year or two. Are you aware that the survey is limited at this point to three adult male correctional facilities and therefore, does not include any females or juveniles?

DR. CURRAN: I am not aware of the details of who is included. The experience has been the overwhelming majority of prisoners with AIDS have been men. If you were going to start in one place, I would start with men. I think it would be good to include women if that could be done.

MS. PULLEN: Juveniles may not have a long enough time.

DR. CURRAN: I don't know whether that was Illinois' choice or whether that was a funding issue.

MS. PULLEN: I would be interested in knowing whether that was Illinois' choice or whether it was the CDC's decision.

DR. CURRAN: If the State of Illinois would like to change their policy and test all their prisoners on entry and exit, we will give you the money that was going to be used for the study. You can do it that way. That isn't going to happen until you build more prisons.

MR. CREEDON: If the Commissioners are agreeable, I would propose that we move on now to Dr. Axelrod. Dr. Curran is still going to be with us, I take it, and we can come back and ask him questions after we have heard from the other speakers. Dr. David Axelrod, who is the Commissioner of Health for New York State.

PRESENTATION BY DR. DAVID AXELROD
NEW YORK COMMISSIONER OF HEALTH

DR. AXELROD: Thank you very much. I appreciate the opportunity, Mr. Creedon, Mr. Chairman, members of the Commission, to present a view from one of the states which has clearly been affected to the greatest degree by the AIDS epidemic. The questions, Mr. Creedon, which you have been putting to Dr. Curran in the last several moments I think are indicative of the problems that are being faced by public health officials because of our lack of information. The difficulties are multiple, as you have heard from Dr. Curran. There has been some confusion as to what the questions are that we as public health officials should be answering and we are not sure or have not clearly identified the importance of those questions and their relationship to the public health initiatives that need to be pursued. When you talk about the information, the accuracy of the information, the problems with the interpretation, I think that is indicative of the fragmented incrementalism, if I can call it that, that has characterized a large part of the AIDS initiatives that have occurred in this country.

I think the Commission has an opportunity to bring about a major transition with respect to federal policy and to provide for the kind of epidemiologic data that are going to be

required for us to attack a public health problem. Epidemiology is the basic tool of public health and I think our ability to attack it has been hampered by the kinds of questions that you have in fact raised in the course of your questioning. We need a very concerted effort, a clear definition of what the hierarchy of priorities are with respect to the information that is going to allow us to take the kinds of actions that are absolutely essential if we are to deal with the AIDS epidemic that we are faced with at the present time more effectively. There is clearly a need for information. Again, I think in the questions you were asking Dr. Curran, you also identified a very major problem with respect to epidemiologic curves, subepidemiology, epidemiologic populations, and what we are ultimately dealing with in any epidemiologic event is a series of infinite subpopulations, no matter how it is defined. In this instance, there may be a real and valid reason for separating some of our subpopulations and dealing with them perhaps separately in terms of their predictive ability. I think we have to be cautious in dissecting the epidemiologic evaluation which we are doing into an infinite number of subpopulations and thereby defeating the purpose of some of the questions and supposedly some of the answers that we need to address.

The Commission, I think, also has an opportunity to foster the development of a policy which requires participation at every level, whether it is federal, state, local, there does need to be a clear commitment for a greater level of assessment, a greater level of monitoring, a greater level of surveillance than we have had up until now. We also have to provide for an assurance that there are services that are going to be available within the community, that they are going to be accessible, that they are going to be of high quality for all citizens, and to develop a capacity building process, which I think again provides the Commission with an unique opportunity.

MR. CREEDON: When you talk about federal, state and local cooperation, what type of a vehicle do you envision for having that happen?

DR. AXELROD: I think the Commission has recognized the need for a single coordinated effort rather than the kind of fragmentation that currently exists with respect to the large number of entities that are involved, whether it relates to drug and substance abuse, which is a very major arena, whether it relates to the activities of the Centers for Disease Control, whether it relates to the Public Health Service generally, and clearly there have been conflicting messages from within the federal government with respect to the appropriate role of preventive activities that are the appropriate purview of public health officials throughout the country. I think there are conflicting messages. They serve to demean public health generally. They serve to confuse the process and raise serious

questions about the credibility of many of us who are engaged in efforts to change the process and to certainly have an impact on the populations with respect to behavior modifications. I think it relates to technical formulations. It relates to the political process that provides for our ability to do the kinds of things that are the responsibility of public officials. I think it relates to our educational capabilities, whether it relates to providing education within the school system or any other element of our society; physicians, health providers. There is no shortage of individuals within our society that do not fully understand the nature of the epidemic with which we are currently faced. It extends from the lowest level of education within our society to the highest level of education. There are clearly many positions within our society who do not clearly understand what the process is, who do not clearly understand the threats it represents. There are major issues with respect to management of the whole of the process. There are questions about programmatic organization, and clearly there are major issues, associated with the fiscal capabilities of states, that affect the Health Care Financing Administration or other areas of government that are clearly responsible for assisting at least localities and states in their abilities to deal with the epidemic.

MR. CREEDON: Are you saying the federal government is not cooperating as you think it should with the states in trying to deal with this?

DR. AXELROD: I think there is not a fully coordinated effort to address the various areas that deal with epidemiology, that deal with the organization of basic research, that deal with prevention and education, that deal with service availability, that deal with manpower, training and development and that deal with the burdens of cost associated with the AIDS epidemic; yes. That's exactly what I am saying. I think that needs to be done. I think it needs to be done quickly. I think the Commission provides a vehicle for achieving a coordinated effort to deal with the multiplicity of problems that we face and for once and for all to establish a clear hierarchy of what our priorities are with respect to dealing with the problems at every phase and every level of the AIDS epidemic. One of the interesting aspects of all this is we have dealt and you have dealt with the whole aspect of testing. Testing of itself is only a small component of the public health process. Testing is important with respect to the blood supply. That is indeed a public health effort. Testing is important only as a tool with respect to reaching out, with respect to identifying populations that we can target. Testing is important because we educate and counsel individuals by virtue of the testing process. Testing is not an end in itself. It is distressing to hear the kind of focus on the testing process without a full recognition that testing isn't going to solve anything, what is going to solve things is the

kind of education and counseling that can be provided to individuals who avail themselves of testing opportunities, whether it is in a sexually transmitted disease clinic or whether it is in a family planning clinic, wherever it happens to be. That is where the basic public health impact is going to be realized and the process of testing.

Sure, we have made major progress with respect to public health by virtue of the limitations that have occurred as a result of testing our entire blood supply. There are other circumstances in which this has been critical. I think the importance of the testing process is that it is a tool for doing what is the most important thing that we can do and that is educating and counseling and hopefully effecting the kind of behavior modification that we are going to achieve. I think with all due respect to the concerns about testing, the testing is not of itself a public health initiative except as it relates to our ability to prevent the disease, to prevent the transmission, to prevent recruitment of IV drug abusers or drug abusers into the IV drug abusing population.

MR. CREEDON: I think one of the thrusts of the questions that we had with respect to testing was if testing is a way of finding out how many people have the virus and we know how many people who have the virus are eventually going to require medical care, then we can start to estimate at least how many hospital beds you need, how many hospices, what the costs are going to be, who is going to pay for it. These are all things we are looking at. Testing is one way of helping us form a judgment on that.

DR. AXELROD: Yes. What I am trying to do, Mr. Creedon, is to separate our assessment of long term resource needs from basic public health initiatives that relate to the prevention of the transmission of the disease and the opportunities that testing affords us with respect to the education and counseling of the populations that are at highest risk. Our seroprevalence testing allows us to target those populations, those localities, as already indicated by Dr. Curran, those subpopulations, where we can indeed have an impact or hopefully have an impact on behavioral modification. Those are the kinds of things that can come. Certainly we need as a government, as a federal government, a way in which we can assess the resource requirements and to develop those resource requirements. That is an after the fact activity. That relates to a population that is infected. That relates to a population for whom we have an obligation. There is also a very, very large population out there for whom we also have an obligation, and that population is one which needs to be counseled, and that

population is one which needs to be educated, if indeed we are going to see a drop in the seroprevalence rates as a result of deaths rather than an increase. We are going to have to take advantage of the opportunities that testing affords us.

MR. CREEDON: Coming back to your comment about the effort not being coordinated adequately. There are so many associations in the world. There must be an association of the Commissioners of Health from the various states.

DR. AXELROD: She sits with you.

MS. GEBBIE: I refuse to be a whole association all by myself.

MR. CREEDON: Is it your opinion that that association or the Commissioners who belong to the association would share your view that there is not a coordinated effort and somebody has to get the states and the federal government and localities together and provide some type of vehicle for them to work more effectively?

DR. AXELROD: I would allow Ms. Gebbie to speak for herself since she represents the Association of State and Territorial Health Officers. I think there has been a general thrust of the state and territorial health officers and they have indeed met with a number of arms of the federal government to try to provide for a more coordinated strategy to deal with some of the issues that currently confront us.

MR. CREEDON: Thank you.

DR. AXELROD: I have given you a series of charts and tables that relate to specific problems in New York State. I am going to go through them very quickly. I think your head is probably spinning as a result of the extraordinary amount of data Dr. Curran has provided. As I have indicated, New York State represents in many ways a microcosm of the problem, although it does represent some 27 percent of the national total at the present time. As all of you clearly recognize, New York State has reported more AIDS cases than any other state. The New York City metropolitan area has reported more than twice as many AIDS cases as San Francisco; some 2,170 cases as opposed to 1,050. As of a week ago, New York State had a reported cumulative total of 12,500 CDC defined AIDS cases, roughly 27 percent of the total 47,000 cases.

The New York State's share of AIDS cases has been declining, whereas its share was 40 percent just three years ago, it has obviously continued to decline. Additionally, the IV drug risk group represents a particularly difficult challenge to New York State, where it represents at the present time

roughly one-third of the total number of cases as opposed to the numbers that you heard from Dr. Curran. Clearly, the problems that we are facing with respect to the IV drug abusing population forces us to focus on efforts to provide for behavioral modification within that population. The estimates of the numbers of infected members of that population range up to 65 percent at the present time. The rate of seroconversion of that population has been estimated to be on the order of 7 or 8 percent. There is only a small population left that we can save and we do indeed have an obligation to provide for an accelerated effort to deal with them.

It is also of concern to us that there has been a continuing outbreak of oral drug abuse which frequently leads to the conversion to IV drug abuse. That appears not to be occurring in new recruitment into the IV drug population at this time, it appears not to be as great as it has been in the past, although it still appears to be occurring in some subgroups of our populations.

MR. CREEDON: Is this because of educational efforts?

DR. AXELROD: Educational efforts and fear. Street groups within New York State as part of the Division of Substance Abuse have found that more than 95 percent of IV drug abusers are aware of the threat of AIDS by virtue of needle sharing. It is not a matter of their not knowing about it. It is a question of their ability to break the habit or the percentage of individuals who are already infected. Clearly, the problems also are identified with respect to potential cohorts or collaterals of those individuals who are IV infected, in terms of the numbers of individuals who are likely to be born, children born as a result of transmission from that heterosexual IV population to their children. That remains a very major factor. We also are very much concerned with something else which is distinct from what Dr. Curran has told you in terms of the syphilis problem. We are currently encountering in New York State a very major increase in syphilis. The increase in syphilis has been substantial. The first quarter of 1987 as compared to 1986 represents a doubling of the cases of primary and secondary syphilis.

The reason for the significance of that doubling, I think it is obvious to all of those who have followed the African problems and the potential for transmission to the heterosexual community and the potential for a breakout of the existing high risk groups on which we have concentrated up until now. As we look at the problems, we find ourselves confronted with two major areas in which there is the potential for additional transmission to those groups which have not generally been characterized as high risk groups. Again, a need for emphasis on preventive activities and the use of the testing for education and counseling --

MR. CREEDON: I am not sure I understood.

DR. AXELROD: Sexually transmitted disease and IV drug abuse.

MR. CREEDON: Do we know why there is an increase in syphilis?

DR. AXELROD: There have been a lot of suggestions as to why it has occurred but does anyone really know? I don't think anyone really knows why there has been an increase. It is not as Dr. Curran has indicated within the homosexual community which has had generally a decrease in primary and secondary syphilis.

MR. CREEDON: We had some testimony this morning that indicated some of these diseases have been going down rather than going up.

DR. AXELROD: Yes, the New York experience would be similar to that which Dr. Curran has identified in terms of the homosexual population, that there has been a very major reduction in venereal disease generally. Overall, the number of primary and secondary cases in the first half of 1987 compared to 1986 has effectively doubled. It is still a relatively small number. It is one that is of very great concern to us because of the potential implications.

MR. CREEDON: How many?

DR. AXELROD: I think it is about 2,200 cases in the first half of 1987.

DR. PRIMM: I was going to ask you, Dr. Axelrod, weren't those cases concentrated in the minority communities, Harlem, South Bronx, Bedford-Stuyvesant, Brownsville, New York?

DR. AXELROD: Yes, but that doesn't change their significance. I mean, yes, that is true, but I still think that our concerns nevertheless have to remain with the potential route that may provide for extension into the heterosexual community in manners that have been attributed, at least, to the spread within our African countries.

DR. PRIMM: But, too, there has been very little, if any, expansion in drug treatment in those areas. And I'm particularly concerned about that in New York.

DR. AXELROD: There are currently some 40,000 methadone treatment slots in New York State. The estimated drug population is someplace between 200,000 and 250,000. 10,000 additional slots have been added by the Governor this past year, and we are

about to add additional slots for methadone treatment. You have, in a sense, anticipated some of my comments with respect to drug treatment and the need for the federal government to recognize that it also has a major obligation with respect to its expansion of assistance to the states to provide for additional drug treatment activities. The AIDS problem is very much an IV drug problem. It relates to the allocation of resources that has been made, the priorities that have been established by government generally with respect to the treatment of those individuals who are currently addicted and are part of our intravenous drug-abusing population.

Now there is clearly an absolute need for everyone to recognize the need for a major new resource commitment to deal with that population. I think there is also a need to recognize that not only is there a need to deal with that population because of their intravenous drug abuse, but the risk that they bear, the risk that they bear to the children that ultimately will be born as a result of their collaterals, a result of the risks to the heterosexual population that they represent, but there is also, I think, an absolute opportunity for education and counseling these individuals through methadone treatment centers that probably allows us the most easy access to those individuals that have otherwise been difficult to access within the community. Our best guess is that as many as 50 percent of those ho are currently IV drug abusers would take advantage, if it were made available under the right circumstances, of methadone treatment.

The issues also relate to the regulatory process which extend to methadone treatment centers. I believe that we should reevaluate at the present time the requirements for methadone treatment centers to ensure that we take every effort to bring them in for whatever level of treatment we can provide, even if it isn't the full spectrum of services that are currently required in our methadone treatment centers to assure that we have the opportunity to educate and counsel these individuals. That requires changes with respect to substance abuse. It requires changes with respect to limitations of the FDA in terms of methadone allocation. But it is -- it seems to me that in terms of the potentials that we face with respect to this population that we have opportunities that need to be exercised, and we do need to take some major actions with respect to that population.

MR. CREEDON: Does your paper spell this problem out with the FDA? Does it specifically do that?

DR. AXELROD: No, it does not. It does not.

MR. CREEDON: If you could give us more information on that, that could be helpful.

DR. AXELROD: Yes, I would be happy to.

DR. PRIMM: Dr. Axelrod, the other thing that I would like you to elaborate on, if you would, is the expansion of primary care, primary medical care, in methadone maintenance treatment centers and in drug treatment programs in general, because it's there generally where the intravenous drug user comes in contact with any officialdom in the health- giving community, for example, and we don't have the kind of funds to do that, yet we are heavily, as you know, monitored and regulated by the Division of Substance Abuse Services and, of course, the Food and Drug Administration. We do need increased dollars in order to expand the program to do the kinds of counseling that you suggest.

DR. AXELROD: Dr. Primm, I agree with you absolutely, and I think that we are saying the same thing.

DR. PRIMM: Yes.

DR. AXELROD: There needs to be changes with respect to the regulatory process to facilitate the activities of the methadone treatment centers to become a major player with respect to education and counseling, and I am prepared to advocate and have advocated major changes that would allow for the role that you have identified for the methadone treatment centers. I think it is absolutely critical that we utilize those centers to provide the kind of information and primary care that they can provide.

DR. PRIMM: My point was, in order to be specific, so you would know, is that it would be highlighted in front of the Commission, so that I don't sound like a broken record myself when I talk to my fellow Commissioners and to the public. I know you have, and this way it's now officially on the record that it's strongly endorsed, and so has Dr. Curran today, and I'm highly appreciative of that also.

DR. AXELROD: Thank you. The epidemiologic information currently being obtained in New York State, as you know, is coming from a variety of different areas. We have it from alternate sites which have existed -- blood banks, the military screening program -- to the point that at the present time we have screened roughly two million individuals, or there have been two million blood tests in New York State, and we have roughly 10,000 positives which have occurred as a result of that extensive testing. The most extensive testing that we have been engaged in is one which we have just initiated and have just completed the evaluation of some 5000 samples, and that is the evaluation of every newborn within the State of New York, and we expect to do some 260,000 individuals who are born in New York

State to give us a seroprevalence, at least within the childbearing community within New York State. Lest you think that is going to be a panacea, you should recognize that these are going to have to be evaluated with respect to a number of other features, such as fertility, abortion rates, and I could go on and identify some of the other factors that are going to have to be taken into account in evaluating even this 100 percent sample in terms of determining the level of seropositivity among childbearing women in New York State.

We hope to have certainly some definitive information by the end of the first quarter of this year that will give us for the first time at least an opportunity to evaluate the future potential for children who will be born in New York State with AIDS, who are likely to be seropositive, and perhaps a better indication of the extent to which it has entered the heterosexual community within New York State as a result of this extensive testing procedure.

MR. CREEDON: Is this that each mother would be tested? Is that what you're saying?

DR. AXELROD: Every mother is currently being tested. The process that we have initiated is related to the newborn screening sample, which is required within New York State. Every infant is tested for PKU and a number of other congenital diseases. Once that is completed, all identifiers are removed from the sample, and we are doing testing for not just HTLV-III or the AIDS virus, but we are also doing testing for some of the other viruses that have been related to determine their prevalence within the general population.

MR. CREEDON: Does that include HTLV-I?

DR. AXELROD: Yes, it includes HTLV-I.

DR. SERVAAS: Dr. Axelrod, when you test, then the mother goes ahead to nurse her baby, she's not told that she's positive?

DR. AXELROD: We don't know who the mother is.

DR. SERVAAS: You don't. Do you test in the prenatal clinics?

DR. AXELROD: We recommend it; we don't mandate it. We recommend all our prenatal clinics -- we have, in fact, identified -- we have sent information to every obstetrician in New York State, recommending that he raise this issue with every prospective mother. Our family planning clinics are aware of it, and we are doing screening directly in some cases in family planning clinics and other prenatal clinics that are operated by

the counties as well as by the state. But in this situation, we have no way of identifying who the mother is, because it is done on a totally anonymous basis, and I think it's important to distinguish information which is being gathered for epidemiologic purposes on a blind study, such as Dr. Curran identified, and our urging the mothers to go to the clinics and to be tested or urging doctors to have potential mothers tested by virtue of one of our anonymous testing sites that exist throughout the state. There's a very major distinction which Dr. Curran made before, and I think he made it very eloquently, so I don't need to say it again.

MR. CREEDON: I didn't know whether there was a difference of opinion between the two of you on this issue. Is there?

DR. AXELROD: No.

MR. CREEDON: Because from --

DR. CURRAN: I think New York State is really in many ways a model program for some of the family surveys. We're working closely together.

MR. CREEDON: I mean, from a policy standpoint, one could argue that if you're going to go to the trouble of testing, you really ought to find out, you know, who has the virus and tell them.

DR. AXELROD: That raises a whole new series of questions, and I think in terms of our ability to have a 100 percent sample, which is what we set out to achieve, and not bias the sample, to seek consent, which we would have to do under those circumstances, would change the value of the information that we otherwise would obtain. The value of this information is that it is not selective, except for those characteristics which I've already indicated to you that are going to have to be evaluated before we draw any conclusions. But at least in terms of the population, it is not additionally biased by a self-selective process in terms of who provides consent and who does not. And I would be reluctant to test samples with identifiers. I certainly would not be permitted to do so without the consent of the individual.

DR. CURRAN: I can give you an example of how that works. You take a state like Georgia, where we have, I mentioned, one hospital where 1 percent of the pregnant women are positive. Obviously the thing to do there is to go into the hospital and start some programs for care and prevention and things like that. But let's say, you say, well, we know that that's true in one hospital. How many other hospitals are there in the State of Georgia that might have similar rates or even

rates that are 1 in 1000, and how many don't have any at all? It is almost impossible to go around to every hospital where babies are delivered in the State of Georgia and start these kinds of programs, because just getting them going would be an enormous task. PKU testing, however, is done on a state basis in every state by mandate, and little pieces of filter paper are shipped into a state laboratory in one place. There's a little bit of extra blood in all of these filter papers. So all you have to do -- and you have age, race, and sex, without name, and your hospital number -- all you have to do is blind those, and you'll know immediately what it is in every pregnant woman in the state. Then you know where to go to start your prevention programs. I think that's the idea that you can focus your prevention efforts based upon.

DR. AXELROD: Precisely.

DR. CURRAN: I don't know if they understood what the PKU filter paper thing is. It isn't a question of going to the woman. It's a question of going to some room where all this stuff is kept and testing it all, you know. But you have to blind it. If you don't blind it, then it's, I think, unethical.

DR. AXELROD: There's another advantage in terms of the way in which this is being done, and that, of course, is that it's being done all in one laboratory, that there is no problem of interlaboratory comparison, that all of these things are being done in one location and is engaged in some fairly extensive proficiency testing to assure, at least, that there is a similarity with respect to the procedures that are followed, and you do not deal with the multiplicity of problems that ultimately you have to deal with when this is extended to a wide number of laboratories. As I mentioned to you earlier, we currently have reported a total of about 12,500 AIDS cases. We are currently seeing about 300 per month, and that has remained relatively stable over the last six, eight months. Since January of '86, in fact, case counts have been averaging about 300 month, but there has not been a major change. I would caution that you not pay very much attention to the reports subsequent to January '87 because of the lag that has already been referred to in Dr. Curran's comments in terms of the reporting. But we certainly seem not to be proceeding at an accelerated pace, and if anything, there appears to have been reached, at least, a plateau with respect to the numbers of new cases being reported in New York State. The next chart that you have is one which I think --

MR. CREEDON: Is there any change in the nature of homosexual versus the number of IV drug abusers?

DR. AXELROD: Yes. The number of IV drug abusers is representing an increasingly higher proportion of those

individuals, as is the number of children who are being reported. Although that is a very low number, there is an increasing number of children who are being reported. The next chart which I've provided to you is an indication of the fact that the number of deaths is continuing to increase and is --

MR. CREEDON: Which chart is this, David?

DR. AXELROD: It's "AIDS Deaths in New York State, 1983-1987, Monthly Resident Deaths," which should be part of your package. The point, of course, is simply not the chart, but the fact is that we are experiencing, as you would expect, given the large infected population, the large number of AIDS case that exist, both diagnosed and characterized and those perhaps not characterized, the number of deaths that is occurring is continuing to rise in a linear fashion, so that we can expect at the same time as we appear to be decreasing the number of cases being reported, the number of new cases being reported, there is a major increase in the number of deaths. The concern, of course, is that there will be a panic with respect to a large number of deaths that is occurring, that will not fully acknowledge the effectiveness of the public health initiatives that are underway, and the fact that the number of new cases, in fact, may be decreasing. So that while the number of deaths is very frightening to all of us, it is, I think, a recognition of the fact that we do have a large infected pool.

As of November 1986, 57 percent of the reported AIDS cases in New York State have died. The mean survival time for AIDS diagnosed cases in New York State is roughly 8.7 months. Risk factors for AIDS you already know about. 13 percent of the homosexual/bisexual men are expected to live four years, compared to 7 percent of the IV drug abusers or individuals who are both homosexual/bisexual and IV drug abusers. The number of hospitalized AIDS patients in New York State with PCP, pneumocystis carinii pneumonia, has grown from 690 in 1983 to 4202 in 1986 or a sixfold increase. Interestingly enough, at the same time, the number of hospitalized patients with Kaposi's sarcoma increased twofold between 1983 and 1985, but in 1986, the number actually declined. And while the absolute numbers may not be entirely correct, we do believe that there has been a decline in the number of Kaposi's sarcoma associated with the homosexual population. That is consistent with other reports that suggest that the relationship of anal receptive intercourse in the homosexual population has decreased and along with it the number of cases of Kaposi's sarcoma that are being seen.

So we view this as an indication, at least, if the reports that have been provided, including a recent one in the New England Journal of Medicine, are indicative of changes in behavior, then certainly the data that we have with respect to Kaposi's is consistent with the changes that we have observed.

MR. CREEDON: And again, David, these changes in behavior presumably occurred back --

DR. AXELROD: Earlier.

MR. CREEDON: Four years ago or something like that.

DR. AXELROD: Well, we don't know how long ago. I don't think anyone knows precisely the point of contact and all of the cofactors involved with the development of Kaposi's sarcoma. But the answer, yes, is that there have been behavioral changes undoubtedly that have affected the number of cases of Kaposi's that are currently being seen and the changes in the number of cases that are being diagnosed. There is a series of charts, and there is one in which there is a warning clearly evident by virtue of showing you what the change is with respect to the reporting at any given year because of the lag that occurs, which is approximately one year. So my caution is that you not take the 1986 data at this point as being definitive. There undoubtedly will be additional cases reported. You already have heard something about the tuberculosis case rates, and as Dr. Curran has indicated, it will be in the MMWR this week, and there's no point in my discussing it. Obviously it is a problem for us.

The next chart which you have -- I believe you have it -- is the pediatric AIDS cases, which shows an increase. This is a plot at six-month intervals of the number of cases being diagnosed, and what it does is, I think, confirm what you otherwise would have concluded with respect to the increasing number of intravenous drug abusers within the reported AIDS population. I have also provided you with information with respect to the number of AIDS cases, hospital discharges, hospital days, and deaths since 1983. The numbers, I think, are rather interesting with respect to several factors, and that is that the number of deaths is now beginning to exceed the number of cases. The number of hospital discharges is continuing to go up linearly, as is the number of hospital days, although the average length of stay has declined substantially with respect to hospitalization. The AIDS cases, hospital discharges, and deaths are represented in the chart which you also have, and I'm going to try to move through this quickly, but I think you can see that while we have certainly reached a plateau perhaps with respect to the number of new cases being reported, we have no such plateau with respect to the resource needs of the population that already exists. We have an extensive system in New York State, a data system that allows us to monitor some trends in inpatient care for AIDS, and what you can see is that the primary care mix of AIDS patients has changed since 1983. In 1983, about 40 percent

of AIDS patients were on Medicaid. By 1986, the fraction of AIDS patients on Medicaid has increased nearly 50 percent. The Blue Cross share decreased from 34 percent to 26 percent from 1983 to 1986.

I think the point of all this is that we are seeing a situation in which the combination of Medicaid and medically indigent account for some 70 percent of the total number of AIDS being treated in hospitals in New York State. That represents an enormous burden, a financial burden to the state, and again cries for a greater participation of the federal government in the problems of financing this enormous cost of hospitalization. We certainly have been successful in reducing the number of days for each hospitalization, but if you will look at the information with respect to expected payer, it is very, very clear that the Blue Cross share continues to go down; the self-pay, the medically indigent continues to go up, and Medicaid also will continue to go up.

It also makes it very clear that there is a need for the federal government to recognize, as we have suggested that they should, that the states require some direct assistance with respect to the financing of those individuals who are currently without any source of payer. We have suggested that Medicare consider this population to be similar to that population with advanced stage renal disease and be eligible for immediate Medicare services with, I think, a change in the nature of the way in which services can be provided in terms of an increased availability of other non-hospital services. I believe that there can be major changes with respect to the way in which treatment is carried out, and while our primary responsibility is not a reduction in costs, I believe there can be some additional reductions in costs associated with a greater flexibility in terms of federal participation in the care of these individual patients. You have also before you a chart which identifies a change in the percentage of beds in New York City that represents beds occupied by AIDS patients. For these charts, we have used a definition which is different from the CDC definition. We've used a definition of HIV with illness as being the mechanism for identifying resource needs. So when you look at these hospitalizations, they represent not the AIDS definition itself, but a rather broader definition which we feel is more relevant to the kinds of projections that we --

MR. CREEDON: I think that makes more sense in terms of trying to evaluate what our expenses are, rather than classifying as AIDS or ARC or some other.

DR. AXELROD: We have no ARC classification. We have AIDS and HIV with illness as a mechanism for identifying resource needs. There have been a variety of projections as to what the number of cases will be in New York State, and I have given you a

chart with a range of potential cases. We expect that the total by 1991 will be roughly 50,000 with approximately 20,000 of those still alive in 1991. We have by risk group provided you with information in terms of what we feel are the rates of increase in each of the populations, based upon extrapolation from existing information, as well as the data that we have available through December 31st of 1986 in terms of the extrapolation. Those represent our efforts to provide a range, given all of the different estimates that have been made, the different models that have been suggested, the difficulty in using any of those models, because of the problems that we have with the kinds of subpopulations that Dr. Curran referred to earlier. Those represent, I think, some of the major problems that we have. I think they're a summary of the kinds of information in New York State. But I again would urge that the Commission consider the various problems that we have with respect to the coordination of the epidemiology, the nature of the questions being asked, the priority of the questions and how they relate to our basic public health mission, the allocation of dollars, the coordination of the research that is currently taking place, the relationship to other public health disorders such as TB, venereal disease, how they interact with the problems of AIDS, the effectiveness of our prevention and education programs, the relationship to the drug programs, and our ability to address the collaterals and spouses of those IV drug abusers who are -- remain a major current source, the need for the federal participation and the expansion of service availability.

For example, the hospice regulations are totally at variance with the experience of all of us in terms of the needs care of the AIDS-afflicted population. At the present time, hospice is available under Medicare for those who spend 80 percent outside of the hospital and 20 percent in the hospital. I think it is probably the reverse with respect to AIDS patients, so that effectively they are precluded from participating in a hospice under existing regulations. Manpower is becoming an increasingly critical element. There is a need to make all of those involved in the delivery of health care services aware of the kinds of preventive activities that they can engage in to prevent their own risk. But there is also a need for manpower training development to deal with the special problems of those who are afflicted with AIDS, and clearly the federal government needs to deal more effectively with the cost burdens that are being borne by the states. And finally, I would be remiss if I didn't identify the problems that result from a fragmented policy with respect to addressing the discrimination that takes place with respect to those who are afflicted with AIDS. The AIDS population is a population that is already largely discriminated against because of race, and without the kinds of protection that can be provided on a federal level, we have a fragmented system in terms of further protecting that population from all kinds of prejudice that exists within our society.

Members of the Commission, I am confident that you represent a social conscience for government and will provide the thrust that will enable us to have a more responsible social role, all of us, in dealing with the multiplicity of problems that all of us are confronted with. The data are all secondary. The responsibility is one of our society, and I think we have the opportunity to demonstrate the compassion and the concerns that I believe the society has identified in dealing with disasters and catastrophes that we have had to deal with in the past. If this is indeed the number one public health problem that we face, then clearly there is much more that we can do. There is much more that we should do. And the kind of commitment that we have made as a government is far less than we should have made, if, indeed, we are to conquer the problems, if we are to deal effectively with the problems that confront us. Thank you very much.

MR. CREEDON: Thank you very much. Questions? Dr. Walsh?

DR. WALSH: David, certainly you have had to face this problem to a greater degree than anyone else, being in your position in New York State, and I've had the opportunity to talk with you many times and hear you many times. I'm very impressed with your experience and your ideas. Just one comment before my question so that you won't misunderstand any preoccupation on the testing business from the Commission. To add to what John Creedon has said, part of the reason we are interested in getting a handle on as accurate projections as we can is for the very reasons you brought up, not only the care aspect, but if you're looking for federal funding for assistance in the training of counselors, improvements in education and the like, it just helps us to know the enormity of the problem to a greater degree than we are getting now from a mixture of reports. I just wanted you to know that. We are not looking at testing as an end in itself.

DR. AXELROD: I didn't mean to be pejorative in my comments. What I think I was voicing was a sense of frustration with respect to focus on the test; because from my perspective, in some ways it doesn't matter whether or not the patient who comes in is negative or positive. What it does is provide the opportunity for education and counseling, and that, it seems to me, has to be the thrust of our program to expand the intravenous drug abuse activities.

DR. WALSH: The next question I have, one of the two questions I have which pertains to the testing, is blind or anonymous testing unfortunately doesn't enable you to carry out the counseling, and I wondered, for example, when you have the increase in, say, syphilis in New York State, in the sexually transmitted disease centers, do you blind test for the HIV virus now?

DR. AXELROD: We are doing it in selected clinics, yes.

DR. WALSH: In selected clinics?

DR. AXELROD: Yes.

DR. WALSH: But are you -- they're true blind? You're not able to identify?

DR. AXELROD: No, but I think that in some of these areas, what it does in terms of the location of the clinic, it allows us to focus our activities through bringing in mobile vans, for example, and to provide for on-street education of individuals, which is also what we intend to do with some of the information that we get from the seroprevalence study of all women who have delivered children. This affords us an opportunity by geographic location to target for special attention those areas that have sero- prevalence rates that we think are going to cause us some additional problems. It provides for the kind of focus that Mr. Creedon was, I think, attempting to address in his questions.

DR. WALSH: This increase indicates, at least to me, that our education programs, for better or for worse, are not getting through on prevention. But let me ask you this, and this is a massive question, and you may have to perhaps submit this later; whatever the Chairman prefers. As the Chairman alluded in his report to fragmentation, you have alluded to fragmentation. I must say that most of the people involved, like Jim and the others, all are aware that there is a degree of fragmentation taking place. If you were in the position of being the czar in Washington, what would you do to correct that situation?

DR. AXELROD: As you indicated, that's not a question I think that I can answer in several sentences, but I think that there is a mandate for a single coordinating body which can make recommendations and allocate resources more effectively than is taking place at the present time. I think that there is a need for participation of a number of different agencies, some of which are within Health and Human Services but some of which are outside of Health and Human Services, like the Department of Education, that have a very major role to play in terms of our addressing this epidemic. I would be delighted to indicate to you some ways in which I think this can take place. I'm not sure I would want to define it with an off-the-cuff response, because I think it is the key question at the present time.

DR. WALSH: I think it would be helpful because, you know, I have a horror, frankly, of Manhattan Project thoughts; but, on the other hand, this seems to be something that's been suggested by others, but I think it would be helpful since in the

State of New York you have been through the mill on this to a greater degree than anyone I know, certainly. I think we would benefit a great deal, Mr. Chairman, by having Dr. Axelrod really submit to us after due thought his thoughts on what we could recommend or what may be considered to get better coordination than we are getting, because there are people in authority here in Washington who feel they do have proper coordinating bodies and so on, and if they do have and they're not working, perhaps you can suggest why and suggest what could be done to improve them. We will make this a blind paper if you like.

DR. AXELROD: Well, I would do it with great caution because of an experience that was related to me by the late Baniford Bush who, in the course of identifying the enormous impact that a single individual can have, identified himself as the single person responsible for the Sputnik lag by virtue of the information he gave to the President telling him that he need not worry about the future of rocketry and that it was not going anywhere. He related that to me as the potential dangers of a single person or entity being responsible for those things, but I would be happy to try and frame it with that as the question.

MR. CREEDON: Clearly, you know one of the issues we will be addressing, although not today and not at these hearings, is the question of what part of the financial burden should rest with the federal government, the state government, the local governments, Medicare, Medicaid and whatever. This is part of the issue, but right now we're trying to get a handle on the scope of the problem. Mr. Chairman?

ADMIRAL WATKINS: I guess we will close this out. We want to have questions for both of you, but we need to get on to the next two witnesses. If you can both stay throughout that, the Chairman would like to press on with the next witnesses. We do have lots of questions for you, and then I want to lay some ground rules on follow-on questions to you individually that we would like to exchange in writing. But in closing out on what Dr. Walsh has said, Dr. Axelrod, we are going to have one open hearing late in the cycle before we have to make our final report to the President. Clearly by that time, we will also have been through the mill a lot more, and we will have a greater grasp on the scope of this whole set of issues. I think at that time we'll be better prepared to discuss the issue of what follow-on institutional process has to be recommended to allow this president to pass the baton to the next president in a much more orderly way than he might have if we leave the fragmentation unattended to. So we don't know what that is. The AMA has made a recommendation along these lines. It's not all that well defined. The National Academy's Institute of Medicine has also made the same kind of recommendation. You're now talking about it.

We believe there's something there. We don't know what it is. But we certainly are open to that kind of presentation, and it would be helpful to receive your input with the idea it may help us frame a follow-on hearing. I believe it's in May or certainly late in the cycle when we have an open window, where this issue will have to come up from selected witnesses who have really given some thought to what we're really talking about. We certainly don't want an overwhelming bureaucracy. We want to do a lot of coordinating. We want to facilitate advice to both executive and legislative branches. We want to see that kind of antifragmentation regime as limited in bureaucracy and staff as necessary, but also we'd like to see it there and to be able to carry some national stature baton for the leadership in the country until such time as we feel the institutional process has built itself up and can get control of this. So it's an important issue. It's a little off our prevalence issue, but since it was raised here and since obviously you have some very strong feelings about it, it would be helpful to us to get that input from you so we can maybe frame our thoughts a little better for what we will now agree to as a necessary hearing on that particular set of issues.

DR. AXELROD: I'd be pleased to do that.

MR. CREEDON: Our next witness is Dr. Alexander Langmuir, Chilmark, Massachusetts. Dr. Langmuir was at one point the chief epidemiologist of CDC. Welcome.

PRESENTATION BY DR. ALEXANDER LANGMUIR

DR. LANGMUIR: Thank you, Mr. Chairman and Commissioners. I deeply appreciate the honor of being invited from really active retirement in Martha's Vineyard to testify along with my colleagues. They are now very much on the firing line in this very serious epidemic crisis. I once was there, too. In fact, I had my full measure of this at CDC for 21 years, and these men have my very warm sympathy and very best wishes. I have issued for you beforehand two documents which are merely supportive, and my testimony was distributed this morning. The charts on the back of my testimony are the same as the charts on the back of the paper I issued before. My long-held view which is now becoming widely known to at least some is that the projections of the incidence of AIDS, basically the Coolfont projections which Dr. Curran has shown, are rather too high. I presume this is the reason I've been invited here to testify and am most happy to do so.

The active practice of epidemiology has been my professional career for 50 years, and during this time I have become increasingly intrigued with epidemic theory which I learned at Hopkins as an MPA student, and I've applied it essentially constantly in my very active career. Epidemic theory

is the effort to divine the laws, the underlying biological forces that control epidemics and then to express them mathematically. Dr. Curran mentioned three expressions in one of his presentations. This is basically epidemic theory. Now, progress in this has been very distressingly slow. The problems, the factors, the forces, the infinite varieties of subpopulations have to be included, and then you add to this a variable and long incubation period. The mathematics becomes impossible even with the aid of the most modern computers.

But there are some factors. It's not totally empirical. In fact, I have no use at all for purely empirical curve fitting. I don't think there's any place for that. You can fit almost anything to a curve. You need a biological basis of some kind to start with and then see if your curve comes anywhere near meeting those fundamental conditions. I'd like to explain. Back in 1840, a very great epidemiologist, William Farr, who set up the vital statistics program for Great Britain that set the pattern for the world, observed early in his career that, in watching a smallpox epidemic and sort of playing with it mathematically, that there seemed to be an orderly arrangement. The ratios of one month to the next fell into an orderly pattern. Almost 100 years later, Dr. Brownley showed that this really was the statistical normal curve, the Delsean curve which is the basis of classical statistics. Dr. Brownley, very enthusiastic about Farr, proceeded to say this is Farr's law, which says nothing but that epidemics rise and fall in a cocked hat normal curve and a Delsean curve fits it pretty well. But this is what I mean by Farr's law, and I invoked it only in the most broad terms. Obviously they're not strictly a normal curve, but this does describe a very large number of epidemics. It's a sort of a traditional biological epidemiological inference involved there.

Then later in a cattle plague epidemic, Farr, who was a temerarious fellow, proceeded to write a letter to Parliament and charge that the fears expressed in Parliament that this rising epidemic of cattle plague was going to ruin the economy of London. He proceeded that the curve was, indeed, rising up into 50,000 attacks in the cattle and cows of the area around London but that the rate of increase was falling off. It was veering off. He then proceeded to do the extraordinary thing of predicting that it was going to turn over and crest in the next month and decline. Dr. Frost, whose successors taught me at Hopkins, said this was the most courageous epidemic prediction a public official had ever given. Now I am known also now as one of the more temerarious predictors. I try to predict every time I get a chance. I've been right some of the time, and I've been wrong on very many occasions. I persist in this trait for several reasons. First of all, it's exciting and fun to do so, and what's important than to not have fun in your job. To be on the cutting edge of a new epidemic problem and sometimes a step or two over is a place that I have enjoyed being all my life.

Now, more seriously, to make reasonably responsible predictions demands at least the beginning of an understanding of this underlying theory of the disease. When predictions are fulfilled, you gain great confidence, and you then proceed to elaborate your theory more accurately. When your predictions are wrong, you look at why. You re-examine your premises and Start over again. I first indulged in my obsession of predicting on AIDS in October of 1985 when I was drafted by Dr. Fred Robbins, president of the Institute of Medicine, to open a discussion on the epidemiology of AIDS during that October 1985 meeting devoted entirely to that subject. Jim Curran was there and commented on my remarks. Fred Robbins said be provocative, so I started off by quoting William Farr on the cattle plague. I then went on to challenge the prevalent and still now widely held view that AIDS is going to increase continually, even logarithmically. We heard today more than I've heard ever before of the fact that some, at least among the homosexuals, it is leveling out.

I stated categorically on the basis of my own broad professional judgment that no biological system, whatever it may be, can increase logarithmically and geometrically for long. It just is not biologically a tenable idea, although in 1985 this was a widelyheld belief. I argued that among the four principles of transmission categories, none of them had the basic ingredients of further logarithmic increase. I then went on to what I say hazard a forecast -- prediction would be too strong a word at that time -- that the epidemic would crest in the midsummer of 1986. That was a year and a half ago. This caused not a ripple of interest in the reading. Jim Curran made a few polite remarks, and the panel went on and discussed everything else except my contribution. Perhaps this is just as well. The forecast clearly missed. The incidence continued to increase; to some, continuing alarmingly, but to me, I looked at it and said it's dampening off further, it is steadily progressing, the doubling time is increasing. So I was not too discouraged, even though I was wrong in the exact dates.

Now, with my colleague, Dennis Bregman, with whom I have worked for a number of years on GBS and other problems, influenza, we submitted a brief manuscript to the CDC to focus this issue. We proposed a publication in the Morbidity-Mortality Weekly Report which has done some of this, not often. Being the editor and really the founder of the modern report, I took some pride in making a submission to it, even though the submission was respectfully declined. Again, we predicted peaking this month, December of 1987, and, again, it looks a little bit better, but we were basically considered wrong. Our reassessment of our failures led to what we think are rather clear explanations. We are not discouraged. In the first time, I had grossly underestimated the incubation period. I thought it was two or three years perhaps. Now almost everyone is aware

that this incubation period is not only long but quite variable. I believe it falls into a log normal curve, that it runs from one year to 25 years or a lifetime. That makes it very difficult for theoreticians to put it into an equation, but it clearly fits everything that I'm aware of the data. This is a disease where we're seeing the effects now of that big activity back in the early 1980s. In that error, I must say I had very ample company.

The second failure, the one where I predicted it would crest this month, was very clearly an artifact of reporting. I was in Martha's Vineyard and getting the weekly reports and studying them carefully, but I was not as alert to the lag between the time a case is seen and diagnosed and the time that report gets to Atlanta. In the late fall of '86 and January and most of February of '87, there was the dearth in reporting several thousand cases. This gave a false and encouraging feel that the epidemic was curving over more and peaking. Well, Dennis Bregman and I have persisted again, and I would like to go now to the Table 1 in the data we present. Table 1 shows the classic data from CDC. It comes directly from those official reports, and essentially everyone is broadly familiar with it. Sometimes it's reported and presented arithmetically, as Jim did in that rising curve with the Coolfont predictions. I believe it's sounder to present this on a logarithmic scale. If we may go to Figure 1, the four disease categories are shown there on a log scale. That's not terribly esoteric. Every time you look at a stock report in the New York Times, it compares the Dow Jones average with the Standard & Poor. This is charted on a log scale. It is the way you show relative changes where you compare what it's doing and how one curve is varying in proportion to the other as compared to absolute numbers. Notice that the homosexual curve arises steeply and then veers off; the drug abuser curve also and the transfusion and the hemophiliac curves also.

To me, those curves are amazingly congruent. They all arise and veer off in parallel. I did not expect this. I expected the transfusion hemophiliacs to be lagged behind. I expected a variety of differences. These are really quite different populations. They are all moving together. To me, broadly speaking as an epidemiologist, some primary major force is affecting these curves, and it's the same broad force. I think that is a logical conclusion. What is that force? It's not any single one. It's a composite, what we call in mathematics a vector resultant of many, many forces applying. Basically, to me, it was a whale of an epidemic of this disease spreading in the early '80s, and we're still dominantly influenced by that fact. Now, then, to get a curve fitted to this which any student using William Farr as a role model couldn't resist, I've taken the homosexual/bisexual cases and the intravenous drug cases, added them together along with that category where they can't tell the difference. This makes 90

percent of the total cases, and that proportion remains a constant.

I've added them together on an annual basis, and there we have in '82 881 cases, building up to 25, and I then take a simple arithmetic test. What is the percent increase from one year to the next, the first ratio, take off one, and you have 186 percent, then 106 percent, then a 75 percent increase. This is the same thing. The curves are veering off, and I won't get into the mathematics of this, but, simply, if you take a ratio, a second ratio, you get a measure, what is called a deceleration, and that's surprisingly constant. It permits us to draw a normal curve which is in the last figure. This is my prediction or, I say, my projection, not a prediction, of the course of the AIDS epidemic in homosexuals and IV drug abusers, 90 percent of the total problem. This looks different because this is now on an arithmetic scale. But looking at the logarithmic scale, this is veering off, and I predict it will peak in July of 1988 and then decline. The area under that curve by 1995 will only be about 130,000 cases. I have no brief for the accuracy of that estimate. The important thing is that I believe it's going to crest next year within six months and start down. I believe it won't go down symmetrically. I think there are many, many forces which I can't go into that will tend to make it trail off longer. But I believe we have seen the resultant of this force in the early '80s, and it's going to wear off slowly, and we're going to go to a low and declining endemic level through the rest of this century. I appreciate the opportunity of presenting my rather maverick views.

MR. CREEDON: Thank you very much, Dr. Langmuir.

MS. GEBBIE: In making your predictions, Dr. Langmuir, to what extent have you taken into account the data on the number of infected people already known? If we take even the most conservative estimate that we heard earlier today of 350,000 already infected people, the total I get out of your chart is about 82,000. That is a fairly low number of cases out of the number already infected. Did you take that number into account or --

DR. LANGMUIR: This is totally the AIDS reports corrected as accurately as possible for reporting. These are date of diagnosis correctives. These are October data and limited to 1986. There was a nine month period to catch up and we found that was not enough, we increased the figures by another 5 percent by each category exactly. I think the data are okay. This is what William Farr did. I think it is rather neat and simple. It is a projection on a totally different basis. It is a projection that has some biological precedence and therefore, I believe it should be considered. I believe it is more valid than an empirical projection that has no biological basis.

MS. GEBBIE: In trying to consider it, and I think we should consider all possible projections that are put in front of us, where one looks remarkably different from the others, if we are to go with it, it seems to me we have to be able to explain what the differences are. Perhaps one of the things you could provide us as subsequent material is how you would account for what appears to be a much lower rate of illness in infected people using your model than in any other --

DR. LANGMUIR: I don't believe that is necessarily true. I believe the infected figures. I think the estimates ranging from say 500,000 to 1.5 million are quite within the range. We don't know what proportion of the infected people are going to develop AIDS. Almost certainly in any biological system except guillotining in the French Revolution, it doesn't take 100 percent. Whether it is 50 percent or on the average say 25 percent, whether the co-factors in the homosexual population of AIDS, hepatitis, herpes, are going to make that proportion higher, I don't know. I have no knowledge or basis of interpreting what proportion of infected people will come down with AIDS.

MS. GEBBIE: Your curves would seem to take a much lower view than anybody else's.

DR. LANGMUIR: Not necessarily, a lower proportion of them, yes. I don't know what that figure is. We saw the estimated curves. I suspect this will be different with hemophiliacs and blood transfusions than with homosexuals. It will vary with homosexuals in different areas. That is a great figure and I agree we need to know. More important in the projection, we need to have a better measure of what this incubation period is. I've been wrong twice. If the incubation period averages six years which spreads out to 12 years, maybe one year to seven years and tail out to 25 years, this is crucial. I believe that where you get this will be the transfusion data. The transfusion data ought to be nearly perfect for this. I am urging CDC to follow every transfusion case just as fast as possible, be very up to date with it. Very shortly, if it is going to turn over, the transfusion data will show this turnover most accurately and soonest.

MS. GEBBIE: I don't think I asked my question plain enough. I will write it out and ask for an answer. I do want to see that. Thank you.

DR. LANGMUIR: On the infections, I have no way of judging what proportion of the infections will come down with AIDS. Therefore, it doesn't come into this projection.

MR. CREEDON: I think that is your answer.

DR. LANGMUIR: I tried to answer.

MS. GEBBIE: From my point of view, that makes it hard to use this because we have infected people out there. If we don't have some grasp of how many of them are going to become ill --

DR. LANGMUIR: These are the numbers of AIDS cases I project. These are the ones you have to plan medical care for and each state is going to have its own curve and so on. If this curve has any applicability, as I believe it does, it should be very helpful to each area to make this curve for their own region and get at least a quick first order approximation of what their problem will be. I think it is very useful or could be.

MS. GEBBIE: I am having trouble seeing it in the context of the other data which I have, but I appreciate your efforts to help me understand it.

MR. CREEDON: Any other questions of Dr. Langmuir?

DR. LEE: I would love to hear Dr. Curran's comments on Dr. Langmuir's.

DR. LANGMUIR: It is not the first time he has seen it.

DR. CURRAN: It won't be the first time Alex has heard my comments either. Well, I think Alex and Dennis, as many of the other people involved in mathematical epidemiologic models, have called our attention to the key variables to look for. I think I would agree with Alex, Dr. Langmuir, in saying that since we are not seeing an exponential increase in AIDS, which we have never really seen beyond mid-1982, that is it is not strictly exponential, doubling every "x" number of months, then that is telling us something about both the natural history of infection as well as the number of people who are becoming infected. Where we differ is in the use of the logistic model. The logistic model makes the assumption, the biologic assumption of saturation of infection and disease and it should fit, I believe, the hemophilia group, where the cohort of hemophiliacs in the United States can be essentially assumed to be saturated and no longer to become infected.

It is somewhat confusing whether the curve would exactly fit because the curve then is measuring past infection and future natural history. I think the truth is somewhere between a logistic curve, which assumes saturation, and an exponential curve, and the three curves that we submitted, the damped exponential, is the one which comes with 1 million to 1.5 million most closely, the damped exponential assumes continuing susceptibles entering the population. The reason I say that curve would fit the biologic plausibility better is that

logistic models have not fit well those infections which are most like in my view HIV infection, that is infections like hepatitis B, gonorrhea, syphilis, infections that are sexually transmitted, which tend to result in epidemic curves which peak and then level off.

I think we would agree that this is not going to go up forever. I think it is going to peak. I don't know -- I am concerned about predicting peaking in mid-1988 because I believe that is premature. I think it will peak but instead of going down all the way, it will level off a couple of steps below the peak. The question we all have is how far below the peak. I believe that is very much up to what happens in society in terms of the numbers of new susceptibles entering the population, the efficacy of education programs, et cetera. There has not been a sexually transmitted disease that I know of that has obeyed Farr's law, so to speak.

DR. WALSH: Alex, do you make that same projection effective for outside the United States, where the disease is primarily heterosexual?

DR. LANGMUIR: One, I challenge that statement. I don't believe African AIDS is primarily heterosexual. There is so much blood and so many needles and ulcers, I don't think we know how AIDS is spread in Africa.

DR. WALSH: I can only quote the Africans. They believe it is heterosexual. WHO has accepted it as heterosexual there. I just wondered --

DR. LANGMUIR: I have no thought of applying this outside of the U.S.A.

DR. WALSH: You are very correct on the blood business and there is very little progress being made there on controlling blood supply. I didn't think you did but I wanted to be sure.

DR. LANGMUIR: I would say I don't think there is heterosexual spread of any consequence in this country. I think we are seeing a homosexual and IV drug problem dominantly from 1980 to 1982 or 1983. Since then it has fallen off by behavioral changes in homosexuals, somewhat less for the IV drug users. That is why I predict this curve is going to go down, go down steadily, not necessarily symmetrically, but down to a progressively lower level for the rest of our life and that of most of our children.

DR. PRIMM: Dr. Langmuir, what we are seeing in intravenous drug using programs, sexual behavior among IV drug users, is a tendency for under 35 year old IV drug using males to have as a sexual partner a female who is of course heterosexual

and not an IV drug user, and another sexual partner, female, who is an IV drug user and usually is infected with the virus or is HIV antibody positive. In your explanation, how do you account for this not being a great window of spread, and we are seeing more and more of these cases coming up every day. I am seeing them on a personal basis, the heterosexual population that has nothing to do with IV drug abusers, women who are not IV drug users but who happen to be dating an in the closet IV drug user or in the closet bisexual male, particularly among blacks and hispanics. How do you explain that with Farr's phenomenon?

DR. LANGMUIR: Simply by the parallel of those curves. If these factors were of consequence, I'm sure they are there anecdotally and so on, and my friend, Dr. Henderson at Hopkins, jumps all over me with this projection, because he sees the cases infected in the OB Clinic at Hopkins. I say, look at the congruity of those curves, look at the stability of how the CDC classifies heterosexual cases, half of them from foreign born, other Third World countries, and half contacts of high risk groups. If this was a factor of consequence, these groups should be increasing in proportion to the total. It has stayed a constant 7 percent, less than 7 percent, steadily without any change. It cannot be an epidemiological factor of consequence. It is a secondary, minor force.

DR. PRIMM: What about the underreporting that Dr. Redfield talked about with the population that is volunteering for the Army and that really boils down to an underreporting of the numbers that are really out there, because we know that about 55 percent of high school, blacks in high school and Hispanics in high school, drop out before the 10th grade, so they don't have a high school diploma and 67 percent of that group use drugs, more than those who stay in high school. What about that population, do you think it is small?

DR. LANGMUIR: I am dealing with the national reports from the states, local cities, to CDC. This has been what I have done all my life, relied on this system, morbidity/mortality reports, then developed into an organ of great precision to primarily the state health officers and everyone else interested. I believe, certainly in the homosexual group, responsible group, concerned deeply, the reporting is probably improving rather than being under. Admitting the problem, everybody is familiar with it, the clinics are there, the reporting mechanism should be up to high gear. We believe in San Francisco, it is very good.

The IV drug problem is more difficult but they are coming in under care also. I think there is a little reluctance on the part of the reporters, the doctors, to report these. The hemophiliacs, again, over time, the doctors have been most reluctant to be responsible for giving a death certificate to somebody. Over time, they are familiar with this, they are aware

of how responsible it is. I believe the lag and the reluctance to report is going down. I think the reporting, although there may be lags in getting to CDC, is basically improving over time, because there is more recognition of the seriousness of the problem. I am thinking in the broad macro picture, the total nation. I look for evidence of heterosexual spread outside of the context. I have pounded CDC and Jim Curran and his colleagues. I do not see the data over time of what is called the not identified risk, the number must be so small, well under 1 percent, or it would have been recognized and talked about.

MR. CREEDON: Maybe we can move onto our last witness, who is Dr. Michael Osterholm of the Minnesota Department of Health. Dr. Osterholm?

PRESENTATION BY DR. MICHAEL T. OSTERHOLM

DR. OSTERHOLM: Mr. Chairman and members of the Presidential Commission, I too want to thank you for the opportunity to address the Commission today, to share with you a perspective on the Acquired Immune Deficiency Syndrome problem in the heartland -- that area in the middle of the United States not often thought of in the national AIDS picture. Although there are many regions in this country where the AIDS epidemic has yet to be experienced in the ways that we have come to know it in many of our East and West coast cities, my public health colleagues and I in Minnesota, and other Midwestern states, believe it is just a matter of time before we begin to document an increased -- if not similar -- incidence of HIV-related morbidity and mortality in the heartland.

This may seem a bit premature, considering that the incidence of AIDS in Minnesota to date is only 69 cases for one million population, ranking us 25th nationally. It is a figure that is more than ten-fold lower than that documented in the state of New York, and seven-fold lower than that found in California. However, many residents in Minnesota -- as do residents of other states in the heartland -- continue to deny that AIDS will ever be a real problem. This denial sets the state for a very serious AIDS problem into the 1990s. For the purpose of describing the AIDS problem in Minnesota, I would like to provide you with an overview of our state's population. Minnesota has a population of approximately 4.2 million people, with half of the population residing in the Twin Cities metropolitan area. Although not easily quantified, a substantial number of persons at increased risk for HIV infection are estimated to reside in Minnesota. An estimated 100,000 homosexual or bisexual men live in the state, with a majority thought to be in the Twin Cities metropolitan area. This estimate is subjectively supported by demographic variables used by the CDC to measure the disease impact of AIDS. In the discussion I would be happy to elaborate on how those estimates

were arrived at. But more importantly, we estimate that less than five percent of these men are Gay identified. Rather, the majority of these men live in a world of denial of their own sexuality that makes it very difficult, if not impossible, to penetrate so as to bring home the perceived risk of HIV infection.

These types of problems are different than those often seen in more widely open Gay communities of the East and West Coast. The number of chronic intravenous drug abusers residing in Minnesota -- again, primarily in the Twin Cities metropolitan area -- is estimated by our Minnesota Department of Human Services Chemical Dependency Program to be between 1.5 and 2,000 persons, a number substantially less than that probably in one area of New York City. The number of persons who use intravenous drugs recreationally has not been well quantified, but it may be many times that number. Personally we have worked up a number of large outbreaks of viral hepatitis type B associated with IV needle use in recreational drug users. Three to four hundred persons with hemophilia in Minnesota are estimated to have received blood products potentially contaminated with HIV.

Based upon these estimates of the at-risk population, and the seroprevalence data collected by us and others within our state, we estimate that at least 20,000 Minnesota residents are currently infected with HIV. We believe many will ultimately know some form of HIV-related disease. As of December 7, 1987, 289 cases of AIDS, with 163 deaths, have been reported to our Department. However, the total number of cases represents a 43 percent increase in cases since July 1 of 1987. Of the 287 cases, 251 -- or 87 percent - - have resided in the Twin Cities metropolitan area at the time of diagnosis. This is changing, however; and, in fact, there was a 75 percent increase in case numbers in rural Minnesota between July 1 and that of December 7. Most Minnesota cases have occurred in homosexual or bisexual men. As of December 9, 1987, 239 -- or 83 percent -- of our AIDS have resulted among Gay or bisexual men. Nine -- or three percent -- have occurred in intravenous drug abusers; and 17 -- or 6 percent -- have occurred in Gay or bisexual men with a concurrent history of IV drug use. The remaining 22 adult or adolescent AIDS cases have occurred in persons with hemophilia, as a result of transfusion, as a result of heterosexual contact; and, in four cases, transmission categories remain undetermined at this time as investigations continue.

To date, only two cases of pediatric AIDS have been reported in Minnesota. One occurred following a blood transfusion, the other one remains unidentified, as we are continuing to work that case up. The racial distribution of Minnesota AIDS cases is as follows: White, not Hispanic: 88 percent; Black, not Hispanic: nine percent; Hispanic: three

percent; Other: one percent. A disproportionate number of AIDS cases have occurred among people of color in Minnesota. Blacks have accounted for nine percent of our AIDS cases, yet only comprise 1.3 percent of our state's population. In addition, Hispanics account for three percent of AIDS cases, and comprise only .8 percent of our state's population. Unfortunately, many of us in public health may take some comfort in recognizing that many of the observations to date regarding the increased risk of AIDS among our communities of color come from places like New York City, and Newark, New Jersey, and thus hold only limited implications for the remainder of the country. We, in the heartland, must remember that early in the HIV epidemic many practitioners in clinical medicine and public health believe that AIDS in Gay men would be an important problem only in New York City, San Francisco, and several other metropolitan areas in the East and West coasts.

Today the heartland is repeating that early experience of those coastal metropolitan communities with regard to AIDS and Gay men. We believe that the metropolitan areas of the heartland will also repeat many of the experiences with AIDS in communities of color. What does all this mean for the heartland and AIDS of the future? It is difficult to impress upon residents of the heartland the long term importance of AIDS upon their health. For example, in Minnesota only 162 residents have died from AIDS through 1987, while in 1986 572 residents died on our highways in that single year. This will change, and it will change dramatically. In a recent publication from our Department, we projected the morbidity and mortality from AIDS in our state through the year 1990. While these projections were made in 1985, they remain accurate within several percent of the original projections as of today. By the end of 1990, we predict that there will be between 1,300 and 1,900 AIDS cases among Minnesota residents. Also by that time, the person years of potential life loss for AIDS will exceed for all the causes of years of potential life lost for single, never-married men ages 25 to 44 in our state.

In addition, it will be the number two cause of years of potential life lost among all men 25 to 64 years of age, only falling slightly behind that due to heart disease. By 1991, AIDS will even be the number one cause of years of potential life lost in this latter group. Unfortunately, we in public health have concluded that there have been only limited changes in risk behavior in our state at this time. In part, this is due to the lack of perceived risk related to HIV infection. I think many of the situations we have heard today relative to major behavior changes have occurred in areas where the high incidence of AIDS makes the problem much more visible than in an area such as ours. For example, although we too in Minnesota have documented a significant decrease in the incidence of syphilis in Gay men in our state, we have been unable to document any change in the

incidence of acute clinical viral hepatitis type B among Gay or bisexual men in our state, from January 1982 through June 1987. As you know, the risk behaviors responsible for the transmission of hepatitis B are similar to those responsible for the transmission of HIV. In addition, we estimate at this time that the incidence of intravenous drug abuse in our state is at an all time high.

It is apparent that AIDS will have a dramatic, nationwide impact on all aspects of society. In some areas, the impact is obvious now. For other areas, like the Heartland, it will not begin to realize a dramatic impact until 1990 or later. It is critical that this Commission and all other federal and state and local agencies involved with the AIDS epidemic realize that we have yet to appreciate the likely or potential impact of AIDS in many areas of our country. We urgently need to expand our current efforts in bringing about behavior changes in these areas. We still have a chance in these areas to have significant impact on those who are currently at risk. We recognize that programs aimed at behavior change and, in some settings, major social change, require extensive economic and human resources.

However, the added burden and cost of life lost in our society as a result of high AIDS incidence rates in metropolitan areas nationwide -- and, to a lesser degree, in our rural areas -- should be taken into account when examining the cost of programs which impact on HIV transmission. Allocating resources now for such programs may prevent a much greater cost in the future. Public health officials are the first to acknowledge that behavioral and social change will not be easily realized. Therefore, we must also consider the more limited, traditional public health strategies and disease prevention and control. We must also begin to focus on the issues related to behavior formulation, rather than emphasizing behavior change. These issues should be raised in our younger age groups, where the developing behavior patterns can be influenced, rather than attempting to devote all of our resources to behavior change among adults and older adolescents.

Finally, I have come to more fully appreciate the impact of AIDS when I realize that my nine year old daughter and my six year old son will grow up into a world of AIDS. Unfortunately, this will occur regardless of whether they live in New York or California, or if they live in Minnesota or Iowa. AIDS in the heartland will take a serious toll. Maybe not now, but eventually. It is critical that we not forget that area which has been considered to date as often the flyover land for AIDS. Thank you.

MR. CREEDON: Do we have some questions? Yes, Cory?

DR. SERVAAS: Could you clarify something; we talked about it earlier, and it has to do with prevalence. That is the testing of the blood donors in Minnesota. You had in excess of 250,000 low-risk, and no positives. Could you explain that?

DR. OSTERHOLM: We have a somewhat unique situation in Minnesota, with a very close working relationship between our state health departments and the two blood banks which are responsible for testing all the residents within the state. Within the context of that, we do all the follow-up through the state health department and any HIV positive, in this case talking about a reactive EIA positive Western Blot donor. As of last month we had tested a total of 520,000 different donations, which is approximately 320,000 different donors. It was raised this morning that a number of them are repeat donors. To date we have identified 15 positive individuals, of which we have followed up all 15; 14 of the 15 had acknowledged high risk behavior; one did not. We have completed culturing 13 of these individuals which included the one individual who did not acknowledge risk factor; 13 of 13 are virus positive.

The other two are undergoing culture procedures right now. We have every reason to believe, because both are high risk -- and one actually has clinical diseases -- they will both be positive. So, in our state, in a very low risk setting with two very, very outstanding laboratories, we did not find a single positive in 520,000 tests. Excuse me, false positives in 520,000 tests with 320,000 different individuals. We are continuing to monitor that.

MR. CREEDON: Any other questions?

MS. PULLEN: Does your state require reporting of HIV positive individuals, or just of cases?

DR. OSTERHOLM: We do require reporting by all health care officials for anyone who is HIV antibody positive, as defined by a positive Western Blot or other confirmatory tests.

MS. PULLEN: What do you do with that information?

DR. OSTERHOLM: Several things. First of all, we do -- as has been indicated by the Centers for Disease Control -- try to define how we can, in the best ways possible, the demographic aspects of that information. We have initiated a number of surveys within our states so as to attempt to define that part of the iceberg underneath the water line. But also, in addition, in terms of risk reduction information, we do have a very active contact notification program which we then do follow-up with these individual patients when reported. We now have more than

we can handle. We have had over 600 individuals who are HIV positive reported to us in the last several months, so that we are a bit overwhelmed, and we do have a priority system for that.

In terms of unsuspecting contacts, et cetera, in terms of following that up. So we have made every attempt, either through our own agency or through local groups which we support, in terms of risk reduction programs to provide that. I think one of the things that I would like to emphasize relative to that is that we are very aware of -- and I am sure that this is not anything new to anyone in the audience -- that unfortunately we have had a certain fixation in this country upon testing an individual, providing them with an hour of counseling, and appreciating that we will be able to change one of the most intimate behaviors in our lives with that testing and one hour of counseling. I think that we are initiating a number of programs to look at long-term behavior change support programs that will allow that individual to continue to receive that kind of behavior change support necessary.

MS. PULLEN: Have you been able to identify any seropositives through the contact notification program?

DR. OSTERHOLM: Yes, we have.

MS. PULLEN: Have you experienced any difficulties with confidentiality in that program?

DR. OSTERHOLM: We have not experienced any problems with confidentiality; but, in terms of the overall program, Minnesota probably has the tightest single piece of legislation in the country on a statewide basis, in terms of confidentiality. It is a result of efforts years ago to appreciate the importance of confidentiality, whether the record happens to be associated with mumps, measles, rubella, or HIV. We have very strong protections, including penalties for release. But, more importantly, our records are not even discoverable in a court of law by law. So that should we be provided with a subpoena, we do not have to surrender those records.

MS. PULLEN: Would you provide a copy of that statute to us please?

DR. OSTERHOLM: Sure, I would be very happy to.

MS. PULLEN: Thank you.

MR. CREEDON: Have you had much of a public outcry about this program?

DR. OSTERHOLM: I would say yes and no. I don't know how to answer that, in the sense that I think that unfortunately

far too often there have been certain what I would call fringe elements who have received a great deal of publicity, and who have received a great deal of attention, who hardly represent the mainstream of the infected individuals involved. Yet it seems as if there is a lot of outcry. I had the dubious distinction, for the first time in my career last fall, of having someone call for my resignation.

It happened by two different people on the same day, totally by accident. One was a Lyndon LaRouche Congressional candidate from southwestern Minnesota, and the other was a well known, outspoken Gay activist from the Twin Cities. One because I was turning the state over to Gay men, and the other one because, in fact, I had been bought over by the Gay lobby. I think that when you try to appraise that type of outcry, you then begin to put yourself somewhere in the appropriate perspective of where public health has to be and should be. In terms of the mainstream, no. In fact, I think there has been tremendous support from within various groups within the state.

DR. WALSH: Did I understand you to say that you contact tracing?

DR. OSTERHOLM: We do contact notification, yes. We have several forms of it.

DR. WALSH: Have you had any resistance from the contacts when you traced them?

DR. OSTERHOLM: Are you talking about the individuals whose names have been provided?

DR. WALSH: Yes.

DR. OSTERHOLM: Actually I can say that I know of none specifically. I think, again, that most of the times when one is working with partner referral contact notification, (a) it works in those areas where the seroprevalence is still quite low. I think in a place like Minnesota that is one particular option. (b) It is a method to bring home that personal vulnerability far in advance of the deaths, or at least the visible sign of AIDS, which is in many cases, I think, a major motivating factor in some of our larger cities of the East and West coast. And (c) I think the point is that the contact notification is only as good as the voluntary nature upon which people will, in fact, identify contacts or can identify contacts. The first thing one does is, in fact, attempt to help the individual do the contact notification themselves. That is always the best, if it can be done and is done. In some cases, that is not elected to be done. We actually have a program that we have developed and which we call Partner Outreach Service, where we actually will help individuals through several sessions to develop the skills to do

their own contact notification. Then we have our own separate notifiers that will do the same thing. But I think on the whole no, we have not really experienced any of the kinds of --

DR. WALSH: That bears out the same experience that Colorado has had. They have had virtually no resistance on contact tracing.

DR. OSTERHOLM: I think I should emphasize again that this is a very labor intensive effort, not one that I think should be taken lightly, but it can only be a small piece of a very large prevention program, because of the number of people you can reach. But I think clearly for unsuspecting contacts it can be a major effort.

MR. CREEDON: Terry?

DR. CRENSHAW: I think you made just a critical point that I would like you to elaborate on, and that I think is not very well appreciated. That is that in counseling and testing, just as with sex, often once is not enough. One hour of information when a patient learns of their positive status, when anxiety levels are so high, does not necessarily sink in and induce behavior change. Could you elaborate a bit on your programs of reinforcement, and how you are finding that to be effective?

DR. OSTERHOLM: First of all, let me point out that, in fact, some of the most significant changes from a population base standpoint of sexual behavior in Minnesota have occurred among Gay-identified men. I want to make that point up front, because I think these are the individuals who come to grips not only with their sexuality, but with the AIDS problem. The larger problem that we have in Minnesota -- and I think is characteristic of much of this country -- and should not, and is often unfortunately characterized by the experiences of places like New York City and San Francisco, is appreciate that the vast majority of men who have sex with men are not Gay-identified. This probably came home best to us a year and a half ago, and we had a male prostitute who came forward who is infected with HIV; and, based on signs and symptoms, had been infected for at least several years.

In the previous four years he had had sex with over 1,000 different Twin Cities men from the affluent suburbs of the southwestern part of the Twin Cities. In most of the cases, he had to crawl over the children's toys to get in the front door back into the bedroom. And, on a number of occasions, had to crawl out the back window as the wife came home early unexpectedly. We did a lot of follow-up in those settings.

Unfortunately, the idea of human sexuality -- we often talk about the Kinsey scale, and I am not one to lecture to you about human sexuality; but I think we in public health in Minnesota fully appreciated that from that zero to six, whether you are heterosexual or homosexual. There are a lot of people out there that might be one number in terms of what they do romantically, one number in what they do emotionally, and one number what they do physically. Our biggest problem, then, in attempting to deal with HIV is attempting to get people to come to the realization of their own human sexuality. They are in such denial with it that it makes it much more difficult for us to even begin to deal with AIDS. That is in stark contrast to that area where people are Gay-identified, they are openly part of a Gay "community." It makes it much easier to deal with HIV. That's why, in Minnesota, that combined with the relative absence of acute frank AIDS cases yet makes this idea of one hour kind of support -- it is like telling the drunk driver one time on the highway as he is driving home, You shouldn't do this, even though he is a chronic drinker, and expect that you have just solved his chronic drinking and driving problem.

DR. CRENSHAW: Do you have any follow-up on your more frequent counseling approaches and impact upon behavior?

DR. OSTERHOLM: I think one of the real difficult aspects of this epidemic is, in attempting to plan "research strategies" concurrently with intervention, as we so have devised it, it is very difficult. Some of you may be aware in Minnesota -- where some of the finest work in the country has been at the University of Minnesota on non-smoking and youth, and that whole area of behavior -- we are working with that group to begin to define and further characterize how can one actually begin to look at behavior change in human sexuality. I would go back and reemphasize, though, I think from our experience with all other "preventable high risk behaviors" that formulation is a heck of a lot better than change.

DR. CRENSHAW: That is another exceedingly good point that you raised, because I think people nix the advice of the kind that you give to someone once they are already either sexually active or active in substance abuse. Once they are not yet sexually active, or active in drug abuse, and how you can influence that behavior. Thank you.

MR. CREEDON: Cory?

DR. SERVAAS: Could you tell us how you would approach getting other laboratories in the country up to speed? And you mentioned that Iowa City has a good lab also. But if Minnesota can do it, and Iowa can do it, how could we get uniformity in the country, do you think?

DR. OSTERHOLM: Well, first of all, let me just indicate for the record, I'm an epidemiologist and not a laboratorian, so that I don't speak out of turn. I think that one of the things that I've been very careful about emphasizing is that the data I've just provided to you from Minnesota relative to our blood bank testing -- and I might add that these two laboratories, in fact, also do all of our high-risk testing, and we have actually taken 400 specimens of which we had approximately 100 positives and blindly provided them to the two laboratories independently, and they had 100 percent agreement on 400 specimens, so it's not even a function of just they were lucky at their labs. I mean, action and proficiency, they're very good. But I think it's developing that kind of expertise. I think Dr. Francis made an excellent point this morning. Others have commented that where you do have proficiency interest and you do have the kind of laboratory expertise, this test in the hands of those kinds of laboratories, I think it's true; the clerical errors exceed the errors that come from the laboratory tests themselves. I might add that even in our own state, we have even developed the expertise not only in testing HIV-infected individuals for antibody, but also in culture. In work that was done at the University of Minnesota by Dr. Hank Balfour and colleagues, we've just completed 56 asymptomatic individuals with hemophilia who are Western Blot positive, and virus was cultured from 56 of 56.

I think the techniques in the laboratory have improved significantly over the last two years, such that to do it, I would say working in conjunction with the CDC through their proficiency testing program, and I would have to say that the laboratorians on a whole, I think, are doing a lot themselves. I think the problems have come in, when I've seen it come in, are some fly-by-night companies that have no interest in necessarily legitimizing the proficiency issue have come onboard, and maybe that's an area that needs to be addressed. But I think there are many qualified laboratories out there now that could do the kinds of testing that we're talking about.

MR. CREEDON: We can open the questions, I think, to the entire panel now. You may have skipped asking a question before when we were moving on. Yes?

MS. GEBBIE: Actually I have the same set of questions for Dr. Axelrod and Dr. Osterholm. We heard this morning a good deal about the present estimates and calculations of incidence and prevalence in this country, and it's very clear that we're working from limited data, from special populations, and kind of interpolating various places. It's not complete. A key question, I think, for this panel on a national basis, which each of you must have answered on a state basis, is whether the kind of information we have now, even though it's a range estimate rather than a specific number of infected and so on, whether

that's adequate to make the kind of policy projections and policy recommendations we're going to be making, or whether it is not, and if it is not, can each of you identify the specific kinds of studies that you think would be most critical to do to start filling those data holes?

DR. AXELROD: Well, I would first say that I don't think the data that we have represent the kind of information that I think is adequate to allow us to address the public health needs. As I indicated earlier, epidemiology is the tool of all of us who are involved in public health, and the tool that we have is a very blunt one right now in terms of our ability to deal with the kinds of special resource needs that have to be allocated within the community. I don't think that we are able to establish the kind of hierarchy that we need to establish with respect to public health initiatives with the information that we have.

What are the kinds of things that can be done? Well, I think that the CDC effort and our own with respect to testing a very large segment of the population to determine the seroprevalence among both high-risk and no-known-risk populations is very, very critical. I think it's also important that we do some analyses of cases, of individuals who have various kinds of infections as part of the linear study of what is happening to populations within certain ages who are being hospitalized for infections that would not normally require hospitalization, so that we can begin to get some better idea of the progress of the disease and perhaps more information with respect to those cases by virtue of this kind of evaluation of what the outcome is going to be.

As Dr. Langmuir correctly pointed out, we don't know whether the case mortality rate is going to be 50 percent or 60 percent or 30 percent or whatever it is. But we do know that there appears to be a great deal of variation, and we don't know whether that variation relates to cofactors which we can define by virtue of the kind of studies that I think can be undertaken. So I think that there is a great deal of need for additional epidemiologic studies to sharpen our ability to allocate the scarce resources that we have, whether it be in prevention, education, counseling, or the direct provision of health care services.

DR. OSTERHOLM: I would agree largely with those comments. I would add, however, that if we're talking about behavior change, then we do need more information relative to how and where do we target that. But if we're talking about behavior formulation, we don't. We don't need to be told anymore that our youth are going to grow up into a world of AIDS, and that that those problems which are affecting our adults today will be the problems that will affect our youth tomorrow. We

don't need to be told anymore that it's much easier to formulate behavior than it is to change behavior. And yet I see a real absence in this country of any concerted effort for real youth education relative to HIV prevention in a way that I think will provide us the kinds of benefits tomorrow and next year. I think far too often we've been preoccupied with this epidemic, and appropriately so because of the size of it, the next six months, the next year, or the next two years, and we need to start looking at a generation. I think even you as a group have heard already the likelihood of a vaccine. If even a vaccine is available, what would be the likely outcome in terms of the number of infected individuals.

I would like to say one thing. I think that we do now realize, I think, that if we look at the risk behaviors out there, we're at an all time high in this country for hepatitis B. We've already heard information on heterosexual transmission of various sexually transmitted diseases. I can tell you in Minnesota and many other areas like us, that there still is a relative absence of belief in the AIDS epidemic. I keep getting challenged on this whole issue, because it just hasn't hit yet. And it's like the person who can't see the tornado in the middle of the night on the plains out there and doesn't believe it's coming until after it just went by their house, and when it finally came in the middle of the night, they believe it was out there. I think that's where we have the problem. In fact, there are some programs we can begin to deal with. I would say that the CDC family of studies approach, which I find, I think, a very positive approach, I know in our own state, as an adjunct to what we're already doing, will help us to further refine where the infection is and where we need to target what resources.

DR. AXELROD: I think I would just make one other comment which I have not, because I suspect most of you are aware of it, and that is that New York State has a mandated AIDS curriculum currently that begins in kindergarten and runs throughout the entire curriculum, so that although there has been a great deal of controversy about certain sections of it, there has been the acceptance of a need for an AIDS curriculum which will be in place and mandated by the Regents.

MR. CREEDON: Dr. Curran?

DR. CURRAN: As long as everybody is getting in their wish list for data, in thinking down the road, I think that -- I really agree with Mike that behavior formulation would be the answer. I think that there's not been a lot of research in the last few centuries, decades, years on how -- what formulates promiscuous sexual behavior and intravenous drug abuse, and I think that we know that it shouldn't be formulated, but the characteristics that lead to it are pretty complex socially and psychologically, and I think that probably there's a need for

quite a bit more research in those areas. They have not been areas that a lot of people have jumped into. All of the sex research societies are relatively new, and you can count the number of books recently on why people are heroin abusers, you know, relative to the importance of the problem.

MR. CREEDON: What is your reaction, Dr. Curran, to some of Dr. Axelrod's more recent statements, as well as his earlier statements, about a lot more needs to be done in order to get a handle on it? I mean, do you think -- I guess in part it's the same question that Ms. Gebbie asked, you know. In other words, are there additional studies that are not -- that have not been done or are not being planned or contemplated that we should be thinking about over and above the ones that have already been planned?

DR. CURRAN: Well, I agree with just about everything that Dr. Axelrod said. I'd have trouble repeating it. [Laughter.] But I've always agreed with just about everything he's said. [Laughter.]

MR. CREEDON: Well, we have it on the record here.

DR. AXELROD: I'll write that down.

MS. GEBBIE: He didn't make that in the future tense, though.

[Laughter.]

DR. CURRAN: I don't know what "federal coordination" means, but I think a Manhattan Project would probably be based in Albany.

[Laughter.]

Or in Manhattan, one of the two. I think that we, as a society, don't understand heroin abuse, homosexuality, and sexual promiscuity very well. I've always been amazed at how much -- I used to work in STDs before AIDS. I was always amazed -- as I've become middle-aged, I understand it better, but I was always amazed at how many people could get STDs each year and how few middle-aged people ever had one.

[Laughter.]

And I think sexuality is a phase we all pass through, and we don't know how we got there, and we can't remember how we left it. I mean, --

MR. CREEDON: Are you speaking for yourself here?

[Laughter.]

DR. CURRAN: I mean, I'm in part serious. It's amazing how we can watch the TV shows every day and see all the blatant sexuality thrown at us without ever dealing with it on an interpersonal basis. Almost none of us, I'm sure none of you panel members have really talked about your own sexual lives with each other, and yet all you do, you know, probably 60 hours a week is work on this problem. But as individuals, we don't do that. Maybe Dr. Crenshaw, who works in this all the time, is more open. But I mean seriously, as a society, we don't provide much guidance for our children. I have trouble -- I have kids about the same age as Mike's, and it's awfully tough. It's tough for parents. I mean, if we say it's the parents' job to give kids sex education, how do they do that? How do we do that? How do we tell them to do that? I mean, what is this process of behavior formulation, that I agree with Mike is important, you know?

DR. CRENSHAW: Jim, I want to underscore here that we don't know what we don't know, most of us. Everybody, if they've had sex once or twice, feels that they have a perspective on the world of human sexuality and are completely oblivious to the true spectrum of activity that is occurring. And what I'll add there, when you're talking about multiple partners or promiscuity, it's talked about as though there is a non-promiscuous person and a promiscuous person, and indeed what you're more likely to find are episodes in a person's life, not just in their teenage phase, but in between marriages perhaps or during periods of being single, when they may go through very aggressive or even compulsive sexual activity, and then spend the majority of their life, once they get trapped into or find a relationship, where they are not being as sexually active with as many partners. So there are many, many different phases in addition to the Kinsey spectrum that you mentioned of sexual orientation in our society.

DR. CURRAN: I think Mr. Creedon and Dr. Walsh may remember. I referred to that as serial monogamy.

MR. CREEDON: I remember it very well. You said serial monogamy with some occasional deviation; was that what it was?

DR. CURRAN: Yes, that's what it was, something like that.

DR. WALSH: I think one thing you have to keep in mind with your children, in my case my grandchildren, if you wait until they're 15, it's too late. You're invading their privacy. You've got to get them earlier, if you're going to talk to them at all about sexual behavior. You've got to get them before that.

DR. OSTERHOLM: But I think that one of the points that I would really like to emphasize here, and it's been driven home to me as someone who is really out in the trenches. Several years ago, I was in a community giving a lecture on AIDS, and a gentleman who is a well recognized individual in the community was on the same program with me, and I basically made the spiel that I just made just now about the need for behavior formulation, and he very appropriately got up as part of the parent group and emphasized that, in fact, that was important, but that it really should be at home, and it should start at home, and the schools really didn't have business being involved with it.

And in fact, I might add, it was at the same meeting that when I talked about sex education, I had an individual stand up and said that he had 20 years ago completed schooling on how to weld, and now he welds, and so he didn't think we should be teaching sex education in school if we're really going to deal with the AIDS epidemic. But in fact, I think that what happened here was very, very instructive to me, because this individual, after saying this, had talked about in his own family. He and his wife had just spent the last 25 years raising their kids in a way that they were very proud of, and that they all had healthy sexualities, et cetera, et cetera. Seven months later, this individual's son, who is married and had three children, was diagnosed with AIDS in another state and was an unknown bisexual to his father and his mother and to his wife. I think the whole point is, I appreciate this more and more as somebody who has some academic friends in the area of fish and wildlife biology, that in fact we know more about the sex lives on a population basis of white-tailed deer and ruffed grouse than we do about human beings, and we're trying very hard to change human behavior relative to this whole issue of human behavior.

And so I'd have to say, to get back to behavior formulation, it's very critical that some of the research not be just done in seroprevalence surveys. We can do seroprevalence surveys until we're blue in the face, but the ultimate point is changing behavior. And I am not one to ascribe to the fact that if you tell someone they're at risk, that means you change behavior. We've got to get to the very basic level of behavior formulation and behavior change. And social scientists in this country have been grossly underfunded. I'm not a social scientist, so I'm not putting a plug in for my own area. We don't know.

MR. CREEDON: Well, you know, one of our primary motives is survival, and I guess if people think that their survival is threatened, they'll change their behavior maybe. Yes, Dr. SerVaas?

DR. SERVAAS: We know what Dr. Axelrod has done with pregnant women's blood and serum and Dr. Curran. But in Minnesota, do you have very much good help for the pregnant women who are HIV positive, and what do you do in Planned Parenthood?

DR. OSTERHOLM: Well, I think at this point, we have tried very hard in our family planning facilities and in prenatal care to emphasize the need for risk screening and so forth. I think that one of the problems we have is that, as one of the individuals you will hear from tomorrow, Dr. Landesman, found in a recent study in New York, half of the individuals, who were HIV infected at the time presenting with delivery, had no identified risk factor other than that they were a member of the community of color, and they'd had multiple male partners throughout their life. We have tried to emphasize more of that. We are beginning to look in Minnesota as part of the family of surveys and other statewide activities what Dr. Axelrod described earlier in doing testing of all newborns to try to better target that program. We are, you know, looking at that as an approach.

DR. SERVAAS: Then do you let them know, so they won't nurse their babies, or do they just go on and nurse their babies?

DR. OSTERHOLM: Well, at this point, if we know, we clearly believe they have a right to know and should know.

DR. SERVAAS: And so you do tell them?

DR. OSTERHOLM: When we have anyone who is HIV positive, we will. Now we haven't done any blinded studies that way, so we would not be in a position. On the other hand, we have missed a lot of HIV-infected individuals, I'm sure, as we're starting now to see a number of HIV infected children, not yet AIDS cases. We only have two pediatric AIDS cases, and I know of many, many children we're currently following who are HIV infected, who will be AIDS cases within the next several, you know, years probably.

MR. CREEDON: Our time is about up, so I'd like to turn the chair back to Admiral Watkins. I would like to just ask Dr. Langmuir before I do that, you keep us informed of your -- however often you make these projections, that you let us know when it starts down. That would be very helpful.

DR. LANGMUIR: I will be watching what comes from CDC.

MR. CREEDON: Thank you.

ADMIRAL WATKINS: Dr. Curran, in your family of surveys that you posed in your latest -- in the CDC report to the Domestic Policy Council, you talked about sentinel surveillance

in 30 of the standard metropolitan statistical areas, and you talked to us about how vast a survey that was, and it seems to me in discussing that, you opened the door to the possible rejection by certain people who will be tagged in that survey that may not come forward. And the question is in my own mind, then, it's fine to lay out this concept of survey, but who else is getting involved to lay the groundwork and prepare the way for the Lord on this one? It seems to me that an effort can be made to optimize that 30 SMSAs to make them as productive as possible by an education and leadership program that is a precursor and walks us up to it to the point where the nation knows it's going on, knows who's leading it, encourages the participation, so that when we get that sample, it becomes a useful sample in a seroprevalence database and is not just another verification that we're at 1.5 million, because we really can't trust it anyway. You see, we had so many people not come forward that we're not really sure what we have.

It just seems to me that we don't need to accept that. Now you also talked about, and perhaps you were interested in some antidiscrimination things. Dr. Osterholm says they have the tightest thing going in Minnesota, and it's not a problem there. Capitol Hill says it's a big problem. There's fractionation in the states. We don't have the proper groundwork laid. We should have federal laws. Dr. Bowen says, no, we shouldn't. We should take it easy, let the states do their thing. Two years ago, there was only 40 pages on AIDS and what states were doing. Today there's three volumes on AIDS, what the states are doing.

This is still a very confusing area, and it seems to me that if we're going to make some recommendations to the President on seroprevalence, and you're moving out with a plan that perhaps has already been bought by the Domestic Policy Council as the way to go -- I haven't seen that support, but I assume it's going to come -- and that really we have to wait for two years to get the ultimate survey, but actually this 30 SMSAs starting May of '88 could well suffice as a much more accurate baseline data from which we could make projections -- then it would seem to me we'd optimize that and make it a new kernel of credibility in this database and have a less vacillating sort of approach to it. Could you fill us in on how you would better do that? What recommendation might you make to make this a much more accurate -- let's say the optimum would be that everyone would come forward, because you could prove the anonymity; you could prove that what you were doing was legitimate; you've laid the groundwork to encourage people in the high-risk areas to come forward -- so can you give us a little idea of what you might do there?

DR. CURRAN: Sure. I think first of all, you're right about the Domestic Policy Council and the President. The report was submitted to the Domestic Policy Council on the day of your

press conference, and Attorney General Meese endorsed it enthusiastically, as he had in previous meetings, the issue of the family of surveys. We were assured that the resources would be available to do that. In anticipation of those resources, we detailed 125 CDC employees who weren't working on AIDS to assist state and local health departments in those 30 areas to prepare and plan and a budget request, which they are doing, which is due Monday, to actually begin these surveys in those 30 metropolitan areas. The issue of leadership is again like the epidemic; it's a multiple one. There's the national leadership, the federal leadership. There's the state and local leadership. And then there's leadership not only for the surveys themselves, but for the prevention and control programs which are going on next to them.

I think there's again some -- it's very difficult to separate the prevention and control activities from the surveillance activities which target those control activities and evaluate them at the same time. For example, you can do a blinded testing program in a VD clinic, which is offering voluntary testing and counseling at the same time. You may have half of the patients in the clinic undergo voluntary testing and counseling and half don't. What you want to know is, what's the level of infection in that clinic. So being tested blindly, for example, doesn't preclude you from getting tested voluntarily and getting counseled. The same person might get tested twice, but for a different purpose. Do you see what I mean? So what you want is leadership at the local level and at the federal level for the prevention and control activities and for the surveillance activities.

Now in the FY '88 budget, federal budget, there's quite an expansion of testing and counseling efforts, as well as community education efforts, which will provide funds to state and local governments. It can be argued whether they're enough, whether they're the right focus, but there's quite an expansion over the '87 budget. We don't have an FY '88 budget yet. This is one of the longest, I think, times. You know this from your years in government -- you've never had a budget on October 1st. December 10th is a little later than normal. But we presume that the '88 budget will be some combination of what Congress wants, what the President has requested, and it will be -- whatever it is, it will be a big increase over '87, and a lot of that big increase will be for testing and counseling. That money will go to the states close to the same time as the survey money. The money will not be focused in those 30 SMSAs, but it is weighted toward where the problems are, and this is an urban disease to a large extent. So a lot more of the money will be available in those areas where the surveys are and where the disease is.

ADMIRAL WATKINS: But don't you agree it would be -- as part of the strategy, to start building the educational program

for the nation as a whole of what these 30 SMSAs are, what the intention is, so that there's some basic knowledge. The people that will read your report, the technical people, all understand it; but the American people are not going to get into that report in that kind of depth, and it just seems to me that national leadership, state leadership, and local leadership should be integrated in some way to optimize the outcome of that very incredible survey. It just seems to me, I don't see that coming out of any entity.

DR. CURRAN: Well, I think I would agree with you. You're talking about coordinated leadership.

ADMIRAL WATKINS: Something like that.

DR. CURRAN: If you will. Something that would say, this is what the prevention program is. This is what the surveillance program is. This is what the education program is. It's fully supported, and it's nationally coordinated at the national level and the state level and the local level.

ADMIRAL WATKINS: And whatever obstacles there are, they'll be removed. If Minnesota has no obstacles because of laws, other states might. And it seems to me that's something that the state legislature, were they to hear that kind of strategy, may work on very hard in this forthcoming legislative cycle that may pull the states more together on the kinds of things that they feel may be necessary.

DR. CURRAN: Well, I can't speak for the health care part. The CDC is involved in prevention programs and only partially involved in prevention programs in the IV drug use area. But I can say that we're in close contact with the state health officers and the state epidemiologists, and it would be very easy for us -- we already are getting constant readings from them about what type of leadership and coordination they want from the federal government.

ADMIRAL WATKINS: Dr. Axelrod, a couple of things came up. We heard here that in New York, for example, there may be a three to six month wait in some of the drug treatment centers before people can even be admitted because of a shortage. You talked about the fact that a 1,000 to 10,000 treatment slot increase in New York was going to take place. Is that enough to get the waiting lines down to something that is reasonable or is that still so inadequate that it is like a little drop in the ocean?

DR. AXELROD: I think it will get the waiting list down but there will be a new waiting list that will develop. As I indicated, there are currently 40,000 slots. Our estimates are there are 250,000 IV drug abusers.

MR. CREEDON: What is a "slot?"

DR. AXELROD: A position for someone to fill who is in need of service or willing to accept service. There are roughly 50 percent of the 250,000 that probably could be induced to participate in the methadone maintenance program of one form or another. Even increasing it to 50,000 or 60,000, it still leaves a large potential unmet need that could be addressed by expanding both the number of sites, the number of available slots for methadone maintenance, but also to change the nature of the slots to bring the methadone to the places where the individuals are, whether it is some of the shelters we have for the homeless. The idea is to move the methadone maintenance to where the individuals are, not alone to require those who are the drug abusers to come to the centers. I think that we require a rather new view of the way in which we are going to provide those services and to address the needs of the individuals rather than address the needs of the providers.

ADMIRAL WATKINS: I take it that when you mentioned this was one area where the federal government needed to focus and it is certainly one of the major areas that we are going to be addressing next week in our hearing, trying to get some feel for what the Federal role would be. Let's take it in the State of New York vis-a-vis availability of drug treatment centers.

DR. AXELROD: Absolutely, Mr. Chairman. I think we have all recognized the fact that our efforts, no matter how bold, to interdict the flow of availability of intravenous drugs into this country have not met with overwhelming success. Having failed and it may be a modified failure, having failed in terms of total interdiction, we as a government have an obligation for that failure to address those who have been affected and who are part of our drug abusing population. I don't feel we as a nation have effectively addressed the large number of intravenous drug abusers that exist in our country. I think we have an obligation that in fact is a failed obligation.

ADMIRAL WATKINS: You also implied that the federal government needs to get into the business of fixing the discrimination issue. Why can't New York State solve its discriminatory practices either in law or by attitudinal change, educational programs, much as Minnesota has done?

DR. AXELROD: I didn't suggest we couldn't. I think the issue that you raise is one of leadership and where this nation as this nation stands with respect to discrimination, how we as a government, and I speak of the federal government, want to deal with the problems of discrimination and confidentiality. I think it can be done in such a way as to make it uniform and make it a clear issue with respect to where this government, this federal government stands. We can do it in New York State. We

will. That's not the issue. The issue is where is the leadership. Where is the determination, that this is not going to be tolerated by this state or by this nation, what is more important, the state or the nation. I think that each state represents a small fragment. We can get into a long discussion of Jeffersonian or Hamiltonian views of government, but that gets us nowhere. The issue is leadership and you have identified it, and the leadership should come by a national commitment to the elimination of discrimination.

ADMIRAL WATKINS: Is it possible from your point of view as the Centers for Disease Control moves down this seroprevalence survey nationally and their stepping stone technique, to use that as the opportunity to provide that leadership? Does that enhance the work of their survey and the value of it?

DR. AXELROD: I think absolutely. The worth of their survey is clear to all of us in public health. I think you are quite correct in suggesting that there needs to be a greater public recognition of that worth and how it relates to our efforts to deal with the problem. I think it takes a clear statement by the federal government, not necessarily the CDC, by the Domestic Policy Council or someone else at that level of coordination of governmental activities. We were successful in New York State by virtue of the Governor placing this issue right up front and saying this is what we are going to do, this is absolutely critical to our ability to address the issue as a state, and we were going to do this. I can assure you it wasn't all roses. At the same time, we did educate a lot of people about what we were doing, why we were doing it and how the information was going to be used.

ADMIRAL WATKINS: Dr. Curran, with that statement from Dr. Axelrod, it seems to me that it would be very valuable for this Commission to have you review your own survey plans that you have and give us some thoughts, come back and talk to us perhaps as a body or talk to me individually, and tell me what your people think, in your connections with the state and local health officers and the others who are going to have to work this problem in the survey, and tell me what you think the obstacles are to your getting the very best data. The goal is highest value for your survey. If I were to have the best of all worlds, I would knock down these obstacles as we move down this survey path to optimize it. If you will give us those obstacles, maybe we can pick those up one by one and we can get some consensus to knock them over and make this a very effective survey for you. Does that sound like it is doable?

DR. CURRAN: Yes, sir.

ADMIRAL WATKINS: Let's get all the obstacles out in the open. What would make you very happy, if you could walk into a situation where everybody is going to stick out their arm and bleed?

DR. CURRAN: Get rid of discrimination, provide medical care.

ADMIRAL WATKINS: That is good but let's get very specific. What do you mean by that? Do we have manpower shortage problems? Is that the issue? Are there bureaucratic hurdles we have to get over? What kind of resources are you really talking about? I think we have to get very specific now. This is something we might be able to recommend to the President in time to assist you. I would like to have the other Commissioners just nod whether they agree that this is an useful thing for the Commissioners to have from Dr. Curran.

DR. WALSH: I think it is useful. I wonder where he will be working next month if he does it.

[Laughter.]

ADMIRAL WATKINS: He's courageous.

DR. WALSH: Part of the obstacles he has to remove --

ADMIRAL WATKINS: He made some comments today that were very open and refreshing.

DR. WALSH: If you will give us the recommendations, I think they would be invaluable and we will ascribe anonymity and confidentiality.

DR. LANGMUIR: As a general epidemiologist, not involved at all in the survey issue, I have been listening, and there is one crucial point in the random family sample survey, namely, this is very expensive. Somebody has to go and knock on randomly selected doors, be very persuasive, even with all these obstacles broken down, and then take a blood specimen, get it separated, ship it to the lab. I have heard that the price of that is somewhere from $500 to say $1,000 per specimen. That seems low to me. You have to get an organization to do it, travel. If you do a telephone survey, but this is getting that specimen. The term they brought up is a national health survey of 35,000. That is a sizeable number. We admit that seems small. Let's say it is done for 100,000. $1,000 per specimen. You are getting into tight sums of money.

When you are finished, what do you have? You have one figure from a random sample, much like the unemployment rates, for that particular time of the survey which was done over a

period of some months. It tells me as an epidemiologist almost nothing. It may be one percent; half of one percent; some figure. It really makes no difference if it is four tenths or six tenths. The numbers of positives, if it is 1 per 1,000 to start with, there will only be 100 positives in 100,000 samples. To be meaningful, we have to repeat this say every three months or every month like the unemployment survey. If we could do that, we could get the trend. That would be of some value. It still wouldn't tell us where the problem is. The 30 city standard metropolitan area gives us immense amounts of information, crude though they be, variable though they be, they are very useful locally and brought together through CDC into a coordinated regular report, would give us trends and tell us what is really going on. I am much in favor of the 30 area study. I don't see the utility of a random study.

ADMIRAL WATKINS: Dr. Axelrod, would you just give me a feel for the Minnesota experience and its relevance to New York? Let me say New York City in particular.

DR. AXELROD: The Minnesota experience with respect to contact tracing specifically?

ADMIRAL WATKINS: With respect to their experience. They have obviously a different culture in the society there for a variety of different reasons. It was mentioned on the two coasts, we have more out of the closet willingness to come forward. In other words, how do we extrapolate from the State of Minnesota and the Twin Cities to New York and New York City in particular?

DR. AXELROD: I don't think you can extrapolate to the major metropolitan area, the focus of the epidemic, certainly for the IV drug problem in New York, which is Battery Park and extends into parts of New Jersey. If one does the focus, that is where you would find it. The population in New York City is very, very different than that in Minnesota. On the other hand, there are areas in New York State, up state in particular, in which there are similarities to the kinds of things that have been described in Minnesota. Some of the experiences there may be relevant to the kinds of recommendations that would fall from the discussions we have had about Minnesota, but I think in terms of the relationship of the major metropolitan area, the New Jersey/New York City area that is most affected and represents some 90 percent of the cases of AIDS at the present time and 90 percent of the cases of seroprevalence, I'm not sure there is a direct relationship.

There are some areas, some general areas, which are important. Those, I think, relate to the counseling issue, the continuity of counseling, which we certainly agree with; the formulation of behavior, which we certainly would agree with, as

part of the rationale for some of the activities that we have undertaken. The school curriculum which we have developed as part of that aspect of the formulation of behavior patterns that will prevent children during the course of their development from becoming part of the IV drug community or part of the tragedy that is AIDS at the present time. Those elements, I think, are relevant, not just to Minnesota or New York, but to the entire country. I think in terms of the different populations, the populations in fact in New York City and the metropolitan areas of New Jersey, are very different from those that are being observed in Minnesota.

ADMIRAL WATKINS: That closes our meeting for today. What I wanted to make sure of is that we keep the lines of communication open with this Commission. None of the Commissioners are satisfied that we have had enough of an opportunity to ask all the questions we would like to ask of you today. We have a full staff now and our intention is to prepare questions much as prepared in other hearings on the Hill and the like, where we ask you if you would please come back to us and answer certain questions that we were unable to ask and that we feel are very germane, particularly in this set of hearings on incidence and prevalence. We will be putting those together. We will ask the Commissioners to get their questions prepared and submitted to us in the office within the next week, before the next hearings next week on drug abuse. You must have your questions. If you are not satisfied by those prepared by staff that are in your briefing book, I would like to have the additional questions that we can follow up on. I can guarantee we will move expeditiously to the individual panelists, to all the panels, or whoever you feel is appropriate to answer the questions you ask, and we would hope the panelists would be willing to participate with us on answering those as expeditiously as you can, within a couple of weeks. Would that be an acceptable arrangement?

DR. AXELROD: Absolutely. I would suggest, Mr. Chairman, also with respect to your May meeting, we will have seroprevalence studies of effectively 100 percent of all newborn infants in the State of New York over a six month period by the time of that meeting, which I think might be very informative to you. We will have it broken down by major geographic areas, as long as it doesn't potentiate the identification of individuals.

ADMIRAL WATKINS: I want to thank you very much for spending the time to be with us today. It has been very important to the Commission. We appreciate the personal effort, the time and the willingness to spend these hours with us.

MR. CREEDON: Thank you.

[Whereupon, at 5:10 p.m., the meeting was adjourned.]