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ABSTRACT

This document presents witness testimony and prepared statements from the Congressional hearing called to examine the issue of acquired immune deficiency syndrome (AIDS) and the role of the Veterans' Administration (VA) in combating AIDS. Opening statements are included from Representatives G. V. Montgomery, J. Roy Rowland, Joseph P. Kennedy, II, and Bob McEwen. A prepared statement by Representative John Paul Hammerschmidt is given. The Representatives describe the seriousness of the AIDS problem and call for a national policy to fight the disease. In his testimony, John Gronvall, chief medical director of the Veterans' Administration, presents comments about AIDS, describes the status of AIDS in the VA, and briefly reviews AIDS research being conducted by the VA. Committee members' questions are then answered by Dr. Gronvall and his associates from the VA: Howard Cohn, Richard Greene, Susan Mather, Robert Lindsey, and Ralph Ibson. Other testimony is provided by James Curran, director of the AIDS program at the Center for Infectious Diseases, Centers for Disease Control (CDC). Dr. Curran describes efforts being conducted against AIDS, notes the cooperation between the VA and the CDC, and discusses counseling needs of AIDS patients and testing for AIDS. Materials submitted for the record are included. (NB)

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) AND THE VETERANS' ADMINISTRATION

HEARING

BEFORE THE

SUBCOMMITTEE ON
HOSPITALS AND HEALTH CARE

OF THE

COMMITTEE ON VETERANS' AFFAIRS
HOUSE OF REPRESENTATIVES

ONE HUNDREDTH CONGRESS

FIRST SESSION

JUNE 17, 1987

Printed for the use of the Committee on Veterans' Affairs

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CONTENTS

June 17, 1987

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) AND THE VETERANS' ADMINISTRATION

Wednesday, June 17, 1987

U.S. HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10 a.m., in room 334, Cannon House Office Building, Hon. G. V. (Sonny) Montgomery (chairman of the subcommittee] presiding.

Present: Representatives Montgomery, McEwen, Rowland of Connecticut, Burton, Penny, Rowland of Georgia, Kennedy, Kanjorski and Harris.

Also present: Representative Evans.

OPENING STATEMENT OF CHAIRMAN MONTGOMERY

Mr. MONTGOMERY. Good morning. The Subcommittee on Hospitals and Health Care will come to order.

The subcommittee meets this morning to receive testimony about the most serious health matter to face this country during this century, Acquired Immune Deficiency Syndrome, known as AIDS.

As if the terrible human suffering of this disease were not enough, the enormous burden on health care resources reminds us of the size of the problem. Fiscal and human resources devoted to AIDS are increasing. Treatment costs are high. Research costs are high and health education costs are also very high.

While some large gains in knowledge have been experienced, the common wisdom of the capable people who are working in this area is that several years will elapse before a vaccine is developed, and even longer before a cure can be expected.

It is critical that the Nation—and that the Veterans' Administration, as a large part of the U.S. capacity to deliver health care—come to terms with AIDS, and that means in all aspects. And as chairman of the House Veterans' Affairs Committee I have talked to our research people in the Veterans' Administration. We probably have the best research facilities in place than any other Government agency in this country. I have suggested and pleaded that our VA research people go out and find cures for AIDS and find the vaccine that would do the job. And thanks to Dr. Rowland, Roy Rowland of Georgia, a member of this committee, the only physician in the Congress of the United States—he has asked me to have this hearing.

We and the VA will be totally involved in AIDS. Not only are veterans getting AIDS, but they're coming into our facilities and they're talking about a testing program for veterans. So we hope we will gain something—we know we will gain something from having this hearing.

[The prepared statement of Chairman Montgomery appears on p. 61.]

Mr. MONTGOMERY. Dr. Rowland, I will be in and out. While I'm gone I hope you would preside. Do you have any comments before we call our first witnesses?

OPENING STATEMENT OF HON. J. ROY ROWLAND

Dr. ROWLAND of Georgia. Mr. Chairman, good morning, and good morning to everyone. I want to thank you and commend you for having this hearing.

Mr. Chairman, in my opinion over the past several weeks, debates on subjects related to Acquired Immune Deficiency Syndrome have really degenerated into partisan politics and philosophical polemics. What is needed is a scientifically-oriented, integrated national policy, and we don't have that at this time. Together as a Nation, and for that matter the world, we are facing an overwhelmingly threatening disease with a potential which I believe is worse than the Black Death of the 15th century in Europe. And yet, we are quarreling and debating our concerns as individuals.

Mr. Chairman, let there be no mistake. AIDS is a disease of people. Some believe it is a tragedy only for those whose behavior caused their suffering; but in fact, like every disease, from the merely inconvenient to the fatal, AIDS knows no morality. It is not judgmental. It is an affliction that is transmitted through blood and other body fluids, especially by intimate sexual contact and by drug abuse. But its victims are either the newborn or the old, male or female, rich or poor, devout or not.

Mr. Chairman, it is paradoxical that the discovery and identification of this virus—or perhaps, several viruses that attack the immune system in the body—has required the most sophisticated medical technology that has yet been developed by man. And yet, we can control its spread by using the most basic medical principles and education. Increasingly accurate tests for AIDS antibodies which are becoming more available require more and better-trained technicians and more complex laboratory equipment; and yet, ordinary changes in behavior can do much to prevent its spread—the use of commonly-available sexual protections, the use of regular medical decontamination procedures, and the prevention of multiple use of hypodermic needles, to name a few. This paradox of sophisticated and simple only makes the fear of AIDS worse. We who are accustomed to miracles of medicine are anxious about the time that it is taking to find a treatment and a cure. We, who are "can-do" Americans, are mistrustful of low grammar prevention and education programs that are promoted by health experts today for AIDS. We who are accustomed to the Government taking the lead in national crises are sorely agitated by the divisiveness among our leaders.

Mr. Chairman, when I came to Congress in 1983, we faced a different crisis. The Social Security System was mortally ill at that time. What happened was that people of all ideological sides came together as one, and a Social Security Commission, comprised of politicians and economists and administrators and ordinary citizens came together, in nonpartisan manner, to develop solutions. And the Congress, in a display of statesmanship, acted on those recommendations.

What we need now is another commission, formed of the same kind of people who are able to see the greater good: scientists, researchers, Members of Congress, health care providers, ordinary citizens, representing many points of view.

Certainly, research and education will be a part of the solutions recommended by such a commission. Perhaps the most important result, however, would be the unity of effort that would come about.

The VA, with its $10 billion medical care budget, would be impacted by any recommendations by such a commission. Veterans are not resistant to the infection, and the VA's infrastructure in research, in medical education and health care delivery is already being hard-hit by the demands of AIDS.

Today we hope to start towards the development of a unified strategy for AIDS. We must have a national policy, a national plan of attack; but what I have seen thus far is at best unclear, and at worst, confusing. At the very least, in this committee, we need to understand the VA's role in this national policy.

I really do appreciate our witnesses being here today. The demands that have been placed on their time as experts in AIDS are enormous, and their tireless efforts are greatly appreciated.

Mr. Chairman, thank you very much.

Mr. MONTGOMERY. Thank you, Dr. Rowland. And I want to stress again that you feel very strongly in this area and you asked the chairman to have these hearings, and they will be beneficial.

Dr. Gronvall, as I recognize other members, why don't you come to the witness table with those people who are with you? We will go around and recognize Lane Evans, a member of this subcommittee.

Mr. EVANS. Mr. Chairman, actually, I'm not a member of the subcommittee. I'm just sitting in. I appreciate that opportunity and I do applaud you for holding this hearing. I associate myself with Dr. Rowland's remarks; they are right on target. Because this is a problem concerning our veterans, as well as other people in our society, we're going to have to be more involved in the future with this problem, and I think this is a start here today. So we appreciate your holding the hearings and would be glad to help, Mr. Chairman.

Mr. MONTGOMERY. Thank you.

Mr. Kennedy.

OPENING STATEMENT OF HON. JOSEPH P. KENNEDY

Mr. KENNEDY. Thank you, Mr. Chairman.

Mr. Chairman and Dr. Rowland, I want to commend you on having these hearings today. I know that this committee has been

concerned with AIDS amongst the veterans for many years now; this is not a recent development on this committee.

It does seem, in our country today, that we really do face a crisis. The crisis, I believe, emanates out of the lack of leadership that has taken place. It seems that in the Congress itself, we have 435 Congressmen going home each weekend, espousing their own individual AIDS policies; we have 100 Senators doing the same thing, over 50 Governors doing the same thing. We have a Surgeon General whose report is ignored by the highest levels of leadership in our country, and it just seems that a national AIDS policy that would deal with the basic educational needs on how to avoid AIDS; if we could come up with a voluntary, not mandatory, testing program so that we don't drive AIDS victims underground; and that we have a research program that enables us to get on top of this disease over a period of time, is really the best possible policy that we can try to come to grips with.

I am very interested in trying to learn from Dr. Gronvall what the VA's specific policy will be with regard to AIDS, and has been with regard to AIDS; specifically, what kind of care will be provided for the patients that have AIDS, what kinds of ideas they have with regard to voluntary testing and the kind of counseling that would be followed up with that testing, and the kind of education they would like to see veterans of America, who have been willing to put their lives on the line for this country—what they feel is the appropriate way to educate those individuals and protect them against this dreaded disease.

So thank you very much. I am looking forward to your testimony.

Mr. MONTGOMERY. Thank you, Joe.

Bob McEwen of Ohio?

OPENING STATEMENT OF HON. BOB MCEWEN

Mr. MCEWEN. Thank you, Mr. Chairman. With your permission I would ask that the statement of the ranking member be inserted in the record at this time.

Mr. MONTGOMERY. Without objection. John Paul Hammerschmidt had a markup and he'll try to get over here later on.

[The statement of Hon. John Paul Hammerschmidt appears on p. 65.]

Mr. MCEWEN. Mr. Chairman, I would just simply state that the AIDS issue has touched the social fabric and the consciousness of the American people. There is an increasing concern among our citizens about how our Government should address this issue of national dimensions, as well as international proportions.

In my view, it is extremely important that we understand the complexities of the many policy-related and social matters associated with this disease. As Members of Congress we want to do what is right. We want to be in a position to fully comprehend all that it impacts, and we want to be better suited to undertake the appropriate policy measures to ensure the public health and safety of our citizens.

Mr. Chairman, this is a major and unique challenge that we are addressing. It must be done in a pragmatic and expeditious

manner. I look forward to the comments of the witnesses here today, and I want to express my appreciation for their willingness to participate in this important effort.

I thank you, Mr. Chairman.

Mr. MONTGOMERY. Thank you, Bob.

Dr. Gronvall?

STATEMENT OF JOHN GRONVALL, M.D., CHIEF MEDICAL DIRECTOR, VETERANS' ADMINISTRATION; ACCOMPANIED BY: HOWARD COHN, M.D., DEPUTY ASSISTANT CHIEF MEDICAL DIRECTOR FOR CLINICAL AFFAIRS; RICHARD J. GREENE, M.D., ASSISTANT CHIEF MEDICAL DIRECTOR FOR RESEARCH AND DEVELOPMENT; SUSAN MATHER, M.D., CHIEF OF PULMONARY AND INFECTIOUS DISEASES; ROBERT LINDSEY, DIRECTOR FOR OPERATIONS; AND RALPH IBSON, DEPUTY ASSISTANT GENERAL COUNSEL

Dr. GRONVALL. Thank you very much, Mr. Chairman. It is a privilege for us to be here at this very important hearing. Let me just briefly introduce the witnesses from the Veterans' Administration who are here with me.

To my far left, Mr. Ralph Ibson from our General Counsel's Office.

To my immediate left, Dr. Richard Greene, who is head of the research program throughout the VA.

To my immediate right, Dr. Howard Cohn, who is Deputy Assistant Chief Medical Director for Clinical Affairs and has had a very important leadership role in planning our effort in regard to AIDS in the VA.

Next to Dr. Cohn is Mr. Robert Lindsey, our Director for Operations.

To his right. Dr. Susan Mather who heads our Pulmonary and Infectious Disease Program in the Central Office.

Mr. Chairman, we have submitted a detailed written statement which I would appreciate having included in the record of the hearing.

Mr. MONTGOMERY. Without objection, your prepared statement will appear in the record immediately following your oral presentation.

Dr. GRONVALL. Thank you very much.

Let me summarize quite briefly some comments about AIDS. As I said, it is a privilege for us to be here to update the committee on the status of AIDS in the Veterans' Administration.

This disease, as has been pointed out, of course, is a devastating one. It is quite clear now that AIDS is emerging as the first major lethal world-wide epidemic or pandemic of the second half of the 20th century. The Veterans' Administration health care system is a very major part of the resources that this Nation has to care for individuals suffering from this disease, and also to participate in the research that will eventually, of course, bring it under control.

At this time, over 1.5 million people in the United States are believed to be infected, although many feel that even this is a very conservative figure. The estimate of how many infected people go on to develop the frank disease is in dispute. Estimates range from

25 percent to 70 percent. To date, once the disease is established, no cures have been reported.

Within Veterans' Administration during the period September 1983 to May 1987, 2,014 cases of the "full-blown" disease have been reported; 111 of our 172 Medical Centers have had at least one case, although the impact is heaviest in our hospitals on the East Coast and on the West Coast. As we have tried to look ahead and make projections we believe that by 1991 our cumulative experience may reach as high as 14,000 cases of AIDS in veterans.

Treatment of this disease, of course, requires a very dedicated team of medical specialists and subspecialists, and it also places an enormous burden on our nurses, social workers, chaplains, and many other people in our hospitals that support and assist these patients.

We have expanded our laboratories so that we can do AIDS testing at Lexington, New York, Albuquerque, San Francisco, Denver and New Orleans, and we're considering further expansion of our laboratory capability.

During fiscal year 1985 we estimated that it cost the Veterans' Administration some $38,000 per year for each veteran we were treating with AIDS. We have studied this more recently and find that the cost has declined to something like $24,000 per year. The reason for this is that the length of stay in our hospitals and the use of intensive care units has declined as we've gotten more experience with veterans suffering from this disease. At the present time, for this year, we are using about $20,000 per year per veteran as the estimate for the cost of care.

Although the cost per veteran has come down, because the number of cases we're experiencing continues to dramatically increase, we've had to make a supplemental funding allocation this year to our Medical Centers that have treated more than 15 cases.

Of course, as we look to the future, new drugs and new treatments as they become available may remarkably change our cost experience, and the experience could change in either direction as we either gain control of the disease and reduce its dramatic cost or discover new treatments which, themselves, may be very expensive. So the future in terms of cost is very hard to predict.

We are working, of course, very closely with other Federal agencies. We work closely with the Department of Defense. We collaborate with the Department of Health and Human Services, particularly the Centers for Disease Control, and we're part of an intragovernmental task force on AIDS health care delivery. We also participate actively in White House Working Group deliberations on AIDS.

The President recently called for a review of all Federal programs where expanded testing would be appropriate, and this review is underway.

A brief comment in regard to research. Our statement illustrates some of the research going on I would just say that the VA is engaged in the entire spectrum of research on AIDS, including basic science studies having to do with the action of the AIDS virus all the way to clinical trials of various drugs that may be helpful in this disease. We are carrying out a particularly important large-scale clinical control trial to see whether the drug known as AZT

will be effective in preventing so-called "AIDS-related complex" from progressing to the full-blown disease of AIDS, and the results of this trial will, of course, be very important to the Nation. This trial is supported by special AIDS research disease funds from the Department of Defense.

Mr. Chairman, it's clear that the future course of this disease and its health and social consequences can really only be dimly predicted at this time, but we are entirely committed to ensure that the Veterans' Administration does not overlook any opportunity to contribute to bringing this scourge under control. At this moment we are taking steps to strengthen our own organization to ensure that we can better plan our patient care activities, our research programs, and our educational contributions to this fight, and in that regard we very much appreciate the support of this committee as we continue this work.

Mr. Chairman, with this brief introduction, my colleagues and I would be pleased to answer questions that you or the committee may have. Thank you.

[The prepared statement Dr. Gronvall appears on p. 72.]

Mr. MONTGOMERY. Well, thank you for that very good summary. It does give the members a chance to ask some questions and make some comments.

Before yielding to Dr. Rowland, who has a number of questions, the Chair would request that members stay within the 5-minute limit and then we'll come back around again and ask questions.

Let the Chair start, and I'll operate under the 5-minute rule, too. Maybe Dr. Greene can help on this. On medical care in the Federal Government, who has the largest research divisions in the Government? Is it DOD? Is it the VA? Is it Public Health? Who, Dr. Greene?

Dr. GREENE. Well, I think the NIH certainly has the largest single program in any biomedical research activity, about a $5 billion effort, so that is certainly the lead agency for research in any area.

Mr. MONTGOMERY. Who is next, in your opinion? Where does the VA come in on medical research? I thought we had a lot of people doing a lot of work out there all over the country.

Dr. GREENE. Well, we do. We have a very substantial program, supported by approximately $200 million of appropriated funds and probably $100 million in funds from other agencies, supporting about 5,000 investigators. So we are probably the second largest agency of the Federal Government involved in research in the biomedical area.

Mr. MONTGOMERY. Am I being overenthusiastic by being excited that, with your research facilities, you could help or contribute in some way to bringing this AIDS disaster under control?

Dr. GREENE. Well, I don't think it's overenthusiasm. We are very hopeful that we can make a major contribution, and I think our investigators are in fact engaged, as Dr. Gronvall said, in all areas of research, from very basic research on the AIDS virus to controlled clinical trials. I think we will and are making a major contribution.

Mr. MONTGOMERY. And who do you coordinate your research with in the Government and in the private sector? Or is there cooperation, assignment of certain areas to work in?

Dr. GREENE. Well, we work with our colleagues at NIH. We have representation on all the NIH councils. In the private sector, we are working with industry—in fact, the AZT trial is supported in part by Burroughs-Welcome, who makes the drug. So there is very good cooperation, I believe, with other Federal agencies and with industry.

Mr. MONTGOMERY. Well, I know in the VA medical research several years ago, that some of the researchers in the Veterans' Administration won two Nobel Prizes. I know we can do it. This is a great challenge to the VA. I, as chairman of this committee am certainly interested that you do all you can out there, Dr. Gronvall, and make the requests for funding that you need and we'll try to get it for you.

Dr. GRONVALL. Well, Mr. Chairman, I would just amplify and emphasize what Dr. Greene said. It's clear that the solution to this problem will come out of research laboratory work as we understand how the virus infects and affects people and find some way to first cure, and then hopefully entirely prevent, and hopefully some day entirely eliminate the disease. And so we are taking every step we can to strengthen research. During this year we are soliciting an expanded number of proposals to be developed in our Medical Centers. We will be identifying particular Medical Centers that have extraordinary expertise in this area, and we will be expanding their funding. As Dr. Greene said, we work in close collaboration with the other research parts of the Federal Government, and we intend to miss no opportunity to make a contribution to bringing this scourge under control.

Mr. MONTGOMERY. Thank you very much.

Dr. Rowland?

Dr. ROWLAND of Georgia. Thank you, Mr. Chairman.

Dr. Gronvall, we should all be very much concerned about identifying those people that are seropositive. We know that it takes from a few weeks to several months for a person to develop enough antibodies to become seropositive.

In thinking about that, how often do you think that we should test people in order to maximize identifying those that are seropositive?

Dr. GRONVALL. Let me ask Dr. Cohn to make a more specific comment. I would introduce his comment only by saying that you are quite right, that there is a silent period between the time of infection and the time antibodies develop. Hopefully, within the reasonably near future we will have a test that detects for the presence of the virus itself rather than the body's response to the virus. When that becomes available, of course, then we'll be able to do a direct test and identify the presence of the virus, so that will surely improve our testing.

Dr. Cohn, can you comment on the frequency of testing?

Dr. COHN. Thank you, Dr. Gronvall.

Dr. Rowland, I appreciate your question. Testing is a complicated issue, as is almost every issue that one discusses under the framework of AIDS. Let me make some of the following comments:

First of all, in terms of definition, I think we ought to all understand that what we are really testing for is the antibody to the AIDS virus, not to the virus itself in terms of the currently-marketed ELISA test and the confirmatory Western Blot.

Antibody testing is certainly essential in screening blood and organ donors, and I think we all must remember that the tests were originally designed for that purpose and not for the purpose of doing clinical testing, if you will. Certainly, the AIDS antibody test is helpful or [illegible] boratory in making or establishing a diagnosis of AIDS, but it [illegible] in and of itself establish the diagnosis. The diagnosis of AI [illegible] essentially a clinical diagnosis based on the spectrum of illness that a patient would present.

Now, false positives do occur, and false negatives do occur. They are relatively infrequent but they can occur, and we know that in low prevalence regions or populations—for example, multiparous—the rate of false positives would be relatively high compared to high prevalence regions for testing.

It's my personal opinion—and, I think, in coordination with Dr. Gronvall's—that testing should probably be expanded, and that that testing should probably be conducted among those groups at highest risk. Testing, in my opinion, should be always voluntary, and there is no place in my opinion for unauthorized testing.

Counseling must accompany testing. Without counseling there can be no testing, in my opinion, and that includes both pre- and post-test counseling. And I might say at this point that counseling is expensive; in fact, people have done cost estimates for both pre and post-test counseling, depending on whether the HIV is negative or positive, and that is reasonably expensive. There are cost analyses of that.

Clearly, we need better screening tests. As Dr. Gronvall has already alluded to, better screening tests are emerging and I think several are in front of FDA for further consideration and, presumably, eventual marketing, including a test called the Cambridge test.

More specifically to your question, what is the frequency, perhaps, with which high risk populations should be screened? Should they be screened yearly? Should they be screened monthly? Should they be screened quarterly? Sir, I don't know the precise or the exact answer to that. I think that's still open for consideration and discussion among the experts, and I think again it would depend upon the circumstances in a given individual or a given case as to what the answer to that question should be. I don't think you can give a blanket answer.

There is, of course, the lag period or "window" period that you yourself addressed in your opening remarks, indeed, when people who are infected could test falsely negative, and that period can be anywhere from zero to 4 to 6 weeks.

Certainly, the need for education is paramount regardless of antibody state, and that's very important.

Thank you.

Dr. ROWLAND of Georgia. Thank you for that very erudite answer, Dr. Cohn.

We have another sexually-transmitted disease that we were never able to identify the organism itself, and that's syphilis, and

in the latent period we never found the spirochete. We did elaborate the antibodies in the VDRL and the clinical picture, and we made the diagnosis of syphilis. Of course, in the primary stage you can identify the spirochete and you are able to make the diagnosis on that.

So I think that there is a possibility that we may never be able to identify the virus, although that is what we are looking for as a way of diagnosing this. And at this particular point, we will have to rely on the fact that antibodies are present; thus the clinical picture, as you indicated.

I think in those respects, syphilis—which we have known about for many, many years—and AIDS, which we've only known about for some 6 years now, are very similar.

I see that my time is up now, but I just would like to ask one more question relative to what we are talking about.

Does the fact that if a person tests negative when the ELISA test is done—would that cause that individual to be less concerned and less cautious about their activity?

Dr. COHN. No, sir. One would have to examine, of course, what the reasons were behind the performance of the test to begin with. And if we can assume for the purpose of your question that this person may have been a member of a high-risk group—for example, a person attending a sexually-transmitted disease clinic or an individual enrolled in a methadone maintenance program—clearly, a negative result is not the end, and that is the purpose of post-test counseling for negative results. And obviously, we have to embark upon discussion about safe sex practices. We have to talk about the potential contacts that that individual may have, so it is not the end; it's really but a beginning. And it also brings up your former question, what is the frequency with which you would test that individual?

Dr. GRONVALL. If I may, Mr. Chairman, add a sentence to that question.

Dr. Cohn used the term, something like "incredible complexity of every question" in regard to AIDS. In the best instance, if an individual, let us say, is a drug abuser or has engaged in practices that might have exposed him or her to infection and then a test is done and it becomes apparent that the person is not affected, with appropriate counseling that might be a very powerful influence to say to the individual, look, you are very lucky; you have escaped infection; but if you don't change what you are doing, it is predictable that you are highly likely to incur this fatal disease. So it might provide a very powerful incentive.

To flip to the other side, in the worst instance where a test is done and it turns out to be positive, there is in fact some very disturbing evidence to suggest that among some people a kind of fatalistic response occurs: well, since I'm already infected, why should I give up anything I'm doing? It doesn't make any difference now because it's too late.

So exactly the wrong outcome can occur in either case. Again, that all reemphasizes, I think, the extraordinary importance of appropriate counseling to assist every individual to make the best decision to change behavior to prevent or reduce further risk to the

individual, himself or herself, or to others. It's a very complicated matter.

Mr. MONTGOMERY. Thank you, Dr. Rowland. We will get back to you in just a few minutes, and I want you to ask those questions. You're very familiar with the situation. You have the expertise that other committees do not have in the Congress of the United States, and we want to take advantage of that.

Lane Evans?

Mr. EVANS. Thank you, Mr. Chairman.

Doctor, I just have a few questions concerning the cost and, I guess, the eligibility of veterans for care through VA.

First, you indicated that you estimated that the costs had gone down. For fiscal year 1985 you were estimating that it would cost $38,000 a year to treat an AIDS patient; a recent study determined that $24,000 would be more appropriate.

Now, you're saying that based on reduced lengths of stay, less use of intensive care units and better facilities and management of patients, you believe that the cost of an AIDS patient has decreased about 20 percent since 1985, so you're using a $20,000 a year estimate for fiscal year 1987. Is that what it is for this year?

Dr. GRONVALL. Yes.

Mr. EVANS. That's $20,000?

Dr. GRONVALL. Yes. And as you summarize, it's based on gaining experience with the disease and finding that keeping patients in the hospital for a long time doesn't really contribute that much. We've found better ways to support patients on an outpatient basis between episodes of hospital care. That, of course, is more economical.

Mr. EVANS. And increased use of AZT may reduce costs further. Is that correct?

Dr. GRONVALL. That question, I think, is open. The drug itself, of course, is very expensive. If, however, AZT, when given during the time prior to full-blown AIDS—if it will prevent the occurrence of AIDS, then it would prevent a very expensive series of less effective treatments later on.

Mr. EVANS. Well, I guess my concern is that if we're underestimating the cost of this and it is higher, we can't really factor in these things. And given a committee report that the committee put out some time ago, we estimated a cost of about $40,000 per patient per year. We just don't want to be caught in a bind in terms of internal budgeting or our budgeting here in Congress, that we're not caught short. Is that a concern of yours?

Dr. GRONVALL. Yes, absolutely. And in my statement I included the comment that things can change rapidly and unpredictably. For example, it may come about that there may be new forms of treatment which themselves would be even more expensive than AZT, and that could add immeasurably to the cost, even though it could improve the response to the disease.

As we look ahead, it's just very hard to predict with any accuracy, so we make predictions but we then follow them on a current basis and plan to keep reporting to the committee as our experience unfolds.

Mr. EVANS. Well, would it be your best estimate, though, that perhaps the committee should figure higher in a sense because—it

would be nice if it were lower, but if it's higher it's going to be harder to get the money if we've budgeted for a lower amount?

Dr. GRONVALL. That's always a prudent practice, of course.

Mr. EVANS. Let me ask you. We had a breakfast with General Turnage earlier this year, and I don't think at that time—and I'm not sure at this time—that the eligibility criteria for veterans had been established. In other words, does a veteran who has maybe gone through a screening program prior to his admission into the armed forces qualify for AIDS treatment as, perhaps, a service-connected disability if on his discharge he is found to have AIDS?

Dr. GRONVALL. The specific decisions about service connection are not something that I'm really competent to speak to. Let me make a general comment, and then perhaps Mr. Ibson could clarify.

The eligibility for care for veterans with AIDS or suspected of AIDS is not a unique or separate set of eligibility requirements. Veterans fall under the eligibility requirements that were revised last year; and AIDS, like any other disease, falls within those eligibility requirements for care.

Mr. Ibson, if you could expand.

Mr. IBSON. Mr. Evans, this is just by way of a preliminary answer. I don't know if I have a full understanding of the DOD picture, but to the extent that an individual has completed a period of military service and is discharged thereafter with a diagnosis of AIDS, that individual is a veteran and eligible for VA care as any other veteran. Whether or not service connection is established is, as Dr. Gronvall indicated, a different issue.

Mr. MONTGOMERY. Let me see if I can help on that, too, Lane.

As I understand it, if they come in and are screened—they come in as recruits and they discover AIDS, then that would not be service-connected. But once they're in the service and AIDS is discovered and becomes a medical problem, then they would be eligible for service-connected disability.

Mr. EVANS. All right.

Mr. Ibson, are those same kinds of presumptive eligibility criteria that relate to other diseases also applied to AIDS? In other words there are, I guess, Mr. Chairman, at least certain disabilities—if it's incurred 7 years after discharge, a person is presumed to be service-connected. Is that—

Mr. IBSON. I believe those presumptions are established in statute. To the best of my knowledge, there is no specific presumption associated with AIDS or AIDS complex.

Mr. MONTGOMERY. The staff tells me that that's not in the law, presumptive for AIDS.

Mr. EVANS. All right. My time is up, Mr. Chairman. I'll take a look at this issue and perhaps consult with the staff.

Mr. MONTGOMERY. Okay. Well, we'll work back around.

To follow up on one question, Dr. Gronvall, have you requested extra funds to offset the treatment of AIDS?

Dr. GRONVALL. Yes, sir. A part of our budget request that we've developed has identified the projected costs of AIDS, so that's been taken into account as we've projected budgetary needs for the VA. I don't have any of that information right at my fingertips, but we could supply the details on that if the committee would wish.

Mr. MONTGOMERY. Is that for fiscal year 1988? You're specifically going to say, this is extra money for AIDS?

Dr. GRONVALL. I apologize that I did not look back to review our specific fiscal year 1988 request. I do know that as we developed the fiscal year 1988 request our projections of the cost of AIDS care were a part of that projection, but I'd have to review the specific budget to see whether it's identified.

[Subsequently, the Veterans' Administration furnished the following information:]

The fiscal year 1988 budget submitted to Congress did not specifically request additional resources for the treatment of AIDS patients However, the cost of treating AIDS patients and the institutional costs of AIDS to the medical care appropriation will be discussed in developing the 1989 budget request.

Mr. MONTGOMERY. We did make some recommendations—I believe it was around $20 million additional funding—for AIDS for the Veterans' Administration.

Dr. GRONVALL. Yes.

Mr. MONTGOMERY. So we put that in. The committee itself did that.

Dr. GRONVALL. Yes, sir.

Mr. BURTON. If the chairman would yield?

Mr. MONTGOMERY. Yes.

Mr. BURTON. How did you come up with that $20 million figure?

Mr. MONTGOMERY. I believe that was the number of cases anticipated, was the way we came up with the figure. And actually, even though the cost is coming down on treatment of AIDS patients, the committee thinks you're going to have a lot more cases than you've got now, so therefore your cost is going up totally over the individual treatment.

Dr. GRONVALL. Absolutely, sir. And I should clarify that to be sure there's no misunderstanding. Even though improved management of individual cases has reduced the cost per individual veteran per year, the rapid growth of the number of cases makes it inevitable that, for the next predictable period of years, our total cost related to AIDS will increase significantly, and there are no projections that I'm aware of that would show a reduced cost of AIDS. It is going to increase, absolutely certain.

Mr. MONTGOMERY. The Chair recognizes the gentleman from Massachusetts. Joe Kennedy.

Mr. KENNEDY. Thank you, Mr. Chairman.

A couple of questions. First of all, I was glad to hear from Dr. Cohn and his sensitivity towards the mandatory testing issue. And Dr. Gronvall, I think you also indicated that these issues do get very complicated very quickly; but nevertheless you did refer to certain high-risk groups that ought to have greater testing.

One of the problems that we have faced in Massachusetts, where there is a tremendous amount of dollars being spent on AIDS at the moment, is that many people feel that if they go in and take the test, that they are going to be discriminated against by insurance companies, discriminated against in their jobs, at schools and other types of institutions that are set up in our country.

I wonder whether or not you are concerned with that, and what you think—when you say, "high-risk groups," what you're really talking about and how you begin to define that?

Dr. COHN. Well, the issue you raise concerns confidentiality. It is, of course, a critical issue, and I should mention that the CDC conference which was held in February of this year in Atlanta which addressed the overall issue of testing, got into discussion of mandatory versus voluntary testing—the discussion regarding confidentiality was a key part of that. And one of the conclusions that came out of that meeting was that we as a Nation, as a people, need stronger confidentiality laws. So of course, that is part and parcel of this whole testing issue.

Mr. KENNEDY. Well, let me ask you specifically. If somebody comes in and tests positively for AIDS, what happens to their record in the VA? And who has access to that at the moment?

Dr. COHN. The result of that test, the laboratory slip or paper, would be placed on the patient's chart. And that should be held in great confidence and only be available to the physician and the staff, the nursing staff, attending that patient. I cannot tell you, though—I could not sit here and tell you that that record, categorically, is a closed record, and therefore assumes confidentiality. We know that in some instances that would not necessarily be the case.

Mr. KENNEDY. Is it the responsibility of this committee to change those rules? Or is it outside our jurisdiction? I don't know, Mr. Chairman.

Dr. COHN. Well, I can't answer that particular question. But I think it is the responsibility of us as a Nation, if you will, and perhaps the Congress, to consider stronger confidentiality laws. Those laws, conceivably, would impact on the VA health care system.

Mr. KENNEDY. So right now you are saying that if a veteran in fact comes in for testing, that there is no guarantee that that record will remain confidential, although you will make your best efforts to assure that it will? But there is no guarantee; is that correct?

Dr. COHN. I don't think that I said that there was no guarantee. I don't think I could sit here and categorically tell you that the record could not be subject to observation by other people.

Mr. MONTGOMERY. Would the gentleman yield?

Mr. KENNEDY. Sure.

Mr. MONTGOMERY. I'm told on confidentiality that it applies to drugs and alcohol, that for veterans those records are kept confidential. Is that correct?

Mr. IBSON. If I could interject, Mr. Chairman. Federal law does ensure the confidentiality of those medical records against disclosures outside the Veterans' Administration. We do have a provision in Title 38, as well as the provisions of The Privacy Act, to ensure that confidentiality. I think Dr. Cohn's questions go to the extent to which medical personnel within the Medical Center can have access to those records on a "need to know" basis.

Mr. KENNEDY. I see. But this would not be—for instance, in Massachusetts if you were in a testing program, that would automatically go into a centralized computer which any insurance company in the State would have access to. Even though it would not be legal to obtain that information, the fact is that they would have open access to the same central computer bank. So that's not true at the VA?

Mr. IBSON. I don't believe that kind of open access opportunity exists, sir.

Dr. COHN. That's not true, as far as I understand it, from a medical point of view. I might say we published a circular which in part addresses that issue. And of course, our colleagues in the General Counsel's Office helped in the composition of the wording; and we made it quite clear, I think, at least in that guidance to the field, that without concurrence from the patiert that information could not and would not be relayed to any outside entity without concurrence of the patient.

Mr. KENNEDY. I think it would be very useful if a specific report were to be made to this committee that we could perhaps publicize that would indicate exactly what the rules of confidentiality are with regard to the testing of AIDS patients.

My time is up. Thank you.

Dr. GRONVALL. Mr. Kennedy, if I may, we'd be pleased to supply such a report. The matter is complex; but in a general way, as has been described, all medical records in the VA are confidential, and we have a large body of law, procedure, rules and regulations that ensures that. There are the two specific instances having to do with veterans being treated for drug abuse problems and for alcohol abuse problems where there are specific additional statutes, but we could clarify the whole matter of the existing rules and regulations that govern the confidentiality of the medical record.

Mr. KENNEDY. Well, the trouble is that there are existing rules and regulations with regard to certain individuals and how they can be drafted, brought into military service, and other issues that it would seem to me would make the veteran somewhat hesitant to actually get involved in the whole testing program. So it just seems that if that were laid out in a very clear way, it might be helpful in terms of encouraging the kind of testing which seems to be a fundamental of the program that you're outlining.

Dr. GRONVALL. We'd be pleased to do so.

Mr. KENNEDY. Thank you.

[Subsequently, the Veterans' Administration furnished the following information:]

There are primarily three existing laws which provide for confidentiality of medical records These laws provide protection for medical records, which include AIDS test results and related diagnoses and information, in the following ways.

The Privacy Act provides confidentiality for patient medical administrative and treatment record information Generally, patient medical records are not disclosed without the prior written consent of the patient. However, there are a number of statutorily defined situations which allow for records disclosure without prior written consent of the patient Within the VA disclosure of a patient's file is limited to those individuals whose duties necessitate access to a patient's record As for disclosures of VA patient medical records to individuals and institutions outside the VA, the Privacy Act sets forth a number of situations in which such disclosures would be authorized without prior written consent Two of those situations which most often confront the VA include disclosures made pursuant to a routine use published in the Federal Register, and in cases involving health or saftey emergencies. In these situations, the VA would be enabled, but not compelled, to disclose AIDS information as part of the medical record The Privacy Act ceases to provide protection to medical record information once the patient is deceased.

The VA's confidentiality statute 38 U.S C 3301, protects patient name and address information and sets out various situations where disclosure of patient information is permitted Unlike the Privacy Act, the protections provided under this statute do not cease with the death of the patient

The VA's statute for confidentiality of certain medical records is 38 U.S.C. 4132 This statute specifically protects patient information which is maintained in connection with the performance of any VA program or activity relating to drug and alcohol abuse and sickle cell anemia This section specifically limits the circumstances under which the information it protects may be released without the consent of the patient Section 4132 continues to protect record information after the patient's death.

Beyond the aforementioned three laws, it is possible that if AIDS test information or records were collected in regard to an agency quality assurance procedure, that information would be subject to the limited disclosure provisions in 38 U.S.C. 3305(b).

Mr. MONTGOMERY. That's an excellent point. There is a section in the law that staff points out to me on confidentiality of these records, and we could look into it and see if it needs amending, and to further protect the privacy of veterans.

Before recognizing the gentleman from Connecticut, Mr. Rowland, I'd like to ask Dr. Rowland to take the Chair. But before he takes the Chair, let me follow up on the research and just make a comment on it.

Even though, Dr. Greene, you tell us that we have the second-largest, probably, medical research team under the Federal Government, it was pointed out to me that NIH might get more money and be larger. The problem with NIH as I understand it is that they're not across the country, whereas the VA has these research centers up in the eastern part of the country, the western part of the country—where you have these problems.

So I think that as far as research is concerned on AIDS, we could and certainly should be the leaders as far as getting out with the people that have got this disease.

Dr. GRONVALL. Mr. Chairman, I can't agree any more with your statement. I believe that we can and will and have been involved. We have planned to more than double our portfolio of research in AIDS and HIV-infected patients. To increase our research effort, we have many proposals coming in based on a solicitation we sent out recently, and I guess our strongest suit in research at the moment is in the clinical trials area. We've mentioned this AZT trial. I think the fact that we do have a nationwide system and that we can pull together large numbers of clinical studies under one set of protocols allows us to be ready to take on the second and third generation drugs that may prove to be effective with this disease. We are prepared and ready with the implementation of the AZT trial to move into the second and third generation of studies.

So we are very pleased at the support that you are providing, Mr. Chairman, and we are very willing and able to make a major contribution.

Mr. MONTGOMERY. Thank you.

Mr. Rowland of Connecticut?

Mr. ROWLAND of Connecticut. Thank you very much, Mr. Chairman.

First, I'd like to thank you all for being with us this morning. I'd like to just follow up on a couple of questions that I have with regard to testing.

Number one, are we presuming that this is a mandatory test? You mentioned that the testing procedures are under study and review at this time. Do we have a mandatory testing program for every person that comes into the VA hospitals? Will we move in

that direction? On top of that question, have there been any instances where medical personnel have picked up or been subject to the AIDS virus, and do we have a policy for precautions? Let's answer those first.

Dr. GRONVALL. We'd be pleased to.

In regard to testing, we have no policy, mandatory or otherwise, that calls for testing all veterans who come to our hospitals or come to our clinics. At the present time testing is done based on an individual physician's decision that the individual veteran either belongs to one of the high-risk groups or has a set of symptoms or other conditions that would make testing the appropriate thing to do.

You're quite right that I referred to the fact that the whole issue of testing is under review. The President recently called for a review of the issue of testing in the Veterans' Administration; that review is underway. We are participating in the development of material and recommendations which will be presented to the Domestic Policy Council, which will then lead to an Administration position in regard to testing in the Veterans' Administration. But there is no mandatory testing or all-inclusive testing policy at this time in the Veterans' Administration.

You raised a question about whether individual health care workers have been infected. There are such reports. Happily, to date no such instance has occurred in the Veterans' Administration that we are aware of where a member of our staff has been infected with the AIDS virus as a result of caring for veteran patients with AIDS. We have given regular detailed and elaborate instructions, guidance, education to our staff as to how to most appropriately care for infected individuals, and so far we have been free of accidents. We have had staff members working in VA hospitals who have had AIDS, but they have not been infected through care of individuals in our hospitals with AIDS.

Mr. ROWLAND of Connecticut. The concern that I think I have, and many of my colleagues have, with regard to testing procedures—you're reviewing a procedure that really doesn't exist within the VA system. In other words, correct me if I'm wrong, the testing procedure as it stands now—if someone shows a symptom, or if there is reason to believe that the person may have AIDS, then you do the test. I'm not sure if that's a policy or that's just normal practice for anyone.

What is the VA actually doing. What point are you at in the testing review. What do you anticipate you'll be recommending?

Dr. GRONVALL. I really can't speak to that since the review is underway. Background material and alternative proposals and recommendations are being developed for the deliberations of the Domestic Policy Council, so until that has occurred it's really premature to describe any specific proposal.

Mr. ROWLAND of Connecticut. Doctor, would you outline the counseling process? In other words, if you find a patient with the virus, what are the steps? What is the counseling process? What is the counseling policy at that point?

Dr. GRONVALL. I'd like to turn to Dr. Susan Mather, perhaps, to comment on that very important question.

Dr. MATHER. At this point in time we do use the antibody test for clinical purposes for people who either are suspected of having the disease, or for people who suspect that they've been exposed to the disease. Either they ask for the test or it appears indicated to the caregiver. And the kind of counseling that we give includes telling them what the test really is; that if their first preliminary ELISA test is positive, this will be repeated, and then a confirmatory test will be done. And they will only be told they are positive after these three steps have taken place.

We also tell them what a negative test means in terms of false negatives, and the period of time that it takes to develop antibodies. We also try to counsel them that if they are positive, they would be considered infectious, and that this is something that they should share with their sexual partners. And then the testing is done.

We also tell them that the results will be on the chart, and that they should be aware when they sign a release of information—for their family doctor, for example, or for an insurance company—that unless they request that information be withheld, that information will be released.

So this is the kind of counseling that takes place beforehand.

Mr. ROWLAND of Connecticut. What is the actual counseling process? You merely tell the patient—

Dr. MATHER. That's the preliminary. Counseling begins before the test is given.

Mr. ROWLAND of Connecticut. How do you counsel someone that you don't know has AIDS?

Dr. MATHER. Well, you have to tell them what the test means.

Mr. ROWLAND of Connecticut. Well, regardless—what I'm getting at is not the counseling with regard to the testing. What if a person—

Dr. MATHER. After the result has come back?

Mr. ROWLAND of Connecticut. You are told that you've got AIDS, that you should be careful?

Dr. MATHER. The patient is told that they have a positive test. They may or may not have AIDS; the positive test—AIDS is the illness. The positive test indicates evidence of infection. And if they have no evidence of illness, they are told that they are infected with a virus, that they should consider themselves to be infectious. If they share needles, if they are a drug abuser and they share needles with someone, they stand a good chance of infecting that person. If they have sex with some person, they stand a good chance of infecting that person. And then they are given advice on precautions that can be taken if they make the decision to continue to have sexual intercourse.

Mr. ROWLAND of Connecticut. Thank you very much.

Thank you, Mr. Chairman. I would just close by saying that just from what I've heard today, I hope that we can clearly define the testing process, and I hope we can move quickly on that. And as Mr. Kennedy was following up, clearly define what our confidentiality practices will be within the VA, and I hope maybe even a stronger, clearer definition of what the counseling process is going to be. That doesn't seem to be quite as thorough as some of the

other hospital personnel and some of the other hospitals across the country are practicing.

Dr. MATHER. I would just liked to make the point, though, that unless the counseling begins before the test is done, when you get news that your HIV status is positive, you're usually not in a great learning mode. Intellectually and emotionally, few people are able to accept a great deal of education at the time that they learn their test is positive. It's a very emotional experience, as you can imagine.

Dr. ROWLAND of Georgia (Presiding). Thank you, Mr. Rowland.

Before I go Mr. Kanjorski, I want to address a little bit further the issue that was raised by Mr. Kennedy, and also alluded to by you, Mr. Rowland.

Laboratory results are placed on a patient's chart, regardless of what those laboratory results are. And of course, the nursing staff has to know what those results are.

Let me ask you this, Dr. Gronvall. Who else should know whether or not a person has a diagnosis of AIDS? And I'm talking about the CDC criteria for the diagnosis of AIDS at this point. Should practical nurses know about this? Should assistant personnel know about this? Should orderlies know about this, those who will be cleaning up the room of that patient?

Confidentiality becomes a very complex and difficult issue with which to deal. Is there a responsibility on the part of the VA? And in fact, is there a responsibility on the part of any hospitals, whether in the VA or outside of the VA, to make people who are dealing with AIDS patients aware of the fact that they are dealing with a person who has AIDS?

Dr. GRONVALL. The answer to the last part of that question is, absolutely yes. We've taken our responsibility within the VA very seriously to ensure that our staff is educated and prepared to take care of AIDS patients. We have dealt with the issue of who needs to know in terms of the responsibilities of the various parts of our staff cadre who provide care, but we have provided guidance, education, rules and procedures for all of our staff so that those who come in contact with the patient but don't have a need to know about any particular medical determination, in fact, operate using safe practices so that they are not exposed to infection.

Dr. Cohn, you might perhaps elaborate a little on that question.

Dr. COHN. Well, Mr. Chairman, you have again raised a troublesome area in terms of how far should the information reach, if you will. To attempt to answer that I might mention to you that one of the things our in-house ad hoc advisory group within the Central Office accomplished a couple of years ago was to develop a "technical advisory," if you will, for building management employees in terms of how they should deal with the linens, the laundry, and so forth that would be used by an AIDS patient.

We have obviously issued instructions to physicians and nurses, and I might say that in large measure, we have depended heavily on guidance provided by the CDC through the MMWR—and I'm just holding up, for the record, the recommendations and guidelines from that manual which we have replicated for our field people. So I mention the technical advisory as one example.

I personally feel that the more education that you provide at all levels of health care, the more important and the more sensitive those individuals will be in providing the care to AIDS patients. If the issues are psychosocial in character—and as you know, in many cases they are in patients with AIDS—obviously, the mental health team, if you will, has to be aware, whether that's the psychologist, social worker, etc. So again, the issue broadens from a more or less straightforward question. It is, again, not an easy one to answer.

Dr. ROWLAND of Georgia. It becomes a very difficult matter to know how to protect the confidentiality of a person that has AIDS.

One other question in that respect. And individual who is admitted to the hospital—and this may apply to the VA, or outside of the VA—who does not have a diagnosis of AIDS and is tested seropositive, should that person be isolated as we do Hepatitis-B patients? Should anyone be made aware of the fact that the person is seropositive who is going to be dealing with that individual's body fluids?

Dr. GRONVALL. Dr. Cohn?

Dr. COHN. Well, I don't think the hospital at large should be notified if a seropositive individual is in the hospital.

Dr. ROWLAND of Georgia. The people that are dealing with that individual, should they be made aware of that person being seropositive?

Dr. COHN. The persons dealing with that individual should be aware; yes, sir.

Dr. ROWLAND of Georgia. How can you keep a person's confidentiality, then, if staff people and orderlies are going to have access to that information?

Dr. COHN. Again, sir, I think that's part and parcel of the overall educational process that not only the VA, but the whole health care system in this country—and indeed, the world—is faced with. We're talking about human behavior and modifying that; not only among the people that belong to the risk groups, if you will, but also the health care givers.

Dr. ROWLAND of Georgia. It becomes very complex, doesn't it?

Mr. Kanjorski?

Mr. KANJORSKI. We're talking about high risk groups. I would like you to explain, if you can, why we have identified certain high risk groups in this country as opposed to the course of the disease in Africa.

Dr. GRONVALL. I'll give a very general answer and let Dr. Cohn be more specific.

The term, "high risk group," only means some identifier; in this case, homosexual or intravenous drug abuser being the more specific ones, and the implication of the term is that such individuals, on a statistical basis, are more likely to have AIDS than others, based on experience.

Mr. KANJORSKI. Doctor, are they more likely to have AIDS because the AIDS virus invaded their group first? Or are they more susceptible than heterosexual groups?

Dr. GRONVALL. Dr. Cohn, I think you ought to answer that.

Dr. COHN. I'll try.

Indeed, the term, "high risk group," has been a troublesome phrase for the media and for many of the people that are unfortunate enough to have this illness or have seropositivity. And indeed the phrase, "high risk behavior," is probably the more appropriate phrase. We use the former, I think, largely for epidemiologic purposes, for purposes of categorization and so forth.

To answer your question, I think yes, in large measure it is because these groups became infected with this virus first and because of that we have had all the focus primarily upon those groups.

Now, it is clear that certain behavior among people, representative—again, if I can use the term, "groups"—has allowed the virus to spread and spread rather rapidly. But as your chairman said at the outset no group is immune from this disorder, and you've made reference, of course, to the situation in Africa where the ratio, as you know, is one to one, male to female, and heterosexual transmission is thought to be the main route of transmission.

Mr. KANJORSKI Well, at what point are we going to determine whether the heterosexual community should be identified as a high risk group so that we take the onus away? Right now we have a great prejudice in the country, both in the expenditure of funds and the desire for knowledge, because it doesn't affect most of us.

Dr. COHN. Okay. My answer to that, sir—and I'm not an epidemiologist, but the percentage of the total that have fallen into the group of heterosexuals is a relatively small group. We're talking about 4 percent of the total. Now, that has increased slightly, but for the bulk of the duration of this epidemic, since 1981, that group has stayed relatively constant. It has creeped up some; projections out into 1991, growing out of the Cool Font conference which the Public Health Service sponsored, clearly indicated that that percent would increase. I do not think, in my own personal opinion, that it would be appropriate to identify that group as necessarily a high risk group. It is one group, to be sure, from an epidemiologic point of view.

Mr. KANJORSKI. Why is it different in Africa, as I understand that the African disease is primarily in heterosexuals?

Dr. COHN. That is, again—and we've used the word "complex" perhaps too many times—but that is also a complex issue.

I think you have to understand—if I may attempt to do it this way. There are situations prevailing in Africa which allow for the transmission of this virus in a rather efficient way. For example, in many hospitals, I am told, and I have had some conversations with Dr. Jonathan Mann, who is the AIDS Program official for World Health, that they do not sterilize needles? In various studies that have been conducted, for example, using the AIDS antibody test, there is an inordinately high percentage of seropositivity among the health care workers working in these facilities.

So sterilization techniques are not available. I do not have specific data to discuss the issue of promiscuity, but that has been discussed, as well as the possible etiology.

Mr. KANJORSKI. You're satisfied that some sexual behavior, as opposed to other, increases significantly the possibility of contracting the disease? Is that correct?

Dr. COHN. I'm sorry?

Mr. KANJORSKI. Your suggestion is that some sexual behavior, as opposed to other sexual behavior, makes the propensity of capturing the disease much more readily?

Dr. COHN. Yes, sir.

Mr. KANJORSKI. Now, the reason I am asking those questions is not to find out the history of the disease, but rather as to what we're doing in terms of gathering statistics. Is the VA formulating a policy, for instance, with the armed services to follow up what's happening there? And have we gone back to study what has happened in the armed services?

Dr. COHN. Yes. As a matter of fact, we have what is called the DOD/VA Working Group, and I happen to be the co-chairman with an official from the Assistant Secretary of Health, Dr. Mayer's office. We've been meeting quarterly for the past 9 months. The two principal purposes of that working group are, first of all, to exchange information about research in the respective areas; and two, to do what we can to facilitate the smooth transfer of patients that would be leaving the military, that would be medically discharged out of the military and coming into our health care system. We met just the other week, and I'll just cite one issue; I think it's important.

TDRL status is used often—temporary disability retirement list. In any event, that is sometimes used by the DOD as a technique, if you will, for saying to an individual that he is not medically discharged out, but he's on temporary duty. He may come to us—

Mr. KANJORSKI. Does he go on that list when he tests positive for the virus, or when he gets AIDS?

Dr. COHN. Well, let me just say that I'm not a spokesman for DOD, but that policy has been undergoing some evolution. By and large the DOD is retaining people that are seropositive, but only assigning them to duty here in the United States. I do want you to understand that I m not the best spokesman, of course, for the Department of Defense, obviously.

Dr. ROWLAND of Georgia. Mr. Burton?

Mr. BURTON. You indicated the tests—I was reading your discussion of the costs for the ELISA test, and also the Western Blot test, and you indicated that the cost for screening is approximately $5 per test, and the costs for corroborative tests are $17 per test. Dr. Redfield of the Department of the Army, in the military, has been doing extensive testing of 2 million members of the military, and the total cost for the initial test—the ELISA test and the follow-up test; the verifying tests, including two ELISA tests and a Western Blot—is under $5. Why are your costs so far removed from theirs?

Dr. GRONVALL. Dr. Cohn?

Dr. COHN. What we are presenting are the costs that we obtained from our Lexington reference laboratory.

Mr. BURTON. Those are just outside laboratories?

Dr. COHN. No, that's our inside laboratory. But if we did them outside, in commercial laboratories, obviously they would be more than that.

Now, may I say that the costs are coming down, and you buy these tests, if you will, by the kit. So the per test price indeed—

Mr. BURTON. Well, the cost for an ELISA test for the U.S. Army is $0.82, for an ELISA test. And the concern that I have is that I'm

confident that we're going to get into massive testing of everybody in the country, routine testing. You can call it mandatory or routine, but I think that as a matter of procedure every health care facility, every health care person who deals with possible AIDS patients is going to be testing them on a routine basis in the not too distant future, and we need to get a more accurate cost, in my view, so that we in the Congress can decide how much money to appropriate.

If Dr. Redfield is correct and he tells us that we can mobilize the entire country for testing within a 6-to 12-week period—they did it in the Army in 6 weeks—with 250 million people involved, that's a little high. At $5 apiece we're looking at $1.25 billion on an annual testing basis. And I'd just like to urge you folks to maybe talk with the military people, like Dr. Redfield, to give us an accurate figure for massive testing just for hypothetical purposes, because I think that's where we're heading.

Now, the other question I'd like to ask you, and I know I'm going to have some hot discussion with our friends from CDC in a minute, we have—according to most people with whom I've talked—not 1.5 million people infected, but more like 4 million to 5 million. It's doubling every 10 to 12 months. Some people say 14 months.

My question is this. If we have 4 million people infected, and they don't even know they're infected—98 percent, approximately, don't know they're infected—how are you going to stop the epidemic without routine testing? Now, you say education, and you say that we need to continue the scientific research, and I agree with both of those. But how are you going to stop an epidemic that's spreading that rapidly when you have 4 million people infected unless you do routine or massive mandatory testing?

Dr. GRONVALL. I think, Mr. Burton, you are probably asking that question of a group of people who are in fact not best prepared to answer it since we are not epidemiologists or the people who deal on a global basis with preventive health measures. My understanding is that in the community of medical and health experts who deal with those kinds of questions there is a strong consensus that just the act of establishing a widespread or national or global mandatory testing program would have little pragmatic positive outcome in halting this epidemic.

Mr. BURTON. Let me just interrupt here. If somebody has the AIDS virus and they don't know it, the chances that they're going to change their lifestyle is not very great. But if they do know that they have the AIDS virus and you do the counseling, and you tell them that they ought to change that, then there is a possibility at least that they will alter their lifestyle. So there are positive aspects to massive testing and informing people that they have the virus.

Dr. GRONVALL. I'm not saying that there is no positive impact of testing and having an individual find that he or she is either positive or negative. But I believe that the preamble to your question said that a person not knowing whether he or she is infected won't do anything to change. I believe that there is dramatic evidence in this country that behavior of people in this country has remarkably changed in regard to sexual practices because of the informa-

tion available about AIDS. There is very dramatic evidence that sexual practices have changed in a dramatic way in people who do not know whether they have been infected or are carrying the antibody or the virus.

Mr. BURTON. I'd like to see those tests or those studies that show there are dramatic changes because—if I might just finish, Mr. Chairman—we had an educational program on Herpes Simplex II, or genital herpes, back in the last decade. That was about 12 to 15 years ago, and everybody said that if you get herpes—you know the jokes, you'll have it for ever; you can change dates, but herpes is forever. And according to a Time Magazine article and many doctors with whom I've talked, we have approximately 40 million people in the United States infected with Herpes Simplex II. So the education and fear of getting Herpes Simplex II did not stop the sexual practices of this country, and one out of every six people in America has it.

Now, if we get that with the AIDS virus, depending purely upon education and not getting into testing and informing people, then I think we're in for a real, real tough situation.

Thank you, Mr. Chairman.

Dr. ROWLAND of Georgia. Thank you, Mr. Burton.

Mr. Harris?

Mr. HARRIS. I have no questions of this panel, Mr. Chairman.

Dr. ROWLAND of Georgia. Mr. McEwen?

Mr. MCEWEN. Are you having difficulties with the employees in the veterans' hospitals in treating patients?

Dr. GRONVALL. We'd surely have difficulty if you make the question that broad. There is serious concern among our staff people about this illness.

Dr. Cohn, perhaps you could comment on that.

Dr. COHN. My answer to that would be that on a limited basis, there have been some examples where staff clearly have refused to care for patients.

We have taken a two-fold position, that an employee may not categorically refuse to care for a patient unless there is some medical reason which is present in the employee, such as an immunosuppressed employee who might be on corticosteroids for instance. That individual—pregnant women should probably not be involved in the care of an AIDS patient.

We do understand, and there are any number of examples where health care workers have become "burned out" from the constant chronic care of AIDS patients. Obviously, a fatal disease in relatively young people—often the health care giver is of the same age as the dying patient. And in those situations, what we suggest is that the team or the group working with the patient sit down and discuss with that employee his or her reasons why they don't want to be involved any more. We feel that that's the way to work that process through, and in general that has worked. I will not say that it's 100 percent, of course.

Mr. MCEWEN. You mentioned pregnant employees not wishing to be involved?

Dr. COHN. I think that prudent advice would suggest that a pregnant woman should probably not be involved in the care of an AIDS patient.

Mr. McEwen. Why is that?

Dr. Cohn. I think that in light of what you have heard recently in terms of the three accidental exposures, or "splashes," if you will, of contaminated materials on the part of certain health care workers who might not have taken all the precautions but who did not sustain a clear needle stick, at least based on the exhaustive history-taking, I think there's enough of a question to suggest that the pregnant woman should not be exposed. And if I may continue it, the fact of the matter is that if she did become AIDS antibody positive—not necessarily having AIDS—her unborn child has a 50 percent chance of being born with AIDS. That's an extraordinarily high percentage, and you know that the ultimate outcome with that child is often disastrous.

So I think the prudent advice would be not to have such employees involved.

Mr. McEwen. What is the mortality rate of AIDS—of those who carry the virus?

Dr. Gronvall. The mortality rate once the disease is established, the full-blown disease, is to date 100 percent in the sense that no cure has been reported.

Mr. McEwen. You estimated that the cost of caring for these patients is $20,000. How does that compare with the average in-patient for veteran care, annually?

Dr. Gronvall. Mr. Lindsey, I think, perhaps might be able to comment on that.

Mr. Lindsey. We have been looking at the cost of AIDS patients, obviously, because of the criticality of that question.

Mr. McEwen. Excuse me. Maybe I wasn't clear. I know the chairman and all of us are anxious to get on to the next panel, and you have been so helpful and I have many more questions. But just quickly, have we done an analysis of how much it costs to have a veteran in a hospital?

Dr. Gronvall. Yes.

Mr. McEwen. We've done it on AIDS victims at $20,000 per year. What is it for the regular patient?

Dr. Gronvall. Well, we have separate figures for medicine and psychiatry and for surgery, and we can provide that for the record.

Mr. McEwen. All right. Thank you much.

Thank you, Mr. Chairman.

[Subsequently, the Veterans' Administration furnished the following information:]

The $20,000 figure represents the average annual cost of treating an AIDS patient. Because of the attention focused on AIDS, we have computed this average cost per individual patient. This does not include the cost of the new drug, zidovudine (formerly AZT) which approaches $10,000 per year.

On the other hand, our cost accounting system gathers data per average episode of care for medicine, psychiatry and surgery patients In FY 1986, the actual average cost for each discreet episode of care in VA Medical Centers, and not per patient per year was:

Medical bed sections	$2,922
Surgical bed sections	4,677
Psychiatric bed sections	5,281

Dr. Rowland of Georgia. Thank you very much.

Two quick questions, and please give me brief answers, if you will, to this, because we do need to get on to the next panel.

How are VA cases reported to the CDC, Dr. Gronvall?

Dr. GRONVALL. Dr. Cohn should answer that.

Dr. COHN. I'm going to pass it to Dr. Mather who is in charge of the reporting system.

Susan?

Dr. MATHER. The Medical Centers report to their State or local health department, who then report it to the CDC.

Dr. ROWLAND of Georgia. Thank you for that very abbreviated answer.

One other question, Dr. Gronvall. In my opening statement, I suggested that perhaps we should have a commission on AIDS, a commission that would be made up of Members of Congress from both sides of the aisle in the House and the Senate; members from the Administration and members of the public in general, in order to remove this debate from the atmosphere of partisan politics and philosophical differences. Do you have a feeling about that suggestion?

Dr. GRONVALL. I surely respond positively to anything that could be done that could help mobilize the total effort of the country in a focused way to dealing more effectively with this disease. Absolutely.

Dr. ROWLAND of Georgia. Do you feel that the problem of AIDS is an overwhelming threat that perhaps we don't realize in general at this point?

Dr. GRONVALL. I don't want to use the word "overwhelming" because I don't believe that America will be overwhelmed. It is a massive threat that calls for a massive and coordinated response.

Mr. KENNEDY. Dr. Rowland, would you yield for one question please?

Dr. Greene, at the beginning—one of the things that I think confuses Americans is if a central plan exists by the Federal Government to actually deal with this disease. The chairman suggests that there have been two Nobel Prizes offered to the research capabilities by the VA. I just wonder if you could just walk us through how you fit into the overall Federal Government's policy, and who is responsible for that policy.

Dr. GREENE. Well, I think that research in the United States and in the world is carried out by individual researchers, and the job of the Federal Government is to find the best researchers and to give them the resources and support to carry out their studies. And I think in the VA and the rest of the academic world and research centers and other Federal agencies we have very talented investigators who are working on a number of questions. The big question is, how does this virus infect cells? What are the mechanisms that are unique to the virus, and how can we tailor drugs to stop those processes? That's one approach.

Another approach is to actually design drugs that will—

Mr. KENNEDY. I'm not so much interested in the specifics of what the VA has bitten off here as much as I'm interested in what the procedures are for one agency of the Federal Government to get a piece of—and whether or not you have any sense that this is a coordinated policy by CDC or by the Surgeon General. I think that people are very confused about what the hell the policy is.

Dr. GREENE. I think I understand what you're asking. I think in AIDS and all other areas, the way in which research is done is not through some massive plan of attack, but through individual researchers who are talented and focus on one specific question that is answerable. The rapidity with which advances have been made in AIDS in understanding the disease I think is a testimony for that approach, but there is no czar for biomedical research—

Mr. KENNEDY. Is your testimony that that approach—I mean, the progress that we've made to date in terms of solving the problem—

Dr. GREENE. I think it's incredible progress in a disease for which there wasn't a single model. There wasn't a single retroviral disease known until 1981, and I think that biomedical research has made enormous contributions to understanding it. We have a lot more to understand, but I think the way in which the progress will continue to be made is to take the people who are most knowledgeable and trained to do this work, and get them the resources to support them.

Mr. KENNEDY. I can't believe that you think that we've made that type of progress with the kind of funding levels that AIDS has been getting out of the Federal Government. I mean, for you to suggest that this has been an example of a wonderful program that has made such tremendous strides, I am just astounded. I cannot believe—when you've only got $300 million being spent by the Federal Government, and you think that this is a good program by this Government?

Dr. GREENE. I'm never one to say that we have enough funds for biomedical research. I've never said that and I never will. The fact of the matter is that there has been remarkable progress made, and that there is certainly a need for resources to continue that progress.

Mr. KENNEDY. We have a serious disagreement.

Thank you, Dr. Rowland.

Dr. ROWLAND of Georgia. Mr. McEwen?

Mr. MCEWEN. Doctor, do we do routine testing on patients when they come into the hospital? You may have answered that and I may have missed it.

Dr. GRONVALL. Is the question, do we do routine AIDS testing?

Mr. MCEWEN. Yes.

Dr. GRONVALL. No.

Mr. MCEWEN. So a patient could be carrying the virus and we would not be aware of it?

Dr. GRONVALL. That is correct.

Mr. MCEWEN. Does that concern you at all? Because obviously, we're using needles and sharing equipment and we have procedures in which bodily fluids are being moved about.

Dr. GRONVALL. All treatment of all patients in our hospitals, and all utilization of needles, handling of body fluids is conducted by staff who have been educated to treat that as though there is always risk. So the fact that some unidentified patient may in fact carry the virus obviously concerns me, but I believe we've taken appropriate steps to ensure that all needles are sterilized, all health workers know how to treat bodily fluids, blood samples, avoid risk, because in fact, outside of AIDS, it is always the case that in any hospital there may be individuals who carry some in-

fectious organism that is unknown to the staff. So we plan our hospital operation so that all patients are treated as though there may be that risk.

Mr. McEwen. But you do test for other communicable diseases, would you not?

Dr. Gronvall. No, not on a routine basis.

Mr. McEwen. CDC, I understand, requires reporting and that sort of thing for a whole host of potentially communicable diseases. And not all of them are fatal.

Dr. Gronvall. The requirement for reporting is that when a diagnosis is made, the case should be reported. That is quite different than a requirement for routine testing for diseases on that list.

Mr. McEwen. You're not concerned about that?

Dr. Gronvall. Oh, I'm extraordinarily concerned about this whole disease, but the single fact that we do not mandate that all patients coming into our hospitals be tested for the AIDS antibody does not concern me.

Mr. McEwen. Dr. Cohn explained that it is excessively risky for a pregnant nurse to be serving an AIDS victim, and yet we are reluctant to even find out whether or not one of the patients has AIDS. Somewhere or another I'm missing a part of the puzzle.

Dr. Gronvall. Dr. Cohn, you might comment on that.

Dr. Cohn. Well, sir, I don't think I said "excessively risky." At least, I didn't mean to—I did say that I thought that it would be prudent.

But let me come back to the question that you directed to Dr. Gronvall. We're not operating in a vacuum here, sir, as far as it relates to whether we do routine testing or not. There have been any number of studies carried out among health care workers. For example, the CDC has a rather large accumulation of cases where there has been frank needle stick, and Dr. Curran, who is going to address you later on this morning, I'm sure can respond to that in more detail.

But the point I want to make in all of these studies, and there are a number of such studies, the attack rate in terms of the health care worker becoming actually seropositive after frank needle stick is extremely low. It is not zero; the risk is not zero, but the risk is extremely low. And what we do medically is attempt to correlate that to another known infectious disease which has similar epidemiology and transmissibility, such as Hepatitis-B. And if I could just throw one number out for you, if a person is stuck with a needle from contaminated material from a patient with Hepatitis-B, for example, that health care worker has anywhere from a 6 percent to a 30 percent chance of coming down with Hepatitis-B. The range depends on the part of the country and so forth and so on. The percentage possibility in a situation with needle stick from AIDS-contaminated material is something far less than one percent. As I said, it's not zero. So we don't just arrive at these kinds of decisions in a vacuum.

Mr. Burton. If the gentleman will yield just briefly, I really don't know how you can make that kind of a statement without more testing. I mean, you made a categorical statement that it's easier to get Hepatitis-B from a stick than it is to get AIDS, and I think that there just isn't enough conclusive evidence yet to draw

that conclusion. At least most of the doctors with whom I've talked say that.

But let me just—

Dr. GRONVALL. We would be pleased to supply the data upon which that statement was made.

Mr. BURTON. I'd like to have that data.

[Subsequently, the Veterans' Administration furnished the following information:]

The attached which was taken from a publication from the Centers for Disease Control (CDFC) titled, "AIDS: Recommendations and Guidelines—November 1982—November 1986," provides information that indicates that the risk of bloodborne transmission from inadvertant exposure is considerably less for HTLV-III/LAV than for hepatitis B virus infection.

[See p. 96.]

The following excerpt was taken from an article by J Louise Gerberding, M.D., and Merle A. Sande, M.D , in the June 4, 1987 edition of The New England Journal of Medicine which further enhances the need for following CDC's infection control guidelines for transmission of HIV infection:

"It is now clear that the risk of HIV transmission to health care workers is extremely low, even when the special infection control guidelines recommended by the CDC are not followed; a much greater potential for the transmission of numerous other pathogens exists as a result of exposure to infected body fluids."

Mr. BURTON. But let me just say this, or ask this question. If a person comes in to a hospital and has a regular blood workup for surgery or something else, do you check them for syphilis? Is that tested for syphilis?

Dr. MATHER. No longer.

Dr. GRONVALL. No.

Mr. BURTON. What do they test when they do that blood workup?

Dr. GRONVALL. Dr. Mather?

Dr. MATHER. We'd like to avoid the use of routine "cookbook" approaches to medicine. The patient is tested for what is indicated. Generally you want to know the hemoglobin hematocrit—

Mr. BURTON. I know, but if there's any communicable disease of virus in the blood workup, do you check for that?

Dr. MATHER. We do not generally screen for communicable diseases unless there's a reason for doing it. And I think the whole labeling issue—there are just two quick points I'd like to make. One, the VA doesn't have a policy that excludes pregnant health care workers from the care of AIDS patients; I think we ought to make that clear. There might be—I think what Dr. Cohn meant to say was, there might be times when a pregnant health care worker would ask to be excluded from this care, and that this might happen. But it is not our policy to exclude pregnant health care workers from the care of these patients, and I think the problem of labeling—when you're screening for something, you want to have something you can do as a result of that screening. What we generally do is label an HIV-infected patient as we label an antigen-positive Hepatitis patient, "blood and body fluid precautions." But it's a little bit like these automobiles that ride around with "Baby On Board." Nobody aims to nit those cars or any other cars. Nobody plans to have an accident.

So these days, it is prudent for any health care worker to act as though—and to behave as though—all blood and body fluids are infected. And the labeling, perhaps, says "extra caution." But labeling in and of itself never prevented an accident. I mean, nobody

breaks or sticks themselves on purpose, and therefore doesn't stick themselves with labeled blood; it happens as an accident, and we take precautions for the accident. But we are still going to have those patients. Those patients are often sick and need care, and we are going to provide that care, with adequate precautions to our health care workers.

Mr. KANJORSKI. Would the chairman yield just one second?

On that comment, maybe we should tell the armed services not to label minefields for the doctor.

Dr. MATHER. That's a little different.

Mr. KANJORSKI. Well, I think you do take caution if you have notices, is what I'm saying. But the thing that strikes me, and that I think my colleagues on the other side are bringing out, if we're not testing for routine admission—and I'm always reading about it; last time I think I read about it was 1.5 million, and now it's up to 4 million in someone's testimony—where do we get these figures from? Are we just exciting the world with numbers, or are they based on some statistical reality? And if they are, I missed that subject in statistics because I don't seem to think that we're pulling a large enough sample out of the population to know what's going on.

Dr. ROWLAND of Georgia. I expect the CDC would probably be able to address this better for us.

I thank all of the panel for being here this morning. The record will remain open for 5 days for comments and questions by any members of the subcommittee.

[See p. 89.]

Dr. ROWLAND of Georgia. Thank you all very much for being here this morning.

Dr. GRONVALL. Thank you very much, Mr. Chairman.

Dr. ROWLAND of Georgia. The next panel is Dr. James Curran, who is Director, AIDS Program, Centers for Disease Control, and Mr. Joseph Levitt, Executive Assistant to the Commissioner, Food and Drug Administration.

Dr. Curran and Mr. Levitt, we all appreciate your being here this morning, and you may proceed in any manner that you so desire.

STATEMENT OF JAMES W. CURRAN, M.D., DIRECTOR, AIDS PROGRAM, CENTER FOR INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL; ACCOMPANIED BY: JOSEPH A LEVITT, EXECUTIVE ASSISTANT TO THE COMMISSIONER, FOOD AND DRUG ADMINISTRATION

Dr. CURRAN. Thank you very much, Dr. Rowland. I am Jim Curran, Director of the AIDS Program, Center for Infectious Diseases at the Centers for Disease Control. On my left is Joseph Levitt, Executive Assistant to the Commissioner of the Food and Drug Administration.

I am particularly pleased to be here. We have submitted written testimony for the record, but I would also like to make a few summary remarks about AIDS and HIV—

Dr. ROWLAND of Georgia. Without objection, it will appear in the record.

Dr. CURRAN. I am particularly pleased to be here for a number of reasons. I applaud your efforts to make this a nonpartisan effort. And I think that although public policy involves many different areas of society beyond medicine and public health and science, we now have 6 years of experience in AIDS. There is a large number of reputable scientists working on the AIDS problem, as witnessed by the 1,000 scientific presentations made at the AIDS conference here in Washington last week.

A lot of times, the publicity from such conferences is not about the solid science that is going on, and there are people in virtually every State and community who can provide this kind of information.

The cooperation between the VA and the Centers for Disease Control has been quite good. We found reporting of AIDS from the VA Medical Centers to be excellent. From our point of view, our communications with the VA have always been very cooperative and cordial.

Let me briefly provide a couple of definitions before the rest of my remarks. AIDS, as I'm sure all of you know, refers to a number of very serious, fatal infections or cancers or other life-threatening or fatal diseases that result from the serious breakdown in the immune system caused by infection with the virus. We'll call it, for this purpose, the AIDS virus.

AIDS virus infection, which for all practical purposes is synonymous with having a confirmed positive antibody test, refers to a whole spectrum of infections, from asymptomatic infection through AIDS, which often leads to death.

As of now, nearly 37,000 cases of AIDS have been reported to the Centers for Disease Control; almost 15,000 cases were reported in the past 12 months. It is a disease that largely affects people of reproductive age. Ninety percent of cases are in people between the ages of 20 and 50. It's a disease most often of men; 93 percent of the cases are men, and in 1986 we believe AIDS will be the fifth leading cause of premature years of life loss in the United States for men.

The Public Health Service has estimated that by the end of 1991, 270,000 cases cumulatively will have been diagnosed and ultimately reported to the Centers for Disease Control, with nearly 180,000 deaths. Cases have been reported from all 50 States, the District of Columbia, Puerto Rico, and other territories, and now, 112 nations throughout the world.

There is a lot of talk about AIDS by a lot of people, but this is truly an international problem which will be solved best, from my point of view, with a lot of international and national cooperation.

In the United States, the majority of cases have been in homosexual men and in homosexual and heterosexual intravenous drug abusers.

With regard to heterosexual transmission, it's quite important to recognize the roots of heterosexual transmission thus far in the United States. Most of the cases in heterosexual men and women have been in persons who have abused intravenous drugs, primarily beginning on the East Coast of the United States, and primarily in intravenous drug abusers who have been black and Hispanic men and women. For that reason, the heterosexual transmission

epidemic now has its roots in intravenous drug abuse. Solving that problem involves dealing with the problem of intravenous drug abuse as well.

Since perinatal transmission in the more than 500 cases of AIDS in infants in the United States comes from infected women, we have to look at where and who the infected women are. And indeed, 60 percent of the women have been intravenous drug abusers. A growing number have been women who have acquired the infection through heterosexual contact; but once again, 70 percent of them have acquired the infection from intravenous drug abusers.

So we can talk a lot about heterosexual transmission and dealing with it, but it will be fundamental to deal with intravenous drug abuse as we attempt to solve the AIDS problem.

Of 1,400 cases of heterosexual transmission, 500 cases have been reported in children in the United States.

There is no vaccine against AIDS yet. There is a lot of research going on. There has been one drug licensed, AZT, to treat AIDS, and there are many, many studies of that and other drugs which we can address later.

It is important to recognize that people who are infected with the AIDS virus are carrying a virus which they think may some day kill them. I always have to ask myself: if somebody told me I were antibody positive, no matter how I got the virus, what would I want to know? The first thing I would ask the counselor is, am I going to die? When am I going to die? Help me, help me, help me. I would not want to know first how I can stop transmitting the virus to others.

So I think that any counseling is going to have to deal with the enormous grief and shock individuals feel when they know they are infected with the virus. First, you must get their attention and deal with that before you can deal with the transmission issue. But the transmission issue is important because people who are infected with the virus and are antibody positive are capable of transmitting the virus to others, even if they have no symptoms.

At this time, testing and counseling, information and education are the best methods of reducing sexual transmission, IV drug abuse transmission, and transmission from infected women to their newborns. Of course, with IV drug abusers, you have to treat the IV drug abuse. This is an addictive pattern in many people that requires more than just counseling and testing. And with perinatal transmission, it's important to supply adequate family planning services to infected women of reproductive age groups.

There are some very important questions about the natural history and epidemiology of the AIDS virus. The first question is the question I'd want to know the answer to. What is the chance that I'm going to die, and when? And the question can be stated, what is the outcome for an infected person? There have been many, many studies of this with some 25,000 people followed prospectively throughout the world. The largest study is one conducted by the Centers for Disease Control and the San Francisco Department of Health in San Francisco, where men have been followed for over 7 years—actually going back to a year before AIDS was discovered. After 2 years of infection among these homosexual men, only 1 percent had progressed to AIDS, or the life-threatening syndrome. But

after 7 years, 30 percent had progressed to AIDS, and it's very likely that this trend will continue, probably to above 50 percent.

Now, the question is, will the outcomes be the same for other populations? Do we have sufficient data to say that all persons with hemophilia in the country who are infected with the virus will have the same outcome as these homosexual men? Will other groups of homosexual men have the same outcome? Why can't we just say that the outcome will be 100 percent in everybody?

Well, we can't because the data don't allow us to. But we know that the outcome is sufficiently bad that it's a life-threatening infection to acquire and to have, and the most likely hypothesis is that the outcome will be the same among all infected people. But several scientists are looking at cofactors, looking at factors that may accelerate the growth of the virus, at genetic factors and many other things that may change the course of the disease.

We know one thing, that among infants who are infected in utero, the outcome is worse. A much higher proportion develop AIDS, and they develop it faster. The outcome is almost inevitably fatal.

The second important question is, how many people are infected with the virus? Many of you have mentioned various numbers. Whenever you hear large numbers that contradict each other, you can be sure of one thing: no one knows. And that's what was concluded by the Public Health Service at Coolfont, West Virginia, when a group of 85 scientists got together and concluded that the best estimate was a range between 1 million and 1.5 million infected Americans.

My own estimate right now would be that 1.5 million is perhaps our best estimate for the following reasons. A million and a half is a lot of people. While this only represents .7 percent of Americans, we have to remember that our best studies indicate that over 90 percent of those infected are men, and over 90 percent are in reproductive age groups. That would mean that 1 in 30 men between the ages of 20 and 45 are infected with the virus, if 1.5 million people are infected. And 4.5 million were infected, this would mean that 1 out of 10 throughout the Nation are infected. My estimate would be that estimate is too high. Nonetheless, it's very important to know how many people are infected with the virus to plan for targeting the population for medical care. It's important to know this nationally, but it's also extremely important to know this at local and State levels to plan for local and State medical care and prevention programs. That's the prevalence; that is, how many people are infected.

The next important thing to know is how many people are becoming infected; that's the incidence of infection. How many this year will get infected with the AIDS virus; what will the numbers of new infections be? I think we can say with a great deal of certainty that the number of people who will become infected from blood transfusions in the United States, or the number of hemophiliacs who will become infected with the AIDS virus, is a very, very small number, very close to zero in the United States. That's one scientific, public health, and medical accomplishment that we should be proud of.

Note, though, that numbers of cases of AIDS in hemophiliacs and transfusion recipients continue to increase. That's living proof that cases of AIDS don't indicate what's happening with prevention in the United States because the outcomes continue among people already infected.

What do we know about behavior change? Well, we know that in several well-studied groups of middle class homosexual men in cities most affected—cities such as Paris, London, New York, San Francisco, Los Angeles, Pittsburgh, Chicago, Baltimore—behavior is changing dramatically. That is clear from the empiric evidence of declines in AIDS virus infection rates in these men. This is despite the fact that the risk is greater because their partners are more likely to be infected. But this behavioral change is not widespread enough. Syphilis is increasing in heterosexual men and women in the United States now. I don't believe that the heterosexual population has markedly changed its behavior, or has taken AIDS particularly seriously. I believe there is a real information communication problem with black and Hispanic communities, and I'm concerned also about young homosexual and bisexual men. I think that more studies are needed concerning the efficacy of behavior change.

Let me finish on two notes. One is the issue of testing and counselir .

The Centers for Disease Control has strongly recommended that we need to have a lot more routine counseling and testing in the United States, with the belief that many people don't know that they're infected, and many people don't even know that they might be at risk. We have to ask ourselves why that isn't getting done and why we want to do it. Unlike syphilis, where there is a treatment that you could offer an infected person, here we offer people—what? First of all, we need to offer them the answer to the question, what's going to happen to me the rest of my life, Doctor? Am I going to die? And what are you going to do to help me?

We want to test people for the following reasons. We want to identify who is infected, and we want to identify who is at risk, so that they can be counseled to prevent transmission to others or to alter their behavior to prevent acquisition of the virus themselves.

We want more testing and counseling for diagnostic purposes. I can't believe, as a physician, that you don't consider in diagnosing and treating people, both from a sensitivity point of view as well as a medical point of view, that something as important as knowing whether someone is infected with the AIDS virus might not alter your way of caring for people.

And third, we want to identify infected people so that health care professionals can better care for them, and perhaps can take better precautions themselves. We've got to do this in a very nondivisive way, and we have to ask ourselves why it isn't being done if it's so logical. And it gets back to what Dr. Cohn said. This is very, very complicated. If the outcome when we test people is that all the health care providers say, we're not going to take care of you any more, we're going to leave; that isn't going to meet our objectives. If we're going to test people and we're not going to counsel them, that's analogous to finding people with syphilis without treating it.

So, we have to do all of the things, and we have to deal with the concerns about confidentiality and record-keeping, which this committee has already indicated are extremely complicated issues to deal with. How can you tell the antibody test results to everybody who needs to know, and yet keep them confidential in a hospital setting where often nothing is kept confidential? We have to do it. It can be done. Famous people get admitted to hospitals all the time and nobody ever knows it, so it seems to me that somehow or other hospitals can come to grips with this. But, they're facing this at a time when there's an urgent need to increase their counseling and testing.

Finally, in addition to providing the counseling and providing the confidentiality and record-keeping precautions, there's a need for more training and more emphasis on precautions for health care workers. Even testing all patients won't eliminate a lot of the routine risks that health care workers take in outpatient settings or in other settings before the test results come back. Health care workers need to have the support necessary to deal with these things.

I think I'll leave the extensive research, information, education, regulation, training, and organizational aspects of the Department of Health and Human Services and the Public Health Service for questions.

Thank you.

[The prepared statement of Dr. Curran appears on p. 80.]

Dr. ROWLAND of Georgia. I think the statement that you made about the reaction of an individual who is told that he has a positive serology is exactly the same as from a person who is told they have metastatic disease, who has cancer throughout their body: what can you do to help me? Is there any chance for me? I think that is exactly the same kind of a response that you would get, and it is certainly one that places a great burden on the physician and the people who are going to be trying to deal with that individual, and I think that we should never lose sight of the fact that at that point, something needs to be done. You said the person is not going to be concerned about the transmission of that disease; they're going to be concerned about what can be done for them at that time. But I think we should never lose sight of that, the physician and the people who are going to deal with that patient.

Let me ask you, if you will, to talk just a little bit about how the Centers for Disease Control accumulates the data that it gets on infectious diseases, and more specifically AIDS, which we are talking about here. Would you very briefly go through that routine?

Dr. CURRAN. Reporting of communicable diseases in the United States is a State and local health department responsibility, and reports go to State health departments through local health departments and then the information is voluntarily reported, without identifiers, to the Centers for Disease Control. Because AIDS is such a serious problem, there is Federal assistance--both technical assistance and financial assistance—to most State and local health departments for the reporting of AIDS. Validation studies have shown that reporting of AIDS is more successful than for any other common serious disease in the United States.

Dr. ROWLAND of Georgia. What flaws do you see in that system at this point, and how much do you think the AIDS problem is under-reported?

Dr. CURRAN. Well, we see several flaws, although it's a good system. The first flaw is that the serious morbidity itself is underestimated due to at least three factors. One is new knowledge about what causes death. CDC will be changing the case definition to capture additional causes of death—dementia syndrome, disseminated tuberculosis, and something called the "wasting syndrome" with a positive test for virus. The new definition will be completely in effect by September 1st.

Secondly—

Dr. ROWLAND of Georgia. These are the people who do not have opportunistic diseases?

Dr. CURRAN. They do not have opportunistic diseases that fit the case definition. We think from other surveys that this new definition will increase reporting by as much as 5 to 10 percent. Now, that's not a large amount, but it's something.

The second factor is under-diagnosis. We know that in places like New York City, unexplained deaths in minority people, many of whom are drug abusers, occur at large rates. Death rates in IV drug abusers have gone up dramatically. This has not been attributed to AIDS. Some autopsies—on people who die in the street of pneumonia—have led us to believe that these deaths may be AIDS-related. There's not a way to capture this on any national basis without autopsies.

The third factor is under-reporting and delays in reporting. At any point in time, we fell there are about 25 percent more cases in the United States than have been reported at CDC; these will be reported ultimately. That is, we believe there are already 7,000 more cases in the United States that have been diagnosed but not yet reported, that ultimately will be reported to us as they work their way through the system.

Under-reporting is less a problem now in major cities that have good surveillance systems, but I think that concerns about confidentiality can threaten that. We've seen that with some famous people, and I think that it's a perfectly understandable thing. Whether that will increase we don't know, but we have validation studies to look into it. That's one major flaw. I'm always looking at flaws; I've found a whole lot of them.

The second one is the question of what's happening with the infection, and that's the most important one. AIDS itself doesn't tell us how many people are becoming infected. It's conceivable that the infection rate may have leveled off now. We don't know that We know it's gone down in hemophiliacs. National reporting of antibody test results would only partially answer this, because changes in reporting make more difference than changes in incidence. For that, we need special surveys, and the CDC is currently conducting several special surveys now to look at incidence and prevalence of the infection itself.

Dr. ROWLAND of Georgia. The subcommittee members will bear with me. I need to follow up on that question at this point.

I have a great concern that the number of AIDS cases are being under-reported for whatever reason, and I'm not sure that the

MMWR reflects really the number of AIDS cases that we have in this country, the number of potential AIDS cases. And I think that's pointed out by the difference in the number of AIDS cases that the VA itself has reported, as being 2,014 from September of 1983 to May of 1987, while the number that is reported by the Centers for Disease Control from 1981 are 999. What is the reason for almost twice as many being reported in the VA as reported by CDC?

Dr. CURRAN. We're sorry about the unexplained inconsistencies. There are two major factors involved there. One is that CDC has a report from a single hospital. Most patients with AIDS are hospitalized at least three or four times before they die, so the 37,000 cases of AIDS have had as many as 125,000 or more hospital admissions. We get the report only from the reporting hospital, and we don't have records of all of the other hospital admissions. If the person is first admitted to Bellevue Hospital, for example, for AIDS, and is found to be veterans-hospital-eligible, the report might go from Bellevue to the New York City Health Department to CDC. The individual may, on subsequent admissions, go to the Manhattan VA hospital. So that's the major explanation.

The second explanation is probably lags in reporting. The VA may be aware of all cases diagnosed in veterans' hospitals up to May 1987, and there may be some lags in reporting to the city, State, and Federal level by now.

But I believe the first explanation is the major one, and I'm sorry for that inconsistency. When I reviewed Dr. Gronvall's testimony I became aware of it myself.

Dr. ROWLAND of Georgia. The same person may be reported more than once, is what you're saying, then?

Dr. CURRAN. We remove those duplicate reports by a fairly sophisticated soundex system which deals with dates of birth and initial sound codes. If the person is reported more than once, only the initial report is included. So we would not, for example, have records of all patients who have gone through the VA system; we would only have the record of VA admission, if that were the reporting hospital for the first report.

Dr. ROWLAND of Georgia. There may be some additional questions that I want to ask on that point but at this time I'll yield to Mr. McEwen.

Mr. MCEWEN. Dr. Curran, how many communicable diseases does the CDC require physicians to report?

Dr. CURRAN. Reporting for all communicable diseases, for the most part, is voluntary to the CDC and is required, with some differences, by some State and local health departments. A summary of the specified, notifiable diseases by State and local health departments is listed weekly in the MMWR, a CDC publication. It includes many major communicable diseases. Among the diseases that are transmitted in ways like the AIDS virus are gonorrhea, hepatitis, and syphilis and some of the more minor sexually transmitted diseases, like chancroid.

Mr. MCEWEN. I understand that the State of California requires something like 58 different diseases to be reported by physicians? Is that an accurate figure?

Dr. CURRAN. I don't know for sure, but it's a large number.

Mr. McEWEN. And yet, we do not require reporting of AIDS patients? Is that correct?

Dr. CURRAN. AIDS is mandated to be reported in virtually every State in the Union.

Mr. McEWEN. To—

Dr. CURRAN. To the State health departments, and then the State health departments report to CDC. And every State reports to CDC.

Mr. McEWEN. The number of patients—when a physician encounters a patient with AIDS, does he report that?

Dr. CURRAN. He must report that. There may be one or two States in which he could legally get away with not reporting.

Mr. BURTON. If the gentleman would yield on that point, as I understand it in California, if you have full-blown AIDS it must be reported. But if you have the AIDS virus, according to State law, the doctor isn't even allowed to tell the wife, let alone the health agencies or the CDC. So I wish you would differentiate and be very clear on that point. You're talking about full-blown AIDS and not the AIDS virus, and we're talking about 1.5 million to 4 million people that have the virus out there. They are not mandated that they be reported if their blood test isn't found seropositive for AIDS.

Dr. CURRAN. There is a small number of States, Colorado and five or six others, that require reporting of antibody test results to the State health department. But very few States do that. Then there are other laws in some States, such as the California law that you talked about.

Mr. McEWEN. What's the definition of a person with full-blown AIDS?

Dr. CURRAN. Somebody has AIDS if they have a reliably diagnosed, serious, life-threatening infection, like pneumocystis pneumonia, or one of several cancers, like Kaposi's sarcoma, or several other conditions like severe weight loss in the presence of a positive antibody test.

Mr. McEWEN. Well, does a person with full-blown AIDS have any expectation that death is not imminent? I mean, is that the criteria whereby it is identified as "full-blown"?

Dr. CURRAN. About 90 percent of patients reported to CDC with AIDS have died within 3 years. There is a small number of people who have survived as long as 5 years.

Mr. McEWEN. When you're saying that that's the part that's being reported, that's really—

Dr. CURRAN. That's the serious end of the spectrum; those are the people who get hospitalized, for whom reporting is greatest.

Mr. McEWEN. That's inconsequential from a public health point of view in the fact that these people are dying.

Dr. CURRAN. I think there's no question that from the point of view of determining how extensive the infection is, or whether the infection is going up or going down, death is not an adequate monitor. That was the major flaw that I pointed out.

It is extremely important, however, when dealing with issues of planning health care facilities and in looking at the total toll of the disease—and perhaps even at the efficacy of therapy—but there are two different issues here. The other issue, the issue that you're

pointing out, is the highest priority that we have in surveillance now. It is to determine the number of people becoming infected and the number of people infected in each community.

Mr. MCEWEN. Should there be standard reporting for AIDS virus carriers?

Dr. CURRAN. I think a State such as Colorado has standard reporting, and has reporting of antibody test results in what they estimate to be 10 to 15 percent of infected persons in their State.

In addition, Colorado has very strong laws to protect confidentiality, and they have an extensive public health program for counseling and testing—

Mr. MCEWEN. All that's wonderful, but from CDC's point of view—

Dr. CURRAN. Would it help?

Mr. MCEWEN. Yes.

Dr. CURRAN. I think it would be of marginal use nationally. It might be of some use locally. More important would be to have standardized reporting of information from a variety of different health care settings and special surveys.

Mr. MCEWEN. You used a euphemism. Very quickly, if I may, about 1990, the fifth largest—

Dr. CURRAN. That's 1986.

Mr. MCEWEN. Okay, 1986. You didn't say "killer." You said cause of death—

Dr. CURRAN. A measure of premature mortality is years of life lost before the age of 65.

Mr. MCEWEN. And you said it would be the fifth largest—

Dr. CURRAN. In men.

Mr. MCEWEN. You used that explanation.

Dr. CURRAN. One measure of premature mortality is to factor in the age at death.

Mr. MCEWEN. Give it to me one more time.

Dr. CURRAN Years of premature mortality, and years of potential life lost.

Mr. MCEWEN. Thank you.

I appreciate it, Mr. Chairman.

Dr. CURRAN. You'll be misquoted when you use it. I have been.

Dr. ROWLAND of Georgia. It's not an easy quote to understand, is it, Mr. McEwen?

Thank you, Mr. McEwen.

Mr. Kanjorski?

Mr. KANJORSKI. Yes, Doctor. How did you arrive at your opinion that there are 1.5 million infected individuals out there?

Dr. CURRAN. We did it in a number of ways. And again it is not just my opinion that the figure is 1.5 million. The 1 million to 1.5 million was a consensus estimate of some 50 public health scientists and 35 outside scientists who gathered at Coolfont to make the projection and to come up with a plan for prevention and control of AIDS.

We took several things into account: what is known about the size of the high risk groups in the United States; what is known about the number of people infected in the high-risk groups; what is known about the numbers of cases of AIDS reported and underreported, and what is known about the outcomes in those people. It

is inconsistent to say that if you believe reporting is anywhere near complete, that there would be 5 million people infected; that 10 percent per year get AIDS. That would mean that there would be 50,000 cases this year; and that isn't the case. And so you have to factor in all of the different things at once and recognize the distribution of infection. And there's simply no information that would suggest that one in ten American men between 20 and 50 are infected. It's just simply too high a figure from our military screening data, from other data.

Now, let's look at the surveys that are done. If you take the military recruit data—the age-adjusted, race-adjusted, sex-adjusted data from military recruits—and you average that out for the entire American population, you would end up with 260,000 Americans infected. If you took American Red Cross data from first-time blood donors, you would have an estimate of 100,000 Americans infected.

We know that the 260,000 has got to be a dead-level baseline. You can't have anything lower than that because most homosexual men and intravenous drug abusers don't apply to the military. So you know that 260,000 is the bottom level.

I think 1.5 million is the best estimate. I think we need much better estimates. More importantly, each district needs better estimates.

Mr. KANJORSKI. How would you get those estimates if you don't have testing and you don't have reporting?

Dr. CURRAN. Well, we are conducting and proposing a large series of surveys, including a national survey. The national survey could come up with an estimate of the likelihood of the people participating in the survey becoming infected, such as a household survey. In addition, it's important to recognize the value of testing selected subpopulations. One particular study sticks in my mind. That is a study done in Brooklyn in which voluntary testing was done. Two-thirds of the pregnant women participated, and it was found that 2.5 percent of pregnant women in a Brooklyn hospital were infected with the AIDS virus. Almost none of them knew it. Almost none of them thought themselves at risk. And that tells you something about reproductive age women in Brooklyn. That's important.

Mr. KANJORSKI. The other question is, as some of the gentlemen on the other side have asked, do you have opinions as to what we should do about those people that are most likely to be infected by an infected person that doesn't have the full disease of AIDS but has the virus? For instance, do you have opinions as to whether or not the spouse of someone discovered to have AIDS virus should be informed?

Dr. CURRAN. Absolutely.

Mr. KANJORSKI. Do you know whether in fact in the military services, someone who is determined to have the AIDS virus—their spouse is notified?

Dr. CURRAN. I can't speak for the Department of Defense, but I believe that they counsel spouses of active duty personnel.

Mr. KANJORSKI. You believe they do?

Dr. CURRAN. Military recruits are civilians. That's the difference.

Mr. KANJORSKI. Would you be surprised if, in fact, the regulations forbid them to notify the spouse of an infected military person?

Dr. CURRAN. There are a lot of barriers, including concerns about confidentiality, in the prevention and control of AIDS. This is a very difficult situation. But I don't know if I'd be surprised. I'm not surprised at very many things.

Mr. KANJORSKI. Okay. But you do feel a certainty—it's your opinion, as a medical expert—that the information should be passed on as far as those people that are most likely to be subject to infection themselves from a live carrier of the virus?

Dr. CURRAN. My opinion and the CDC recommendations are that sexual partners of infected persons should be counseled about their risk, and that they should be offered testing as well.

Mr. KANJORSKI. Do we require that notification in other diseases in this country, such as tuberculosis or syphilis?

Dr. CURRAN. Contact tracing is done very sparingly for communicable diseases. Usually it is done for diseases for which there is therapy available. It is done on a portion of syphilis cases and a portion of gonorrhea cases due to resistant organisms. If resources were available, probably more of the treatable infections would be traced.

In some circumstances I believe that Government resources and private resources could be used for contact tracing, but I don't think there should be any ambiguity about the recommendation of informing, counseling, and offering testing to spouses or anybody else who may have been sexually exposed or exposed through blood transfusion, or anything else, to HIV.

Mr. KANJORSKI. Okay. If I may just extend one point, Mr. Chairman.

In case we do get a breakthrough in either a vaccine or some curative measure, how would you notify the 90 percent of the people in the country that aren't aware of the fact that they have it?

Dr. CURRAN. If there were some magic bullet, if the virus could be treated with a non-toxic drug, we wouldn't have a problem. We'd all just get out of the way because people would beat down the doors to get tested and treated.

We're not talking about a magic bullet. We're talking so far about one toxic drug that costs $10,000 a year, that wipes out your bone marrow in some cases, and it that approved for treating asymptomatic people.

Mr. KANJORSKI. Would we be capable of—

Dr. CURRAN. If there were a magic bullet?

Mr. KANJORSKI. Yes.

Dr. CURRAN. Tomorrow, everybody would get treated. It would be like the polio vaccine.

Mr. KANJORSKI. So these people that aren't being tested now, it's because they really have no reason to know? Because if they do know, there's nothing they can do about it anyway?

Dr. CURRAN. There are two reasons people aren't tested. Many people may not have any idea they should be. Some people are concerned about the results and what will happen to them. There are waiting lines at virtually every public testing and counseling center in the country. Forty percent of cases of AIDS, and probably

HIV infections, are in black and Hispanic minorities, many of whom receive their health care from the public sector.

There are a lot of reasons that testing and counseling aren't more adequate, and our budget plans would extend greatly the resources available for counseling and testing. That needs to be done. But there are people right now who want to get counseled and tested who aren't being counseled and tested. We want to end those waiting lines, and also end the waiting lines for drug treatment.

Mr. KANJORSKI. Thank you.

Thank you, Mr. Chairman.

Dr. ROWLAND of Georgia. Thank you, Mr. Kanjorski.

Mr. Burton?

Mr. BURTON. You know, you lead us, Dr. Curran, to believe that it's the poor, the impoverished, the drug users and the homosexuals that are the only ones really at risk. But in Africa they have done some studies, and they have found that in the more affluent areas they have higher incidence of the AIDS virus. Although it may be the current situation in the United States that the actual, full-blown AIDS cases have been limited to the people in the high risk groups that you allude to, isn't it the fact of the matter that it could get into the general population at a relatively rapid rate? And in Africa, 50 percent of those who have the AIDS virus are in the heterosexual community.

Dr. CURRAN. I think you make a very good point that was made during the previous panel; anyone can become infected with the AIDS virus.

Mr. BURTON. That's the point I want to make.

You didn't mention AIDS-related complex. Now, I have been led to believe by some scientists that ten times as many people have AIDS-related complex and are dying from it as have full-blown AIDS. Is that a fact?

Dr. CURRAN. No, that's absolutely not true. There are several long studies of people with associated conditions, or AIDS-related conditions. Usually these conditions precede the serious AIDS—

Mr. BURTON. Dementia?

Dr. CURRAN. Dementia is now included in AIDS, and the "wasting syndrome," which is the other major thing, is included in AIDS.

A lot of people have generalized lymphadenopathy, and that is a much larger number of people who require medical care, but—

Mr. BURTON. What percentage would you add onto AIDS for AIDS-related complex?

Dr. CURRAN. I would say it is at least another 200,000 to 300,000, perhaps as many as half a million people who have signs or symptoms related to their AIDS virus infection, most of whom are treated as outpatients or don't even seek medical care.

Mr. BURTON. Well, if it's 200,000 to 300,000, that's almost 10 times—you have, what, 39,000 now or 38,000?

Dr. CURRAN. The question I was responding to was related to dying from AIDS. By the time people die, they have AIDS.

Mr. BURTON. I see. But they have manifestation of some—

Dr. CURRAN. Absolutely. This is not an asymptomatic infection.

Mr. BURTON. Okay.

In Africa—you know, you were talking about the pregnant women who have the AIDS virus, and you were talking about the low percentage; what was it, 1 percent? In Africa, 70 percent in one hospital of the women who are pregnant have the AIDS virus, which leads people to believe that it's very deeply involved in the heterosexual community, and I think that needs to be pointed out to the people of this country so that they can change their sexual attitudes instead of talking only about the high risk groups.

Are you familiar with Dr. Redfield?

Dr. CURRAN. I know him well.

Mr. BURTON. Dr. Redfield, you know, has come out forthrightly for routine testing. Are you aware of that? He's for routine testing of everybody when they come in for regular health checkups and that sort of thing. Are you familiar with that? Why is it that CDC doesn't agree with that?

Dr. CURRAN. CDC has recommended routine counseling and testing.

Mr. BURTON. For everybody in the country when they come in for regular health checkups?

Dr. CURRAN. We've recommended it. Part of the problem is getting from where we are to where we want to be. Where we are is that we don't have counseling and testing routinely available in those areas where the infection is common.

Mr. BURTON. Do you think the United States should mobilize against this disease like it would for a military conflict and have routine testing on a regular basis for everybody going in for health care?

Dr. CURRAN. I think this should be viewed much more as a medical problem. I would like to see a mobilization of the medical and health care community to deal with a lot of these issues that we're talking about.

Mr. BURTON. Then you are for routine testing?

Dr. CURRAN. Particularly in high prevalence areas.

Mr. BURTON. Particularly in high prevalence areas, but not for the general population.

Dr. CURRAN. And in health care settings.

I consider all of the people who are affected also a part of the general population.

Mr. BURTON. So you are for routine testing?

Dr. CURRAN. Yes, I said I was.

Mr. BURTON. Okay

You said 1.5 million. There was a doctor, a scientist from England who came over and did extensive testing in December of 1984, and he estimated that we had 2.5 million people infected with the AIDS virus. You said 1.5 million over a year ago at CDC. Over a year ago, you said there were 1.5 million. Now you're saying we have 1.5 million. Hasn't there been any increase in the last year?

Dr. CURRAN. At Coolfont, in April of 1986, we said between 1 million and 1.5 million, and we also said that insufficient information was available to say for certain. What I said was that my best estimate now was that the upper range was where we are currently, and that more studies need to be done.

Mr. BURTON. Well, many doctors feel—many scientists feel we have 4 million to 5 million, and you heard that in previous testimo-

ny. But you said something earlier about how we need to start planning for health care facilities in the United States if we're going to deal with the health care problems that are going to evolve out of the epidemic, which is already upon us.

We have 1.3 million hospital beds in the United States, as I understand it, right now. Many people feel we have 4 million people infected, and we're getting as many as 10,000 new infections a day. A Howard University study found that approximately 50 percent of the prostitutes in this town have the AIDS virus, and it's estimated that probably 50 percent of the homosexual community does as well, so it's spreading at a rapid rate.

How are you going to determine how many hospital beds we're going to need in 1995 and the year 2000 and beyond unless we get into the routine or mandatory testing on a regular basis very rapidly?

Dr. CURRAN. Those are two questions. One is how planning should be done. I think one of the most difficult things to do in AIDS is to plan for the long run. We are often overcome with the daily issues. And that's one of the things that I dislike most about dealing with the problem.

I think we need to have long-range planning, and I'm happy to say that I think the Health Resources and Services Administration (HRSA) and the Health Care Financing Administration (HCFA) are involved in that. That's something that needs to be done at a municipal level as well, because almost all of the cases are in cities.

The second question is, will mandatory or routine counseling and testing obviate the necessity for that planning or for those beds? And that, I think, is an important question that also needs to be answered. There needs to be much more counseling and testing.

Mr. BURTON. I have one more question, Mr. Chairman. I know my time has expired.

I talked to some people at a medical conference not long ago about the AIDS virus, and I said, "Could it be communicated through casual contact or flying insect vectors or other areas of transmission, other modes of transmission?" And the doctors—one was a previous Under Secretary of HHS—said, no, it can't be communicated through deep kissing or through blood being splattered upon you. And I said, "Well, 230 million AIDS viruses will fit on a period at the end of a sentence. Couldn't that penetrate the skin?" He said no. Three weeks later, on national television, it was reported that three health care workers were splattered with blood and got the AIDS virus.

Now, I wish you would just talk about casual communication of the disease for just a moment. The AIDS virus will live on a dry surface at room temperature for about 7 to 10 days, and maybe up to 2 to 3 weeks on a moist surface, according to most scientists.

So would you respond to this question? Number one, how can it be communicated casually, if at all? And number two, I talked to Dr. Mark Whiteside with the Center for Tropical Diseases in Miami, Florida—and I see you nodding, thinking, oh, my gosh, here we go again—but Dr. Mark Whiteside and Dr. Carolyn McLeod with the Center for Tropical Diseases are absolutely convinced that mosquitoes are a mode of transmission in Belle Glade, Florida, Little Haiti, and throughout Florida in general. And they think

that we ought to be investigating that possibility and dealing with it if that is the case. So would you respond to that?

Dr. CURRAN. I'd love to respond to the Whiteside/McLeod points. This is an example of cases in which people's convictions can yield to science. I'm pleased to tell you that we, along with western Palm Beach County authorities, have conducted a massive survey of the Belle Glade community, in which 5 percent of the people living in Belle Glade were tested for the AIDS virus in a random household survey. And it was found that 4.5 percent of the minority adults were infected with the AIDS virus, and that the infection rates were quite high in the reproductive age categories. Not a single person under age 14, nor a single person over age 60, in the several hundred who were tested, was infected with the AIDS virus.

In addition, we conducted studies of antibodies to other viruses that are transmitted by insects and found that the infection rates for those viruses were no higher in people with the AIDS virus than others, suggesting that there was no risk factor for mosquito-borne virus transmission.

If there were mosquitoes in Belle Glade carrying this virus and biting people, they were neglecting to bite kids and the elderly. They were only biting sexually active-age people.

[Laughter.]

Dr. CURRAN. I think the important point here is that the message from Belle Glade is 4.5 percent of the minority adults are infected with the AIDS virus. What are we doing about it? Are we just going to say, "Well, thank God, it's not mosquitoes; let's forget that and go elsewhere?" The point is that we have to go down there and prevent and control the disease. Sutton's Law, you know. The bank robber Willie Sutton was asked, "Why do you rob banks?" "That's where they keep the money", he said. Let's go where the money is.

Now, 99 percent of the transmission of this virus is due to sexual transmission, IV drug abuse, and perinatal transmission. Let's get to work and prevent that transmission. We can't do that if we have to deal with these kinds of concerns that have no scientific basis. If they have a scientific basis, we have to answer the questions.

Health care workers are at some risk. They need to take precautions. The disease is not spread by casual contact, but health workers do need to be careful; you're right.

Dr. ROWLAND of Georgia. Thank you, Mr. Burton.

Mr. BURTON. What about the follow-up on the casual contact? Did you have any more comment on that?

Dr. CURRAN. There's no evidence that AIDS is transmitted through casual social contact—kisses on the cheek from a son to his mother, eating in a cafeteria, riding in the subway with people. There have been, among the millions and millions of health care worker contacts, a small number of cases where blood has been splashed on the skin of a health care worker who is providing care for an AIDS patient or who is otherwise exposed to AIDS blood. I don't consider that to be casual contact. It's very disturbing. It's very important that health care workers have precautions and take precautions, and it's important that they continue the battle.

In terms of "deep kissing", we have strongly recommended from the very beginning that because of the theoretical risk that open-

mouth, "french kissing", "deep kissing", whatever you want to call it, be avoided by people infected with the virus because it might transmit the virus.

M . BURTON. Thank you.

Dr. ROWLAND of Georgia. Thank you, Mr. Burton.

Mr. Harris?

Mr. HARRIS. Thank you, Mr. Chairman.

Dr. Curran, I just want to tell you how much I appreciate your straightforward and frank testimony, because I feel that as we continue to debate the civil rights aspects of this disease, the numbers continue to increase. Hopefully we're going to reach a point where this is considered, and should be considered, a public health issue. I don't think anyone wants to trample on the civil rights of a particular group of people, but the people that don't have this disease have rights, too, and I think we need to be concerned about them. And I'm especially glad to see that you are recommending that hospitals should be encouraged to conduct testing. As a doctor—well, I'm not a doctor; let me retract that; Dr. Rowland is a doctor—but I read in the paper the other day where a doctor in Maryland had refused to perform heart surgery on people with AIDS. As I understand it, it's not uncommon during the course of surgery for a surgeon to get a nick or two due to the sharp instruments he's handling and so forth.

So we have got to do a better job of not only educating the general public—because people are frightened; there's no question about it, they are frightened—and to do what we can, until we can get a cure for the disease, to help prevent its spread.

I know I speak for all the members here in thanking you for your testimony, and I certainly offer any help and support that I can to help you with the problem because, as I said—I talked with a doctor the other day from California; and the statistics that you had, of course, of the doubling every 11 months, if that continues on, it could become something that could very easily wipe out our civilization.

So I think at some point we leave worrying about the civil rights aspect of it to get to the public health aspects of doing what we can to protect confidentiality of the person, but also doing what we can to help get this matter under control. I know that's not much of a question; it's a statement, but it's something that I feel very strongly about and I just want to compliment you for your efforts, and offer my support.

Thank you, Mr. Chairman.

Dr. ROWLAND of Georgia. We have a vote right now. I think we will recess at this point, go over and vote, and come right back.

Mr. MCEWEN. Before we go I just have one quick question. Thank you, Mr. Chairman.

Dr. Curran, I want to make sure I have this straight, and I don't want your words to get back to Atlanta before you do, necessarily.

But your recommendation, as the Director of the AIDS Program for the Centers for Disease Control, is that we should have routine testing in order to be able to track the spread of this disease?

Dr. CURRAN. The CDC has recommended to the Department routine voluntary counseling and testing in many, many health care settings, and—

Mr. McEwen. Do you mean counseling/testing, or counseling and testing?

Dr. Curran. Counseling and testing.

Mr. McEwen. Thank you, Mr. Chairman.

Dr. Rowland of Georgia. We will come back in about 10 to 15 minutes because there are some very important questions that we want to follow up on, reporting and possible under-reporting.

Dr. Curran. Good.

[Recess.]

Dr. Rowland of Georgia. Dr. Curran, I want to talk some more about reporting. We have already talked about some of the flaws in reporting; there may be others, and that the incidents of AIDS cases are unreported.

Dr. Gronvall spoke of three phases in his presentation that nations go through in coping with the AIDS problem. You said you had read his statement and those from someone else—I think the World Health Organization. The phase of minimization and reluctant acknowledgement and constructive engagement. I am almost at the point of thinking that we are somewhere between minimization and reluctant acknowledgement at this time. There are others who would say that we are in constructive engagement; I really don't think we're that far along. And the reason you've already alluded to is that the seriousness of the problem may not be public in general, and maybe not even by the medical profession. I'm not sure. But I do know in my State, from information I've received, that there was one hospital that had 40 AIDS cases and had reported none of them. I don't know why that was, unless they thought that it wasn't serious enough or the information was being suppressed for some reason.

Do you think there is a possibility, a likelihood, that there is under-reporting based on the fact that it's not considered that serious in some areas now, or reluctance to report because of concern that the institution may be recognized as one that has a significant number of AIDS patients, and that might be a stigma? Or do you think there might be suppression at any area of reporting?

Dr. Curran. We, as well, are very concerned about under-reporting and I would agree with you about the tendency for some to deny the problem, which is part of the minimization process.

Our best information on the adequacy of reporting comes from validation studies in New York City, Miami, San Francisco, and Los Angeles, where we looked at pathology records and death certificates and compared them to AIDS records in those health departments. And there is a variation among States and cities in the adequacy of reporting. The largest cities that have the most cases, like New York City and San Francisco, had very good reporting, about 90 percent reported. Now, that was in 1986. As cases become more and more frequent, and particularly as health departments start doing a lot of the other things which we want them to do—more counseling and testing, more prevalence studies—there will be more strains on the reporting system.

I think there are some health departments in some cities where there is less reporting, and it's a continuing concern. I'm very concerned about it as well. I think nationally it's been pretty good so

far, and we need to keep attention on it, but we also need to move into other areas.

Dr. ROWLAND of Georgia. Do you think the MMWR has been and is an accurate reflection of the number of AIDS cases that we have, as you know it?

Dr. CURRAN. We believe that the weekly report we put out is a good report of cases diagnosed. We know it's a good report of cases diagnosed and reported to State health departments, because they all report to us. And we believe there are about 20 to 25 percent additional cases that have been diagnosed that will be reported. For example, a person goes to the hospital with AIDS this week and gets a diagnosis this week; but there is a time lag before this is reported to the city, the State, and the Federal Government. So that means we think there are another 7,000 or 8,000 cases out there now that have already been diagnosed that will be reported over the next ye- to CDC.

From our 1986 survey, we think that there is about a 10 percent under-diagnosis in addition to that and a 10 percent under-ascertainment in those four cities; that is, people who die of AIDS and their doctors don't even know it. And there's no way to capture those numbers except through special studies.

Dr. ROWLAND of Georgia. Aside from the lag period—you said 25 percent. Is that cumulative, 25 percent more than—

Dr. CURRAN. It's cumulative, yes. Again, it's about 7,000 to 8,000 now.

Dr. ROWLAND of Georgia. As I understand it there are some 36,000 AIDS cases that have been—you're saying that there's maybe 25 percent more than that?

Dr. CURRAN. Yes, 7,000 or 8,000 more that have already been diagnosed that will be reported.

Dr. ROWLAND of Georgia. That have not been reported at this point?

Dr. CURRAN. Not yet. They haven't been. For example, maybe they're in the hospital now.

Dr. ROWLAND of Georgia. You don't have any reason to suspect that there may have been any suppression of any information about reporting on any level?

Dr. CURRAN. I am certain that with other diseases that carry the stigma of AIDS, people will have physicians who will keep it secret until the very last minute. I'm certain that that happens. I think it's remarkable, how good reporting has been for AIDS. That's in part because personal identifiers don't go to the Federal Government. I'm certain that if we required names at the Federal level, the reporting would be not nearly as good. But identifiers aren't important for us; their importance is at the State and local level.

I believe reporting is still quite good but not perfect, and we need to keep attention on it.

Dr. ROWLAND of Georgia. You say that you think that AIDS disease surveillance and control is a State responsibility rather than a Federal responsibility.

Dr. CURRAN. Both.

Dr. ROWLAND of Georgia. Both State and Federal.

Do you have any idea on how we may improve on the system of reporting that we now have in place?

Dr CURRAN. We are trying to simplify reporting. During the past 2 years, we have come up with a standardized, computerized system, with software that can be used so that States can enter data. We receive computer reports of cases from a given State or city, for example, on a weekly basis, so it's easier to make sure of its accuracy. It's easier for States to analyze their own data.

Dr. ROWLAND of Georgia. Where would that be located? Would every local authority have that?

Dr. CURRAN. State health departments often decentralize some of the information when they have a large number of large cities in their State. The State of California has reporting at Sacramento, San Diego, Los Angeles and San Francisco. I believe a State like Georgia probably does not have more than two or three reporting centers to the State Capital.

Dr. ROWLAND of Georgia. Would the CDC ever have any reason to change a..y of the data that came in from the States, for example, in reporting into the MMWR?

Dr. CURRAN. We do cross-check cases. We report cases by State of residence. So for example, if I'm diagnosed with a disease while I am here in the District of Columbia and I live in the State of Georgia, I might be reported to the CDC by a hospital in the District of Columbia. Under some circumstances, we may count that case, but if I were listed on the form as being from the State of Georgia, I would be a Georgia case. So there is some minor modification of cases reported. And the States want that; they want to know how many residents of their State, but there is some modification after the data comes to CDC.

We provide routine printouts and feedbacks to the States of this audit system. We don't change things for reasons other than boring ones, like that.

Dr. ROWLAND of Georgia. CDC would never make any changes in the numbers for, for example, reasons of causing a panic or something of that nature?

Dr. CURRAN. To cause one or avoid one?

Dr. ROWLAND of Georgia. Avoid one.

Dr. CURRAN. No. I've been accused by an equal number of people of causing panic and preventing panic, and I'm guilty of both, I guess.

Dr. ROWLAND of Georgia. It's hard to know what to do sometimes, isn't it?

Dr. CURRAN. Even if you tell the truth, or what you think is the truth.

Dr. ROWLAND of Georgia. We're going to get to you in a minute, Mr. Levitt. You're not going to be left out of this.

Mr. Burton?

Mr. BURTON. In the 14th Century, as you know, the bubonic plague, which was a bacteria, as I understand it—

Dr. ROWLAND of Georgia. That was the 15th century, Mr. Burton.

Mr. BURTON. The 15th century?

Dr. ROWLAND of Georgia. Yes.

Mr. BURTON. Well, I think it was the 14th and 15th centuries, but we'll check our history books.

Dr. CURRAN. You guys are both older than I am.

[Laughter.]

Mr. BURTON. Now, wait a minute.

Regardless of whether it was the 14th or 15th century, it started out as the bubonic plague, but the disease mutated and it became a pneumonic plague; it started being spread through coughing, spitting, and it wiped out a large percentage of Europe. Some say half, some say two-thirds.

What is the chance of the—and I know there's a mutation process that takes place with the AIDS virus within a carrier, as I understand it—what is the chance that this might be conveyed to other people in a similar fashion down the road? Is that a possibility?

Dr. CURRAN. Well, the best models of mutations for an organism like the AIDS virus come from the knowledge we have of animal retroviruses and animal lentiviruses. There has been extensive genetic variation in AIDS viruses. There is one AIDS virus that we've isolated from some serum we had at CDC from an African outbreak of hemmorhagic fever in 1976. The AIDS virus in 1976 is very similar to AIDS viruses we've isolated from the same country in 1986, and there is no more difference between the viruses from 1976 and 1986 and other ones from 1986. There is an enormous difference genetically among the different AIDS viruses. That's important from the point of view, particularly, of dealing with issues like vaccines, where it may suggest that the immune response, if we could find a good one, would be inadequate to deal with the virus. It may have some implications regarding therapy, but there's not yet any evidence that there's a difference with regard to transmissibility, either in terms of modes of transmission or, particularly infectiousness.

My own guess is that it's unlikely that there is going to be a major change in modes of transmission—

Mr. BURTON. But we really don't know yet.

Dr. CURRAN. Well, the reason I say that is that the virus is present, and has been present for a fairly long period of time, in Africa, and it's being studied now in dozens and dozens of countries, and we don't see different patterns among those countries suggesting that there's a difference.

Mr. BURTON. The AIDS virus is a retrovirus?

Dr. CURRAN. That's right.

Mr. BURTON. Is the equinevirus for horses—is that a retrovirus?

Dr. CURRAN. It's a retrovirus. It—

Mr. BURTON. Let me follow up on that. You know how that's communicated, don't you?

Dr. CURRAN. By close contact between horses.

Mr. BURTON. And flying insect vectors, isn't it?

Dr. CURRAN. For that virus.

Mr. BURTON. But it is transmitted from horse to horse by insects?

Dr. CURRAN. It can be.

Mr. BURTON. Now, why—explain to me—I just don't understand, why is it that the AIDS virus can't be communicated in a similar fashion?

Dr. CURRAN. There are two things that are different, I guess. We have to rely upon our empirical observations, and also the inability to infect various insect cell lines at CDC with the AIDS virus. We were unable to demonstrate any replication or dividing of the virus

in a mosquito, so that means that what has to happen is you have to have a sort of physical transmission of the virus from one insect, from one animal to another.

The reason it probably doesn't occur is related to the size of the inoculant. Dr. Cohn was quoting a CDC study of 1,000 health care workers who have received needle sticks. We know that no more than 1 percent of them have become infected, even after getting, say, a 22 gauge or 21 gauge needle with blood in it stuck in their blood. A mosquito carries a small fraction of that, and that makes the biologic plausibility lower.

Mr. BURTON. But the fact of the matter is that a retrovirus, equine—I don't know the exact title of the virus—is communicated from horse to horse by mosquitoes, and it's a retrovirus, and mosquitoes communicate that disease. But you say that the AIDS virus, which is also a retrovirus, can't communicate it? But 230 million AIDS viruses will fit on a period at the end of a sentence, and a mosquito that bites an AIDS patient then turns around and sticks its talon into a person who is not infected would not communicate the disease?

Dr. CURRAN. I don't think a mosquito could pick up a period at the end of a sentence. It's too heavy.

Mr. BURTON. All right. All right.

That's another reason we need to study. I think that they really don't know. But let me ask a couple more questions here, if the chairman will indulge me.

Dr. ROWLAND of Georgia. Make them short Mr. Burton, if you will.

Mr. BURTON. Well, I won't take any more time than the chairman did.

Dr. ROWLAND of Georgia. You go right ahead.

Mr. BURTON. Thank you.

Regarding the casual transmission of the virus—well, let me get into another area. I think this is very important.

When I was talking to you privately after the last session, you indicated that one of the reasons why routine testing isn't done and reported is because there's a fear among hospitals and doctors of legal suits being filed against them which could destroy the institution. Could you elaborate a little bit on that? Because if that is a problem, I think the Congress is the place to help solve that because we have a real public health hazard here, and if we can be of assistance to you and other doctors and scientists around this country in dealing with the epidemic by putting up some shield, as long as you take proper precautions, we ought to do that.

Dr. CURRAN. I think that, in readying the veterans' hospital clinics and in-patient systems for more routine testing by getting health care providers to recommend it on a routine basis, there are a lot of issues that have to be dealt with up front. One of those is the legal concerns that the physicians or the hospitals might have. Another is the confidentiality concerns that hospitals and doctors and patients might have. Another is the concerns about isolation and other things. A lot of policies have to be worked out and anticipated ahead of time.

I think we're moving—you can see from the lines at the voluntary testing sites—to people wanting to get tested, and more physi-

cians wanting to do it. We've got to move the entire medical care system to be part of the process.

I believe that physicians will help us if we make this a routine standard of practice in protecting the confidentiality of their own patients, but you just can't wait until the first problem occurs You have to deal with it at the beginning.

Mr. BURTON. Do you think the Congress ought to look at legislation which would—if a doctor or if a health care facility provided reasonable confidentiality to protect people from being exposed as AIDS patients, that the doctor or hospital should be protected from liability exposure? Would that help with the reporting process?

Dr. CURRAN. I think the confidentiality concerns of patients and doctors and the liability concerns of doctors have to be dealt with. I don't know.

Mr. BURTON. Well, we'll look into that and see if that can be helpful.

One last question and then I'll give up the floor, and that is that the question of condoms has come up time and again. And as head of research at CDC, I'd like to get you on record on this.

Condoms do reduce the risk but they don't eliminate the risk. If a person has the AIDS virus, the best protection is to abstain from sexual contact with another person; is that correct?

Dr. CURRAN. The first recommendation is to avoid sexual contact with an infected person, and for infected people to avoid sexual contact with others. One of the major problems with condoms in preventing other sexually transmitted diseases or with preventing pregnancy is with their inconsistent or improper usage, but breakage is also a problem. I think our recommendations have to be clear on what is definitely effective and what will help, but we have to also recognize that we're moving a spectrum of behavior. I would like to see more condom usage among one people who are going to do it anyway. It's difficult for a physician, in counseling a married couple, for example, to say don't have sexual contact. Sometimes it's easier for us to think of it another way, but our job as physicians is to tell them the truth, and the truth is that if you want to avoid infection, don't have sexual contact. That's the first truth. And they say, Doctor, it's none of your business; my wife and I are going to do it anyway. How can we prevent transmission? Then we say, well, you've heard my first line of advice; my second line of advice is, this is a condom. It doesn't always work. This is how you use it. Most people like you don't always use it right. Do it. It may not work. It's just like advising people on how to avoid pregnancy.

Mr. BURTON. Thank you.

Thank you. Mr. Chairman.

Dr. ROWLAND of Georgia. Thank you, Mr. Burton.

Mr. Levitt, I didn't want you to think that we were ignoring you.

I know that the FDA must find itself in a difficult position in trying to make a determination about when drugs should be used. You maybe find yourself in a situation of being between the medical people and the patient who is going to receive the medication. Would you give us an idea briefly about the process that the FDA goes through in approving a drug for use? There is only one—and

possibly two—at this time, I understand; AZT, and there may be a polypeptide that is more recently being looked at.

What is the process that you go through and the decisions that are made based on that process?

Mr. LEVITT. Let me try and summarize that for you briefly.

FDA works in conjunction with researchers and with drug manufacturing companies to try and facilitate the expeditious development of safe and effective drugs of all kinds. We have placed all drugs that are intended to treat or cure AIDS and AIDS-related diseases at the very top of our priority list so that they get looked at first. In this regard, we have assigned what we call a "1AA" designation to all AIDS drugs. That comes from a pre-existing classification system where drugs listed as number 1 are new molecules, or new chemical entities, as we call them, and class A drugs are drugs with significant therapeutic advances. Drugs that are classified as B drugs have modest but some important therapeutic advance, and C drugs are drugs without a clear advance over existing drugs, although they still may be more useful in some patients.

Historically, the 1A drugs have received FDA's highest priority. Within the last year, we have said that even within the 1A drugs, AIDS drugs get even higher priority than that, so we have moved them right to the front of the line.

There are basically about a half a dozen steps to go through in drug development. First, before FDA even gets involved, a drug is screened in laboratories, and looked at during short-term animal testing, to see if the drug is reasonably safe for testing on humans and has some effectiveness potential. When that drug has reached that stage, the company or the research institution comes to FDA and asks for what we call an "IND," or an Investigational New Drug Application. FDA, under the regulations, has 30 days to review the IND, following which time testing can begin.

One thing that we are doing for AIDS-related drugs, which is unusual, because it takes a lot of time and effort, but we think it's worth it here, is to have special pre-IND conferences with the drug sponsors, the person or organization submitting the application, whether that be the National Institutes of Health (NIH), the drug company, an academic research institution, or whomever, to explain exactly what kind of testing is necessary and how to put the data together. And we have been successful, for example, with AZT in getting the IND approved only 5 days after it was submitted.

Drugs then normally go through three stages of clinical testing, which we generally refer to as phase I, phase II, and phase III. Phase I is the first and shortest phase. It is usually conducted on a small number of people. The purpose is to examine the pharmacologic effect of the drug and to look at basic safety questions. You usually have small numbers of patients involved, often healthy volunteers, somewhere in the category of maybe 20 to 80 patients. As I go through, I'll give a continuing example of where azidothymidine (AZT) (brown commercially as retrovir) fits into this process to give you a clearer idea of how it works.

In February 1985, there were studies at the National Cancer Institute (NCI) that showed there might be some *in vitro* utility to AZT, and an IND was approved in June 1985. So that's when phase I testing began, in June of 1985.

By February of 1986, the phase I testing had shown great promise and they began phase II testing, which is usually controlled clinical trial(s) to examine effectiveness of the drug and to look at safety in more detail. The Phase II study on AZT was conducted and actually halted partway through, in September of 1986, because the study results were so dramatic. Basically, the patients that were being given the drug were clearly living longer than those who were not getting the drug, and it was deemed unethical to continue giving some patients a placebo. So the study was stopped.

At that point, the company (in this case, Burroughs-Wellcome Co.) approached FDA, and we approved what is called a "treatment IND," or a treatment protocol so that patients, even before the drug was approved for marketing, could get access to the drug under the criteria that had been outlined and justified in the study. And again, that treatment IND was approved within a week of when it first came to FDA, in the first week of October 1986.

Now, normally, after phase II, you would go through phase III clinical testing, which is the larger controlled and uncontrolled studies designed to verify the effectiveness of the drug, and to clarify the adverse effects and clear conditions for use in clinical practice. With AZT, that was deemed not to be necessary, because the results from the Phase II trial were so dramatic. So we, in essence, skipped Phase III and went straight to the next stage, which is the submission of a New Drug Application, or an NDA, for marketing approval. That was submitted, I believe, sometime in December of 1986. Again, FDA worked on that very closely with the company, both before it was submitted on how to put it together so it could be analyzed quickly, and after it was submitted, whenever questions arose. We brought it to an outside advisory committee in January of 1987 and in March of this year approved the drug for marketing, 107 days after the drug was initially submitted for review under an NDA.

Now, I would contrast that 107 days, or roughly 3 months, to the average time of about 2 years that most new drugs take to go through the NDA process, and that highlights the extra attention—really enormous extra attention—that is being focused on new drug applications for AIDS diseases. We were helped enormously, of course, by the facts that the data were very clear and very well presented, and that the studies were very well conducted; basically, everything came together very well.

Following marketing approval there are often, as there are now, additional studies to look at additional uses for the drug, and there is also post-marketing surveillance conducted for adverse reactions. We have reporting regulations that govern what has to be reported, and when, to FDA.

That is the general system. I would add only one other point in conjunction with what I said. We have heard a lot today about the need for increased emphasis in coordinated programs. I think that FDA feels that we are part of an integrated program within the Public Health Service under the leadership of Dr. Windom and Dr. Koop, and in close coordination with our sister agencies, especially the CDC and the NIH.

As far as FDA's part, we have put together over the last year phase II of what we call the FDA Action Plan which lists all of our major priorities. This has just been recently released, and it lists AIDS as FDA's number one priority for everything that we do. So we are trying to devote our earnest attention to it, in coordination with everybody else. We basically see our role as the group that tries to take the fruits of research and bring them rapidly to the marketplace in such a way that we are a facilitator, not a barrier, to new product development. We also serve, of course, as a necessary screen to make sure that drugs are worked up right and that the indications are well supported, so that the patients, when they get the drug, have good reason to believe that it's going to do what it's intended to do for them with a reasonable safety profile.

Dr. ROWLAND of Georgia. It must be extremely difficult to reach a decision about what to release on the market and what not to release on the market insofar as treatment for AIDS is concerned. I suppose you really find yourself in a quandary at FDA about doing double-blind studies, and you pointed that out in that you had a double-blind study going and you had to release the group that were getting the placebo because there was such a dramatic improvement in the group that was getting the drug itself.

So do you find that being an impediment in any way to reaching approval for a drug?

Mr. LEVITT. No, I do not think so, and I think there are two reasons for that. First is that the concern that you raised is raised really not just by AIDS, but by any category of drug where death is the end point of the disease. The cardiovascular area is the area that most comes to mind where you have that instance. I think that there is general recognition within the research industry that conducting the placebo-controlled trial on AZT represented the fastest and most effective way to find out if the drug really worked, and I think there's a good feeling that that was done, as it is done in other areas where there are not effective treatments.

I think that one thing you're going to be finding now is that there is more than one way to do a controlled clinical trial. Placebo is one type of control. You also have an active control where you have a drug that is approved that you measure the test drug against, and I suspect that a number of new agents will be tested against AZT rather than against placebo to take into account that concern.

So it's an important concern in this area, but akin to similar concerns in other areas where you're testing a drug to treat a fatal disease.

Dr. ROWLAND of Georgia. Researchers now are going on—the National Institutes of Health, the National Cancer Institute—how much research is going on in the private sector in looking for a vaccine or for an antiviral agent?

Mr. LEVITT. I don't have good data on that, but I can tell you that a number of companies have been approaching us within the last 6 months or so, and that there are several vaccines under development that there are efforts to begin human testing on. We are very optimistic, but also very cautious. I am not a vaccine expert and I'm not a physician, but those with whom I talk explain they expect that there will be a substantial process to go through. FDA

has, in its vaccine program, both a review component—as we have with drugs generally—but also a substantial research component that is located right on the NIH campus, and so we have very close coordination between our vaccine experts, the NIH scientists, and the research community generally.

Dr. CURRAN. I might comment that the 1987 NIH budget is $252 million thus far. The vast majority of that goes to extramural researchers. Similarly, most of CDC's research dollars are awarded for extramural epidemiologic studies, for example.

Dr. ROWLAND of Georgia. Is that contracted?

Dr. CURRAN. It's mostly research grants, but there are also cooperative agreements. Much of the biomedical research reported at the AIDS conference, which 7,000 people attended, was NIH-supported or State-supported. Some States are putting quite a substantial amount of money as well into research.

In addition, there are private research funds. For example, the American Cancer Society, the American Foundation for AIDS Research, and the March of Dimes fund reasearch.

Dr. ROWLAND of Georgia. We talked about the VA earlier, the research that is going on here.

Dr. CURRAN. Dr. Schnazi, for example, works at the VA in Atlanta, and he has done some work on antivirals. He does that with some support from the National Institutes of Health, as well as from the VA, so that's an example of multiple funding of basic science.

Dr. ROWLAND of Georgia. Also you have to approve, in the FDA, testing for antibodies and for the virus itself before that test is put into place. And as I understand it, there is research going on now to improve the techniques for detecting antibodies. I made a statement earlier that we may never be able to identify a test where we can have the virus itself as the basis for saying a person has AIDS. Would you comment on that? I want to clear that area up in my own mind.

Mr. LEVITT. I'm not sure I'm going to be able to help you clear it up very much, not being an expert on the blood test kit issues. We approved the first test kit a couple of years ago, the so-called ELISA test, and this Spring approved a confirmatory test called the Western Blot test. There are substantial efforts underway to improve the quality of the tests and to get better kinds of tests. The exact status of that I'm not personally familiar with; if you would like, I would be happy to get that submitted for the record.

Dr. ROWLAND of Georgia. Would you do that, please?

[The information appears on p. 86.]

Mr. LEVITT. I might just add that these test kits are under our biologics provisions of the law, which is a separate category from drugs, so they are handled in different units under slightly different rules, but the same general process is followed.

Dr. ROWLAND of Georgia. Good.

Mr. Burton?

Mr. BURTON. You sounded optimistic—I think you used that word—about vaccination. Can you give us the basis for that? I'm just curious; is that just speculation on your part?

Mr. LEVITT. I try to be an optimist.

Mr. BURTON. Just being optimistic? Okay.

Dr. Koop and Dr. Curran and others have said a realistic time frame would probably be at least the year 2000 before we had a vaccination.

I'm not putting words in your mouth, am I, Dr. Curran?

Dr. CURRAN. I think many of us want to put it beyond our ability to have to testify next year.

Honestly, the reason for optimism is the incredible amount that's been learned about the virus in a short period of time in the high-powered laboratories working on it. There is not a breakthrough, and in the absence of a breakthrough it's very difficult to predict whether there will be one.

Mr. BURTON. Have there been any vaccinations for viruses of this type that you know of in history?

Dr. CURRAN. Our experience with human retroviruses only goes back to about 1978. There aren't that many known human retroviruses. In terms of animal retroviruses, vaccine development for those never had the priority that the AIDS virus has. The "gas is really turned up" on science. Feline leukemia virus has a licensed vaccine; that's a retrovirus, and the vaccine protects some cats, but that's a much different infection and disease in terms of cats' normal immune response.

Mr. BURTON. Well, we can't compare animals and humans because we couldn't compare the way it was transmitted with flying insect vectors a while ago.

Dr. CURRAN. I wouldn't compare it, only from a prognostic point of view. And I think it's not wise to guess when there will be a vaccine. The question to ask is, will there be one? And it's premature to be optimistic or pessimistic.

Mr. BURTON. The only reason I'm asking for a time frame is not to be argumentative—

Dr. CURRAN. We've got to act now. We don't want to wait.

Mr. BURTON. We have to make plans based upon what we have, and we don't have one. And Dr. Koop said he thought it would probably be the year 2000, so we could have a lot of infections before that and we need to get on with it.

Let me ask you a question about another help or aid for AIDS patients or AIDS victims. I've been receiving calls from some people about Ribavirin, and it's been tested by the FDA. Can you tell me the status on that, as one drug that they're talking about?

Mr. LEVITT. Yes. Ribavirin is a drug that has received, certainly, a lot of attention—you're not the only one who gets letters on it, you can be sure. It has been tested to treat AIDS and AIDS-related conditions. There was a study that was submitted to FDA sometime, I believe, around the first of the year, is my recollection. During the review of the study by FDA, our field audits raised substantial questions as to whether the data supported what the investigators thought that it had.

Mr. BURTON. It's being tested further right now?

Mr. LEVITT. Data from these tests are undergoing further review right now.

Mr. BURTON. So the jury is still out on that one?

Mr. LEVITT. The jury is still out on the drug; except, as I said, the first study on which there was some speculation that it would prove to be a breakthrough did not hold up under scrutiny.

Mr. BURTON. Thank you.

Thank you, Mr. Chairman.

Dr. ROWLAND of Georgia. Thank you, Mr. Burton.

We will keep the record open for 5 days for questions to be submitted.

We've only known about this virus for some 6 years now; there's a lot that we don't know about it. And, Dr. Curran, I believe you said that no one knows about the number of cases, really. There is so much uncertainty that surrounds this, and I think this hearing this morning and the discussion that took place here is an indication of the fact that there's a whole lot that we don't know about this particular virus and about this disease. Most other diseases that we deal with that are life-threatening, we've known about them for a long time, so we're really in a very unusual and difficult situation.

I've suggested that in order to get this debate and discussion into the scientific community, where it should be, and away from politics on a partisan basis and philosophical differences, that we need to have a commission appointed, and we need to have a commission with people from both sides of the aisle in the House and the Senate and from the Administration, and especially from people with scientific backgrounds and people who understand about dealing with medical problems, people that know about treating patients.

Do you have any feelings about having a commission of that type rather than having legislation enacted in a manner that may not take us toward some specific goal, but rather reacting to situations as they arise and which has us moving in various directions, not reaching a consensus?

Dr. CURRAN. I think that partnership, teamwork, long-term commitment and planning will get us to where we want to go, because we've got a lot of very tough problems to deal with. We shouldn't be debating on the periphery on issues that are not central to solving the problem. And I don't believe that there's anything inherently partisan about the issues.

On the other hand, it's a problem that many, many Americans are concerned about. They look to their individual political representatives at all levels, so it's difficult to "nonpartisanize" it. But I am not a politician. We want political support; we want all of that, but we want this to go forward together with teamwork.

Dr. ROWLAND of Georgia. Mr. Levitt, do you have any comment?

Mr. LEVITT. I would just simply echo what Dr. Curran said just now and earlier, that I think all of us are in favor of whatever approach gets us to the end that we all need to get to; working, as he said, in partnership and with teamwork and with clear sight of where we need to get to.

Dr. ROWLAND of Georgia. You're certainly not politicians, but you both gave political answers.

Mr. BURTON. If the chairman would yield real briefly, I think his suggestion is a very good one, and I would be more than happy to co-author a resolution that would set up a commission consisting of Members of both sides of the aisle and the scientific community so that we could have the kind of teamwork that Dr. Curran talked about.

Dr. ROWLAND of Georgia. Thank you, Mr. Burton.
Thank you very much, gentlemen, for being here.
Dr. CURRAN. Thank you.
[Whereupon, at 1:32 p.m., the subcommittee was adjourned.]

APPENDIX

STATEMENT OF THE HONORABLE

G. V. (SONNY) MONTGOMERY

CHAIRMAN

COMMITTEE ON VETERANS AFFAIRS

AT A HEARING ON

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

AND THE VA

JUNE 17, 1987

(61)

- 1 -

GOOD MORNING.

THE SUBCOMMITTEE WILL COME TO ORDER. WE ARE MEETING TODAY TO RECEIVE TESTIMONY ABOUT THE MOST SERIOUS HEALTH MATTER TO FACE THIS COUNTRY DURING THIS CENTURY: ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS).

AS IF THE TERRIBLE HUMAN SUFFERING OF THIS AFFLICTION WERE NOT ENOUGH, THE ENORMOUS BURDEN ON HEALTH CARE RESOURCES REMINDS US OF THE SIZE OF THE PROBLEM. FISCAL AND HUMAN RESOURCES DEVOTED TO AIDS ARE INCREASING:

TREATMENT COSTS ARE HIGH, RESEARCH COSTS ARE HIGH AND HEALTH EDUCATION COSTS ARE HIGH.

WHILE SOME LARGE GAINS IN KNOWLEDGE HAVE BEEN EXPERIENCED, THE COMMON WISDOM OF THE CAPABLE PEOPLE WHO ARE WORKING IN THE AREA IS THAT SEVERAL YEARS WILL ELAPSE BEFORE A VACCINE IS DEVELOPED AND EVEN LONGER BEFORE A CURE CAN BE EXPECTED.

IT IS CRITICAL THAT THE NATION -- AND THE VETERANS ADMINISTRATION AS A LARGE PART OF THE U.S. CAPACITY TO DELIVER HEALTH CARE -- COME TO TERMS WITH AIDS. THAT MEANS IN ALL OF ITS ASPECTS.

I AM PLEASED THAT J. ROY ROWLAND, THE ONLY PHYSICIAN IN CONGRESS AND A VALUABLE MEMBER OF OUR COMMITTEE, IS GOING TO PLAY A LARGE ROLE IN TODAY'S HEARING AND BEYOND. I MUST LEAVE SHORTLY, AND WHEN I TURN THE GAVEL OVER TO HIM, I KNOW IT WILL BE IN GOOD HANDS. LET ME SAY THAT I SHARE HIS CONCERN ABOUT THE LACK OF A NATIONAL POLICY FOR AIDS.

I WILL NOW RECOGNIZE THE RANKING MINORITY OF THE SUBCOMMITTEE, THE HONORABLE JOHN PAUL HAMMERSCHMIDT, FOR ANY REMARKS HE MAY WISH TO MAKE.

REMARKS BY

HONORABLE JOHN PAUL HAMMERSCHMIDT

AT HEARING OF THE

SUBCOMMITTEE ON HOSPITALS AND HEALTH

CARE ON VA AND FEDERAL POLICY ON AIDS

JUNE 17, 1987

10:00 ROOM 334 CANNON HOB

THANK YOU, MR. CHAIRMAN.

OUR HEARING THIS MORNING FOCUSES ON A GREAT PROBLEM OF OUR TIMES. THE DISEASE CALLED "AIDS" AFFECTS A PORTION OF THE VETERAN POPULATION AND THAT IS OUR VERY SPECIAL CONCERN. WE NEED TO EXAMINE WHAT THE VETERANS ADMINISTRATION IS DOING WITH RESPECT TO AIDS AND WHAT IT OUGHT TO BE DOING. IN THIS CONNECTION, IT IS IMPERATIVE IN MY VIEW THAT THE DISEASE BE RECOGNIZED AS A PUBLIC HEALTH EMERGENCY AND BE RECOGNIZED ALSO AS EVERYONE'S PROBLEM.

IN JUST FOUR MORE YEARS, SOME PREDICTIONS ARE THAT AIDS WILL HAVE KILLED MORE AMERICANS THAN THE VIETNAM AND KOREAN WARS COMBINED. THE CENTER FOR DISEASE CONTROL ESTIMATES THAT TWO MILLION AMERICANS MAY BE INFECTED WITH THE VIRUS, AND THAT BY 1991, THIS FIGURE MAY BE AS HIGH AS FIVE MILLION.

MR. CHAIRMAN, IN MY VIEW, THERE ARE SEVERAL THINGS THAT NEED TO BE DONE ABOUT THIS SITUATION.

--WE SHOULD EXPAND EDUCATION AND INFORMATION ACTIVITIES RELATED TO AIDS.

--WE SHOULD ACCELERATE RESEARCH TO POSSIBLY FIND BOTH A PREVENTION AND A CURE.

--WE SHOULD HAVE A CLEARER PICTURE OF HOW THE VIRUS MAY BE SPREADING THROUGHOUT THE POPULATION.

MR. CHAIRMAN, THE VETERANS ADMINISTRATION IS INTRICATELY CONCERNED WITH THE DIAGNOSIS OF AND THE TREATMENT OF AIDS. IT IS AN INVOLVED AND EXPENSIVE PROCESS FOR WHICH VA MAY NOT HAVE BEEN PROPERLY PROVIDED IN TERMS OF BUDGET. WE NEED TO ADDRESS THAT PROBLEM DURING THIS HEARING BECAUSE VA IS THE NATION'S LARGEST AND MOST COMPREHENSIVE HEALTH PROVIDER, AND IT HAS A MAJOR ROLE TO PLAY IN THIS MATTER

MR. CHAIRMAN, IN HIS SPEECH BEFORE THE AMERICAN FOUNDATION FOR AIDS RESEARCH, THE PRESIDENT INDICATED THAT IT WAS VITALLY IMPORTANT THAT AMERICA FACE SQUARELY A DISEASE THAT IS NOW NOT ONLY FATAL, BUT SPREADING. HE ALSO SAID THAT IT CALLS FOR URGENCY AND NOT PANIC, FOR COMPASSION, AND NOT BLAME, AND THAT OUR NATION SHOULD NOT REJECT THOSE WHO HAVE THE DISEASE, BUT SHOULD CARE FOR THEM WITH DIGNITY AND KINDNESS. I COULDN'T AGREE MORE

MR. CHAIRMAN, THE VA HAS HAD SOME RATHER EXTENSIVE EXPERIENCE IN THIS AREA OVER THE PAST TWO OR THREE YEARS. I AM ANXIOUS TO HEAR WHAT OUR WITNESSES HAVE TO SAY.

THANK YOU, MR. CHAIRMAN, FOR SCHEDULING THIS MOST IMPORTANT HEARING.

STATEMENT OF

JOHN A. GRONVALL, M.D.

CHIEF MEDICAL DIRECTOR

DEPARTMENT OF MEDICINE AND SURGERY

VETERANS ADMINISTRATION

BEFORE THE SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE

COMMITTEE ON VETERANS' AFFAIRS

HOUSE OF REPRESENTATIVES

JUNE 17, 1987

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to provide the Committee with an update regarding the impact of AIDS (Acquired Immune Deficiency Syndrome) on the Veterans Administration.

The Epidemic in the U.S. and VA Experience

AIDS is a devastating disease. It is but one manifestation of HIV (Human immunodeficiency virus) infection. In the United States over 36,000 cases of AIDS have been reported to the Centers for Disease Control (CDC). Over 1.5 million people in the U. S. are thought to be infected and many feel this is a conservative figure with estimates ranging as high as 4 million but no one knows for sure. HHS will conduct an epidemiological study to determine the incidence of AIDS in America. In terms of those who will go on to develop symptomatic disease, the estimates range from 25-70%. The cumulative death rate is over 55%; the case fatality rate is approximately 85% for those who have the disease for three or more years. No cures have been reported.

The VA's case load has ranged from 5.3 - 5.8% of the total number of cases reported to CDC. From September 1983 to May 1987, 2,014 cases of "full-blown" or CDC-defined AIDS have been reported to VACO. Ten (10) VAMCs have reported 1,194 of these cases or approximately 60% of the VA total. The Centers with the highest number of cases reported during this period are:

New York (Manhattan)	-	324
West Los Angeles	-	131
San Francisco	-	118
Bronx	-	118
Miami	-	102
Brooklyn	-	99
East Orange	-	95
Houston	-	75
San Juan	-	73
San Diego	-	59

One hundred eleven (111) VAMCs have reported at least one case. The impact on the VA is therefore differential in character: moderately-heavy on several of our Centers, minimal on the majority. The VA Medical Centers in New York State have treated nearly 30% of the total, those in California 21% of the total. Based on the data presented at a conference sponsored by the Department of Health and Human Services in June, 1986, in Berkeley Springs, West Virginia, the situation is predicted to worsen dramatically by the end of 1991: 270,000 total cases cumulatively with nearly 180,000 deaths, again cumulatively, since the beginning of the epidemic in 1981. These figures are now being revised upward due to a modification of case definition by CDC. The VA's cumulative caseload could equal 14,000 cases by 1991 based on these data. However, it is anticipated that the Department of Defense policy on screening all active duty personnel and recruits could modify the VA's future case load. Because the veteran population is composed of relatively few females, increasing numbers of women and children expected to be affected in the future will have less impact on the VA than society at large.

The treatment of AIDS patients is both labor-intensive and cost-intensive. A host of medical specialties and subspecialties are involved, as well as a significant number of staff members from a variety of allied health arenas, including Social Work Service, Pharmacy, Chaplaincy, etc.

Laboratory Support

Laboratory Testing for the antibody to the AIDS virus serves a variety of clinical purposes including: (1) part of the diagnostic work-up of a patient, (2) part of the "look-back" program to determine if patients transfused with blood or blood products prior to the availability of the ELISA test (3/85) are antibody positive, (3) voluntary screening of individuals or groups at high risk, (4) corroborative or confirmatory testing (the use of the Western Blot to confirm a positive ELISA), (5) "tertiary" testing - the performance of sophisticated studies to determine the status of a given patient's immune system (e.g., T4/T8 ratios).

The VA has provided guidance to its field facilities that testing for the antibody to the AIDS virus should be performed when clinically indicated, i.e., in aiding in the establishment of a diagnosis, and in collaboration with the various blood banking associations in the U.S. (project "look-back").

In response to the challenge of AIDS, the VA has expanded the Reference Center for Serology at VAMC Lexington to serve the agency as a laboratory to test for HIV antibody. This facility provides both screening and corroborative testing. Growth of this service has been exponential as AIDS cases have increased, resulting in maximum productivity by the laboratory.

The increased pressure for AIDS testing at VAMC Lexington with its rapidly mounting costs has resulted in the development of a new and innovative method for financing this program, referred to as the "charge back system." This will allow VAMC Lexington to charge other VA medical centers for AIDS testing services. The cost to the VA for screening tests is approximately $5.00 per test and the cost of the corroborative test is $17.00 per test. The cost for this testing service on a fee basis arrangement in the private sector would range from $12.00 to $30.00 and from $25.00 to $45.00 respectively for screening and corroborative procedures.

In 1985 the VA anticipated the approaching demand for tertiary testing for AIDS which requires a flow cytometer and monoclonal antibodies. To meet this need, the VAMCs in New York, Albuquerque, San Francisco, Denver and New Orleans were provided with this technical capability.

The cost to the VA to perform tertiary testing by flow cytometry will vary from $90.00 to $120.00 per specimen depending on the number of monoclonal antibodies used. This same service on a fee basis arrangement ranges from $400.00 to $600.00 per specimen in the New York area.

Costs of Caring for AIDS Patients

There have been numerous attempts both in the VA and out to arrive at cost projections per case. In order to be responsive to facility needs, we have attempted to find a more rational way of funding facilities for AIDS cases. As you know, a facility's resources are based on workload performed two fiscal years prior. Because AIDS is a relatively new disease that is increasing at a rapid rate and is unevenly distributed around the country, it is a special challenge for the few hospitals that care for the majority of the Agency's AIDS workload.

Several months ago a questionnaire was devised that was sent to 11 facilities that had a high number of reported AIDS cases. The questionnaire asked them for certain information concerning their last 10 AIDS patients in FY 1986. Using this data, we estimate that our Resource Allocation Methodology has provided funding of approximately $8,000 per AIDS case to VA Medical Centers.

In FY 1985, we estimated that it cost $38,000 per year to treat an AIDS patient. A more recent study determined that $24,000 a year would be more appropriate.

Based on reduced lengths of stay, less use of intensive care unit days and better facilities to manage these patients, it is believed that the cost of an AIDS patient has decreased about 20% since FY 85. As a result, we are using $20,000 as an estimate of cost per patient per year for FY 1987. Based on this, supplemental funding has been provided for those facilities that have seen more than 15 cases in FY 1987.

Although costs do appear to be coming down, the treatment outlook is unchanged (except for the emergence of zidovudine, formerly called AZT - for selected cases). Increased use of this drug will offset reduced costs. The drug

itself costs from $7-10,000 per year per patient. Also, since the drug is toxic and requires close monitoring, including various laboratory studies, additional costs are incurred.

Intergovernmental Coordination

We are working closely with other Federal agencies to coordinate activities related to this epidemic. An example of one such partnership is the DoD/VA Working Group co-chaired by Dr. H. D. Cohn of the VA's Department of Medicine and Surgery and Captain V. Schinski from the Assistant Secretary of Health's Office in DoD.

The purpose of the DoD/VA Working Group is twofold:

(1) to exchange recent and evolving research and clinical developments

(2) to work toward effecting the smooth transfer of patients with AIDS or the lesser syndromes (e.g., ARC) from the military to the VA health care system. (It is projected by DoD officials that approximately 550 persons will be medically discharged from the three services over the next two years, potentially seeking continuation of their care in the VA).

The VA has also been an active participant in other groups, including the White House Working Group (WHWG) on AIDS, a group now chaired by Mr. Gary Bauer, Policy Advisor to the President. Discussion continues in response to a decision by the President to review all Federal programs where expanded testing would be appropriate. Dr. H. D. Conn also serves on the Federal Coordinating Committee on AIDS Information Education and Risk Reduction and represents the VA on the Intragovernmental Task Force on AIDS Health Care Delivery.

Education Activities

In addition to the provision of high quality clinical care for patients with AIDS or ARC, the VA, of course, has a heavy commitment in terms of educating its health care workers. In this regard a variety of educational programs have been conducted throughout the system:

- 30,500 VA staff trained in FY 1985 at 129 VAMCs involving individuals from all Services.
- 12 RMEC (Regional Medical Education Center) sponsored AIDS programs in FY 1986 - 1240 VA participants
- 4 CE activities sponsored by CHEPS (Cooperative Health Manpower education Programs) in FY 1986 - 53 VA participants
- 3 RMEC sponsored AIDS programs in 1987 - 440 VA participants - others in planning stages (Birmingham - Cleveland - Seattle*).

  * held May 14-15, 1987

The VA has also participated in the distribution of the U.S. Surgeon General's Report on AIDS.

Research

The VA is engaged in the entire spectrum of research on AIDS from basic science studies of the mechanism of AIDS virus infection, through clinical trials of drugs in the treatment of veteran patients with AIDS.

In the area of basic research, a number of VA laboratories are studying the mechanism by which AIDS virus infects cells. Dr. John Ziegler of the San Francisco VAMC is studying the molecular events, triggered by AIDS virus infection, that result in the death of essential cells of the immune system.

Dr. Paul Hoffman of the Baltimore VAMC is using a mouse model of AIDS infection to understand how the virus attacks and kills nerve cells. Dr. Bernard Poiesz of the Syracuse VAMC has been investigating the mechanism by which viruses, similar to AIDS virus, cause certain cancers of the lymphatic system in animals. This area of research is important to our understanding of why some AIDS patients develop these kinds of cancers. In other animal studies, Dr. Stephen Wright of the Salt Lake City VAMC is working on a vaccine for an AIDS related animal virus.

In the three years since it became established, the Virology Reference Center at VAMC West Haven has gained a nationwide reputation for service and excellence. While the Center has elected to continue offering standard viral

serology services as its major mission, it has also established a laboratory for the culture of the AIDS virus. An anticipated benefit of this service will be to enable the center to test the effect of new drugs on the AIDS virus. West Haven is the only VAMC with the capability to grow this virus.

In the area of clinical research, Dr. Susan Zolla-Pazner of the Manhattan VAMC is investigating the impact of AIDS virus infection on the functioning of the immune system, and Dr. Michael Simberkoff, also of Manhattan, is attempting to improve therapy for the serious infections that attack AIDS victims because their immune systems malfunction. Dr. Wallace Tourtellotte of the West Los Angeles VAMC and Dr. Peter Dowling of the East Orange VAMC are studying infection of the nervous system in patients with AIDS. A number of other VA investigators (Drs. Dobbins, Ann Arbor, and Klotman, Durham) are studying "opportunistic infections" in AIDS patients.

Several VA investigators are actively engaged in the development testing of new drugs for the treatment of AIDS infection. Dr. Raymond Schinazzi of the Atlanta VAMC is designing new drugs targeted against the unique biochemical pathways of the AIDS virus. Drs. John Bilello and Paul Hoffman of the Baltimore VAMC are supported by the NIH to test new, potentially useful drugs against AIDS. And the VA is carrying out a large scale, controlled clinical trial of the efficacy of zidovudine, formerly called (AZT) treatment in patients with AIDS-related complex (ARC). This trial is supported by special AIDS research funds from the Department of Defense.

Concluding Remarks

Dr. Jonathan Mann, AIDS Program official with WHO (World Health Organization), has described three phases that nations undergo in coping with the AIDS "issue" or the first AIDS case they encounter:

Phase 1 - minimization

Phase 2 - reluctant acknowledgement

Phase 3 - constructive engagement

These "phases" are probably quite representative of what municipalities, other forms of governments and health care systems experience. We believe that the VA, although the system is affected differentially as pointed out above, has embarked on its own constructive engagement phase.

In terms of planning for the future, the following concerns or actions occupy our attentions.

(1) Continue to cooperate with other Federal agencies (DoD, DHHS, etc.).

(2) VA internal cost accounting and reimbursement methodology are under continuing review.

(3) The feasibility or desirability of identifying "AIDS Centers" in medical centers located in the epicenters of the epidemic.

(4) Continuation of the zidovudine (AZT) clinical research trial in patients with ARC.

(5) Education remains a key ingredient in any program designed to reduce the spread of this life-threatening infection. It also must be continuing, current and targeted for specified audiences.

(6) The VA should be alert to and responsive to development, publication and pronouncements from various divisions of DHHS, the lead Agency in the Federal system.

(7) The VA continues to participate in development of recommendations for the Domestic Policy Council that would increase testing for the antibody to the AIDS virus. Ways to conduct pre- and post-screening counseling capability are also being developed.

Mr. Chairman, this concludes my formal testimony. My colleagues and I will be pleased to respond to any questions that you or other members of the Subcommittee may have.

STATEMENT OF

JAMES W. CURRAN, M.D.

DIRECTOR, AIDS PROGRAM

CENTER FOR INFECTIOUS DISEASES

CENTERS FOR DISEASE CONTROL

PUBLIC HEALTH SERVICE

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE

COMMITTEE ON VETERANS' AFFAIRS

HOUSE OF REPRESENTATIVES

JUNE 17, 1987

(80)

Mr. Chairman and Members of Committee:

I am pleased to have this opportunity to represent the Centers for Disease Control (CDC) and to share our knowledge about the nature of the acquired immunodeficiency syndrome (AIDS). Accompanying me is Mr. Joseph A. Levitt, Executive Assistant to the Commissioner, Food and Drug Administration.

The AIDS epidemic continues to grow. More than 36,000 cases of AIDS have been reported to date; and more than 20,000 of these patients have already died. It is estimated that by the end of 1991, the cumulative total of AIDS cases in the United States will reach 270,000 and result in nearly 180,000 deaths. The President has declared AIDS the number one public health enemy.

Although the majority of cases continue to occur among homosexual and bisexual men and intravenous (IV) drug abusers, the infection is also being heterosexually spread by sexually active individuals who do not abuse IV drugs intravenously. Infected mothers are also transmitting infection to their newborn infants. Thirteen hundred cases of heterosexual transmission and more than 500 cases of AIDS in children have been reported. However; essentially all of these cases are related to contact with persons with AIDS, at risk for AIDS, or are individuals born in countries in which heterosexual transmission is believed to play a major role.

There is no vaccine against AIDS, and only one licensed drug with limited proven therapeutic benefit has been developed. Complicating the picture is the fact that infected persons are capable of spreading the virus to others for years before experiencing the signs or symptoms of AIDS. At this time, information and education, aimed at motivating individuals to eliminate high risk behavior, are the only means we have to prevent the spread of HIV infection--the virus that causes AIDS.

We know that the overwhelming majority of cases continue to occur in populations known to be at risk. Although the number of cases being transmitted heterosexually is increasing, the individuals most affected are sex partners of bisexual men and IV drug abusers--most often bl and Hispanic women.

We are gradually learning more about the natural history of HIV infection. In the San Francisco City Clinic Cohort study of homosexual men with HIV infection, the average annual incidence of AIDS was shown to increase over time. After 2 years of infection, only 1 percent of the men had progressed to AIDS. The rate of AIDS increased to 5 percent after 3 years of infection, 10 percent after 4 years, 15 percent after 5 years, 24 percent after 6 years, and 30 percent after 7 years. Limited data in trends of new HIV infections over time in cohorts of homosexual men have shown declining rates of new infection over the last two to three years. The percent of military recruit applicants and first time blood donors testing positive has not increased significantly in 15 to 18 months of ongoing testing; however, trends in these groups may not accurately reflect trends in the general population.

State and local health departments have reported to CDC a total of 999 AIDS patients diagnosed at and reported by Veteran's Administration Medical Centers since 1981. Of this total, 997 were male and 2 were female. Other VA patient characteristics reveal that 46 percent were white, 39 percent black, and 14 percent hispanic. Seventy-one percent of total VA reported cases were between the ages of 25 and 44. The highest concentration of patients were from the mid-Atlantic States (45 percent). Risk factors reveal that 49 percent are homosexual or bisexual men, 34 percent are IV drug users; 10 percent are homosexual men who use IV drugs; and the modes of transmission for the remaining 7 percent of cases were heterosexual contact with high risk individuals, transfusion related or undetermined.

The only military screening data from the Department of Defense available to CDC is military recruit data which does not directly relate to the VA beneficiary population since those found positive are not accepted for military service. The Department of Defense would be the source for data on active duty personnel who may have future needs for VA medical systems.

Regarding the distribution of the different opportunistic diseases reported in persons with AIDS, an analysis of the 30,632 AIDS patients in the United States reported to CDC as of February 9, 1987, showed that Pneumocystis carinii pneumonia was by far their most commonly reported disease (63.6 percent). Next were oral candidiasis (44.8 percent), Kaposi's sarcoma (20.8 percent), esophageal candidiasis (10.6 percent), extrapulmonary cryptococcosis

(6.8 percent), and cytomegalovirus disease (5.0 percent). All other diseases were reported in fewer than 5 percent of patients with AIDS. These data greatly underestimate the illness burden of patients since only a single report is received by CDC. Most patients with AIDS have multiple hospitalizations, numerous outpatient visits, and several serious conditions.

CDC published precautions related to AIDS for clinical and laboratory staffs in the MMWR in November 1982. Precautions for health-care workers and allied professionals were published in September 1983. These precautions were updated in the 1986 MMWR workplace guidelines.

Recently, three health care workers who developed HIV infection after exposure to blood from infected patients were reported. In many of the instances such as these three, strict following of precautions may have prevented the exposures resulting in infection. The following precautions are recommended by CDC and represent prudent practices that apply to preventing transmission of HIV and other bloodborne infections and should be used routinely:

1. Sharp items (needles, scalpel blades, and other sharp instruments) should be considered as potentially infective and be handled with extraordinary care to prevent accidental injuries.
2. Disposable syringes and needles, scalpel blades, and other sharp items should be placed into puncture-resistant containers located as close as practical to the area in which they were used. To prevent needlestick injuries, needles should not be recapped, purposefully bent, broken, removed from disposable syringes, or otherwise manipulated by hand.
3. When the possibility of exposure to blood or other body fluids exists, routinely recommended precautions should be followed. The anticipated exposure may require gloves alone, as in handling items soiled with blood or equipment contaminated with blood or other body fluids, or may also require gowns, masks, and eye-coverings when performing procedures involving more extensive contact with blood or potentially infective body fluids, as in some dental or endoscopic procedures or postmortem examinations. Hands should be washed thoroughly and immediately if they accidentally become contaminated with blood.

4. To minimize the need for emergency mouth-to-mouth resuscitation, mouth pieces, resuscitation bags, or other ventilation devices should be strategically located and available for use in areas where the need for resuscitation is predictable.
5. Pregnant Health Care Workers are not known to be at greater risk of contracting HIV infections than Health Care Workers who are not pregnant; however, if a Health Care Worker develops HIV infection during pregnancy, the infant is at increased risk of infection resulting from perinatal transmission. Because of this risk, pregnant Health Care Workers should be especially familiar with precautions for the preventing HIV transmission.

In addition, hospitals should be encouraged to conduct routine testing for the HIV virus so that health care workers can take appropriate precautions when caring for infected patients.

The Department of Health and Human Services has the lead role in our efforts to prevent and control AIDS; however, the problem touches many parts of the Federal Government. The President has approved increased testing for Federal prisoners, aliens and immigrants and has requested a review of other Federal programs where routine testing could be done. In addition, HHS is moving rapidly to conduct a nationwide study to determine the incidence of the HIV virus in America and to predict the future of its occurrence. According to CDC estimates, the study should be completed within six months.

The Department's AIDS information/education efforts, as outlined in the Information/Education Plan to Prevent and Control AIDS in the United States, are directed toward four target populations: the general public, school and college-aged youth, persons at increased risk or infected, and health workers. Highest priority are those groups at greatest risk of acquiring or transmitting HIV infection. We are providing assistance to every State, supporting health education/risk reduction and counseling and testing activities.

As part of its research activities on AIDS, CDC designs and conducts epidemiologic studies to determine risk factors, co-factors and modes of transmission for AIDS and HIV infection.

Cases of AIDS like other significant infectious diseases are reported voluntarily by State Health Departments to the Centers for Disease Control. Disease surveillance and control is a State responsibility rather than a Federal responsibility. The CDC works in collaboration with States and provides technical leadership and financial assistance. Among our priorities is maintaining consistency of reporting practices from State to State, which enables CDC to analyze disease trends. A statistic summary report is generated on a weekly bases. This is distributed to all State health departments and approximately 1,500 others who have requested this information. Also, CDC has initiated surveillance of HIV infection working with six hospitals which are conducting studies of blinded random samples

I have very briefly highlighted some of our knowledge about the nature of HIV infection, information on cases reported through the VA medical system, current recommendations for health-care workers, an overview of educational programs and CDC research on AIDS, and Federal policy governing the analysis and reporting of AIDS statistics. There is additional important work going on in AIDS at CDC, and many other Federal, State, and local government agencies as well as voluntary organizations have contributed a major part of this Nation's effort to deal with this major modern day scourge.

This concludes my testimony. We will be happy to answer any questions you may have.

STATUS OF HIV TESTS - AUGUST 1987

Antibody tests

The eight licensed HIV EIA antibody tests were developed principally to test blood and plasma donated for transfusion and further manufacture. Based on studies of patients with AIDS, the sensitivity of these tests now approaches 100%; however, rare persons may have a negative test if they became infected shortly before being tested---normal persons generally develop antibodies to HIV within 6 to 12 weeks of exposure. The specificty of the EIA is defined as the number of blood donors who have denied being at increased risk of infection but yet have positive tests. Using this criterion, the specificity is greater than 99.6 to 99.7%. In normal blood donors between 35 and 65% of repeatably reactive EIA's will be confirmed with a supplemental test, such as Western blotting. The false-negative rate in blood donors has been estimated to be about 1 in 100,000 to 1 in 250,000. The false-positive rate in members of the Armed Services routinely screened, if the testing sequence includes Western blotting, has been estimated to be between 1 and 5 in 100,000. It is unlikely that technical improvements of the EIA will improve the performance of these tests sufficiently to alter these estimates cited sigrificantly. Clerical error perhaps continues to remain the predominant source of false-negative test results.

An additional more specific or supplemental antibody test, the Western blot, of one manufacturer has been licensed. A variety of antibody tests using recombinant antigens or synthetic peptides, competitive inhibition technology, as well as rapid agglutination and "dip-stick" tests have been reported. The latter may have great value for epidemiologic studies t roughout the world and their development has been encouraged by the FDA. None of these tests is likely to change the practice in the United States unless, perhaps, a rapid "dip-stick" test could be used to test emergency room admissions or to prescreen certain categories of blood donors (apheresis donors, for example).

Antigen tests

Several manufacturers have proposed that EIA kits to measure the presence of HIV antigens (antigen capture tests) could improve the reliability of screening of blood and plasma donated for transfusion or further manufacture by detecting antigen during the interval between exposure to HIV and the development of antibodies detected by the antibody EIAs. Although this possibility exists, available data suggest that testing donated blood and plasma with these tests would not improve the safety of the blood supply significantly. These test have proven to be

of value in monitoring in vitro viral cultures for evidence of HIV growth and for following therapy and disease progression in persons known to be infected with HIV. Licensure of none of these tests appears imminent.

DNA Probes

Because viral cultures have proven insenstive to detect HIV infection, several different technologies to define viral DNA integrated into infected peripheral lymphocytes have been studied. These tests match or "hybridize" radiolabeled complementary DNA sequences with those of the virus. These techniques are relatively insensitive unless the quantity of DNA is amplified in some way, as for example, using the polymerase chain reaction. As a research tool, this reaction can identify the presence of one lymphocyte infected with HIV in 2,000,000 uninfected lymphocytes---a very high level of sensitivity. Tests of this nature may be adaptable to automation and eventually be of general value as "gold standard" diagnostics for use in persons with consistently equivocal antibody or antigen test results.

TWVI-MARRONE-8-6-87

WRITTEN COMMITTEE QUESTIONS AND THEIR RESPONSE

Office of the
Administrator
of Veterans Affairs

Washington DC 20420

Veterans
Administration

JUL 20 1987

Honorable G. V. (Sonny) Montgomery
Chairman, Committee on Veterans'
Affairs
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Enclosed please find responses to the questions raised by you and Congressman McEwen for the hearing record of June 17, 1987, by the Subcommittee on Hospitals and Health Care concerning AIDS. Thank you for the opportunity to provide this additional information for the record.

Sincerely,

THOMAS K. TURNAGE
Administrator

Enclosure

CONGRESSMAN MONTGOMERY

Question: 1. I understand that at the Washington, D.C. VA Medical Center, only the Infectious Disease Committee and Service Chiefs can order AIDS tests. What is your view on such a procedure?

Answer: This is one way to control the number of tests done and the way in which they are done so as to improve confidentiality and make sure that the patient receives appropriate counseling and follow-up. This procedure has been followed to control complex and expensive antibiotics in teaching hospitals and is generally agreed to be a useful mechanism to assure the involvement of senior staff in the management of patients whose primary physicians are house staff. Thus it has value in supervision of house staff and appropriate use of medical resources, both important policies of the Department of Medicine and Surgery.

Question: 2. I further understand that at the Washington VA Medical Center such tests do not require the informed consent of patients. If true, what is your view on that?

Answer. The Washington VA Medical Center does not require written informed consent although they have considered using an information sheet/consent form. However, they do require that patients give informed consent as required by statute. This is defined as the exchange of information between patient and care giver about the test. The patient may refuse the test and the exchange is documented in the medical record. This is consistent with VA policy.

Question: 3. Do you have any plans to establish specially designated treatment hospitals for AIDS patients? Do you have any other plans to isolate AIDS patients within the VA system?

Answer: There are no plans to establish specially designated treatment hospitals for AIDS patients although the feasibility of treatment units within VA medical centers is being evaluated and a pilot unit at VAMC New York has been approved. The only need for isolation is that which is necessary in the category recognized by CDC as "blood and body fluid precautions." For most AIDS patients this does not require physical isolation.

Question: 4. What is the cost to purchase and operate the flow cytometers you described in your testimony?

Answer: There are several brands of flow cytometers with costs ranging from $154,000 to $238,000 depending on the degree of automation and associated equipment packages. Flow cytometry is labor intensive but automation of some of the steps in the procedure and in reporting results does reduce medical technologist time. Most laboratories doing flow cytometry do have at least one technologist devoted to the work and use significant input from experienced pathologists or clinical scientists in interpretation. Maintenance of the complex equipment is expensive. Other operational costs depend on the volume of work and the type and number of monoclonal antibodies used in the tests.

Question: 5. You estimated costs to the V[illegible] form tertiary tests on the cytometers at $90 to $120 per specimen. What cost factors are included in the $90 to $120 estimate?

Answer: The costs involved in the test costs include: monoclonal antibodies, reagents, disposables and flow cytometry supplies (such as PBS-BSA, pipets, tubes, monofilament mesh, gloves, whole blood lysis reagents, fluorescent microspheres, floppy discs, etc.), technician time to stain antibodies and do the flow cytometry analysis, and finally the professional interpretation. Also included is instrument time for the flow cytometer/cell sorter which includes prorated cost of equipment service contracts. Therefore the $90 to $120 price is an all-inclusive figure with the variable being the number and types of monoclonal antibodies used.

CONGRESSMAN MONTGOMERY

Question: 6. You stated that the costs of AIDS tests are $5 per test for screening and $17 per test for corroborative tests under the "charge back" system at the Lexington VA Medical Center. Does this cost reflect the staff time required or just the laboratory materials? Does this reflect the cost to purchase and operate the equipment necessary to perform the tests? Is there any reason to expect that these costs will decline over time?

Answer: These costs reflect staff time and laboratory materials in a semi-automated system. If the volume of testing increases to a level that a totally automated system is feasible the unit costs will decrease. However, the equipment for such a system costs $35,000. The confirmatory test (the Western Blot) is labor intensive. Other tests are being developed which may eventually be cheaper.

Question: 7. I understand from talking with regional staff that often a hospital-by-hospital poll is necessary to determine the number of AIDS patients in VA hospitals. Is there a plan to collect such information on a routine basis, perhaps as part of the DHCP system?

Answer: The feasibility of such a plan will be one of the items evaluated by the AIDS Working Group which is being established in VACO.

Question: 8. The Centers for Disease Control testimony reports on a total of 999 AIDS patients diagnosed at and treated in VA medical centers. You report 2,014 cases. Why this discrepancy?

Answer: The CDC reporting system includes only newly diagnosed cases whereas the VA reporting system captures those which may have been diagnosed outside the VA but are new to the VA. For example, a patient reported by a military hospital and then transferred to the VA would not appear as a VA case in CDC records but would in the VA reporting system. This accounts for the major part of the discrepancy. However some VA cases may not get reported to CDC while others are counted more than once when a veteran uses more than one VA facility.

Question: 9. Do you have any kind of an advisory group for yourself or for the Department made up of field personnel from hospitals that are especially impacted by AIDS patients? If so, what do you think of the idea of such a field-based group?

Answer: In addition to the VACO Working Group, a Steering Committee composed of VA clinicians, scientists and academicians active in AIDS is being set up which will meet regularly and report to the CMD. This group will be essential in our efforts to focus on the complex clinical, education and research needs related to the effect of AIDS on the health of veterans.

CONGRESSMAN McEWEN

Question: 1. On page 10 of your testimony, you mention that you are considering the feasibility or desirability of identifying "AIDS Centers" in the epicenters of the epidemic. Would you please elaborate?

Answer: There has been considerable interest in having AIDS Centers or Units within VA medical centers based loosely on the San Francisco General model which combines an AIDS Ward and outpatient clinic under unified clinical management. A pilot program is in the planning stages for VAMC New York and proposals will be sought for two other units within the next month. Requests for proposals for three AIDS research centers have also been sent to the field.

Question: 2. Dr. Curran's testimony speaks to CDC published precaution related to AIDS. How does VA relate to the published precautions? (Dr. Curran's testimony page 4)

Answer: The VA accepts the recommendations of CDC in the control of hospital infections. These recommendations are published regularly in the widely available Morbidity and Mortality Monthly Report (MMWR) as well as the frequently updated CDC publication, Guidelines to the Prevention and Control of Nosocomial Infections. The most comprehensive publication of precautions for AIDS in health care settings appeared in MMWR on November 15, 1985. A circular (10-86-7) bringing these precautions to the attention of field personnel was published by the VA on January 21, 1986. Following the publication of information on HIV infection in health care workers exposed to blood of infected patients in the May 22, 1987, MMWR, another circular reaffirming the VA's commitment to the previously mentioned precautions, was written and is now in the concurrence process.

Question: 3. What is the average length of an inpatient episode of treatment for AIDS? What kind of outpatient treatment takes place after an inpatient episode? What has been the experience of AIDS patients being admitted as inpatients on more than one occasion?

Answer: No precise figures exist on length of stay for all AIDS patients in the VA system. The inpatient stay depends upon the constellation of diseases the patient has as a part of the syndrome called AIDS, community resources, access to outpatient treatment and general health status. Based on a study of 90 patients from around the country discharged in FY 86, the average inpatient admission was 22 days and each patient had 2.6 admissions in FY 86. Patients on the east coast of which the majority are IV drug abusers tended to have longer lengths of stay (average 28 days) than those on the west coast (average 12 days) who primarily come from the gay community. The average patient had 10 outpatient visits (6.7 on the east coast; 17.3 on the west coast). The types of treatment received as outpatient include monitoring of response to medication, both therapeutic and prophylactic, actual administration of IV antibiotics and cancer chemotherapy, nutrition counseling and treatment and psychosocial support.

Question 4. Do education programs exist for VA patients other than AIDS victims so that apprehensions among them are lessened?

Answer: At present there is no formal patient education program designed to allay fears among patients who do not have AIDS. However, there has been considerable effort to educate staff so they can discuss AIDS realistically with all patients. All VA libraries have a variety of materials available on the subject and the Surgeon General's Report is available for patients to read and discuss with staff. Those medical centers seeing most of the AIDS cases report Patient and Family Health Education activities on AIDS targeted at a broad audience. The Office of Academic Affairs is planning a comprehensive VA wide Patient and Family AIDS Education Program. In July, the VA Patient Health Education Conference Call will focus on AIDS.

CONGRESSMAN McEWEN

Question: 5. What is the AIDS ratio of inpatients to outpatients?

Answer: Most AIDS patients are outpatients. There is no way to routinely monitor AIDS patients under care either as inpatients or outpatients in the VA at any point in time. A 1-day patient census revealed that on October 30, 1986, there were 136 AIDS patients hospitalized in the system. The top four stations were New York (18), West Los Angeles (10), Brooklyn (8), and Houston (7). A selected sample of hospitals on May 19, 1987, showed 96 patients in 12 hospitals and the top four were New York (19), West Los Angeles (16), Miami (11) and Brooklyn (10). New York which has consistently seen three times as many patients as any other VA medical center has kept statistics which show an average bed occupancy ranging between 12 and 24 in 1986 during which time they saw 99 separate AIDS patients in the AIDS clinic. These 99 patients had a total of 540 visits to the clinic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Washington, D.C. 20201

JUL 5 1977

The Honorable G. V. (Sonny) Montgomery
Chairman, Committee on Veterans' Affairs
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your letter of June 25 concerning questions on Dr. James Curran's testimony at the June 17 hearing of the Subcommittee on Hospitals and Health Care.

As you requested, we are enclosing the questions and Dr. Curran's answers on a separate page.

Sincerely yours,

Ronald F. Docksai
Assistant Secretary for
Legislation

Enclosure

QUESTIONS OF CHAIRMAN [illegible]
June 17, 1987

Q

1. In your testimony, you refer to three health care workers who developed human immunodeficiency virus (HIV) infection after exposure to blood from infected patients. You go on to say, "In many of the instances such as these three, strict following of precautions may have prevented the exposures resulting in infection."

How many other instances have been reported beyond these three?

A

In addition to the three health-care workers who developed HIV infection following non-needle-stick exposures to blood from infected patients (Morbidity and Mortality Weekly Report 1987,36:285-289,, six persons who provided health care to patients with HIV infection and who denied other risk factors have previously been reported. Four of these cases followed needle-stick exposures to blood from patients infected with HIV. The two other cases involved persons who provided nursing care for persons with HIV infection. Although neither of these two persons sustained needle- tick injuries, both had extensive contact with blood or body fluids of the infected patient, and neither observed routinely recommended precautions for preventing HIV transmission to persons providing health care.

Q

2. The United States relies on the Centers for Disease Control (CDC) to provide many statistics related to death and disease. The CDC must rely on accurate reports from States and agencies. I am concerned that there is a discrepancy between CDC reports of 999 acquired immunodeficiency syndrome (AIDS) cases at the Veterans Administration (VA) and the VA's report of 2,014 cases. What might account for this difference?

A

Reports of AIDS cases meeting the national surveillance definition are submitted to the CDC on standard, confidential report forms which contain a variable "Hospital where diagnosis of AIDS established." Case reports submitted to CDC usually only reflect the initial hospitalization and initial AIDS diagnosis of the patient Unless the initial hospitalization of an AIDS patient was in a VA hospital, CDC case reports would not reflect the patient as a VA case. Thus, AIDS patients diagnosed elsewhere, but subsequently treated at a VA hospital, generally would not be noted in CDC data as VA related. Update reports of subsequent diagnoses and hospitalizations are infrequently (less than eight percent of cases) sent to CDC. Two recently published articles on medical care costs (Scitovsky, Journal of the American Medical Association (JAMA) 1986,256,3103-3106 and Seage, JAMA 1986,256:3107-3109) show the average number of hospital admissions of AIDS patients from time of diagnosis to be 3.2 and 3.3 per year, respectively.

Human T-Lymphotropic Virus Type III/ Lymphadenopathy-Associated Virus:

Agent Summary Statement

INTRDDUCTION

In March 1984, CDC and the National Institutes of Health (NIH), in consultation with scientists physicians, and public health workers in academia, industry, and government, published a manual entitled *Biosafety in Microbiological and Biomedical Laboratories* ("biosafety manual")* (*1*) The manual describes combinations of standard and special microbiologic practices, safety equipment, and facilities recommended for working with infectious agents in various laboratory settings The recommendations are advisory and provide a voluntary code of safety practices.

A section of this manual is devoted to a number of specific "agent summary statements" consisting of brief descriptions of documented or anecdotal laboratory-associated infections, the nature of the laboratory hazards, and recommended precautions to be taken in handling and working with certain infectious agents Contributors to the manual recognized that new agents would be discovered from time to time and recommended that a summary statement for each new agent be developed and published in the *MMWR* The summary statement for human T-lymphotropic virus type III/lymphodenopathy-associated virus (HTLV-III/LAV)† follows All laboratory directors ere requested to put e copy of this summary in each of their copies of the biosafety manual and bring it to the attention of laboratory personnel The recommendations in the summary statement were compiled from published scientific reports and are consistent with the published guidelines for health-care workers (*2–4*)

AGENT SUMMARY STATEMENT: HTLV-III/LAV

As of August 15, 1986, no cases of ecquired immunodeficiency syndrome (AIDS) that meet the CDC case definition and can be attributed to en inadvertent laboratory exposure have been reported in laboratory workers (*5*) One laboratory worker (*7*) was included

*Available from Superintendent of Documents, US Government Printing Office, Washington, D C 20402, Stock #01702300167-1, Price $4 00, and from National Technical Information Service, U S Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161, Stock #PB84-206879, Price $8 00

†The Human Retrovirus Subcommittee of the International Committee on the Texonomy of Viruses has proposed the name human immunodeficiency virus (HIV) for these viruses (Science 1986.232 697)

among the health-care workers who have had HTLV-III/LAV antibody detected in their serum after sustaining a needlestick injury (*2,3,6-10*), but the source of the infection could not be established. Persons who are infected with HTLV-III/LAV may be esymptomatic, may have AIDS-related complex, or may manifest symptoms of overt AIDS (*11*).

In 1985, two different reagent production laboratories reported that several laboratory workers may have been inadvertently exposed to an aerosol of concentrated HTLV-III/LAV, one worker was cut by a piece of glass from a broken carboy that contained HTLV-III/LAV-infected cells and culture fluid None of the potentially exposed persons had shown evidence of seroconversion after 6 months in one incident and 12 months in the other as a result of these occupational exposures.

Other reports dealing with HTLV-III/LAV infection in health-care personnel, including laboratory workers (*3,4,6,8-10*), indicate that the risk of bloodborne transmission from inadvertent exposure is considerably less for HTLV-III/LAV than for hepatitis B virus infection. These reports illustrate the need for complete evaluation by a physician and serologic testing of each laboratory worker definitely or possibly exposed to HTLV-III/LAV in a laboratory setting It is recommended that the Public Health Service guidelines for health-care workers be followed in these instances (*2,3*).

Laboratory Hazards

HTLV-III/LAV has been isolated from blood, semen, saliva, tears, urine, cerebrospinal fluid, brain tissue, and cervical secretions and is likely to be present in other body fluids, secretions, and tissues of infected humans or experimentally infected nonhuman primates. Percutaneous or parenteral inoculation and direct contact of cuts, scratches, abrasions, or mucosal surfaces with suspensions of virus or specimens containing live virus are considered potential routes of infection Possible transmission of infection via the parenteral route can occur through self-inoculation with needles, broken glass, or other sharp objects that contain HTLV-III/LAV Spillage is a possible means of exposure and infection, especially spills accompanied by spraying or splashing of infected cell cultures, viral concentrates, and other infectious materials that may come into direct contact with abraded skin or mucous membranes of the eyes, nose, or mouth, however, there are no data documenting or suggesting that transmission of HTLV-III/LAV has occurred in this manner Ingestion and inhalation have not been documented as modes of transmission of the virus.

Recommended Precautions

1. Biosafety Level (BSL) 2 standards and special practices, containment equipment, and facilities as described in the CDC-NIH biosafety manual are recommended for activities involving clinical specimens, body fluids, or tissues from humans or laboratory animals that may contain HTLV-III/LAV. *These are the same practices recommended for all clinical specimens* Emphasis is placed on the following practices, which are included in the manual (*1*):
   a. Use of syringes, needles and other sharp instruments should be avoided if possible. Used needles and cutting instruments should be discarded into a puncture-resistant container with a lid. Needles should *not* be resheathed, purposefully bent, broken, removed from disposable syringes, or otherwise manipulated by hand.
   b. Gloves should be worn by all personnel engaged in activities that may involve skin contact with potentially infectious fluids, tissues, or cultures and by laboratory workers with dermatitis or other lesions on the hands who may have direct or indirect contact with potentially infectious materials. Handwashing with soap and water should be a routine practice immediately after direct contact with potentially infectious materials and on completion of work, even when gloves are worn.
   c Generation of aerosols, splashes, and spills of potentially infectious materials should be avoided in procedures involving body fluids or tissues, during necropsy of cadavers, and in similar procedures on animals experimentally infected with HTLV-III/LAV Laboratory workers should use a biological safety cabinet when propagating the virus to further reduce the risk of exposure. Although the major precautions are listed here, the CDC-NIH biosafety manual contains additional related precautions (see pages 11-13 for BSL 2 and pages 14-17 [*1*] for BSL 3 when large volumes or concentrates of HTLV-III/LAV are involved). In all instances, the laboratory director is responsible for assessing the biosafety level to be used.
   d. Human serum from any source that is used as a control or reagent in a test procedure should be handled at BSL 2 (see pages 11-13 [*1*]). Appended to this Agent Summary Statement is a statement (Addendum 1) issued by CDC on the use of all human control or reagent sera shipped to other laboratories The Food and Drug Administration requires that manufacturers of human serum reagents use a similarly worded statement.

- Animal BSL 2 practices, containment equipment, and facilities are recommended for activities involving nonhuman primates experimentally infected with HTLV-III/LAV. Laboratory coats, gowns, or uniforms should be worn by laboratory workers, as is customary for other BSL 2 or 3 practices, depending on the nature of the work, concentration of the virus, and volume of material being handled. Because many animals bite, and some throw feces, urine, or expectorate at humans, animal-care personnel must wear coats, protective gloves, coveralls or uniforms, and face shields as appropriate to protect the skin and mucous membranes of the eyes, nose, and mouth from potential exposure to these substances when working with animals likely to manifest such behavior.

2. Activities such as growing research-laboratory-scale amounts of HTLV-III/LAV or related viruses or virus-producing cell lines, working with concentrated virus preparations, or conducting procedures that may produce droplets or aerosols should be performed in a BSL 2 facility with the additional practices and containment equipment recommended for BSL 3 (*12*).
3. Activities involving industrial-scale, large-volume, or high-concentration production and manipulation of HTLV-III/LAV are to be conducted with BSL 3 requirements (*12*).
4. All laboratory glassware, equipment, disposable materials, and wastes suspected or known to contain HTLV-III/LAV must be decontaminated, preferably in an autoclave, before washing, discarding, etc. Incineration of solid wastes may be used as an alternate method of disposal.
5. There is no evidence that laboratory clothing soiled with materials known or suspected to contain HTLV-III/LAV poses a transmission hazard, and the handling of such clothing is covered under BSL 2 practices. However, to be consistent with BSL 3 recommendations (*1*), when laboratory clothing becomes contaminated with HTLV-III/LAV preparations, it should be decontaminated before being laundered or discarded.
6. Work surfaces should be decontaminated at the end of each day on completion of procedures or when overtly contaminated. Many commonly used chemical disinfectants with such active ingredients as sodium hypochlorite, formaldehyde, glutaraldehyde, or phenols (*4,13-15*) can be used to decontaminate laboratory work surfaces, they can also be used to decontaminate some laboratory instruments, specific areas of contaminated laboratory clothing, and spills of infectious materials. Prompt decontamination of spills and other overt contamination should be standard practice.
7. The prudent and recommended approach to handling human serum known or suspected to contain HTLV-III/LAV is to use the same precautions that should be used routinely to prevent transmission of bloodborne infections, including hepatitis B (*16*). Available data on the effectiveness of heat to destroy HTLV-III/LAV suspected or known to be present in human serum are at variance because of variations in volume of serum, concentration of the virus, temperature, and duration of exposure to heat (*14,15,17*). Similarly, results of chemical analyses or antibody assays may vary when sera are heated before testing according to the analysis or assay being performed (*18-20*). However, there is agreement that testing heated serum for HTLV-III/LAV antibody by enzyme immunoassays often yields false-positive results (*21-23*).
8. No HTLV-III/LAV vaccine has been developed, and no drugs have been shown to be safe and effective for therapy. As part of an ongoing medical surveillance program for employees, all laboratory workers before being assigned to activities with a high potential for exposure should have a serum sample obtained and stored at -40 C (-40 F) for possible future testing. Subsequent serum samples should be obtained and stored in accordance with laboratory policy or following an inadvertent laboratory exposure involving materials described above. When indicated, these serum specimens should be tested by a qualified laboratory using currently recommended procedures for HTLV-III/LAV antibody. Furthermore, the physician requesting serologic testing of these serum specimens must first obtain informed consent from the laboratory worker and describe the confidentiality safeguards available to protect test results. The laboratory workers whose serum specimens are to be tested should understand how the test results are to be used, the implications of a positive or negative test result, and the limits, if any, of the confidentiality safeguards. An employee whose serum HTLV-III/LAV antibody test is reactive and whose subsequent tests and evaluation confirm the presence of HTLV-III/LAV infection should be counseled to follow the Public Health Service recommendations for preventing transmission (*24,25*).

9. In addition to HTLV-III/LAV, other primary, as well as opportunistic, pathogenic agents may be present in the body fluids and tissues of persons who are antibody positive or have AIDS-related complex or AIDS. Laboratory workers should follow accepted biosafety practices to ensure maximum protection against inadvertent laboratory infection with agents other than HTLV-III/LAV that may also be present in clinical specimens.

Reported by Div of Safety, National Institute of Allergy and Infectious Diseases, National Cancer Institute, National Institutes of Health, AIDS Program, Hospital Infections Program, Center for Infectious Diseases, Laboratory Program Office, Office of Biosafety, Office of the Director, CDC

ADDENDUM

CDC cautionary notice for all human serum samples used as controls or reagents:

WARNING Because no test method can offer complete assurance that laboratory specimens do not contain HTLV-III/LAV, hepatitis B virus, or other infectious agents, this specimen(s) should be handled at the BSL 2 as recommended for any potentially infectious human serum or blood specimen in the CDC-NIH manual, *Biosafety in Microbiological and Biomedical Laboratories*, 1984, pages 11-3.

One or more of the following statements should be included with the above warning statement.

- This specimen is negative for hepatitis B surface antigen (HBsAg).
- This specimen is negative for antibody to HTLV-III/LAV.
- This specimen is positive for hepatitis B surface antigen (HBsAg).
- This specimen is positive for antibody to HTLV-III/LAV.
- This specimen has NOT been tested for hepatitis B surface antigen (HBsAg).
- This specimen has NOT been tested for antibody to HTLV-III/LAV
- This specimen has been heated at 56 C (133 F) for 30 minutes (which will not inactivate HBsAg but will inactivate HTLV-III/LAV).

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